EXAMINING THE SUSTAINABLE USE OF ORGANIC SOLVENTS FOR THE MANUFACTURE OF PHARMACEUTICAL PRODUCTS

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Dedication

This thesis is dedicated to the cherished memory of my beloved parents, whose virtues, values, and blessings continue to inspire me, even in their absence. Their unwavering belief in my potential and their dreams for my success have been a guiding force throughout this journey. This achievement stands as a testament to their enduring legacy and the principles they instilled in me.

I also dedicate this work to my loving family whose support, patience, and encouragement have been my anchor during the challenges of this endeavor. Without their understanding and constant motivation, this achievement would not have been possible.

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ABSTRACT

EXAMINING THE SUSTAINABLE USE OF ORGANIC SOLVENTS FOR THE MANUFACTURE OF PHARMACEUTICAL PRODUCTS

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This study investigates the sustainable usage of organic solvents in pharmaceutical manufacturing, addressing their environmental and health impacts. The research focuses on three dimensions: the awareness of solvent-related negative impacts among pharmaceutical personnel and students, the practical applicability of regulatory norms governing solvent usage, and the feasibility of avoiding these solvents in manufacturing processes.

Data was collected through a survey of 323 participants, encompassing industry professionals and students. The results reveal that while awareness of solvent impacts is moderate among students, professionals exhibit a deeper understanding, attributed to their direct involvement in manufacturing processes. Despite the existence of robust regulatory guidelines, challenges in their practical implementation persist due to resource constraints, varying enforcement standards, and industry resistance to change.

The study also discusses alternative technologies, such as solvent-free methods and green chemistry principles, which demonstrate promise in reducing or eliminating organic

solvent use without compromising product quality. However, widespread adoption requires substantial investment and industry collaboration.

This research concludes that bridging awareness gaps, particularly among future professionals, is critical to fostering sustainable practices. It calls for targeted educational initiatives, enhanced policy enforcement, and incentives for adopting greener technologies. By addressing these gaps, the pharmaceutical industry can significantly reduce its reliance on organic solvents, contributing to global sustainability efforts.

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INTRODUCTION

1.1 Introduction

Universe has limited resources and we as mankind need to increase our collective efforts in terms of conserving these for the generations to come. For instance, mankind has seen the worst challenge of modern times where the worldwide population was seen grappling with a multitude of Covid attacks. Man-Made calamities are becoming the norm, and many times, we are unwittingly the instigators of this. Disasters waiting to happen can be curbed with various measures, one of which is awareness. We really cannot control what we are not aware of, this thought thus leads to the subject which has become the buzzword of one and all, the area of 'Sustainability' which is gaining tremendous momentum in all forums, and Sustainable solutions for all fields are becoming the mandate where conservation of natural resources, curbing misuse of the same, preventing harm to mankind could be the main targets. Global industries are gearing up to meet the challenges of the future, and the pharmaceutical industry is no longer a bar.

Pharmaceutical companies perform a substantial function in discovering, developing, producing, and marketing drugs required to cure, vaccinate, or relieve symptoms. Brand medicines could originate from the drug discovery process of an innovator company, while pharmaceutical corporations may produce generic or brand drugs and medical equipment, ("Pharmaceuticals Global Market Report 2022," n.d.). Pharmaceutical companies must adhere to several rules and regulations overseeing the research, testing, development, patenting, synthesis, safety, efficacy, and marketing of pharmaceuticals. In 2020, the pharmaceutical healthcare sector globally developed treatments valued at $1,228.45 billion, reflecting a compound annual growth rate (CAGR) of 1.8% due to recent occurrences, including COVID-19 pandemic as Referenced from the Pharmaceutical Sector from Wikipedia, the free encyclopedia.

The Pharma industry has never been under more focus other than with the advent of the horrific experience of the covid pandemic ("Pharma Under The Microscope In The COVID-19 Crisis - Health Policy Watch," n.d.). Pharmaceutical companies upped their ante and rose to the occasion to fight the COVID-19 virus with the able weapon of vaccines. The first to file Company, the first to reach the millions of public were of course the kind of Global leaders setting the path for more companies to follow suit. This is a glaringly evident example on the Global scale as to what the pharmaceutical industry can do for the world as the provider of solutions to all kinds of diseases and ailments ("Spotlight on Indian pharma's resilience during pandemic times - The Hindu Business Line," n.d.). However, as with any other Industry where inputs generate outputs that may not only be a boon to mankind but also generate by-products, wastes as well as effluents and the pharmaceutical industry is no exception.

Pharmaceutical products have complex manufacturing processes, the innocuous-looking tablets/capsules/injections undergo a series of rigorous highly controlled processing to be made into attractive and aesthetic finished dosage forms. When there are solid dosage forms like tablets, capsules input materials which are the active medicine/s along with one/more inert ingredients (referred to as excipients) are to be converted into a form amenable to tableting or encapsulation. Now, this process of conversion of the powder materials into a granular blend is called granulation (Shanmugam, 2015). Here, application of solvents that could be either aqueous (based on water) or non-aqueous (organic) for binding components together performs an essential function. This paper will discuss the usage of non-aqueous (organic solvents) for pharmaceutical manufacture and their after-effects. Employees in the pharmaceutical industry, particularly those involved in the production of solid oral dosage forms, are subjected to these solvents nearly every day (Jovanovic and Jovanovic, 2004). Their use has become so commonplace that they are frequently mistaken for any other innocuous solvent, such as water, and are used without considering the potential consequences of their widespread use. This paper will discuss this subject in detail further.

1.2 Research Problem

Pandemic stories are reigning the roost, now and then we are regaled with the terrible times we have all been through for the past years of COVID-19 prevalence. However, there is no dearth of calamities often competing with the horrific challenges of Covid times. In our daily lives, we are inundated with tales of extremes of climate change, flood situations, and terrible heat waves all being the forefront topics in the media, be it the Newspapers, Television, or social media sites. Scientific studies indicate that climate change is exacerbating the frequency and intensity of such disasters, with global warming leading to rising sea levels, prolonged droughts, and unpredictable weather patterns (I. S. Report, 2023). It is with a sense of trepidation that we read and imbibe this news and the self-consoling lingering thought that probably such calamities happen to others and not to us! However, the day is not so far off that each one of us will be suffering from and exposed to such catastrophes soon! However, research suggests that no region is truly immune, and soon, each one of us may face direct exposure to such catastrophic events (Sophie

Langendijk et al., 2022). The stories also speak out glaringly about how we as humankind are responsible for slowly destroying the natural habitats of flora and fauna. Deforestation, industrial pollution, and excessive exploitation of natural resources continue to deplete the planet's ability to sustain future generations, leaving an uncertain legacy for those to come (I. Report, 2024). The natural environment and resources easily available to our generations may not be at the disposal of the future generations to come unless immediate and sustainable actions are taken.

Social media and print media like the programmes on Television Channels like National Geographic, Discovery, Sony, etc. all project and channelize so many stories of how the earth and the world and thereby mankind is being destroyed and adversely impacted by all this, all of which cover the media representations of the environment and environmental issues globally (Hansen and Cox, 2015). Sustainable green revolution is the way forward in which each one of us can contribute to improving the world for subsequent generations, where all humans can live well, within the means of one planet Earth ("Global Footprint Network," 2009).

A sustainable green world envisions a future where humanity lives in harmony with the environment, balancing economic growth and development with the preservation of natural resources. This world prioritizes clean energy sources, efficient waste management, and responsible consumption to reduce pollution and combat climate change (ROCKSTRÖM et al., 2023). In a sustainable green world, ecosystems are valued and protected, biodiversity thrives, and natural habitats are preserved for future generations. Urban areas are designed to be eco-friendly, with green spaces, sustainable architecture, and efficient public transportation, (Steffen et al., 2015). Agriculture emphasizes organic practices, biodiversity, and soil health, aiming for food security without depleting resources. The transition to a sustainable green world also involves social equity, ensuring all communities have access to clean air, water, and green spaces. This vision combines technology, innovation, and a respect for nature, aiming to create a resilient world that supports both human life and the planet's ecosystems. As stated in the SDG (Sustainable development) report (Sachs et al., 2013)which aims for Universal quality education and innovation-based economy with Universal health coverage, Zero-carbon energy systems, Sustainable ecosystems, sustainable agriculture, and climate resilience and Sustainable.

The Research Problem

The motivation for this research stems from a firsthand workplace incident in the Research and Development department of a pharmaceutical company, highlighting the casual approach toward the use of organic solvents. A senior scientist was consistently using Acetone, a Class 3 organic solvent, in product formulation despite its presence being unacceptable due to regulatory concerns (Anonim, 2021). Resistance to changing the solvent was observed due to its superior solubility profile, a common issue faced in formulation development. However, after internal discussions emphasizing sustainability, the unacceptable solvent was eventually replaced with an alternative. This incident was an eye-opener, shedding light on the widespread yet often unexamined use of organic solvents in pharmaceutical research. It raised the critical question: Do we fully comprehend the risks associated with solvent use, both for human health and the environment?

This study seeks to investigate the awareness and attitudes of pharmaceutical professionals and students regarding the use of harmful organic solvents. While existing literature has explored solvent toxicity, environmental impact, and regulatory guidelines, there remains a gap in understanding how sustainability principles are applied in practice within the pharmaceutical industry. This research aims to address the following questions:

Research questions:

A) What is awareness of the negative impacts of solvent usage in Pharmaceutical Personnel as well as Students?

B) What is the practical applicability of the Regulatory norms that govern the usage of Organic solvents?

C) Can the usage of Organic solvents be avoided in the manufacture of pharmaceutical dosage forms?

By examining these aspects, the study will contribute to a deeper understanding of sustainability in pharmaceutical industry and provide insights into potential industry-wide changes toward greener alternatives.

The Pharmaceutical industry faces significant challenges in transitioning from organic solvents to sustainable alternatives. The continued use of organic solvents contributes to environmental pollution, health hazards, and regulatory compliance issues (Constable et al., 2007; Sheldon, 2017). This research aims to investigate the factors influencing this transition, including awareness, perceptions, and barriers.

The pharmaceutical industry, while essential for human health and the survival and well-being of mankind, leaves a significant environmental footprint due to its diverse and varied operational fields, all of which have their own carbon footprints, generating evolutes and wastes which add to the already existing ones. Since it develops drugs to manage chronic disorders, prevent and treat diseases, while enhancing the quality of life (QoL), pharmaceutical sector is essential to improving human health and well-being (Kümmerer, 2009). However, this critical industry also leaves a significant environmental footprint, raising concerns about sustainability and the long-term impact on ecosystems. Energy-intensive manufacturing methods and toxic organic solvents are frequently employed in pharmaceutical production processes, especially in active pharmaceutical ingredients (APIs) synthesis with development of final formulations (drug products or finished dosages). These processes release byproducts and pollutants, including greenhouse gases, volatile organic compounds, and toxic wastewater, contributing to air and water pollution (Constable et al., 2007; United States Environmental Protection Agency, 2022). In addition, pharmaceutical waste that is not properly disposed of can enter natural water systems, affecting aquatic life and potentially causing bioaccumulation of harmful chemicals within food chains.

Disposal of unused or expired drugs is a major pharmaceutical sector environmental concern. When drugs are improperly discarded they can contaminate soil and water, impacting wildlife and even re-entering human water supplies. Wastewater treatment plants are often not equipped to filter out pharmaceutical compounds completely, meaning that trace amounts of medications such as antibiotics, hormones, and painkillers end up in rivers, lakes, and oceans (Bengtsson-Palme and Larsson, 2016; Daughton and Ternes, 1999) . This contamination can disrupt the hormonal and reproductive systems of fish and other aquatic species, with antibiotics in particular contributing to the growing threat of antimicrobial resistance.

Additionally, the industry's reliance on synthetic chemicals, organic solvents, and complex supply chains leads to substantial carbon emissions. Manufacturing facilities consume significant amounts of energy to maintain clean-room standards, and global distribution networks for raw materials and finished products add to the carbon footprint. Single-use plastic packaging, commonly used to ensure product safety and sterility, also contributes to plastic waste, a major issue in environmental pollution today (Jiménez-González et al., 2011; Thakur et al., 2018).

To address these issues, the pharmaceutical industry is beginning to adopt green chemistry principles (Ivanković, 2017a), to reduce the application of harmful chemicals while minimizing waste. Companies are also exploring sustainable packaging solutions, such as biodegradable materials and recycling initiatives, to reduce pollution from the use of plastics (Thakur et al., 2018). To reduce their carbon footprints, some companies have begun investments in renewable energy sources and energy-efficient industrial techniques. Furthermore, there is a growing emphasis on designing drugs that are 'benign by design,' meaning these drugs break down more easily in the environment without producing harmful residues.

While there is still a long way to go, these efforts mark a positive shift toward a more sustainable pharmaceutical industry. Balancing the need for effective medications with the imperative to reduce environmental impact requires innovation, collaboration, and commitment from all stakeholders like governments, companies, and consumers alike. In striving for sustainability, the pharmaceutical industry can continue to support human health while reducing its environmental footprint and safeguarding the planet for future generations. These efforts mark progress, yet balancing efficacy and sustainability requires stakeholder collaboration (Sheldon, 2017).

Organic solvents employed for producing APIs are indicated as an unprecedented health and environmental hazard. These solvents, which are mostly VOCs, heavily contribute to air pollution, further climate change, and also to water contamination (United States Environmental Protection Agency, 2022). VOCs used as solvents in pharmaceutical manufacturing contribute to air pollution, further climate change, and also to water contamination. VOCs used as solvents in pharmaceutical manufacturing contribute significantly to environmental pollution since these solvents easily volatilize and release their fumes into the air thus evaporating into the atmosphere, where they can combine with nitrogen oxides to generate ground-level ozone, which is the main component in smog. Smog is the main factor in air pollution. This air pollution not only affects human respiratory health but also harms the flora and fauna, the trees vegetation, and wildlife animals being also impacted adversely. VOCs operate as greenhouse gases, retaining heat in the atmosphere thus aggravating global warming. Additionally, during disposal or accidental spills, VOCs like solvents can infiltrate water sources, contaminating rivers, lakes, and groundwater. This water pollution can have severe toxic effects on aquatic ecosystems, as VOCs disrupt the health of fish and other marine organisms, and they can even enter the human food chain, thus considered a long-term health concern (Kümmerer, 2009). To minimize the pharmaceutical industry's adverse environmental impact and safeguard natural systems and public health, it is imperative that VOC emissions be reduced.

Dick (2006), mention that Occupational and Environmental Medicine Organic solvents are utilized extensively globally in a variety of industries, especially in the pharmaceutical sector. "A liquid that can dissolve, suspend, or extract other materials, without causing chemical change to the material or solvent" is definition of solvent. Paints, degreasants, cosmetics, adhesives, insecticides, printing inks, and home cleaners are just a few of the industries that use organic solvents, that are prevalent in our conventional age. Chlorinated solvents, toluene, isopropanol, xylene, trichloroethylene, methylene chloride, perchloroethylene, and solvent combinations including white spirits are examples of frequently employed solvents. Dick (2006) further state that the annual sales of chlorinated solvents total about 300,000 metric tons in Europe alone. According to the UK Health and Safety Executive, 8% of workers use organic solvents regularly. The coatings sector, which is the largest end-user, depends heavily on solvents for the longevity and quality of paints and varnishes. In certain industries, including dry cleaning, the amounts of organic solvents utilized are decreasing, mostly as a result of advances in machinery and procedures. Due in part to environmental regulations on VOC emissions, solvents have been recovered and recycled at an increasing rate. Furthermore, the usage of paints that are water-based has increased in North America and Europe due to environmental regulations, with more conventional solvent-based coatings becoming less popular. Dick (2006) also refer to the 1987 Montreal Protocol and state that the manufacturing of some ozone-depleting solvents was limited or phased out as a result of the 1987 Montreal Protocol, which marked a turning point in environmental legislation. The protocol arose from concerns about the adverse impact of some solvents, including chlorofluorocarbons, on tropospheric ozone. Recently, 1-bromopropane, a solvent introduced to replace ozone depleting agents such as 1,1,1-trichloroethane (methylchloroform), has been shown to be neurotoxic in humans (Sheldon, 2017)

The development of ecologically friendly and sustainable manufacturing techniques has also been hampered by the pharmaceutical sector's reliance on organic solvents. Additionally, the pharmaceutical industry possesses some of the blame for the industrial VOC emissions (Sheldon, 2017). These emissions contribute to smog formation, which can exacerbate respiratory diseases and lead to premature death. Additionally, the release of organic solvents into the environment can contaminate groundwater and soil, posing risks to human health along with ecosystems (Kümmerer, 2009). Organic solvent application in pharmaceutical manufacturing is often necessary for processes such as extraction, purification, and crystallization (Byrne et al., 2016; Watson, 2014). However, there is a growing recognition of the need to reduce the industry's reliance on these harmful chemicals. Transitioning to more sustainable alternatives can not only reduce environmental risks but also enhance the pharmaceutical sector's overall sustainability, necessitating a thorough evaluation of alternative solutions, regulatory policies, and industry-wide implementation (Sheldon, 2017).

It is hence crucial that we examine alternatives that reduce or eliminate the application of organic solvents in pharmaceutical manufacture given that they pose serious health and environmental hazards (Winterton, 2021) . This research aims to investigate the feasibility of transitioning to more sustainable practices, including the identification of potential alternatives, the assessment of regulatory frameworks, and the evaluation of industry-wide awareness and adoption (Winterton, 2021). By addressing these key factors, we can work towards a more environmentally responsible and sustainable future for the pharmaceutical industry.

1.3 Purpose of Research

Research primarily attempts to comprehend the present status of organic solvent utilization in the pharmaceutical sector, identify key barriers impeding the adoption of sustainable alternatives, and investigate potential solutions to promote this transition. By tackling these difficulties, the pharmaceutical sector may promote a more sustainable and eco-friendly future.

The primary objective of the research is to increase awareness among stakeholders in the Pharmaceutical Sector on the detrimental effects of excessive solvent usage (Jiménez-González et al., 2011; Sheldon, 2017). According to "Pharmaceuticals Global Market Report (2022)," n.d., the pharmaceuticals healthcare sector globally is estimated to increase from $1454.66 billion (2021) to $1587.05 billion (2022) at 9.1% CAGR. Growth is attributed to companies reorganizing while recovering from COVID-19, which had caused social alienation, remote working, and commercial activity closures, which caused operational issues. Market is estimated to attain $2135.18 billion in 2026 at 7.7% CAGR. Research claims that organizations, lone traders, and partnerships that develop pharmaceuticals for diseases market drugs and related services. Any drug utilized for treating diseases is a pharmaceutical.

As per the "Pharmaceuticals Global Market Report (2022)," n.d., Pharmaceutical and biologics manufacturers are in this business of producing Cardiovascular, dermatology, gastrointestinal, Genito-urinary, haematology, anti-infective, metabolic, musculoskeletal, therapeutic nutrients and minerals, central nervous system, substance abuse, respiratory, ophthalmology, oncology, vaccines, and addiction among the primary categories of pharmaceutical drugs. Drugs that influence the heart and blood arteries are termed cardiovascular drugs. Commonly prescribed drugs influence the cardiovascular system. Generic and branded medications exist. Pharmacy chains, hospital pharmacies, and other avenues distribute the items. As of 2021, North America was the largest pharmaceutical market. Forecasted growth is the fastest in the Middle East. It covers Asia-Pacific, North America, South America, Western Europe, Eastern Europe, Middle East, and Africa. Thus Pharma's world reach is far and wide. Can we imagine the magnitude of the usage of Solvents this Global healthcare Industry must be into?

The report Polypropylene Market | Global Sales Analysis Report - 2030, states that the global pharmaceutical solvents market would expand at about 4.40% CAGR and then attain US$ 3.74 billion by 2022. US$5.29 billion in pharmaceutical solvent demand is predicted by 2030. Market sales are being driven by the growing need for solvents in pharmaceutical medications, vaccines, and other products. For more information, see the table below:

Table 1.1 Pharmaceutical solvents market size

Attribute	Details
Pharmaceutical solvents Market Size Value in 2021	US$ 3.58 Bn
Pharmaceutical solvents Market Size Value in 2030	US$ 5.29 Bn
Pharmaceutical solvents Market Historical CAGR (2015-2021)	4.10%
Pharmaceutical solvents Market CAGR (2022-2030)	4.40%

Ref: Table 1.1 is referenced from Polypropylene Market | Global Sales Analysis Report - 2030

As per the Polypropylene Market | Global Sales Analysis Report – 2030 , which examines the current and future trends influencing the global polypropylene market, including demand, production, and pricing and thereby predictions for the solvents market, states that the pharmaceutical industry has expanded by 150% in the past decade due to medical technology and this pattern is expected to continue. These factors were predicted to drive the pharmaceutical solvent market to increase by 4.40% in 2022-2030 (as observed in Table 1.1), contributing 8-9% to the international solvent industry.

Over forecast period (2022-2030), ("Polypropylene Market | Global Sales Analysis Report - 2030," n.d.) Future Market Insights (FMI) expects global pharmaceutical solvent demand to expand 1.5x. Pharmaceutical solvents sales are expected to grow as healthcare infrastructure improves. Pharmaceutical solvent demand has increased due to novel drug delivery system investments and escalating vaccination and medicine demand.

As per ("Polypropylene Market | Global Sales Analysis Report - 2030," n.d.) Drug and vaccine manufacturers employ pharmaceutical solvents to dissolve other substances. These solvents are increasingly employed in purification and extraction. Isopropanol, glycol, and ethanol are common medicinal products manufactured with alcohol solvents.

The report ("Polypropylene Market | Global Sales Analysis Report - 2030," n.d.) Positive vaccine and medicine reimbursement policies, specifically in emerging economies, will increase market demand. The pharmaceutical solvents market is predicted to be most appealing in Europe, followed by North America. U.K. healthcare infrastructure expansion and fresh medical research and development drive regional growth.

Further as stated in the report, ("Polypropylene Market | Global Sales Analysis Report - 2030," n.d.) Pharmaceutical solvents and chemicals are expensive and wasteful, thus important manufacturers are investing in green chemical processes. Demand for pharmaceutical solvents is rising due to green chemistry. Regulatory clearance of green chemical processes is also driving prominent firms to embrace these strategies. EPA, Environmental Protection Agency recognized the requirement for green chemical techniques to eliminate harmful drug formulation chemicals.

The report ("Polypropylene Market | Global Sales Analysis Report - 2030," n.d.) also mentions that according to the EPA, Environmental Protection Agency, the pharmaceutical industry is expected to save US$65 million in production expenses by 2020 as a result of its utilization of green chemical processes. Adopting these procedures may effectively reduce risks associated with and employ environmentally safe medication solvents.

As per ("Polypropylene Market | Global Sales Analysis Report - 2030," n.d.) significant expenditures have been invested in the pharmaceutical sector to develop drug delivery and medical technologies. Vaccines and drug formulation are becoming more dependent on these solvents. Contrary to this, ecosystem is suffering from the release of hazardous chemicals and leftover solvents. Given this, regulatory agencies enforce strict rules about solvent toxicity that are utilized. Manufacturers are therefore investing an extensive amount of money in developing green chemical processes to limit toxicity through utilizing fewer solvents and lowering toxicity. Key stakeholders in the green solvents industry should find a wealth of opportunities consequently.

Europe will dominate the worldwide pharmaceutical solvents market in 2022 with a 29.10% market share, according to (“Polypropylene Market | Global Sales Analysis Report - 2030,” n.d.). The increasing number of U.K. and German pharmaceutical companies could increase regional demand. A strong supply chain and logistics are additionally benefiting the U.K. pharmaceutical solvents industry. FMI predicts that expanding knowledge of pharmaceutical drugs' benefits in addition to the demand for vaccination and drug solvents would increase sales.

The analysis depicted in (“Polypropylene Market | Global Sales Analysis Report - 2030,” n.d.) predicts that China, U.S., and Germany will have over 38% of the demand share by 2022 and beyond. With China dominating, East Asian pharmaceutical solvent demand has the potential to expand. Leading pharmaceutical companies' dependence on API and solvents would drive demand in China. Increased usage of medicinal solvents in food and beverages would contribute to market.

Pharmaceutical solvent market leaders suspect India to be the most profitable South Asian market and as mentioned in the (“Polypropylene Market | Global Sales Analysis Report - 2030,” n.d.), Pharmaceutical companies Pfizer, Novartis, and others are adopting green chemical techniques for medicine formulations. India is world's third-largest pharmaceutical manufacturer and predicted to dominate global supply chains, according to India Brand Equity Foundation. Government laws that restrict solvent toxicity are also driving demand for eco-friendly solvents and medication formulations. This could increase the Indian pharmaceutical solvents market as mentioned in the (“Polypropylene Market | Global Sales Analysis Report - 2030,” n.d.) .

Chemically, ester and ether-based medicinal solvents would account for around 30 percent of sales in 2022 states the report (“Polypropylene Market | Global Sales Analysis Report - 2030,” n.d.). The pharmaceutical business is rapidly increasing the requirement for organic solvents. Methanol, acetone, ethyl acetate, and ethanol are also being employed for high-quality tablet coatings. Ethanol and isopropanol sales shall increase demand for alcohol-based medicinal solvents. Over the forecast period, FMI forecasts the alcohol segment to expand by 4%.

The global pharmaceutical solvents market is fairly concentrated, according to FMI, with major companies holding nearly fifty percent of the market. To improve their profits, major producers of medicinal solvents are concentrating on solubilization technology. In contrast, some businesses are working with universities and start-ups in emerging nations to develop eco-premium solutions. According to the report (“Polypropylene Market | Global Sales Analysis Report - 2030,” n.d.), they are also launching novel products to comply with stringent guidelines set by the government.

This presents a paradox. As evidenced from the (“Polypropylene Market | Global Sales Analysis Report - 2030,” n.d.), while the global economy is thriving with increasing demand for solvents, the pharmaceutical industry continues to emphasize the use of "green" solvents. However, are major pharmaceutical companies truly considering both the short-term and long-term adverse impacts of solvent usage? A fundamental shift is required, a pivotal shift which redefines how solvents are perceived and utilized in the pharmaceutical sector. This transformation should be so profound that it leads to a complete restructuring of the value chain and supply chain, ultimately eliminating solvents from the list of essential input materials.

This paper thus aims to examine past research on pharmaceutical solvents while exploring future prospects in this field. It seeks to address the question: What direction is the world taking regarding solvent usage? The primary objective is to review existing literature and industry practices related to organic solvent use in the pharmaceutical sector. Additionally, the study will assess the level of awareness of pharmaceutical professionals as well as students. Engaging these future professionals early in their education could help instill a strong foundation of awareness, ensuring that sustainability considerations become an integral part of their careers.

Purpose of Research:

The purpose of this research is to analyze the current state of organic solvent usage in the pharmaceutical industry, identify barriers to adopting sustainable alternatives, and explore potential solutions for promoting greener practices. By increasing awareness among pharmaceutical stakeholders about the adverse effects of excessive solvent use, the study aims to highlight the need for sustainable approaches. It also seeks to assess the level of awareness among both industry professionals and students, recognizing the role of future professionals in driving change. Ultimately, the research aspires to contribute to a shift in industry practices, encouraging the adoption of environmentally friendly solvents and regulatory measures for a more sustainable pharmaceutical sector.

1.4 Significance of the Study

Literature review conducted to analyze past work done on the subject matter and gain insights into the findings reveals the summarized findings as listed in this section.

It is stimulating to see that several groups, primarily in the discipline of Chemical Engineering, are starting to approach solvent selection and optimization with greater consideration, according to Constable et al. (2007) . Nevertheless, these methods are still relatively new and not widely applied. Furthermore, they endorse the frequently stated but difficult-to-implement idea that to transition to more sustainable solvent use, there needs to be more cooperation between the chemical engineering and synthetic organic chemist communities. It will take a lot of ingenuity on the part of many people to make the shift to more sustainable chemical synthesis happen.

According to Constable et al. (2007) in a basic pharmaceutical batch chemical process, the use of solvents regularly accounts for 80–90% of mass utilization. Furthermore, solvents dominate the overall toxicity profile of any particular process in these operations; that is, they make up the majority of the process's chemicals of concern on a mass basis. Solvents proved simply a medium for reactions for the average synthetic organic chemist; reactivity and molecular structure considered more significant. Consequently, particle engineering, separability, and solvent as well as solvent-reactant interactions are typically omitted from a standard retrosynthetic investigation. Additionally, the optimal conditions for this reaction are not taken into account; that is, sequence of addition, heat/mass transmission, configuration, reaction space, etc**.** This article makes the case for an increased understanding of solvent problems in batch chemical processes, which are commonly encountered in the pharmaceutical sector.

According to Raymond et al. (2010), compared to similar operations for commodity chemicals, virgin solvent production, and solvent waste treatment generate substantially greater life cycle emissions, with CO2 among additional greenhouse gas emissions accounting for the majority of this waste. We examined Novartis, Bristol-Myers Squibb, and Pfizer cases. API synthesis incorporated solvent recovery and reduction strategies, in these cases. It was demonstrated that a complete life cycle analysis is the only way to truly realize the amount of the environmental footprint decrease. These case studies revealed 3 aspects of solvent reduction and recovery. The first is that a pharmaceutical API's life cycle emissions are significantly influenced by the production and burning of solvents. These emissions can be significantly reduced by putting in place a solvent recovery or reduction system. Second, contrasted to the releases from the production and burning of solvents, the process's energy and related emissions are negligible. It is clear from this that the emission reductions brought about by the decreased quantity of virgin solvent along with solvent waste outweigh the additional energy and related emissions brought about by the inclusion of a solvent reduction/recovery system. In certain cases, adding a solvent recovery system could reduce the process's total energy needs. Solvent recovery and reduction last and prominent features are only when considering procedure from the standpoint of its full life cycle do the resulting process emission reductions become noticeable. The worldwide effects of solvent reduction and recovery are ignored by the gate-to-gate method related to productions within an API manufacturing facility. Cradle-to-grave life cycle analyses demonstrate these emission reductions. A more thorough choice for the most environmentally friendly method of producing an API can be made based on such an examination.

According to (Grodowska and Parczewski, 2010a) organic solvents have been frequently utilized in pharmaceutical companies as reaction media, for equipment cleaning, as well as for synthesized products' separation and purification. Aspects of organic solvent application in pharmaceutical products as well as API manufacturing are discussed in this study. Since leftover solvents are undesirable ingredients in a finished product, many techniques for getting rid of them can be employed as long as they meet safety standards. The analysis must be conducted following the drying process to ensure that the solvent levels employed at any stage of production are not above permissible limits (derived from pharmacopoeias or the ICH Guideline). Additionally, novel solvents are being established to replace conventional organic solvents in pharmaceutical production procedures such as ionic liquids or supercritical fluids.

In their study, (Grodowska and Parczewski, 2010a) discuss how to stay away from organic solvents. They claim that a lot of work was conducted to decrease the quantity of organic solvents employed for APIs and pharmaceutical product synthesis. Pharmaceutical businesses are always trying to stop using organic solvents by adopting more ecologically friendly practices from other industries. Manufacturers attempt to replace more hazardous solvents with less harmful ones that have comparable qualities (for example, toluene instead of benzene) or search for new developments. Potential reaction media include materials like flourous phases, ionic liquids, alumina, zeolites, supercritical fluids, water, clay surfaces or interiors, and silica gels.

Supercritical fluids (SCF) are one example of those alternatives given by (Grodowska and Parczewski, 2010a). Supercritical fluid is material above its critical point, where phase boundaries become less distinct. It is necessary to achieve specific temperature and pressure conditions to surpass the critical point. The dissolving properties and mobility of supercritical fluids yield high mass transfer, high solvency, and effective penetration into porous matrix, similar to gases as well as liquid solvents. Supercritical Fluid's solvent capacity could be adjusted to specific operations by adjusting the temperature and pressure since their solubilizing power is sensitive to even slight variations in the process operating conditions. Even though the use of supercritical fluids has advanced significantly and successfully over the past 20 years, the pharmaceutical sector still does not make extensive use of them. Since they are not limited to use in the food or pharmaceutical industries or as residual solvents, they may be a more environmentally friendly option than organic solvents. These days, the most common application for them in this sector is the extraction of natural goods, such as caffeine or aromatic oils. The manufacturing of some medications, the extraction and separation of active pharmaceutical substances, and the decrease of particle size can all benefit from the application of supercritical fluids as solvents. Contrary to this conventional microencapsulation, which makes extensive use of organic solvents, they provide innovative solventless methods for creating drug-loaded microspheres. Furthermore, SCF technology provides creative and affordable ways to create particle delivery systems without the need for solvents. The most popular SCF for pharmaceutical applications is carbon dioxide due to its low critical temperature, non-flammability, and non-toxicity all of which are crucial characteristics for compounds that are sensitive to temperature. In addition to having extreme solute capacity or high solvation power at their critical points, supercritical fluids can also have their solubility altered by adding co-solvent or co-solute. To get the necessary polarity and solvent strength, co-solvents are mixed into SCF in tiny amounts (1-5%). Common co-solvents include methanol, ethanol, acetone, and dimethyl sulfoxide.

The pharmaceutical industry uses several supercritical fluid technologies, such as Rapid Expansion of Supercritical Solutions (RESS), Gas Antisolvent Recrystallization (GAS), and Solution Dispersion by Supercritical Fluids (SDSF), to improve API or additional substance particle quality (Grodowska and Parczewski, 2010a). These technologies enable the production of narrower and smaller particles. Additionally, supercritical fluids may be used in place of organic solvents at different phases of the medicinal product development process. If so, what prevents the pharmaceutical businesses from using them more frequently? The response is that it has several restrictions that prevent SCF from being widely used in industrial operations.

The lack of a thorough grasp of the underlying principles involved and the expense of the specific equipment required for the necessary operating pressure and temperature are obstacles to the successful practical use of these novel technologies. Achieving a supercritical state for solvents can occasionally be challenging when precise pressure and temperature requirements must be met. Another issue stems from the absence of a precise and accurate solubility database for crucial lab-scale models. Supercritical fluid methodology is still in its infancy, which is another reason it is not widely employed in continuous production.

In 2010, (Grodowska and Parczewski, 2010a) additionally defined ionic liquids (ILs). IL or ‘green solvents’ are salts that have weakly coordinated ions, converting them into liquid at ambient temperature or even below 100 degrees Celsius. For organic ionic liquids, when the amount of applied organic anions and cations is limited, almost every combination differs from one- and multi-component inorganic liquids. Because of their high solvency, broad liquidus range, and low or even undetectable volatility, ionic liquids are widely employed in a variety of applications and are frequently thought of as a substitute for organic solvents in the chemical and pharmaceutical industries. Pharmaceutical companies have examined them as crystallization or API synthesis solvent substituents. It is hoped that by using them, the synthesis process will become more effective and thus substitute organic solvent usage.

The effects of ionic liquids on air and water, as well as how to dispose of the wastes from which they originate, are still unknown. Additionally unknown is the impact of ionic liquid residues in the pharmaceutical finished dosages, contamination of pharmaceutical items. Additionally, producers may encounter difficulties obtaining regulatory agency (such as FDA) approval. Since each operation would need its own recycling, storage, and recovery units, this would most likely be important. It is anticipated that these issues and uncertainties will soon be resolved, and the pharmaceutical sector will either find a better solution or switch from the standard organic solvents to the ones listed as alternatives.

In emerging nations, GMP and drug legislation require that API and drug product producers follow GMP to reliably regulate residual solvents (Grodowska and Parczewski, 2010b). For cost-effective reasons, pharmaceutical companies frequently purchase API from underdeveloped developing nations like China or India. Production locations for APIs may experience certain issues with GMP requirements to be stringently met at all these API manufacturers however at times API producers may not be sufficiently examined for GMP compliance in the majority of nations. Drug laws in developing nations are generally lax and can encourage the distribution of dangerous or ineffective medications since they lack the money and ability to regulate API producers. It is costly to establish an efficient drug regulation system in a developing nation, and it calls for experts, suitable laws, and institutional setups. Only then, with the approval of regulatory bodies in wealthy nations that are set up to adhere to certain rules, can poor nations rely on them.

According to Vaccaro et al. (2014) Green chemistry and flow chemistry work well together to define highly effective synthetic tools and get access to new chemical regions. In this review exercise, the selection of article contributions for this review was based on the benefits provided in terms of characteristics that are not directly related to traditional green metrics, such as reduction in reaction time, optimizing time screening, minimizing waste, improving safety, intensifying processes, and making them easy to scale up, and being energy and cost-efficient. Because of these characteristics, reactions in flow are very intriguing for the development of sustainable and green chemistry. To sum up, green chemistry benefits from any technical development, particularly when those developments enable the realization of innovative chemical processes and the attainment of high chemical and environmental efficiency. In light of this, flow technology is undoubtedly among the most intriguing instruments available for creating a more sustainable and environmentally friendly chemistry. Green and flow get along well and represent two research areas that have a long road ahead and various possible adventures to share, but as with many other partnerships, it is not always easy to determine whether two partners can contribute to each other's aims.

Lipshutz et al., 2016 conducted a thorough analysis of the evolution of solvents in organic chemistry. They inquire whether benzene, introduced by Faraday in 1825, was the initial solvent, which subsequently emerged as an industrial solvent with excellent dissolve capabilities. Or was it ethanol, another innovation by Faraday? Regardless of historical context or solvent type, it is evident that contemporary organic chemistry adopted organic solvents as the preferred reaction media. They express regret for the negative environmental consequences since the world currently bears the significant costs of policies made over a hundred years ago. Organic Waste over 80% generated using synthetic chemistry globally can be attributed to one reaction variable: organic solvent. A significant portion is extracted from petroleum reserves, refined, and utilized in chemical processes, and subsequently, the waste generated is disposed of, either through incineration or recycling, after its removal from the laboratory. "Is it contaminated with water, salts, and organics, merely buried at sites that are currently deemed 'approved'? Few individuals among us are likely to answer; even fewer appear to be concerned with their statements."

Lipshutz et al., 2016 question how we got here. Why do we pay upfront for solvents and then more to have costly service cart them? They could assert that they have no alternative since numerous organic substrates especially catalysts are only soluble in organic solvents. How is it that Nature has been doing chemistry in water with both water-soluble and water-insoluble elements for millions, if not billions, of years without organic solvents? Unfortunately, organic chemistry has developed in organic solvents since brilliant minds decades ago chose that path. So, we have an excellent, sophisticated science, however, it also produces volumes of waste each year that are beyond our comprehension. The evidence indicates that existing organic chemistry is unsustainable. Academicians, who practice small-scale chemistry, often regard organic waste as an industry concern.

Several studies state that milligrams of the metal catalyst in milliliters of organic solvent cannot generate organic waste. Academic research groups are the worst offenders. Reactions involving small organic solvents are often processed in a 50- or 100-mL separatory funnel utilizing different quantities of water. Subsequently, additional organic solvent is used to conduct several extractions utilizing innovative solvents, succeeded by brine drying, concentration, and vacuum collection, which swiftly results in waste. When the quantities of all solvents and contaminated water are aggregated and their total weight is divided by the weight of the isolated product, the reaction's E Factor (considering solvent and/or water usage) may go into the hundreds! This applies to nearly every graduate and postdoctoral reaction conducted daily worldwide. What is waste produced in undergraduate organic teaching laboratories? Industrial laboratories, particularly pharmaceutical chemistry laboratories, generate a greater quantity of byproducts and waste per reaction, as yield is not a primary consideration. Waste streams from processes could be substantial at virtually any scale. Despite the emergence of novel techniques for circumventing or recycling organic solvents as reaction media (e.g., ionic liquids, scCO2, flourous media, ball milling), nature continues to provide proven principles for synthetic chemistry. Is it possible for a model to be improved? Despite possessing these directions, chemists disregarded them.

Lipshutz et al., 2016 discussed additional reaction media. They emphasize that various global organizations have recognized the necessity for novel organic reaction media that are unable to generate similar waste streams, so initiating a transition away from organic solvents. Fortunately, there exist more sustainable solvents, that include 2-Me-THF as an alternative to water-soluble THF, and selection guidelines are now prominently displayed in most pharmaceutical companies' hallways; however, these remain organic solvents, many derived from petroleum reserves and other natural sources. Ionic liquids (ILs) have been developed extensively, however their postreaction fate, including organic solvents released into the environment, should not be neglected. Biodegradability, toxicity, and mutagenicity are becoming more important. Low volatility, inertness, thermal and chemical stability, and resilience are ILs' advantages. An additional solvent, supercritical CO2, is non-toxic, non-flammable, non-polluting, and easily removed from the result. CO2 compression requires tremendous pressure.

Another reaction medium employs fluorinated solvents, initially perfluorinated hydrocarbons, followed by flourous amines and ethers. As mentioned by (Lipshutz et al., 2016) these solvents are generally immiscible with most organic solvents and water; however, solubility varies with temperature. Heating a flourous-bound catalyst with non-polar solvent to attain homogeneity initiates catalysis, then subsequent cooling facilitates phase separation, hence simplifying product extraction from the organic solvent layer. The abundance of organic chemistry, including innovative flourous solvents, catalysts, and reagents, along with reduced costs, renders this bond formation technique a compelling alternative to conventional media. Organic chemists may also circumvent the use of organic solvents through other methods. 'Switchable' solvents are an effective method for "wastewater treatment, CO2 capture, and solvent recovery".

Parmentier et al., 2017 in their research entitled 'Switching from Organic Solvents to Water at an Industrial Scale,' outlines the progress in employing alternative media to replace polar aprotic solvents that consist of dimethylformamide (DMF), dimethylacetamide (DMAc), along with N-methyl-2-pyrrolidone (NMP). There has been an emphasis on employing non-ionic designer surfactants (e.g., TPGS-750-M) in aqueous solutions instead of conventional organic solvents. Substantial emphasis has been focused on its application in several frequent transformations in API synthesis, that include amidation reactions, Suzuki–Miyaura cross-couplings, nitro group reductions, and aromatic nucleophilic replacements. Investigations illustrate successful applications of improved green processes. Prospects along with recent observations employing customized reagents suitable for micellar environments are discussed.

(Jimenez-Gonzalez, 2019) explicitly state that the most sustainable solvent is a substance that is not utilized. However, avoiding the use of solvents may prove impractical requiring measures for reducing their environmental impact. This includes minimizing the volume of solvent employed and then reducing impacts throughout the solvent's life cycle, encompassing raw material extraction and production, manufacture, transportation, usage, recycling, and final disposal. Evaluating solvents without a life cycle perspective would underestimate repercussions, conceal trade-offs, and perhaps result in unfavorable substitutes. This research investigation analyzes critical variables for evaluating and selecting solvents adopting a life cycle assessment technique.

(Jimenez-Gonzalez, 2019) further state that incorporating life cycle thinking (e.g., raw material extraction, manufacturing, usage, recycling, disposal) into solvent selection processes is vital to perform thorough evaluation of impacts and trade-offs. The primary objective from a sustainability perspective is to eliminate the application of solvents. When unfeasible, selecting a solvent with diminished environmental impact may appear challenging; however, it may be summarized by adhering to complementary principles:

(a) Selecting solvents that exhibit reduced environmental implications across their entire life cycle per unit.

(b) Reduce the net usage to reduce consequences during the entire life cycle.

To facilitate this, as stated by (Jimenez-Gonzalez, 2019) guidelines and methodologies designed to assist scientists and engineers in selecting 'greener' solvents must systematically integrate life cycle assessments. Assessing solvents without a life cycle approach would underestimate consequences, obscure trade-offs, and even lead to undesirable substitutes. Evaluating life cycle issues not only minimizes environmental impact, underscores trade-offs, and mitigates the danger of unpleasant substitutes, but also aids in cost reduction.

The researchers (Jimenez-Gonzalez, 2019) present numerous novel alternatives. Nanofiltration (NF), a membrane technology in ultrafiltration (UF) and reverse osmosis (RO), is increasingly used in water treatment to remove natural organic debris, salts, colors, and organic compounds, according to (Yang et al., 2001). It rejects organic molecules better than UF and operates at a lower pressure than RO. By charge interaction and size exclusion, NF eliminates organic molecules and multivalent ions from water. Organic molecule molecular size and NF membrane nominal molecular weight cut-off (MWCO) can forecast their retention in aqueous solutions. A 1–2 nm pore diameter is thought to characterize NF membranes. NF membranes typically have 100–1000 MWCO. In recent years, NF has been suggested for organic treatments. The literature on NF membrane transit and retention in organic solvents is scarce, and the mechanism of transfer is unclear. Yang et al. (2001) discovered that organic solute retention varies by solvent and that the manufacturer-specified nominal MWCO does not reflect solute retention. The current research employed methanol, ethyl acetate, and toluene, three organic solvents that are utilized in pharmaceutical and chemical industries. For comparison, water has been examined. Organic molecule retention in aqueous solutions is more predictable (by employing manufacturer-specified MWCO) than in organic solutions. Organic solvents reject identical chemical and membrane discs in smaller quantities than aqueous solutions, therefore the solvent has a considerable effect on rejection. This indicates that the organic solvent may have an unknown transport mechanism. Solvent-solute–polymer interactions and organic solvent transport and retention through NF membranes need additional study. Solvent-resistant NF membranes are convenient to manage, prepare, and preserve and have high fluxes of common industrial solvents and solute retention within the 200–500 Da molecular size range. Commercializing such NF membranes for organic synthesis, separation, recovery, and concentration of high-value compounds is required.

Green technology explores novel solvents to replace harmful, volatile organic solvents (Paiva et al., 2014) that evaporate volatile organic chemicals into the atmosphere. ILs' weakened biodegradability, biocompatibility, and sustainability inquire about their 'greenness', despite their scientific attention. IL alternatives include DES. Solid or liquid mixtures with a high melting point depression become liquids at normal temperatures as DES. When DES contains primary metabolites such as amino acids, organic acids, sugars, or choline derivatives, it is identified as a natural deep eutectic solvent (NADES). NADES addresses green chemistry concepts entirely. Can NADES be considered next-generation solvents with a similar trajectory to ionic liquids?

(Paiva et al., 2014) have examined the contemporary advancements in these solvents and provided an overview of their various proposed uses, notably in biocatalysis, electrochemistry, and the extraction of novel data. Various NADES cytotoxicity was assessed and then compared to traditional imidazolium-based ionic liquids, revealing insights into the extraction of phenolic components from green coffee beans and the foaming properties of NADES.

Due to their versatility, nontoxicity, and biodegradability, deep eutectic solvents (DES) have been utilized in the biomedical sector (Paiva et al., 2014). DES has been demonstrated to dissolve model pharmaceuticals, enhancing solubility, penetration, and absorption. The formulation of a DES solution possesses medicinal effects, composed of menthol, camphor, and dissolved ibuprofen. NADES solubilized significantly greater quantities of ibuprofen than water. The incorporation of a polymer produced a polymeric eutectic drug delivery system. The integration of NADES with bioactive compounds, including ibuprofen, menthol, or mandelic acid, alongside biodegradable natural polymers and supercritical carbon dioxide (scCO2), presents a feasible alternative for the development of drug delivery systems, scaffolds for bone therapy, along with various biomedical applications. Doping biopolymers with NADES generates a medicinal agent delivery structure. Doped biopolymer foams when exposed to scCO2, increasing its porosity and surface area. This method additionally involves molding polymers to any desired shape employing a template.

There are various metrics to measure process sustainability, although the E-factor is among the most frequently employed. Total waste divided by product yields the E-factor. NADES (Paiva et al., 2014) has a theoretical E-factor of 0. NADES synthesis requires no chemical reactions, hence the atom economy is 100%. When only the mixture of the two components is required, carbon efficiency (carbon in the result divided by carbon in the reactants) is 100%. Whenever the starting components require being heated or solubilized, indirect carbon usage calculations should be more specific. NADES are versatile comprising ionic liquids, however, they are inexpensive and greener since they consist of natural primary metabolites. As NADES fundamental research advances, biocatalysis, extraction, electrochemistry, and biomedical applications should benefit. NADES, formerly a scientific curiosity, is now considered the next generation of solvents and will contribute towards more sustainable industrial development (Paiva et al., 2014).

'Nature vs. the organic chemist: who wins?' has been extensively covered by (Lipshutz et al., 2016). They claim that the medium with the widest range of applications will probably be selected by nature, being water. The majority of enzyme activities occur in an aqueous environment, where several well-known transformations can be successfully executed for synthetic benefit. However, within domain of naturally occurring enzymes, numerous valuable reactions are unknown. However, protein engineers are altering that. Through repeated mutagenesis, enzymatic characteristics are being adjusted so that, for instance, anomalous educts can be identified. It is now possible to develop biocatalysts that exhibit remarkable enantioselectivities typical of enzyme activities, as well as effective synthetic chemistry in water. From an industrial perspective, exceptional efforts have resulted in the development of a modified enzyme that considerably improves availability of substantial quantities of the atorvastatin side chain (Lipitor). Thus, chemists might modify many families of enzymes in a similar way, which should, by definition, result in reactions that take place in mild environments, have high efficiency and stereo control, and have excellent potential for sequential, one-pot processes. There are simpler substitutes for enzymes designated for particular synthetic transformations in addition to these intricate techniques for extending enzyme-mediated reactions in water. One approach is to completely avoid employing organic solvents by employing water as the reaction medium. A great deal about the interactions between substrates, catalysts, and water remains unidentified based on the history of reactions conducted 'on water'. The synthetic potential of such heterogeneous catalysis is further supported by research demonstrating that a novel catalyst (copper catalyst) may result in asymmetric conjugate additions with educts, with an enantiomeric excess of 80–98%. The most fascinating aspect is that the reactions occur at room temperature even though neither the copper catalyst nor any of the starting components are miscible with water. Utilizing alcohols (MeOH, EtOH) or organic solvents (e.g., DCM, THF, DMSO, etc.) possessed adverse effects in terms of yield and enantiomeric excess. The success of this novel chemistry may depend on the existence of higher aggregation states associated with the insoluble catalyst, that are only generated in an aqueous solution.

Although it is rare, and often the experimentalist's initial preference, utilizing water as the solvent is the medium forcing fresh, hydrophobic interactions that result in the selectivity observed (Lipshutz et al., 2016). It is obvious since numerous educts are insoluble in water at room temperature, which makes it almost impossible when predict the results of reactions under these unpredictable heterogeneous conditions. However, micellar catalysis is the method that permits water to function in that capacity (as the only medium) and results in the solubilization of both the catalyst and the substrate, followed by a reaction at mild temperatures. Surprisingly little has been done with micelles in transition metal-catalyzed synthetic chemistry, despite their extensive history and an abundance of information.

Lack of applications (Lipshutz et al., 2016) could be due to:

(a) only recent increase in attention paid to environmental issues associated with organic synthesis;

(b) apparent lack of interest in investigating these chemicals in water, where systematic investigation that matches this technique to the intended synthetic goals had yet to be conducted;

(c) limited training that organic chemists receive in this area.

The contrast between modern organic synthesis and Nature is evident, but it should not increase. Today, synthetic chemists may attain the required outcomes in critical bond constructions by altering their method, in which water is the medium and micellar catalysis supplies the 'solvent' for chemistry (Lipshutz et al., 2016). There's more to gain from greener chemistry than removing organic solvents, decreasing energy input into processes, and overcoming metal shortages by developing similar or better chemistry that employs only ppm. Scientists in this new environment encounter surprises, where concentrations might be ten times that in traditional organic reactions and where the laws so well established in organic media may not only be different but perhaps just emerging. Thus, this 'new world', that borrows from organic chemistry and alternative media, offers several intriguing opportunities for discovery.

Can a better reaction medium than H2O be developed (Lipshutz et al., 2016)? Not probable. Since numerous technologies enabled by micellar catalysis in water are available, many organic synthesis reactions can be converted to greener processes employing this medium. Thus, organic solvents and the energy required for many reactions will reduce, and the chemical industry's organic waste should decrease. What about transition metals, especially endangered ones, and their usage and release into the environment? How may water chemistry be better used? New platforms for nanoparticles could put trace amounts of highly active metal atoms on a surface to avoid aggregation-induced deactivation. The nano-to-nano idea, where PEG-induced chelation and stabilization deliver the substrate(s) to the NP catalyst, might be applied to NPs with ppm levels of ligated (or not) metals.

This delivery technique (Lipshutz et al., 2016) functions in water with or without a cosolvent (1−10% by volume), as nano micelles cannot be generated in organic solvents alone. Heterogeneous catalysis' elevated reaction temperatures are avoided. This principle has been applied to Lindlar reductions and Suzuki-Miyaura reactions, where low levels of Pd (almost undetectable) may lead to cross-couplings in water under mild conditions.

Synthesis of nonracemic micelles that induce asymmetry without ligands where the nano micelle is the solvent and ligand is another potential subject (Lipshutz et al., 2016). Further advances in micellar catalysis-matched ligands provide considerable synthesis potential, as those the community currently embraces mightn't be ideal for water-based synthesis. There are also intriguing continuous flow applications that are still yet to be published.

Imagine technology today having followed Nature 100+ years ago. Change is long overdue. Research will require time and effort. This overview (Lipshutz et al., 2016) should demonstrate that organic chemists may resolve environmental problems resulting from those who came before us and those who refuse to acknowledge the environmental impacts of traditional work. Can we pollute the world continuously? Whether due to health/toxicological difficulties, environmental disasters, energy shortages, geographical constraints, economic restrictions, public relations, political pressures, or even a lack of palladium, change is inevitable. The change would happen eventually.

(Parmentier et al., 2017) critical assessment examined surfactant technology's improvements in water transformations. Breakthroughs like Fe-NPs and their comprehension allowed them to develop innovative and sustainable procedures with minimal endangered and precious metal use. This field is opening new perspectives; the TPGS-water system will discover novel applications immediately with long-term applications to a broad range of reactions. Personalized reagents are being developed for applying this medium more selectively and efficiently on known chemistry. The application of surfactant in water has demonstrated promising as a dipolar aprotic solvent replacement, however, the field is still nascent requiring additional research for industrial application.

In the paper titled “An Overview of Common Organic Solvents and Their Toxicity,” (Joshi and Adhikari, 2019) discuss solvent toxicity and search for safer alternatives. They state that much research is needed to determine the micro and micro effects of each solvent on humans, animals, aquatic life, and the environment. (Joshi and Adhikari, 2019) have reviewed various organic solvent dangers and several significant solvent toxicity discoveries. n-hexane toxicity is recorded. The reactive oxygen species (ROS) modulated the P450 enzyme to cause neurotoxicity in rats, toxicity to female mice's gonads, and alteration in the expression of a gene involved in DNA methylation and ovarian hormone production in adult female rats. They also listed the works of many other authors on hydrocarbon toxicity, dioxin and its aryl hydrocarbon receptor biology, petroleum hydrocarbon in corals, hydrocarbon-induced neuropathy in males, gamma benzene hexachloride, polycyclic aromatic and halogenated hydrocarbon mediated by AHR, its toxicity as well as tumorigenesis, and Eventually, bacteria's tolerance to organic solvents and solvent toxicity to other microorganisms are examined. The pharmacokinetic-based investigation of organic solvent vapor toxicity suggests fume hood solvent safety. Much has been written about organic solvents' nature and toxicity. Researchers, pharmaceutical companies, and other concerned parties are working on a better, safer choice, but it's not enough. Green solvents tend to be preferred for preventing the toxicity of regular organic solvents, thus numerous organic syntheses are performed in water.

Organic solvents are considered to be essential chemicals in the chemical industry and research labs due to their high annual use (Joshi and Adhikari, 2019) Solvents are serious human and environmental toxins. In the research and chemical industries, economic, logistical, and safety factors determine solvent selection for reaction, cleansing, and other chemical operations and waste solvent management. Decision makers often ignore environmental issues due to a lack of proper tools, which accumulates such happenings from large groups of the chemicals industry, institutes, researchers, etc., causing chemical toxicity and severe environmental and human problems.

In their review, (Joshi and Adhikari, 2019) described the solvent's composition and toxicity. In their article, they classified organic solvents and rated some by toxicity. They assume organic solvents are carbon-based and characterized by their volatility, boiling point, molecular weight, and color. With huge dangers, organic solvents are employed for millions of applications, making us consider their toxicity. Almost all solvents are harmful if consumed or inhaled in large amounts, and most cause skin irritation. Acetone, ethyl acetate, hexane, heptane, dichloromethane, methanol, ethanol, tetrahydrofuran, acetonitrile, dimethylformamide, toluene, dimethyl sulfoxide, etc. are common solvents Regular usage of these solvents by chemical industry and research center researchers, scientists, and workers affects them greatly. Additionally, soil, water, air, and other contaminants influence adjacent residents. Constant solvent exposure harms the CNS along with other body parts. Depending on solvent content, time, length, frequency, and character, common consequences include headache, dizziness, weariness, blurred vision, behavioral changes, unconsciousness, and death. To combat it, green chemistry is increasing rapidly, and many large firms and research institutes employ the solvent selection guide. Researchers and chemical workers are the main users of solvents, thus they have to consider these factors for their health and the welfare of the environment. Their review provided a basic understanding of common organic solvents and their potential toxicity to encourage researchers to think twice about employing safe and green techniques for their health and the environment. Due to their high annual use, organic solvents are the most significant substances in research and industry. Thus, solvents demonstrate majority of humans in addition to environmental toxicants. Research and chemical companies select solvents for reaction, cleansing, and other chemical operations and manage waste solvents based on economic, logistical, and safety factors. Because of the lack of easy access to proper tools, environmental concerns are often ignored by decision-makers, which results in chemical toxicity in the environment, humans, as well as everywhere else. In this review, researchers describe the solvent's nature and toxicity. This precise knowledge is crucial for chemical workers, therefore we hope researchers and other concerned parties will utilize solvents sensibly as well as practice accordingly to preserve humans along with the environment.

Summary of the Literature Review:

The literature review can be summarized as below with the following important aspects:

Organic solvents usage and their toxicity: Solvents constitute 80–90% of mass utilization in pharmaceutical processes (Constable et al., 2007). Solvent toxicity significantly contributes to environmental and health risks in pharmaceutical manufacturing (Joshi and Adhikari, 2019). Traditional organic solvents are derived from petroleum and generate considerable waste, which is expensive to treat and dispose of (Lipshutz et al., 2016).

Sustainable alternatives: Several sustainable solvent alternatives exist, like supercritical fluids, ionic liquids, deep eutectic solvents (DES), and water-based systems (Paiva et al., 2014). Supercritical CO_2, in particular, is non-toxic, non-flammable, and environmentally friendly but remains underutilized due to technical and cost barriers (Grodowska and Parczewski, 2010a). Green chemistry approaches, such as flow chemistry and micellar catalysis, show potential for reducing solvent use and waste generation (Lipshutz et al., 2016; Vaccaro et al., 2014)

Barriers to alternatives: Regulatory barriers and lack of clear guidelines hinder widespread adoption of alternative solvents in pharmaceutical manufacturing (Jimenez-Gonzalez, 2019). The high cost of new technologies, such as solvent recovery systems and supercritical fluid processing, discourages companies from transitioning away from traditional solvents (Grodowska and Parczewski, 2010a). Limited awareness among industry professionals and researchers about the long-term environmental impact of solvent usage (Jimenez-Gonzalez, 2019).

Regulatory and compliance issues: Enforcing Good Manufacturing Practices is often a struggle in Developing nations, leading to inconsistent solvent regulation and potential safety risks. Stringent solvent residue limits, as per ICH guidelines, require improved detection and elimination techniques (Grodowska and Parczewski, 2010a).

Gaps in the Literature:

The Gaps in the literature review can be summarized as below:

Lack of awareness: Studies highlight the environmental and health hazards of organic solvent usage, but there is insufficient data on awareness levels among pharmaceutical professionals and students.

Limited practical implementation of alternatives: While many alternative solvents have been researched, their practical application in large-scale pharmaceutical manufacturing remains low (Lipshutz et al., 2016). Barriers such as cost, regulatory constraints, and lack of standardized protocols hinder their widespread adoption (Jimenez-Gonzalez, 2019).

Absence of long-term impact studies: There is a lack of longitudinal studies on the environmental and health impacts of solvent usage, particularly in emerging economies. Research on the persistence and bioaccumulation of solvent residues in ecosystems is insufficient (Joshi and Adhikari, 2019).

Regulatory gaps and inconsistencies: While regulations exist, compliance varies across different regions, especially in developing countries (Grodowska and Parczewski, 2010a)**.** The impact of international regulatory frameworks on solvent reduction strategies in pharmaceutical manufacturing remains underexplored (Jimenez-Gonzalez, 2019).

Cost impact of sustainability: More research is needed on the cost-benefit analysis of green solvent alternatives to encourage industry adoption (Parmentier et al., 2017). Economic incentives or policy-driven solutions for reducing solvent usage in pharmaceutical production have not been extensively studied (Vaccaro et al., 2014).

Significance of the Study:

The study is significant as it addresses the critical issue of organic solvent usage in pharmaceutical manufacturing, which accounts for 80–90% of mass utilization in pharmaceutical batch processes (Constable et al., 2007). Given the substantial environmental footprint of these solvents, contributing to greenhouse gas emissions, toxicity, and waste generation Raymond et al. (2010) it is essential to explore sustainable alternatives. Despite growing interest in green chemistry, the widespread adoption of alternative solvents such as supercritical fluids, ionic liquids, and deep eutectic solvents remains limited due to technical, regulatory, and economic challenges.

This research will enhance awareness among key stakeholders—including pharmaceutical professionals, regulatory authorities, and students—about the adverse impacts of solvent usage. By evaluating solvent reduction strategies and assessing industry awareness, the study will contribute to bridging the gap between academic research and practical implementation. Engaging students in sustainability discussions at an early stage is particularly crucial, as it fosters a culture of environmental responsibility within the future workforce (Jimenez-Gonzalez, 2019). Furthermore, the study aligns with global sustainability goals by promoting eco-friendly manufacturing practices and advocating for regulatory frameworks that encourage solvent reduction and recovery. The findings can provide valuable insights for pharmaceutical companies to transition toward greener production methods, reducing both their environmental footprint and operational costs (Lipshutz et al., 2016; Vaccaro et al., 2014). Ultimately, this research aims to support the long-term goal of achieving a sustainable pharmaceutical industry while maintaining efficiency and regulatory compliance.

1.5 Research Purpose and Questions

As confounded by the literature review presented, we can observe that though much thought, exercise, and discussions have been dedicated to the usage of solvents in

Pharmaceutical medicines, it has been mostly about an overview, a larger picture rather than having a concrete path forward, which makes it even more imperative for further sensitization of the Pharma world on the sustainable use of solvents, especially at the grassroots level. There has to be a responsible and ethical usage of these solvents or rather no permissible usage of the solvents at all in the Pharmaceutical industry right from the emerging chemists, pharmacists, and scientists through the ranks of the Pharmaceutical world. The impact of this will be felt throughout the value chain as we have already seen how fast and booming the worldwide Market is for solvents. All the papers presented have explained the concept of organic solvents in detail, and some have provided alternatives too. However, the alternatives are yet to be practically implemented in most cases.

Reviewing the literature and identifying current knowledge and potential future developments in the pharmaceutical industry about solvent use form the basis of this paper's primary study. Papers have been presented on the subject of organic solvents, however, none of these provide any concrete and practical evidence for the control of the usage of solvents about sustainability. The awareness level amongst budding chemists, scientists, and pharmacists, students has not been touched upon by any of the papers and neither has the current level of understanding on the subject matter of overcoming the humungous use of Organic solvents been explored.

Considering the body of work presented in this paper, based on reading about the work executed by distinguished personnel, and eminent authors, it could be summarised that, the necessitation for sustainable solvent usage is indeed the need of our times and for the future. Some of them have traced the origins of Organic solvents (Lipshutz et al., 2016), others have spoken about the varied uses of Organic solvents (Grodowska and Parczewski, 2010b), and some have waxed eloquently about the virtues of the solvent's usage and how humankind cannot do without using them (Joshi and Adhikari, 2019). However, slowly the realization has been dawning as to the negative effects of this solvent usage Raymond et al. (2010). Some of the authors had dealt with the work done on the toxicity aspects of the Organic solvents. However, they also mention that this is a vast field and a lot more research work is needed on this front Constable et al. (2007). Some of the researchers have conducted forays into the options available for avoiding the usage of Organic solvents, mostly alternate reaction media, catalysts, etc, and the most important one being the use of aqueous media or water alone (Parmentier et al., 2017). This has been garnering much attention, however here too there are plenty of angles left to be explored (Paiva et al., 2014). Thus for the past few decades, work has been going on, however, there is no relentless pursuit of the cause of completely avoiding organic solvents (Lipshutz et al., 2016). There are groups of like-minded thinkers probably aligned with this cause, however, the majority of the personnel in the field continue with their work with Organic solvents. The question here is, this is the way Chemistry has been, so the basics of the toxicity of organic solvents and the severe drawbacks of solvent usage must be highlighted in early phases of chemist's life cycle, pharmacists, researchers, scientists, and the like Constable et al. (2007). Awareness must be accorded its due, right at the early beginning. If we hope to bring a paradigm shift, we must commence these activities right now. However not much work has been done on this front, and that is where we hope this paper can afford some insights. We hope to first gauge the baseline knowledge, and the current thinking on this topic of personnel from the pharmaceutical fields, the best approach is to conduct a question-based survey. A survey will be done amongst stakeholders from the Pharmaceutical world like Pharmaceutical professionals and 'budding' Pharmaceutical professionals as students of Pharmacy and based on the outcomes of the survey, the current thinking, the constraints faced, and future options will be presented. Identification of the risks involved and the impact on sustainability about the environment is the basic goal here. The possibility of a paradigm shift from the booming solvent industry to minimalistic usage of hazardous solvents will be explored Constable et al. (2007).

The objective of this paper is basic research, contributing new findings to the body of existing knowledge. Survey method would be employed here, to gauge the current thinking of the participants, about the usage of organic solvents (Joshi and Adhikari, 2019). The currently available research on the subject matter does not provide any such information, and no question-based survey inputs have been exhibited by any of the authors discussed in this Paper (Grodowska and Parczewski, 2010b). The research has been purely technical, solution based and many tentative answers to the problem have been provided which may hold scope for the future Constable et al. (2007). However, the basic premise and the thinking of whether the main stakeholders or end users are aware of the need for avoiding the usage of Organic solvents remains unexplored Raymond et al. (2010). It is at this very point that this paper aims to test the current scenarios and put forth the outcomes. An in-depth understanding of a typical Scientist' mindset about the usage of organic solvents is the key here and this will be explored at various levels in the life cycle of the user Scientist (Lipshutz et al., 2016). For instance, a young student Scientist may in his learning stages be fully into experimenting with chemical reactions using organic solvents as prescribed by his academic curricula (Paiva et al., 2014). What would his understanding be of the topic of discussion? The same Scientist would then step into his inventive research, searching for solutions to a hypothetical Scientific problem. Then technically would he by choice prefer to use Organic solvents or other alternatives? Would he propagate the use of solvents or alternatives to organic solvents? Further, when he joins academia or seeks a professional position in the Pharmaceutical Industry what would his drive towards the usage of organic solvents be? Later on in his career, he may be in a position of influence where his views would be actively sought and imbibed, would he be pushing for the cause of not using organic solvents and saving our planet? Even if one person understands the odds at stake in terms of preserving the environment, it would be fruitful, since he would in turn set off a chain reaction of influencing others and thus propagate the cause (Jimenez-Gonzalez, 2019). Thus, raising awareness on the subject matter is imperative. There is plenty of work available and alternatives suggested by Researchers for the usage of organic solvents (Grodowska and Parczewski, 2010b). However, these solutions will be fruitful only when there is mass movement and recognition of the problem at hand to save the environment and our responsibility towards sustainable use of solvents Vaccaro et al. (2014). This research will employ a Question-based survey as a technique to bridge this gap. The measurement instrument would be the Questionnaire and the measurement items would be the review questions. The target audience would be mixed respondents as students, pharmaceutical professionals, etc. The steps followed would be to have a hypothesis, selection of variables and measurements, Survey design/questionnaire, Conduct the survey, Data collection, and Data analysis (Parmentier et al., 2017).

For the survey, the following key areas will be broadly explored through the questions:

(a) The existing level of awareness and understanding of the environmental impacts of organic solvents among both pharmaceutical professionals and students.

(b) The perceived challenges in transitioning from organic solvents to sustainable alternatives.

(c) The factors influencing the adoption of sustainable alternatives within the pharmaceutical industry, including economic considerations, technological feasibility, and regulatory requirements.

CHAPTER II:

REVIEW OF LITERATURE

2.1 Theoretical Framework

The theoretical framework for current research on sustainable usage of organic solvents in pharmaceutical manufacturing involves key concepts, theories, and some past research that has already been conducted on the subject. Excerpts of some of the past research are listed in the literature review below. Thus the sustainability of organic solvent usage in pharmaceutical manufacturing is framed by multiple theories and research that explore the environmental, economic, and social impacts of green chemistry. This section will also highlight the key theories relevant to the research questions at hand.

During the literature review, a lot of work on the Sustainability approach done in the past was explored. Some of the important works are presented in this section, and the concepts and theories which have been majorly pursued also are discussed further.

(Frank Roschangar et al., 2017) state that Green and sustainable drugs manufacturing are closely related to forward-thinking ideas that aim to strike a balance between sustainability of environment, business, as well as society over the long run. Commercial potential for green chemistry have been hampered by a lack of standardization among accessible indicators, and the development of objective goals has been complicated by uneven analytic starting points and unnoticed challenges for different production procedures.

Initially (Frank Roschangar et al., 2017) used the Green Aspiration Level (GAL) to address metrics unification initiatives. To provide the much-needed uniformity in smart green manufacturing goals, they recommended the GAL as the preferred indicator and presented a method based on data from an analysis of 46 pharmaceutical manufacturing procedures from nine significant pharmaceutical firms. They established Green Scorecard as a value-added sustainability communication tool. They measured the significance of green chemistry in the heavily impacted but frequently disregarded outsourced sector of the supply chain. Key information about the existing manufacturing process, the drug's lifecycle status, process complexity, and the GAL target are all included in the scorecard. Green overall process improvement statistics are displayed, which were attained by reducing process waste and increasing innovative complexity.

As this study demonstrates (Frank Roschangar et al., 2017), the GAL is not merely another process statistic but rather the first meaningful green efficiency target for any manufacturing process for a specific drug. It provides a distinct advantage over other traditional waste metrics in estimating the expected environmental impact of synthesizing any drug by accounting for the complexity of its ideally suited synthesis method. Green chemistry process goals can be made manageable and credible by using this quantified description, which makes process greenness measurable. Process energy, safety, and environmental effects are all crucial elements of the stated Life Cycle Analysis (LCA), but GAL intentionally ignores them because it assesses process waste.

Second, they (Frank Roschangar et al., 2017) investigated the idea in two prominent green chemistry industry consortia to achieve the challenging objective of industry alignment and widespread application of the GAL technique. The International

Consortium for Innovation & Quality in Pharmaceutical Development and the ACS Green Chemistry Institute Pharmaceutical are adamant that the GAL is a crucial tool for evaluating the best green chemistry alternatives. Thus, they chose to use the GAL to evaluate the production of green drugs. To do this, they standardized the methodology and established a single waste goal based on smart process complexity.

(Frank Roschangar et al., 2017) concluded by demonstrating that process greenness can be objectively tracked and evaluated, making the manufacturing of green drugs entirely under control. As part of their vision to fully realize the potential of green chemistry, they have put forth an integrated approach to (1) standardize green chemical production parameters by using standardized starting points. Along with (2) employing GAL, establish quantifiable, universal green manufacturing targets that account for process complexity. Jake Laban and Jack Green, however, assert that "the best strategic plans in the world are not likely to be successful if they are not effectively communicated to those who must implement them." To inform and initiate the implementation of their plan throughout the industry, including the crucial supply chain, they subsequently developed the Green Scorecard. It's possible that as the GAL gains traction, it will be used as a crucial criterion in the selection of green chemistry awards and become a widely used tool beyond the pharmaceutical industry.

(Miller, 2020) speaks about Triple Bottom line (TBL): What it is and Why is it important, Kelsey MiIler a contributor, dated December 8, 2020, for Sustainable Business Strategy which discusses the world's uncertainty and the pressing issues that affect everyday life, such as poverty, inequality, and climate change, which appear to be becoming worse every day. The necessity for change is one certain thing. In addition to making money for shareholders, a sustainable business plan seeks to improve society, environment, or both. The effectiveness of sustainable business practices in addressing the world's most pressing issues and boosting their companies' success is becoming increasingly apparent to company executives. It might be challenging to define sustainability, establish clear, attainable goals, and create a strategy to achieve them. A common method of assessing a company's sustainability initiatives is TBL, a business concept that stresses that organizations should assess their social and environmental impact in addition to their financial performance, rather than focusing solely on making a profit, or the ‘bottom line’. The ‘three P's’ that comprise TBL are profit, people, as well as planet. These categories can assist companies in considering their environmental obligations and determining any negative social impacts they might be causing. Then, to not only turn a profit but also have a positive social and environmental impact, businesses can integrate sustainable practices into every facet of their operations, including supply chains, business partners, and the usage of renewable energy.

In a capitalist economy says, (Miller, 2020)a company's success is primarily determined by its financial performance or the profit it generates for shareholders. Important business choices and strategic planning initiatives are usually carefully considered to maximize profits while reducing costs and risk. In the past, many firms have only taken economic impact and growth into account when determining their goals. It is now becoming clear to purpose-driven leaders that they may use their businesses to change the world without sacrificing their financial success. Business success has often been demonstrated to rise with the implementation of sustainability practices.

As mentioned by (Miller, 2020) in Triple Bottom line (TBL), the TBL's second component highlights a business's social impact or devotion to people. It is essential to distinguish between shareholders and stakeholders in a business. To make money for the owners of their company shares, businesses have historically prioritized shareholder value as a metric of success. As companies have gradually embraced sustainability, they have focused on creating value for all stakeholders impacted by their decisions, including customers, employees, as well as community members.

Further says (Miller, 2020), the final component of the TBL is having a positive influence on the world. The enormous quantity of pollution that large corporations have contributed to the environment since the start of the Industrial Revolution is one of the primary drivers of climate change and environmental problems. According to a report by the International Energy Agency, the global energy sector discharged 135 million tonnes of methane into the atmosphere in 2022.

Although businesses have historically been the biggest contributors to climate change says (Miller, 2020), they also can encourage positive change. Many business CEOs nowadays are aware of their social responsibility to do so, which is the Corporate Social resonsibility (CSR) which many organisations are working towards. Not only are the biggest companies in the world making this effort, but practically every business has the opportunity to put policies in place that reduce their carbon footprint. Making adjustments like using ethically sourced materials, cutting back on energy use, and speeding up shipping processes can lead to long-term sustainability.

In addition to helping companies capitalize on the growing demand for sustainable products, implementing sustainable business practices can be highly attractive to investors. Businesses use environmental, social, and governance (ESG) measures, which are an external evaluation of the TBL, within it. They hold businesses publicly accountable for prioritizing sustainable practices over just making money (Miller, 2020).

According to Sustainable Business Strategy (Miller, 2020), there is growing evidence that businesses that implement promising ESG practices tend to produce higher financial returns. As a result, more investors are now considering ESG factors while choosing investments. Implementing the TBL requires purpose-driven leaders to initiate good change as global concerns grow; however, enacting these changes is a formidable task. As stated in Sustainable Business Strategy, "Finding these opportunities and making them successful takes both real courage and grindingly hard work." "It's often the firms that have a purpose—beyond simply making money—that make the first move."Despite lengthy and unpredictable journey ahead, it is crucial to remain undeterred. The initial actions toward achieving sustainability objectives commence with individual. Companies can eventually come together around a common objective and provide a noticeable, measurable impact. According to (Miller, 2020),, "It's not only OK to take your values to work; it's required."   "A shared purpose can make firms both more productive and more innovative. But what's most important is that, in the end, [our values] are all we have."

(Geissdoerfer et al., 2017) mention another sustainability-related concept, pointing out that Circular Economy has been gaining popularity recently. It explains how natural resources affect the economy by serving as both inputs for production and consumption and a sink for waste. It also focuses at the way contemporary economic systems are both linear and open-ended. This is supported by Boulding's (1966) research, which found that because the earth is a closed, circular system with a finite capacity for assimilation, the economy and ecological should coexist in balance. Stahel and Reday (1976), who focused on industrial economics, were the first to introduce some elements of the Circular Economy. To describe industrial techniques for dematerializing the industrial sector, resource efficiency, waste prevention, and job creation in the area, they created the idea of a loop economy.

Numerous concepts that share the idea of closed loops have helped to advance our understanding of the Circular Economy and its real-world applications to economic systems and industrial operations . Some of the most relevant theoretical influences are the following: industrial ecology (Graedel and Allenby, 1995); biomimicry (Benyus, 2002); the looped and performance economy (Stahel, 2010); cradle-to-cradle (McDonough and Braungart, 2002); the laws of ecology (Commoner, 1971); regenerative design (Lyle, 1994); and the blue economy (Pauli, 2010). The Ellen MacArthur Foundation gave the most famous explanation of the circular economy, defining it as "an industrial economy that is restorative or regenerative by intention and design."

The Circular Economy is characterized as a regenerative system that minimizes resource input, waste, emissions, and energy leakage by slowing, closing, and narrowing material and energy loops (Geissdoerfer et al., 2017). This definition draws on a variety of contributions. This can be accomplished by recycling, remanufacturing, reuse, maintenance, repair, and long-lasting design.

Thus as can be observed and concluded from the Literature presented, it is clear that there are lots of theories manifested about Sustainability, like GAL, TBL, (Circular economy), and also the Principles of Green Chemistry, however practicing sustainability is a choice that can be made only when and where there is sufficient awareness, which is the main proposition in this paper.

(Ivanković, 2017b) provided a summary of the 12 principles' relevance as well as upcoming developments in green chemistry in their study. The creation of chemical products and processes that reduce or eliminate the use and production of hazardous compounds is referred to as green chemistry or sustainable chemistry. Only chemical methods and substances that don't harm the environment are utilized. The initial development or replication of substances, materials, reactions, and processes that are safer for the environment and human health can be done using its 12 principles. In their 1998 book, Green Chemistry Theory and Practice, Paul Anastas and John Warner of EPA also noted that they developed the Twelve Principles of Green Chemistry and explained ways to put them into practice. During the synthesis, production, and use of chemical products, green chemistry aims to reduce or eliminate the use of chemicals that are harmful to the environment and human health. Green chemistry seeks to implement as many of the principles as possible at specific synthesis stages, even if it is impossible to meet all twelve of the process's needs simultaneously.

Preventing trash formation is the fundamental principle of green chemistry (Ivanković, 2017a) . It's better for environment and individuals, and it is ultimately less expensive than treating garbage and destroying it after it has appeared. The principles of green chemistry cover a wide range of synthetic organic synthesis, such as designing organic synthesis processes to reduce waste and the production of byproducts, using fewer hazardous chemicals and raw materials, and using more environmentally friendly or safer solvents, (bio)catalysts, and renewable raw materials that use the least amount of energy. Green chemistry also focuses on the most efficient way to dispose of trash as well as ways to design chemical product breakdown after use, all while adhering to sustainable development and pollution avoidance strategies. Green chemistry uses a variety of well-known methods to achieve its goals of environmental protection and financial gain, such as catalysis, biocatalysis, the use of alternative renewable raw materials (biomass), alternative reaction media (water, ionic liquids, supercritical fluids), alternative reaction conditions (microwave activation, mechanochemistry, and ultrasound), and innovative photocatalytic reactions. The purpose of this study was to establish that green chemistry reduces the environmental impact of chemical processes and technology by using examples and current trends to increase understanding of the principles and practices that support green chemistry.

The disadvantages of green chemistry (Ivanković, 2017a) , which aims to develop chemical products and procedures that reduce or eliminate the use of harmful and dangerous substances, are also covered in this paper. The largest obstacle to achieving this goal is the absence of green chemistry, which expresses itself in time, expense, and knowledge. More specifically, designing or redesigning a new product or process can be difficult and expensive, and switching from an old, conventional product or process to a new 'green' one takes a long time. The notion of a safe method or product is another point of disagreement. Lack of green chemistry is also a result of the high implementation costs and information gaps, as there is currently no known substitute for chemical raw materials or alternative technology for environmentally friendly processes. Furthermore, there is a shortage of expertise and human resources. Further research is not well funded, and the supply chain does not share the risks of switching to environmentally friendly products and procedures. It is thought that ionic liquids will be a deceptive future for green chemistry. Those are undoubtedly helpful in chemical synthesis, but it's becoming more and more disputed if they live up to expectations. Ionic liquids don't appear to be very green when compared to the 12 principles that define green chemicals. Some believe that it is unreasonable to anticipate widespread use of ionic liquids within the next ten years given the current state of scientific advancement. The low vapor pressure of ionic liquids is known to make them relatively volatile, but this is only one of many parameters that determine what color a chemical is. For example, ions, imidazoles, and fluoroanion-based liquids are likely harmful but are unable to evaporate into the environment. The problem is that most ionic liquids dissolve in water and can easily enter the biosphere through that pathway.

Mol and Sonnenfeld (2014) discuss the EMT, Ecological modernization theory, and its core themes, the basic aim of this EMT being to analyze how contemporary industrialized societies deal with environmental crises, hence this is important and relevant to the topic under discussion in this paper regarding usage of organic solvents. Mol and Sonnenfeld (2014) have mentioned institutional transformations which have been and still are at the core of ecological modernization, like firstly the changing role of science and technology, secondly Increasing importance of market dynamics and economic agents like producers, customers, consumers, credit institutions, insurance companies, etc. as carriers of ecological restructuring and. Mol and Sonnenfeld (2014) next refer to transformations in the role of the nation-state with more decentralized, flexible and consensual styles of governance emerge, with less top-down, national command-and-control environmental regulation. Mol and Sonnenfeld (2014) also recall Modifications in the position, role and ideology of social movements where increasingly, social movements are involved in public and private decision- making institutions regarding environmental reforms, in contrast to having been limited to the periphery or even outside of such processes and institutions in the 1970s and 1980s. Lastly Changing discursive practices and emerging new ideologies where complete neglect of the environment and the fundamental counter positioning of economic and environmental interests are no longer accepted as legitimate, Mol and Sonnenfeld (2014).

(Grodowska and Parczewski, 2010b) mention that Organic solvents used in pharmaceutical goods are subject to a wide range of regulations. Several articles discuss these rules, which are primarily motivated by the "INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE ICH HARMONISED GUIDELINE IMPURITIES: GUIDELINE FOR RESIDUAL SOLVENTS -ICH GUIDELINE FOR RESIDUAL SOLVENTS NUMBER Q3C(R8)".

(Grodowska and Parczewski, 2010b) discuss the laws and regulations. The pharmaceutical industry is often a highly regulated manufacturing sector for objective reasons. For this reason, some associations have established RS limitations for pharmaceutical goods and excipients depending on the toxicity of individual solvents. In the past, the pharmaceutical sector had to standardize residual solvent limitations and rules. The only pharmacopoeia that defined limitations for residual solvents in medicinal products for a long time was "the US Pharmacopoeia" (chapter Organic Volatile Impurities). Pharmeuropa and "the second International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use" (ICH) guideline draft both recommended RS limits in 1990. In December 1997, the ICH released its Guidance for Industry Q3C, and it came into force in March 1998. The ICH guideline jeopardized members of the research-based pharmaceutical sector as well as regulatory bodies from the US, Japan, and Europe.

This ICH Guideline for Residual Solvents's, Conference et al. (2011) objective is to recommend acceptable amounts of pharmaceutical residual solvents for patient safety. Proposal defines limits deemed toxicologically acceptable for certain residual solvents and suggests using less harmful solvents. In the pharmaceutical sector, residual solvents are organic volatile chemicals that are used or produced during the manufacturing of drug components or excipients or during the processing of pharmaceutical products. Practical production procedures do not eliminate the solvents. Selecting the right solvent for the synthesis of a medicinal molecule can improve yield or determine properties like solubility, purity, and crystal shape. Thus, in the synthesis process, the solvent may occasionally be a crucial factor. Solvents that are intentionally employed as excipients or solvates are not covered by this regulation. However, it is important to assess and justify the solvent content of such goods. Remaining solvents should be removed as much as feasible to meet product requirements, GMPs, or other quality-based criteria because they have no therapeutic benefit. Drug products shouldn't have more residual solvents than safety evidence can warrant. Certain solvents that are known to induce unacceptable toxicities (Class 1, Table 1 as stated in the ICH Guideline, Conference et al. (2011)) should not be used in the production of therapeutic compounds, excipients, or drug products unless a risk-benefit analysis can provide strong justification for their usage. Restriction of certain solvents associated with less severe toxicity (Class 2, Table 2 as stated in the ICH Guideline, Conference et al. (2011)) is necessary to shield individuals from possible adverse effects.

Where possible, it is preferable to utilize less hazardous solvents (Class 3, Table 3 as stated in the ICH Guideline, Conference et al. (2011)).

The lists provided in the ICH Guideline for Residual Solvents' Conference et al. (2011) are not exhaustive, and other solvents may be employed and subsequently included in the lists. The recommended thresholds for Class 1 and 2 solvents Conference et al. (2011), or their categorization, may be amended if new safety information becomes available. The safety data for a marketing application of a novel drug product with a new solvent may depend on principles specified in this guideline, the qualification of impurities as described in the drug substance guideline ("Q3A, Impurities in New Drug Substances", Niazi (2009b)), the drug product guideline ("Q3B, Impurities in New Drug Products", Niazi (2009a)), or a combination of these three guidelines.

The scope of the Guideline, ICH Guideline for Residual solvent's Conference et al. (2011) pertains to residual solvents present in therapeutic components, excipients, as well as formulations. Therefore, when production or purifying operations are known to produce residual solvents, testing for these solvents should be done. Testing is required just for solvents utilized or generated during the manufacture or refinement of pharmaceutical components, excipients, or drug formulations. A cumulative method can be employed to ascertain the residual solvent levels in the drug product based on the levels present in the ingredients utilized to produce it, despite manufacturers opting to test the drugs directly. Testing for residual solvents in the drug product is unnecessary if the quantity determined is equal to or below the threshold specified in this guideline. The pharmaceutical product must undergo testing to determine if the formulation procedure has reduced the solvent level to an acceptable range, should the calculated level exceed the recommended threshold. If a solvent is employed in the manufacturing of the drug product, it should also be examined.

Excipients, drug products, and possible novel drug substances utilized in clinical research stages of development are not covered by this guideline, ICH Guideline for Residual Solvents's Conference et al. (2011), nor are currently marketed drug products. This rule applies to all dose formulations and administration modes. Under some circumstances, such as topical or short-term (≤30 days) treatment, higher quantities of residual solvents might be permissible. These levels must be justified individually.

Residual solvents are categorized according to risk assessment in the ICH Guideline, ICH Guideline for Residual Solvents's Conference et al. (2011). The World Health Organization (WHO) and various national and international health entities utilize the term "acceptable daily intake" (ADI) to denote exposure limits to toxic substances, whereas the International Program on Chemical Safety (IPCS) employs the term "tolerable daily intake" (TDI). The present guideline establishes the term "permitted daily exposure" (PDE) as a permissible pharmacological intake of residual solvents to eliminate confusion regarding varying ADIs for the same chemical. Appendix 1 of the ICH guidleine contains a list of common names and structures for the residual solvents evaluated in this guideline. After being assessed for potential health risks to people, they were divided into three groups: Class 1 solvents: Avoid using solvents. There are environmental risks, known human carcinogens, and human carcinogens that are highly suspected. Class 2 solvents: Restricted application of solvents that are non-genotoxic carcinogens identified in animals or potential agents of other irreversible toxic effects, such as teratogenicity or neurotoxicity. Substances believed to possess more significant yet treatable toxicity.

Solvents classified as class 3 have a limited potential for toxicity. Solvents having a low potential for human toxicity; no exposure limit based on health is required. PDE levels in class 3 solvents are 50 mg or above daily.

Solvents are categorized into four classes based on ICH Guideline for Residual Solvents's Conference et al. (2011) provided as diferent Tables. Table 1 enumerates established human carcinogens, substances strongly suspected of being human carcinogens, and environmental hazards within the first category (Class 1). Refrain from using these solvents unless necessary. Class 1 solvent limits are quantified as absolute parts per million in the tested substance (drug or excipient). The class 2 solvents enumerated in Table 2, being either non-genotoxic animal carcinogens or prospective agents of irreversible toxicity, such as neurotoxicity or teratogenicity, need restriction. They may also have additional serious, reversible toxicities. Two approaches exist for enumerating the restrictions of class 2 solvents. Option 1 is employed when the daily dosage is predetermined or constant, articulated using the formula: Concentration (ppm) = (1000 × PDE) / dose (in grams per day), where PDE represents permissible daily exposure limit in milligrams. Option 1 employs absolute parts per million of solvents present in the substance under examination. Option 2 mandates that the total daily concentrations of residual solvents in all drug product components must be below the values specified by the PDE. Illustrative tables depicting a passing and failing Option 2 scenario are incorporated in the ICH Guideline for Residual Solvents's Conference et al. (2011). A sample complies with the residual solvents criterion if it does not fulfill Option 1 but adheres to the conditions of Option 2. A sample does not meet the residual solvents requirement if it does not meet Option 1 as well as Option 2 criteria. Class 3 solvents may be subjected to a daily exposure limit of 50 mg (0.5%), corresponding to 5000 ppm or 0.5% as per Option 1 for

Class 2 solvents. When the producer establishes that the levels of Class 3 solvent are justifiable concerning manufacturing capacity and adherence to good manufacturing standards, elevated quantities may also be authorized. None of the solvents in this category are recognized as a threat to human health at concentrations commonly present in pharmaceuticals. In genotoxicity assessments, the results are negative, and in acute or short-term studies, they exhibit reduced toxicity. Furthermore, there exist Class 4 solvents. Insufficient toxicological evidence exists for this category to set acceptable limits. Manufacturers must provide an explanation for the residual amounts of Class 4 solvents in a medicinal product if they wish to utilize them. Like other guidelines, ICH Guideline for Residual Solvents's Conference et al. (2011) does not cover materials used in clinical studies; it only covers marketed items. Table 3 of ICH Guideline for Residual Solvents's Conference et al. (2011) enumerates the organic solvents most commonly employed in the chemical industry.

(Grodowska and Parczewski, 2010b) have discussed the ICH Guideline for Residual Solvents's in details and also mention additional justifications for residual solvent control. The principal and unequivocal rationale for regulating residual solvent levels is toxicity; however, the presence of residual solvents at levels deemed acceptable may occasionally pose risks of phase transitions, jeopardizing the physicochemical stability of an active ingredient and, ultimately, the quality of the dosage form. A few studies on the impacts of residual solvents have been published in the literature. For example, methylene chloride's effect on ampicillin trihydrate's crystallinity along with effect of residual ethanol on orthorhombic paracetamol's phase change. The taste or odor that organic solvents can produce are other justifications for eliminating them from the drugs (Grodowska and Parczewski, 2010b).

As mentioned by (Grodowska and Parczewski, 2010b), Regulatory guidelines provide recommendations about the usage of solvents, their classification based on toxicity, and their permitted levels in Pharmaceutical products, however, these do not restrict/prevent the use of Organic solvents, they do not penalize the usage of organic solvents, and neither do they govern the rampant usage of organic solvents. Hence the necessity arises to raise the awareness bar concerning organic solvents and promote the limited or no usage of organic solvents with enhanced usage of alternatives.

Based on the literature presented, a brief outline of the Theories popular for Sustainability initiatives is listed below:

Green Aspiration Level (GAL), (Frank Roschangar et al., 2017): A systematic approach to assessing and measuring the environmental impact of pharmaceutical manufacturing processes is provided by the GAL. It assesses environmental impact of solvents used by examining their waste and process complexity, providing a benchmark for reducing solvent usage. This framework is integral to addressing the first research question: "Can the usage of organic solvents be avoided in pharmaceutical manufacturing?" By analyzing manufacturing processes through the GAL lens, companies can identify areas for eliminating or reducing solvents while maintaining production efficiency.

Triple Bottom Line (TBL), (Miller, 2020) the TBL is central to sustainability discussions in any industry, including pharmaceuticals. It highlights the need for businesses to balance profit with environmental and social responsibility, emphasizing ‘people, planet, and profit.’ This theory is particularly relevant to the third research question: "Awareness of the negative impacts of solvent usage." TBL promotes the idea that pharmaceutical companies should not only seek profit but also minimize their environmental footprint and ensure social well-being by reducing harmful solvent use.

Life Cycle Assessment (LCA), (Frank Roschangar et al., 2017)LCA investigates a product's overall environmental impact, from raw material extraction to disposal. LCA offers a comprehensive way to assess whether solvents can be replaced or reduced at any stage of the pharmaceutical production process. In addressing the first research question, LCA helps quantify the environmental benefits of alternative methods and supports the argument for eliminating organic solvents in manufacturing.

Corporate Social Responsibility (CSR), (Miller, 2020) Pharmaceutical businesses have an ethical obligation to reduce negative effects of their activities on environment as well as society, according to CSR. This CSR theory is critical for analyzing the practical applicability of regulatory norms, as it highlights how firms interpret and implement solvent regulations. Companies that adopt CSR frameworks are more likely to embrace sustainable practices beyond legal obligations, contributing to environmental protection.

Ecological Modernization Theory (EMT), (Mol and Sonnenfeld, 2014) EMT suggests that environmental regulations can drive technological innovations and efficiency in industries. This theory helps explore the second research question: "The practical applicability of the regulatory norms governing the usage of organic solvents." EMT posits that well-structured regulations can encourage companies to innovate and adopt sustainable practices, potentially leading to safer and more efficient alternatives to traditional solvents.

Circular Economy (CE), (Geissdoerfer et al., 2017): The CE concept promotes reusing as well as recycling materials to minimize waste, aligning perfectly to reduce solvent usage in pharmaceutical manufacturing. The circular economy's principles can be connected to awareness of solvents' detrimental effects as businesses investigate methods to reduce solvent waste and enhance resource efficiency.

Summary:

The Theoretical framework literature review explores various theories and frameworks relevant to sustainable organic solvent usage in pharmaceutical manufacturing, highlighting environmental, economic, and regulatory aspects. The Green Aspiration Level (GAL) (Frank Roschangar et al., 2017) provides a structured approach to assessing solvent waste and process complexity, offering a benchmark for minimizing solvent use. Triple Bottom Line (TBL) (Miller, 2020) emphasizes balancing profit with environmental and social responsibility, while Life Cycle Assessment (LCA) (Frank Roschangar et al., 2017) evaluates a product's overall environmental impact, aiding in identifying opportunities for solvent reduction. Corporate Social Responsibility (CSR) (Miller, 2020) reinforces the ethical obligation of pharmaceutical companies to minimize harmful solvent use, whereas Ecological Modernization Theory (EMT) (Mol and Sonnenfeld, 2014) suggests that well-structured environmental regulations can drive technological innovations, making solvent reduction more practical. The Circular Economy (CE) (Geissdoerfer et al., 2017) encourages recycling and reusing materials to reduce solvent waste, aligning with sustainability goals. The Principles of Green Chemistry (Ivanković, 2017a)for safer chemical processes and also highlight challenges such as high costs and limited alternatives. Lastly, Regulatory Frameworks (Grodowska and Parczewski, 2010b) such as the ICH Guideline for Residual Solvents categorize solvents based on toxicity and recommend limits but do not enforce restrictions, underscoring the need for greater awareness and voluntary reduction initiatives. Overall, the literature indicates that achieving sustainability in solvent usage requires a combination of regulatory compliance, corporate responsibility, and technological innovation, forming a strong theoretical foundation for assessing awareness, regulatory applicability, and solvent reduction feasibility in pharmaceutical manufacturing.

2.2 Theory of Reasoned Action

The Theory of Reasoned Action (TRA), developed by (Ajzen, 2012), is a socio-psychological theory that explores how individual behavior is shaped by attitudes and subjective norms. A person's desire to engage in a particular action (such as adopting sustainable practices) is impacted by their attitudes toward the behavior as well as the social pressures they encounter, according to TRA.

(Ajzen, 2012), discusses the Theory of reasoned action (TRA), the most widely used conceptual framework for forecasting, elucidating, as well as modifying human social behavior is reasoned action approach. The theory of planned behavior, the most widely used model in this school, has produced a substantial body of empirical research bolstering the fundamental principles of this methodology. Subjective norms, behavioral intentions, and perceived behavioral control are based on behavioral, normative, and control beliefs, respectively; behavioral intentions and behavioral control are predictive of actual behavior; and behavioral intentions and behavioral control together articulate a significant amount of variance. Researchers have been able to create successful behavior modification programs by using these ideas.

The reasoned action method, TRA (Ajzen, 2012) explains human social behavior in terms of readily available factors when people are thinking about committing to a particular conduct. It is possible to understand the factors that influence people's behavior by taking into account their beliefs about the likely outcomes of their actions and how these beliefs shape their attitude toward the behavior; their beliefs about the actions and expectations that are important to other people and how these beliefs create a subjective norm; and their beliefs about control factors and how these beliefs foster a sense of behavioral control or self-efficacy. Despite the lack of evidence that humans make rational judgments, it is thought that intents and behavior follow rationally from these types of considerations, often without any cognitive effort (Ajzen, 2012). Furthermore, as expected, intervention studies have demonstrated that altering people's normative, behavioral, along with control beliefs affects their behavior as well as intentions (Ajzen, 2012).

In the context of this research, TRA (Ajzen, 2012) is particularly relevant to understanding the behavior of decision-makers in pharmaceutical companies regarding solvent use. Attitudes toward sustainability, coupled with the perceived norms of industry practices, can significantly influence whether a company adopts greener alternatives to organic solvents. For example, if industry leaders believe that solvent reduction aligns with both environmental responsibility and social expectations, they are more likely to commit to these practices.

Additionally, TRA (Ajzen, 2012) can be applied to examine the awareness of the negative impacts of solvents. Awareness alone may not drive behavioral change unless it is accompanied by strong social norms and attitudes that favor sustainable practices.

The key work by Fishbein and Ajzen, who developed the theory in their seminal work, (Fishbein and Ajzen, 1977) seeks to accomplish two objectives:

(1) to provide a comprehensive review of a wide range of the theoretical and empirical literature devoted to attitudinal phenomena, and

(2) to demonstrate that this literature can be incorporated within a unified and systematic explanatory structure. An evaluation of their efforts requires an assessment of the degree to which each of these goals has been achieved.

Summary:

The Theory of Reasoned Action (TRA) (Ajzen, 2012) is a socio-psychological model that explains how individual behavior is shaped by attitudes and subjective norms. It posits that a person’s intention to engage in a behavior—such as adopting sustainable practices—is influenced by their attitudes toward the behavior and the social pressures they experience. TRA serves as a foundational framework for predicting and modifying human social behavior, emphasizing that behavioral intentions and perceived control significantly determine actual actions. The theory suggests that people’s beliefs about the likely outcomes of an action shape their attitudes, while their perception of societal expectations forms subjective norms. Although individuals may not always make rational decisions, TRA assumes that intentions and behavior generally follow logically from these factors.

In the context of pharmaceutical manufacturing, TRA is particularly relevant in understanding decision-makers' approaches to solvent use. If industry leaders perceive solvent reduction as aligning with both environmental responsibility and social expectations, they are more likely to commit to greener alternatives. Moreover, while awareness of the negative impacts of solvents is essential, TRA suggests that behavioral change occurs only when strong social norms and favorable attitudes support sustainability. Originally developed by (Fishbein and Ajzen, 1977), TRA provides a structured approach to analyzing how beliefs, attitudes, and norms influence behavior, making it a valuable framework for assessing sustainability initiatives in the pharmaceutical sector.

2.3 Human Society Theory

As we have seen, sustainability and having sustainable businesses are fast becoming the main crux of influence for upcoming environmental and sociological influences. Based on the literature and work done in the past, many eminent Scientists and personnel have shed a lot of light upon issues of concern for us human beings in context of our adverse health impacts, reduction in human life expectancy, and various other issues due to rampant usage of solvents.

Organic solvents and their impacts:

Some of the Literature reviewed to understand the impact of Organic solvents is presented in this section, before embarking on the Human Society Theory and its applicability to the topic of this Research.

(Hellweg et al., 2004) have researched three appropriate environmental evaluation methods for the creation of environmentally friendly chemical processes and products. Three methods are presented in this paper for assessing the environmental impact of chemicals with different application areas, areas of focus, and data requirements. The first step in designing a chemical process is to determine any potential hazards to human health, the environment, and public safety. Developing screening indicators for undesired chemical exposure in the environment based on persistence as well as spatial range is second strategy. Conducting comprehensive LCA is the third strategy. First, a theoretical discussion of the methodologies' differences is given, followed by a case study including 13 solvents. Outcomes of all 3 techniques show that while solvents like methanol, toluene, isopropanol, as well as xylene are less harmful, chlorinated solvents should be avoided. Additionally, some outcomes are exclusive to each method: LCA indicates that energy usage accounts for significant effects for solvents like aniline. In addition to chlorinated solvents, nitrobenzene has the potential for prolonged along with extensive exposure; formaldehyde, benzene, as well as acetic acid should be carefully handled in terms of health, environmental, as well as safety concerns. Three approaches in the case study yield consistent findings for the chemicals' overall environmental assessment as well as for specific elements like toxicity or degradability.

Fraser et al. (2003) in "Mutual vulnerability, mutual dependence: The reflexive relation between human society and the environment," noted that while human civilization influences environmental change, it is equally susceptible to it. Numerous theories that concentrate on how we influence the environment or how the environment influences us have been produced by this relationship. There aren't many theories that specifically address the interaction. This study defined the range of information needed to evaluate a community's capacity for adaptation (social resilience) and the likelihood that an ecosystem will change (environmental sensitivity). These results enable us to develop a novel approach to evaluating the reflexive relationship between the environment and society.

Adaptive frameworks: environmental sensitivity and social resilience: Fraser et al. (2003) suggested the framework, which uses two important factors to incorporate multi-scalar social as well as environmental data: (1) Environmental sensitivity, which describes the relative likelihood of damage occurring due to an attack by pests, exposure to toxic materials, or adverse environmental conditions and (2) Social resilience, which focuses on whether a society will be able to respond to environmental changes.

The purpose is to establish fundamental linkages between society and the environment by investigating way environmental channels interact with the local social context. By doing so, we intend to make a significant contribution to the discussion about the relationship between society as well as environment. Through mapping these chains throughout a landscape, we can understand the way people interact with, influence, and are affected by their environment.

Sheldon (2019) additionally said in 'The greening of solvents: Towards sustainable organic synthesis', that critical evaluation of the latest advancements in evolution of more environmentally friendly solvent use in organic synthesis is conducted. Commonly used organic solvents and less popular bio-based ones are ranked and evaluated based on waste disposal, environmental impact, health, and safety factors. The use of water as a solvent, including aqueous biphasic catalysis, micelle-enabled catalysis, and biocatalysis, provides a sustainable, efficient, and eco-friendly alternative to processes in organic solvents. Since so many of the solvents that organic chemists favored are now on the black list, the entire subject of solvents in organic synthesis needs to be reexamined. In addition to using excessive amounts of solvent, organic chemists frequently make poor solvent selections. First of all, is a solvent required? Water is the ideal solvent (diluent) if one is required.

Solvents, which account for 80–90% of the mass of non-aqueous materials used in the manufacturing of APIs, are responsible for a significant quantity of waste. Despite their long history of usage in organic syntheses, solvents such as benzene, petroleum ether (a low-boiling combination of aliphatic hydrocarbons), diethyl ether, dichloromethane, and chloroform are classified as dangerous or hazardous compounds, and their use is strictly restricted by regulations. However, over the past 25 years, there has been development in the direction of more environmentally friendly solvent use. It is obvious that so-called neoteric solvents, encompassing liquid polymers, ionic liquids, deep eutectic solvents, and SC CO2, offer a lot of potential.

Cseri et al. (2018) address the negative health effects of exposure to organic solvents, pointing out that solvents generated in vast quantities were of low quality until the middle of the 20th century when chromatography was invented for solvent purification and analysis. After being used, these solvents were burned or disposed of in ponds and pits. Regulations to understand and control human and environmental exposure to organic solvents and their fumes did not begin to develop until the end of the century when it was realized that they must be used with caution. Solvents and other chemicals are governed by the Toxic Substances Control Act (TSCA), US. The Environmental Protection Agency (EPA) keeps an eye on the discharge of VOCs into the atmosphere. Particularly for carcinogenic, mutagenic, and reprotoxic compounds, the European Union's Solvents Emission Directive 1999/13/EC16, which went into force in October 2007, limits the 'loss of solvent to atmosphere.' A few examples of consumer products that may expose consumers to organic solvents include paint and coatings that contain aliphatic organic solvents (like hexane), adhesives and printing inks that contain aromatic organic solvents (like toluene, xylene, and benzene), paint strippers that contain dichloromethane, dry cleaning products that contain perchloroethylene, nail polishes and polish removers that contain ethyl acetate and acetone, and cleaning supplies and cosmetics that contain glycol alcohols, ethers, as well as Cyclopentasiloxane. Manufacturing exposure occurs as a result of solvent evaporation or leakage in normally closed processes.

Cseri et al. (2018) indicate Organic solvents can have two types of impacts: acute effects are short-term, reversible, and persist for a few hours or days. Chronic effects, on the other hand, are permanent and long-lasting consequences of repeated exposure. Certain organic solvents have the potential to cause cancer, while others may have negative effects on the skin, eyes, heart, neurological system, and circulatory system. It is challenging to determine the risk of released solvents, and threshold limit values are used to control solvent exposure. Certain techniques, such as biological and environmental monitoring, can be used to monitor exposure and exposure values. Certain solvents are employed as anesthetics because of their narcotic or depressive properties. In the 19th century, chloroform was also used for analgesia and anaesthesia. Between around 1865 and 1920, chloroform was utilized in all anesthetic procedures carried out in the United Kingdom and German-speaking nations, despite concerns about its safety being raised from the start. Because crime fiction authors frequently depict criminals using rags soaked in chloroform to render victims unconscious, the public has learned to understand chloroform as an incapacitating substance.

Nonspecific irritation of skin and mucous membrane tissues, which leads to irritating contact dermatitis, is the most common moderate adverse effect of solvent exposure., Cseri et al. (2018). Dryness, scaling, and fissuring are the characteristics of this ailment, which is caused by cleaning procedures or handling solvent-polluted items. In many cases, solvent vapors cause generalized irritation of mucous membranes, which irritates the eyes and other areas of the respiratory system. Benzene, toluene, or styrene exposure has been attributed in numerous studies to an increased risk of leukemia, nasopharyngeal carcinoma, and lung cancer. Exposure to toluene has been connected to a higher risk of developing several gastrointestinal cancers. Chlorinated substances including trichloroethylene, chloroform, and methylene chloride most frequently target the liver, kidney, and lung. Additionally, it has been shown that workers at gas stations exposed to organic solvents for prolonged periods experience serious harmful effects, including reductions in lung capacities and volume.

Impact on the Environment was referred to by (Cseri et al., 2018) about Organic Solvents in Water and Organic Solvents' Water Miscibility, which is one of the most crucial factors for solvent recovery, harm to the environment, and exposure to humans. The more soluble a solvent is in water, the more likely it is to be transferred to other parts of the environment and finally integrate into the hydrologic cycle. The solvents' and solvent wastes' solubility and miscibility in water can affect the extent of leaching into surface water, such as rivers and lakes. Aqueous solubility also affects the way a substance is removed from the atmosphere by dissolving into precipitation and surface waters. It is extremely difficult to separate miscible organic solvents in aqueous media, which leads to further issues with solvent recycling, waste management, and discharge. Water is less thick than chlorinated solvents. As a result, aquatic life is harmed by these harmful substances that sink. Dichloromethane, carbon tetrachloride, perchloroethylene, chloroform, trichloroethylene, as well as trichloroethane are chlorinated solvents that are most commonly encountered in the environment. An estimated 10,000,000 chlorinated solvent discharges occurred nationwide in 2012, according to the US EPA Toxic Release Inventory.

(Cseri et al., 2018) discuss a 2010 study that found a connection between an increase in liver cancer and groundwater contaminated by chlorinated solvents. It has been discovered that wastewater or municipal water supply treatment systems that employ coagulation, sedimentation, precipitative softening, filtering, and chlorination are ineffective at reducing certain chlorinated solvents to nonhazardous levels. Crude oil and petroleum products are lighter than water. Thus, they split at the topmost layer of the water. However, several of these compounds dissolve in water and may be toxic to aquatic life. Therefore, it is not recommended to release these compounds into the environment, and any spills or leaks must be stopped right away. By using activated charcoal, groundwater contamination from industrial chlorinated solvent discharge has been successfully reduced. NMP and DMF were extracted from industrial effluent using a variety of sophisticated adsorbents, including graphene-based materials, metal-organic frameworks, zeolites, as well as molecularly imprinted polymers. Wastewater may be successfully treated to remove over 99 percent of these polar aprotic solvents, and the recovered water can be recycled back into the original process. About 99% of manufacturing process's mass intensity can be decreased using the suggested waste water treatment method. Additionally, to produce acclimated biomass, a pilot-scale activated sludge system comprising acetone, methyl ethyl ketone, cyclohexanone, tetrahydrofuran, carbon tetrachloride, 1,1,1-trichloroethane, 1,1,2-trichloroethane, trichloroethylene, tetrachloro ethylene, chlorobenzene, and ethylbenzene solvents has been developed. Nine of the eleven pollutants had a reduction of over 94% in just seven weeks, with an estimated biodegradation of up to 93.4%.

According to a different study (Cseri et al., 2018), experimental microcosm subsurface constructed wetland system, which comprised duplicates of wetland plants like Juncus effusus, Carex lurida, Iris pseudacorus, and Pondeteria cordata, was used to treat postprimary municipal wastewater contaminated with acetone, tetrahydrofuran, and 1-butanol. In 3, 5 -10, and >10 days, respectively, microbial bioremediation method removed 90% of 1-acetone, butanol, as well as tetrahydrofuran. Preliminary investigations revealed that microbial bioremediation was used to remove most of the solvent. According to Cseri et al. (2018), biodegradation is the predominant removal method in the model systems; however, sorption may account for up to 20% of the overall removal.

(Cseri et al., 2018) explain Airborne Organic Solvents and their Mitigation Technologies. Organic solvents can either slowly photodegrade or react with gas-phase radicals to initiate catalytic oxidation after they are released into the atmosphere by evaporation. Organic solvents can be eliminated from the air via thermal oxidizers or adsorption. Thermal oxidizers are designed to accomplish 95% - 99% destruction of virtually all VOCs at about 800 °C with a residence time of less than 1 second. Catalytic oxidation systems directly combust VOCs like thermal oxidizers but at 300 – 500 °C. This enormous reduction in temperature and energy costs is made possible by catalysts, which lower the activation energy for combustion reactions and, as a result, the overall energy demand. Reverse flow reactors, also referred to as adiabatic packed bed reactors, change the feed flow direction regularly. Consequently, the reactor has to operate in temporary conditions. Because the chemical process may benefit from unsteady state reactor operation, RFR presents a novel alternative to eliminating VOCs from contaminated air. In a technique termed biofiltration, contaminated air is pushed through a porous packed media that supports flourishing colony of microecology. Before being converted into biomass, carbon dioxide, water, and inorganic compounds, pollutants are first pulled from air into medium's water/biofilm phase. Biofiltration's capacity to degrade is essential to its success.

(Sanni Babu and Reddy, 2014) state that environmental pollution's effects on public health, particularly the worldwide burden of sickness, have raised concerns on a global scale. Based on WHO estimations, extended exposure to environmental pollutants is the cause of roughly 25% of the ailments that people currently face. The majority of these environmental diseases, however, are difficult to identify and may be acquired in childhood before showing symptoms in later life. When natural or synthetic chemicals build up to dangerous amounts in the environment or are released into the environment, they can lead to toxic pollution, which can harm ecosystems, endanger human health, and reduce wildlife populations. Examining the presence, exposure to, and type of environmental toxicants as well as their relative effects on various organisms, environmental toxicology is a relatively new field of study. It is important to identify high-risk populations that are most exposed, and raising people's knowledge of the community's pollution sources will help them stay away from them. This presentation describes how the use of organic solvents to harm the environment has been replaced by bio-based products, which are safe, effective, and environmentally sound.

Uzma et al. (2008) state that prolonged exposure to air pollution and solvents might negatively impact thyroid, haematological, and respiratory functions. Their study sought to determine whether long-term exposure to contaminants like carbon monoxide and solvents like benzene had a negative impact on blood parameters, thyroid, and respiratory systems in gas station workers. 42 healthy, nonsmoking, 20–50 year old gas station employees with employment (exposure) durations ranging from 2–15 years made up the study group, while 36 healthy volunteers in same age range acted as controls. A portable electronic spirometer was used to measure lung functions and conduct a physical examination. Normal haematology lab procedures were used to generate complete blood pictures (CBP), and Chemiluminescence immunoassay (CLIA) light absorption methods were used to evaluate hormone levels. The restrictive pattern was more prevalent in the workers than in the control groups, and lung volumes, as well as capacities, significantly dropped. However, among workers exposed for over a decade, the restrictive pattern changed to a mixed pattern. When compared to the control participants, workers with longer exposure times showed significantly higher levels of hemoglobin (Hb) (>16 mg%) and red blood cells (RBC) (5.4 million cells/mm3) (14.483 mg% and 4.83 million cells/mm3 for Hb and RBC, respectively). Workers had a much lower white blood cell count than controls, except for eosinophils and platelets. Between the long-term exposed and non-exposed groups, there was a notable drop in thyroid stimulating hormones (TSH), tri-iodothyronine (T3), and a marked increase in tetraiodothyronine (T4) and free thyroxine (T4F). Up until now, researchers have solely examined the effects of solvent exposure on professionals, ignoring the impact of concurrent air pollution. The current study's findings show that workers exposed to solvents and air pollutants for extended periods experience a considerable harmful effect. To address environmental health concerns for gas station workers, better detection and prevention technologies are required.

Summary of Impact of Organic solvents:

In the assessment of Environmental Effects, (Hellweg et al., 2004) explored three methods for assessing the environmental impacts of chemicals: early-phase hazard identification, screening indicators for chemical exposure, and life-cycle assessments. Chlorinated solvents were identified as particularly harmful, while methanol and toluene were less problematic. Energy use during production significantly contributes to environmental impact. Environmental Impacts like Water Pollution where High-miscibility solvents contaminate water bodies, affecting aquatic ecosystems. Effective treatment methods include advanced adsorbents and bioremediation, achieving up to 99% removal of some solvents. Air Pollution also is not to be ignored at all since Solvents evaporate into the atmosphere, causing photodegradation or forming volatile organic compounds (VOCs). Mitigation technologies include thermal oxidizers, catalytic systems, and biofiltration.

Socio-environmental frameworks where Fraser et al. (2003) highlighted reflexive relationship between environment as well as society, introducing a framework of environmental sensitivity (likelihood of damage) and social resilience (ability to adapt). This approach helps understand the interplay between human activities and environmental changes. Sustainable Organic Synthesis, where (Sheldon, 2019) reviewed advancements in sustainable solvents. Water-based alternatives and neoteric solvents (e.g., ionic liquids, SC CO_2) show promise. Many traditional solvents like benzene and chloroform are toxic and heavily regulated. Solvents constitute a major waste source in pharmaceutical manufacturing, necessitating greener practices.

Effects on human health, where Cseri et al. (2018) documented acute (short-term) as well as chronic (long-term) effects of solvent exposure, such as respiratory and cardiovascular issues, carcinogenic risks, and damage to organs like the liver and kidneys. Workplace exposure to solvents in industries and consumer products is a major concern, requiring stringent monitoring and threshold limits. Pollution and Public Health, studied by (Sanni Babu and Reddy, 2014) linked solvent pollution to public health issues like diseases acquired during childhood but manifesting later. They emphasized bio-based products as eco-friendly alternatives. Occupational exspoure (Uzma et al., 2008)was investigated for workers at gas stations exposed to pollutants as well as solvents, reporting decreased lung capacity, altered blood profiles, and thyroid dysfunction. Long-term exposure led to mixed respiratory impairments, highlighting the need for preventive measures.

These studies collectively underline the need for sustainable solvent practices, stricter regulations, and advanced mitigation technologies to reduce environmental as well as health impacts.

Human Society Theory:

Available literature was reviewed to explore the Theory of Human Society in relation to the topic of this study. The following studies discuss various aspects of this theory. (“Studies in the Theory of Human Society,” 1922) where Prof Giddings argues that rather than exciting discoveries, science has been making corrections this century. The basic ideas of sociology are especially affected by this. These "Studies," which are usually intriguing, suggestive, and often illuminating, are a contribution to the revising of the idea of human society that has been required by the increasing clarity and precision in scientific vision that has occurred over the past 20 years. It is challenging to provide a succinct description of the author's accomplishments in this area due to their somewhat discursive nature; however, in summary, it can be claimed that to account for social origins and the stages in the evolution of society in terms of the struggle for existence, a psychological interpretation was applied to the conclusions of authors like Darwin, Spencer, Bagehot, and Kidd, to name the more significant. According to Professor Giddings' theory of human society, social phenomena are the result of stimulus that is reacted to by ‘pluralistic’ behavior, which in turn gives rise to consciousness of kind, the ‘herd instinct’ of other writers, from which discriminating associations, the ethical code, cooperation, and the division of labor are eventually derived, as well as the selection and perpetuation of the appropriate, the ‘fit’ of an older terminology.

Human Society Theory Studies in the Theory of Human Society (1922) focuses on the interrelationship between human behavior, societal norms, and environmental impacts. This theory emphasizes that societal progress and environmental sustainability are interconnected. In the context of organic solvent use, this theory helps explain how societal awareness and environmental education shape industrial behavior.

By adopting sustainable practices, industries contribute to the broader societal goal of environmental protection. The pharmaceutical industry, as a key player in global healthcare, has a societal responsibility to minimize its environmental footprint, including solvent use. This theory underpins the research on awareness by examining how shifts in societal norms can influence corporate behavior in managing solvents Studies in the Theory of Human Society (1922).

In this research, Human Society Theory Studies in the Theory of Human Society (1922) provides insights into how regulatory frameworks, industry standards, and societal pressures can create a movement toward more sustainable manufacturing processes. The practical applicability of regulations may also depend on the collective societal pressure to adopt greener practices, aligning corporate interests with societal welfare.

Thus, the Human Society Theory examines the interconnectedness between societal norms, human behavior, and environmental impacts. It posits that societal progress and environmental sustainability are interdependent, with changes in social awareness and regulatory frameworks influencing industrial practices. In the context of organic solvent use, societal norms, awareness, and education can shape how industries, particularly the pharmaceutical sector, approach environmental sustainability.

(Hopwood et al., 2005) have discussed sustainable development as a difficult and contentious idea. They point out that the pervasive increase in support and interest in the idea of sustainable development could represent a significant change in how people view their interactions with one another and with nature. A few unique places have been protected as wilderness or parks, but for the majority of the last century and a half, the environment has been viewed as something that exists outside of humankind and is meant to be used and exploited. The perception of environmental issues was primarily local. The interaction between humans and the environment was generally thought of as a triumph of man over nature. According to Dryzeck (1997), the Promethean paradigm held that human knowledge and technology could overcome any challenge, including environmental and ecological ones. The rise of capitalism, the industrial revolution, and contemporary science were all associated with this viewpoint. The world was created for man, not the other way around, as one of the pioneers of modern science, Bacon, once said. The majority of governments and companies, except for local issues and wilderness protection, focused their environmental management and concern on natural resource management. They give as an example the theories of Pinchot in the USA (Dryzeck, 1997), who acknowledged that natural resources are necessary for human use and that they should be managed rather than quickly exploited to achieve maximum long-term use. With economic growth, which is characterized by rising production, as the top priority, economics emerged as the primary concern in human connections (Douthwaite, 1992). Growth was viewed as the key to achieving human well-being since it would lift those at the bottom of the poverty scale while enabling everyone to rise. Concerns about a healthy future for humanity, socioeconomic challenges related to poverty and inequality, and expanding environmental problems have all been attributed globally, leading to the idea of sustainable development. Socioeconomic and environmental issues are closely related. The World Conservation Strategy was the first significant use of the term in 1980 (IUCN et al., 1980). In the Brundtland Report, sustainable development was defined as "meeting the needs of the present without compromising the ability of future generations to meet their needs" (WCED, 1987, p43). This process of combining environmental and socioeconomic issues was most famously expressed in this definition. As Lee (2000, p32) has stated, "sustainable development is an unashamedly anthropocentric concept," which defines demands from a human perspective. Sustainable development has gained widespread popularity, according to this research, since it can be interpreted in a variety of ways. Crucially, it incorporates the most important human concerns: how to make life worthwhile, how we relate to the environment, and how we relate to one another. The idea of sustainable development is not abandoned; rather, it offers a helpful framework for discussing the options available to humanity. They have maintained that understanding the intimate connections between society and the environment, which include mutual feedback loops, and that social and environmental fairness are essential concepts should serve as the foundation for sustainable development. Given the necessity of fundamental change, the close relationship between human existence and the environment, and the intrinsic linkage of power structures that exploit both people and the planet, we would contend that transformation is imperative. However, they did not believe that a sole commitment to change was required or rational. Reforming now is preferable to doing nothing at all, although change might not be possible right away. Raising awareness of the problems, successfully mobilizing the media, and forming alliances between researchers, public protest, and direct action should be the primary goals when working with the government and industry to implement reforms.

Catton and Dunlap (1978) introduced this concept in their work on environmental sociology, arguing that human societies are intrinsically linked to ecosystems and that industrial activities can either harm or support ecological health. Their article speaks about NEP, 'New Environmental Paradigm' which notes that "a) Human beings are but one species among he many that are interdependently involved in the biotic communities that shape our social life, b) Intricate linkages of cause and effect and feedback n the web of nature produce many unintended consequences from purposive human action, c) The world is finite, so there are potent physical and biological limits constraining economic growth, social progress and other societal phenomena."

Catton and Dunlap (1978) highlighted that we live in a world of scarcity that we have inherited and will continue to do so because there are not enough resources to meet all of our needs. Due to its restrictions, conflicts, and constraints, it is a world that necessitates collective coordination and cost-bearing. Exemplifying by the U.S., with its ‘non-redistributive’ economy as the solution to environmental and resource problems sand which has increasingly opted for ‘managed scarcity’. For example, managed scarcity entails preventing ecological disruptions by requiring industry to reduce pollution, which results in higher prices for consumers, and preventing resource shortages by imposing higher taxes (and consequently higher consumer prices) on the limited resources. The obvious fact that shortages are imminent, the substantial health risks caused by pollutants, and the possibly disastrous changes in the biosphere brought about by unchecked economic and technological expansion.

In this research, the Human Society Theory, Studies in the Theory of Human Society (1922) provides insights into how collective societal pressures—through awareness campaigns, education, and policy changes—can drive industries toward more sustainable solvent management practices. This theory Studies in the Theory of Human Society (1922) is particularly relevant in industries like pharmaceuticals, where both societal expectations for sustainability and regulatory frameworks influence corporate behavior. As public awareness of environmental issues grows, the pharmaceutical industry is facing increasing pressure to adopt sustainable practices, such as reducing reliance on organic solvents.

Survey data in this research supports the Human Society theory Studies in the Theory of Human Society (1922) Prof Giddings by showing how respondents' awareness of environmental impacts correlates with their support for regulatory norms promoting sustainable alternatives. This reflects how shifts in societal awareness, combined with regulatory action, can lead to more sustainable industrial practices.

This is aptly supported by the paper presented by Shetty (2023) which claims that the idea of human society places a strong emphasis on how social variables influence people's attitudes, beliefs, and behaviors. It can be utilized in research to investigate how social factors impact a range of phenomena, such as institutions, culture, and human development. Human societies are made up of people with similar organizational and lifestyle patterns. To conceive and examine intricate social processes in survey research, the idea of human society offers a useful framework. Researchers can provide more complex and theoretically informed insights into the social world thanks to it Shetty (2023). The growing interconnectedness of the world's ecological, social, and economic systems makes it difficult to forecast how societal decisions will turn out. A vast array of perspectives and methodologies are included in this theory to comprehend the dynamics of human social systems. It focuses on the way people and groups interact, how institutions and social structures form and are maintained, and how larger historical and cultural settings influence social life. Survey interview research can be guided by the theory of human society when formulating research questions, sampling plans, and data processing techniques. For instance, theories of class and social stratification may be used to guide the research topics and sample strategy of a researcher who is interested in the creation and perpetuation of social inequality. Likewise, an investigator examining the rise and spread of novel technologies might formulate survey questions and conduct data analysis grounded in social network and cultural transmission theories Shetty (2023).

Summary:

The Human Society Theory by Prof Giddings in Studies in the Theory of Human Society (1922) explores the interconnectedness of human behavior, societal norms, and environmental sustainability. It suggests that social awareness and collective behavior drive societal progress, influencing industries to adopt sustainable practices. In the context of organic solvent use, this theory explains how public awareness, education, and regulatory frameworks shape corporate behavior in industries like pharmaceuticals.

Scholars such as (Catton and Dunlap, 1978; Hopwood et al., 2005) expanded on this theory, emphasizing the relationship between human societies and ecological systems. They highlight the shift from an exploitative approach to environmental resources to a sustainability-driven perspective, advocating for reforms that integrate economic growth with environmental responsibility. The New Environmental Paradigm (NEP) Catton and Dunlap (1978) further reinforces the idea that human activities must align with ecological limits, underscoring the need for industries to adopt responsible resource management.

Survey data in this research supports Human Society Theory by demonstrating how increased awareness of environmental impacts correlates with greater acceptance of regulatory measures promoting sustainability. As societal expectations evolve, industries, particularly pharmaceuticals, are pressured to align with sustainable practices, such as minimizing solvent use. This aligns with Shetty (2023), who highlights how social factors shape behaviors, institutions, and policy adoption, reinforcing the role of societal influence in driving sustainable industrial practices.

2.4 Summary

Chapter II explores the theoretical framework surrounding the sustainable use of organic solvents in pharmaceutical manufacturing. It presents key sustainability theories, including the Green Aspiration Level (GAL) (Frank Roschangar et al., 2017), which provides a structured approach for evaluating solvent waste and process complexity. Triple Bottom Line (TBL) (Miller, 2020) emphasizes the balance between financial profitability, environmental responsibility, and social well-being, while Life Cycle Assessment (LCA) helps assess the overall environmental impact of solvent use. Additionally, Corporate Social Responsibility (CSR) (Miller, 2020) highlights the ethical responsibility of pharmaceutical companies in reducing harmful solvent use, and Ecological Modernization Theory (EMT) (Mol and Sonnenfeld, 2014) suggests that regulatory frameworks can drive innovation and sustainable practices. The Circular Economy (CE) (Geissdoerfer et al., 2017) promotes recycling and resource efficiency, aligning with the reduction of solvent waste. These theories collectively provide a foundation for assessing awareness, regulatory applicability, and solvent reduction feasibility in pharmaceutical manufacturing.

The Theory of Reasoned Action (TRA) (Ajzen, 2012) is explored to understand how individual behavior is influenced by attitudes and social norms. TRA posits that decision-makers in pharmaceutical industries are likely to adopt sustainable solvent practices if they perceive them as beneficial and supported by industry norms. Awareness alone may not drive change unless strong social and regulatory norms reinforce sustainable behaviors.

The Human Society Theory, Studies in the Theory of Human Society (1922) examines the interconnectedness of societal norms, human behavior, and environmental sustainability. It suggests that regulatory frameworks, industry standards, and societal pressure collectively influence corporate behavior toward greener practices. Studies by (Hopwood et al., 2005) and (Catton and Dunlap, 1978) highlight the shift from an exploitative approach to environmental resources to one centered on sustainability, reinforcing the need for industries to align with ecological limits. Survey data in this research supports this theory, showing that increased awareness of environmental impacts correlates with stronger support for regulations promoting sustainable alternatives.

The chapter 2 also discussed the impact of organic solvents on human health and the environment. (Hellweg et al., 2004) assessed environmental risks using screening indicators and life-cycle analysis, identifying chlorinated solvents as particularly harmful. (Fraser et al., 2003) proposed a framework linking environmental sensitivity and social resilience, emphasizing how societies must adapt to environmental changes. (Sheldon, 2019) reviewed sustainable solvent alternatives, highlighting the potential of neoteric solvents such as ionic liquids and water-based alternatives. However, widespread adoption remains limited due to regulatory and cost barriers.

Health risks associated with solvent exposure are a significant concern. (Cseri et al., 2018) documented both acute and chronic effects, including respiratory and cardiovascular issues, carcinogenic risks, and neurological disorders. Workplace exposure in industries and consumer products underscores the need for stringent monitoring. (Sanni Babu and Reddy, 2014) linked solvent pollution to long-term health risks and emphasized bio-based alternatives as safer solutions. (Uzma et al., 2008) studied gas station workers exposed to solvents, finding significant declines in lung capacity and changes in blood parameters, reinforcing the need for preventive measures.

Environmental pollution due to solvent use includes water contamination (Cseri et al., 2018), where high-miscibility solvents pollute water bodies, impacting aquatic ecosystems. Advanced adsorbents and bioremediation techniques can remove up to 99% of certain solvents, improving water quality. Air pollution results from solvent evaporation, forming volatile organic compounds (VOCs) that contribute to smog and respiratory problems. Mitigation technologies such as thermal oxidizers, catalytic systems, and biofiltration can reduce VOC emissions.

To address these concerns, regulatory frameworks such as the ICH Guideline for Residual Solvents (Grodowska and Parczewski, 2010a) provide classification and permissible limits for solvents but do not enforce restrictions on their use. This highlights the need for stronger regulatory measures and increased awareness to drive voluntary reduction initiatives.

Conclusion:

The literature review underscores the necessity of combining regulatory compliance, corporate responsibility, and technological advancements to achieve sustainability in solvent usage. Theoretical perspectives such as TRA, Human Society Theory, and sustainability frameworks provide valuable insights into the role of societal awareness, industry norms, and regulations in promoting sustainable practices. The adverse environmental and health impacts of organic solvents emphasize the urgency of adopting alternative solvents and more effective mitigation strategies. As pharmaceutical industries face increasing pressure to reduce their environmental footprint, integrating sustainability-focused policies and innovations will be essential for long-term environmental and societal well-being.

CHAPTER III:

METHODOLOGY

3.1 Overview of the Research Problem

The Research problem examines the unsustainable use of organic solvents in pharmaceutical manufacturing, a practice that has considerable environmental and health repercussions. The usage of these solvents contributes significantly to air and water pollution, ultimately escalating climate change. This study is designed to assess awareness among professionals in the pharmaceutical sector regarding sustainable alternatives, as well as the perceived practicality and effectiveness of adopting such alternatives. The research also seeks to understand the influence of regulatory norms and societal pressures on the industry's transition towards sustainability.

While existing studies have shed light on organic solvents' usage and impact, notable knowledge gaps persist that hinder the progression towards sustainable practices in this field. These include:

1) Environmental Impact Assessment: More comprehensive assessments are essential to determine the full extent of organic solvents' contributions to climate change and ecosystem degradation.
2) Long-Term Health Effects: Further exploration is needed into the chronic health impacts of exposure to organic solvents in the workplace, as these effects are often underreported or inadequately understood.

3) Sustainable Alternative Development: Current research is limited in the development of effective, sustainable alternatives suited to the complexities of pharmaceutical production processes.
4) Regulatory impacts: There is a need to evaluate the effectiveness of existing policies and regulations, highlighting areas for improvement to promote sustainability.

This study fills in these research gaps and advances a more comprehensive understanding of the opportunities and difficulties related to lowering the use of organic solvents in the pharmaceutical sector.

To deepen our understanding, theoretical frameworks encompassing TRA, Theory of Reasoned Action, Fishbein and Ajzen (1977), Human Society Theory, Catton and Dunlap (1978) as well as Corporate Social Responsibility (CSR), Archie B. Carroll (1999) provide valuable perspectives on attitudes, societal impact, and corporate decision-making, respectively.

The Theory of Reasoned Action (TRA), according to Fishbein and Ajzen (1977) TRA explores the connection between beliefs, attitudes, intentions, and behaviors, emphasizing rationality in human decision-making. TRA helps us understand the factors influencing professionals' attitudes toward sustainable practices, framing behavior as a product of rational processing of available information. Fishbein and Ajzen posit that beliefs, attitudes, intentions, and behaviors are interrelated, affecting whether an individual adopts sustainable practices. This understanding is critical in examining the attitudes of pharmaceutical professionals toward sustainable solvent alternatives.

In the Theory of Reasoned Action (TRA) Click or tap here to enter text. Fishbein and Ajzen (1977) mention how they seek to accomplish two objectives as explained previously, to provide a comprehensive review of a wide range of the theoretical and empirical literature devoted to attitudinal phenomena, and to demonstrate that this literature can be incorporated within a unified and systematic explanatory structure. Given that "attitude" has been a fundamental conceptual concern of social psychology Fishbein and Ajzen (1977) constructed a set of interrelated models addressing the processes of the formation and change of beliefs, attitudes, and intentions. This is important in the context of why people behave in a certain manner and what is the driving factor behind this, probably their attitude?

(Fishbein and Ajzen, 1977)insist on the necessity of distinguishing between four classes of variables: beliefs, attitudes, intentions, and behaviors. They also make certain crucial assumptions about these variables and the nature of human conduct. The assumption that humans are essentially rational information processors whose ideas, attitudes, intentions, and behaviors are influenced by the information at their disposal is the greatest degree of abstraction. So, they say that an attitude is a bipolar aspect of affect.

(Fishbein and Ajzen, 1977)devote considerable attention to the analysis of prejudice, treating this concept at times as if it were what they would term a ‘global attitude.’ If attitudes are unidimensional, then logical consistency demands that this assumption must hold for all attitudes including the most global. Nevertheless, research on prejudice, including some of that cited by these Authors, suggests that the phenomenon consists of a configuration of effects rather than a single evaluative continuum. They then built a series of connected models that addressed how attitudes, beliefs, and intentions are formed and altered.

Human Society Theory, as discussed in the previous section, (Catton and Dunlap, 1978)address the intersection of economic expansion and ecological disruption, describing three potential responses to resource utilization. Economic Synthesis which focuses on maximizing growth, often ignoring ecological repercussions. Managed Scarcity Synthesis which seeks to control resource utilization impacts by regulating certain industries. Ecological Synthesis aims to minimize disruptions and ensure sustained resource yields through production and demand management. This theory provides insight into societal pressures faced by the pharmaceutical industry, wherein economic goals and ecological responsibility must be balanced. The conceptual issues introduced by the Human Society Theory (Catton and Dunlap, 1978)given the thesis that "economic expansion is a social desideratum" along with the antithesis that "ecological disruption is a necessary consequence of economic expansion," a dialectic occurs with the proposition's acceptance that "ecological disruption is harmful to human society". There are three different ways to synthesize the dialectic: 1) an economic synthesis that focuses on growth and ignores ecological disruptions; 2) a managed scarcity synthesis that addresses the most glaring and harmful effects of resource use by enforcing restrictions on specific industries and resources; and 3) an ecological synthesis that uses 'substantial control over both production and effective demand for goods' to reduce ecological disruptions and preserve a 'sustained yield' of resources.

Corporate Social Responsibility (CSR), Archie B. Carroll (1999) framework on CSR highlights industry's function in balancing profitability with societal expectations.

CSR encompasses four categories of responsibility—economic, ethical, legal, as well as philanthropic—and serves as a guiding framework for businesses to act as responsible corporate citizens. CSR’s relevance to this study lies in its potential to encourage sustainable practices through stakeholder-oriented business strategies, ensuring that companies align their operations with broader social and environmental goals.

Corporate Social Responsibility (CSR) Archie B. Carroll (1999) can explain the industry's decision-making process regarding sustainable practices. The history of corporate social responsibility, or CSR, is extensive and diverse. Evidence of the corporate community's interest in society dates back hundreds of years. However, the majority of formal work on social responsibility dates back to the 20th century, particularly in the last 50 years. Furthermore, formal writings have been most noticeable in the United States, where a substantial body of literature has accumulated, even while CSR thought can be seen in many places throughout the world (particularly in developed nations). Even though CSR had been mentioned several times before the 1950s, that decade marked the beginning of what may be referred to as the ‘modern era’ in terms of CSR definitions. The literature on CSR underwent significant development in the 1960s. Definitions of CSR started to spread widely in the 1970s, with academics promoting the majority of this definitional literature. In the 1980s, there were more initiatives to assess and study CSR, less original definitions of the term, and different thematic frameworks. Though no new definitions were introduced to the corpus of literature, the idea of CSR underwent a considerable transformation in the 1990s to alternative themes such as stakeholder theory, business ethics theory, CSP, and corporate citizenship.

The trend of operationalizing the CSR idea Archie B. Carroll (1999) and articulating other concepts that were consistent with CSR theory but that used different emphases or themes as their focal point was carried on during that time. Additionally, the terminology of CSR is still being used today, with a growing focus on both theoretical advancements and measurement measures. Since the CSR concept is a fundamental component of many other theories and consistently aligns with what the public expects from the business community today, it will continue to be a crucial component of corporate language and practice. Scholars may update and modify current definitions of CSR or introduce new definitions into the literature as theory and research progress, but it is currently difficult to envision how these new ideas could emerge independently of the foundation laid over the previous 50 years. There will probably be new areas to consider in the way firms should respond to their stakeholders, especially on a global scale and in new and developing fields, technologies, and commercial applications. Because it fundamentally tackles and encapsulates the most significant public concerns about the interactions between business and society, the CSR concept seems to have a bright future in this environment Archie B. Carroll (1999).

CSR must be presented in a way that embraces the full spectrum of corporate obligations for the ethical businessperson to embrace it. Four types of social responsibilities: economic, legal, ethical, and philanthropic are proposed here to make up total CSR Archie B. Carroll (1999). Of course, all of these kinds of duties have always been there in some form or another, but only recently have philanthropic and ethical roles gained prominence. Put more simply and managerially, the CSR corporation should aim to be profitable, ethical, compliant with the law, and a decent corporate citizen. The concept of corporate social responsibility and an organization's stakeholders are a good fit. By identifying the particular groups or individuals that businesses should take into account in their CSR approach and activities, the stakeholder idea personalizes social or societal duties. Stakeholder nomenclature, then, gives "names and faces" to the individuals of society that are most significant to business and to whom it must respond. In particular, CSR was placed under the category of "corporate social performance." Since it is nearly impossible to precisely and fully isolate CSR into its category in content analysis, three other subject themes embrace CSR issues. Stakeholder theory, business ethics, and Corporate social performance (CSP) are the three CSR-related ideas or theories that have drawn the greatest attention in the 1990s.

In essence, this study seeks to investigate the barriers hindering the adoption of sustainable solvent alternatives, drawing on the above theories like TRA, Theory of Reasoned Action, Fishbein and Ajzen (1977), Human Society Theory, Catton and Dunlap (1978) as well as Corporate Social Responsibility (CSR), Archie B. Carroll (1999) to analyze how attitudes, societal pressures, and corporate accountability influence decision-making in the pharmaceutical sector.

In conclusion, this chapter highlights the serious problems related to the unsustainable use of organic solvents in pharmaceutical production, highlighting the necessity of sustainable substitutes to lessen negative effects on the environment and human health. The study identifies key knowledge gaps, including long-term health effects, environmental impact assessments, alternative development, and regulatory effectiveness, while drawing on TRA, Theory of Reasoned Action, Fishbein and Ajzen (1977), Human Society Theory, Catton and Dunlap (1978) as well as Corporate Social Responsibility (CSR), Archie B. Carroll (1999) frameworks to analyze the factors influencing sustainable adoption. These theoretical perspectives help contextualize the industry's decision-making, highlighting the role of attitudes, societal expectations, and corporate responsibility in addressing the challenges of sustainable solvent use.

3.2 Operationalization of Theoretical Constructs

This section details how key theoretical constructs from the Theory of Reasoned Action (TRA), Human Society Theory, & Corporate Social Responsibility (CSR) are operationalized and measured in this research. The constructs are translated into measurable variables within the survey instrument, allowing for an empirical investigation of how these theories apply to the use of organic solvents in the pharmaceutical industry.

A) Awareness of environmental impacts:

Theory: Derived from Human Society Theory, which emphasizes the role of societal norms and awareness in shaping industrial behavior Catton and Dunlap (1978).

Operationalization: Assess participants’ knowledge of the negative effects of organic solvents.

Survey Questions: Questions evaluating participants' awareness of the negative impacts of organic solvent use.

B) Perceived effectiveness of sustainable alternatives:

Theory: Based on the Theory of Reasoned Action (TRA), which highlights that beliefs influence attitudes and behaviors toward adopting sustainable alternatives (Fishbein and Ajzen, 1977).

Operationalization: Assess how participants perceive the effectiveness of alternatives to organic solvents.

Survey Questions: Questions focus on the perceived effectiveness of sustainable solvents.

C) Perceived costs of switching to alternatives:

Theory: Linked to Corporate Social Responsibility (CSR) Archie B. Carroll (1999) and Ecological Modernization Theory (EMT), which suggest that economic considerations influence sustainability practices Mol and Sonnenfeld (2014))

Operationalization: Assessing participants' views on the financial implications, operational costs, of adopting sustainable solvents.

Survey Questions: Questions examine the perceived cost burden associated with transitioning to green alternatives.

D) Perceived practicality of switching to alternatives:

Theory: Derived from Ecological Modernization Theory (EMT), which addresses the balance between technological feasibility and environmental responsibility Mol and Spaargaren (2014).

Operationalization: Gauging participants’ beliefs about the practicality of adopting sustainable solvents, considering regulatory requirements and technological challenges.

Survey Questions: Questions assess the various barriers to implementing greener alternatives.

E) Regulatory norms promoting sustainable alternatives:

Theory: Stemming from Human Society Theory and CSR, which emphasize the role of statutory policies in shaping industrial behavior toward sustainability.

Operationalization: Measured by evaluating participants' perceptions of the effectiveness of regulations that promote sustainable solvent use.

Survey Questions: Questions assess the perceived strength and influence of statutory norms on the adoption of sustainable practices.

3.3 Research Purpose and Questions

In Section 1.5, it was stated that for the survey, the following key areas will be broadly explored through the questions:

(a) The existing level of awareness and understanding of the environmental impacts of organic solvents among both pharmaceutical professionals and students.

(b) The perceived challenges in transitioning from organic solvents to sustainable alternatives.

(c) The factors influencing the adoption of sustainable alternatives within the pharmaceutical industry, including economic considerations, technological feasibility, and regulatory requirements.

Accordingly, the Research Questions statements were refined as follows:

A) Awareness of the negative impacts of solvents usage in Pharmaceutical Personnel as well as Students.

B) Practical applicability of the Regulatory norms that govern the usage of Organic solvents

C) Can usage of Organic solvents be avoided in the manufacture of pharmaceutical dosage forms

Further, based on the probable factors that could be impacting the adoption of sustainable practices regarding usage of organic solvents within the Phrarmaceutical industry, the following are the Sub-questions on which the Survey Questionnaire is based:

A) Awareness and attitudes

To what extent are pharmaceutical professionals aware of the environmental impacts associated with the use of organic solvents? How does environmental awareness impact professionals' attitudes toward adopting sustainable solvent alternatives?

B) Perceived effectiveness and practicality of sustainable alternatives

How do pharmaceutical professionals perceive the effectiveness and practicality of sustainable solvent alternatives? What are the barriers to implementing these alternatives in pharmaceutical manufacturing processes?

C) Influence of regulatory policies and societal pressures

How do government regulations and industry standards influence sustainable practices related to solvent usage?

To what extent do societal expectations and pressures impact pharmaceutical companies' decisions to adopt sustainable alternatives?

D) Health and environmental concerns

What are the perceived long-term health effects associated with exposure to organic solvents in pharmaceutical manufacturing?

How significant is the contribution of organic solvent usage to environmental issues, such as air and water pollution and climate change?

E) Development and adoption of alternatives

What are the current challenges in developing effective and feasible sustainable alternatives to traditional organic solvents?

How can the pharmaceutical industry address these challenges to promote the adoption of green practices?

Summary:

Tthis chapter establishes the purpose of the research and lays out key questions that drive the study, emphasizing the need to understand the awareness, attitudes, and barriers to sustainable solvent usage in pharmaceutical manufacturing. The research objectives outlined here provide a framework to systematically explore and address these issues, ultimately contributing to the field's advancement toward more sustainable practices. By answering these questions, this study aims to deliver actionable insights for policymakers, industry stakeholders, as well as researchers to foster a shift toward environmental sustainability in pharmaceutical manufacturing.

3.4 Research Design

This part describes the study design used to investigate sustainable practices regarding organic solvents in pharmaceutical manufacturing. The design includes the research approach, data collection methods, sampling techniques, and analysis methods. Given the exploratory nature of the study, a survey-based quantitative approach is used to capture a broad view of awareness, perceptions, and attitudes toward sustainable solvent practices among professionals in the pharmaceutical industry.

About the Research Approach, this study adopts a quantitative survey-based approach to explore awareness, attitudes, and perceived barriers regarding sustainable organic solvent usage. By collecting standardized data from a chosen population sample, the survey method makes it easier to perform statistical analysis along with spotting trends and patterns in the pharmaceutical industry.

The Survey Methodology consists of a structured questionnaire with selective questions aimed at assessing various aspects related to sustainable solvent use, including awareness of environmental impacts, attitudes toward adopting sustainable alternatives, and perceptions of regulatory influences. This method provides a consistent data set across respondents, allowing for comparative analysis and enhancing the reliability of results.

3.5 Population and Sample

In this research on the sustainable usage of organic solvents in pharmaceutical manufacturing, the population consists of individuals within the pharmaceutical industry, and students with relevant knowledge or interest in organic solvents and sustainability practices. This broad population includes individuals aged 15 to 50 years, covering both established professionals and those at the educational or early-career stages who may have emerging views on the industry's sustainability challenges.

To obtain a representative view of the attitudes and awareness levels regarding organic solvent usage, the sample was created by employing a non-probability sampling technique. In particular, convenience sampling was employed to gather responses quickly and efficiently, focusing on participants readily available through professional networks, industry events, academic institutions, and online forums related to pharmaceutical studies and practices. The sample aimed to include a balanced mix of pharmaceutical professionals with hands-on experience in the industry, as well as students and recent graduates who are familiar with the topic through academic exposure.

The final sample size, totaling 323 respondents, was selected to provide a meaningful representation that allows for significant insights into the target population's awareness, attitudes, and perceptions regarding sustainable practices in the pharmaceutical sector. Given the focus on environmental sustainability in manufacturing, this sample provides data essential to understanding the knowledge gaps and potential areas for promoting eco-friendly practices among current and future industry participants.

Limitations pertaining to Convenience sampling, while beneficial for accessibility and speed, may introduce biases, as respondents are not randomly selected. This limitation is acknowledged, as it may affect the generalizability of the findings. However, by ensuring diversity within the sample—both in professional experience and educational background—this approach provides a preliminary, valuable overview that can inform further studies or initiatives aimed at enhancing sustainability practices in the pharmaceutical industry.

The target population was pharmaceutical professionals working in various roles within the industry, including research and development, manufacturing, quality control, and regulatory affairs. Participants were drawn from a range of pharmaceutical organizations. Another part of the target population was Students since they would bring in their understanding as the younger Generation.

Sampling Technique: A purposive sampling technique is used, targeting individuals in the pharmaceutical industry with knowledge or involvement in manufacturing processes where organic solvents are commonly used. This approach ensures that participants are familiar with the topic and can provide relevant insights into sustainable practices. Pertaining to students, only students from the Scientifc and Pharmaceutical streams are allowed

Sample Size: A sample of about 300 - 350 professionals and students was targeted to achieve a sufficient level of statistical power and to enhance the generalizability of findings within the industry.

Ethical Considerations: To protect privacy and confidentiality, the study complies with ethical guidelines. Informed consent from all the participants. is obtained from each participant at the start of the Survey itself, such that they complete the survey with a sense of participation on completion, with an explanation of the study’s purpose and the voluntary nature of participation. Responses are anonymized, and data from each participant is stored securely, accessible only to the Researcher. Thus participation in this survey was entirely voluntary, and no formal signed consent was further necessitated. A statement at the beginning of the survey informed participants that their decision to complete the survey indicated their consent to participate. Confidentiality was assured, and all responses were reported in aggregate form to protect participant privacy. This approach ensures transparency and demonstrates that ethical considerations regarding consent were respected during the data collection.

3.6 Participant Selection

Participants in the current research have been selected according to sustainable usage of organic solvents in pharmaceutical manufacturing based on their relevance and insight into the industry. Participants included pharmaceutical professionals actively engaged in manufacturing, regulatory, and quality control roles, as well as students and recent graduates in pharmaceutical sciences. This composition was intended to capture a comprehensive understanding of attitudes toward sustainable practices across different levels of expertise and awareness. So also the Students chosen were from the Scientific and Pharmaceutical streams who maybe having knowledge of the subject matter rather than selecting students from the General sections.

Inclusion Criteria: Participants were selected based on their age, knowledge, and/or involvement in the pharmaceutical professional or educational field, within an age range of 15 to 50 years. This range was chosen to include younger students as well as experienced professionals, ensuring a wide range of perspectives on organic solvent usage. Another criterion was familiarity with or exposure to environmental and sustainability concerns in the industry, allowing for meaningful responses and minimizing the likelihood of uninformed answers that could skew the data. The purpose of this research is to analyze the current state of organic solvent usage in the pharmaceutical industry, identify barriers to adopting sustainable alternatives, and explore potential solutions for promoting greener practices. The study aims to increase awareness among pharmaceutical stakeholders about the adverse effects of excessive solvent use (Jiménez-González et al., 2011; Sheldon, 2017). Given the pharmaceutical sector's significant reliance on organic solvents for drug formulation, purification, and manufacturing, addressing sustainability concerns is crucial for minimizing environmental and health risks. Additionally, the industry's reliance on synthetic chemicals, organic solvents, and complex supply chains leads to substantial carbon emissions. Manufacturing facilities consume significant amounts of energy to maintain clean-room standards, and global distribution networks for raw materials and finished products add to the carbon footprint. Single-use plastic packaging, commonly used to ensure product safety and sterility, also contributes to plastic waste—a major issue in environmental pollution today (Jiménez-González et al., 2011; Thakur et al., 2018). The research evaluates awareness levels among both industry professionals and students, as early engagement with future professionals is essential for fostering long-term sustainability and thus to ensure a broad and informed perspective, participants were selected based on their age (15 to 50 years), knowledge, and involvement in the pharmaceutical professional or educational field. This inclusion criterion allowed the study to capture insights from younger students, who represent the industry's future, as well as experienced professionals with practical expertise in solvent use. Moreover, participants were required to have familiarity with or exposure to environmental and sustainability concerns in the industry, ensuring meaningful responses and minimizing data distortion due to uninformed opinions, recent research highlights that pharmacy students often prioritize sustainability in education but perceive a disconnect between curricular content and real-world practice (Chen et al., 2023; Odeh et al., 2022). Ultimately, this study aims to contribute to a shift in industry practices by promoting environmentally friendly solvents and regulatory measures for a more sustainable pharmaceutical sector. Recruiting participants with direct experience in pharmaceuticals aligns with purposive sampling principles, which prioritize domain-specific expertise for credible results, ensuring technical accuracy. For example, (Suri, 2011) emphasizes that purposive sampling of stakeholders with field-specific knowledge enhances the validity of qualitative research in applied sciences.

Recruitment Methods: Participants were primarily recruited through professional networks, industry conferences, academic partnerships, and online forums dedicated to the pharmaceutical field. Industry professionals were approached through LinkedIn groups and personal contacts, while students and recent graduates were recruited from academic institutions offering pharmaceutical sciences programs. This dual approach facilitated diversity among respondents, allowing the study to capture insights both from individuals with practical experience and those with a theoretical understanding of sustainable practices.

Ethical Considerations ensured voluntary and informed participation, each respondent was provided with detailed information on the study's purpose, scope, and confidentiality assurances at the start of the survey in the survey form itself and no separate consent form was thus necessitated. All participants consented to participate without coercion and thus completed the survey, and their anonymity was guaranteed. This ethical framework was vital to maintain the integrity of responses.

Limitations of Participant Selection: While the targeted selection criteria helped achieve a sample reflective of the study's goals, reliance on convenience and network-based recruitment may introduce biases, as it limits generalizability to some degree. However, these steps were taken to ensure that participants had the necessary knowledge base to contribute meaningful insights on sustainable organic solvent use, thus aligning with the study's objectives of assessing awareness, attitudes, and gaps in sustainable practices within the pharmaceutical industry.

3.7 Instrumentation

To gather information on participants' knowledge, opinions, as well as attitudes regarding organic solvents or sustainable substitutes, a systematic questionnaire was created. To collect a range of information, the questionnaire had open-ended as well as closed-ended inquiries. The questions from the detailed survey are listed below, there were 25 questions totaled in all, bucketed as per the question under study, commencing with the questions about Demography.

At the start of the Questionnaire, the following introduction with explanation of the survey purpose and enabling consent of participants as a voluntary effort was provided for ease of understanding and ethical concepts about the participants,

"Hello, I Varsha S. Choudhary, am working on a survey pertaining to the sustainable usage of Organic solvents, and for this purpose, I would be delighted if you could spend some time answering a few questions listed in this Google form. The responses will be used to gauge the current status and future prospects (if any) on the sustainable use of Organic solvents. Your response should be based on your basic knowledge and experience with Organic solvents in your field.

Participation in this survey is entirely voluntary. You are free to stop at any point, and there are no penalties or consequences for choosing not to complete the survey. All responses will be kept confidential and used solely for research purposes. Data will be reported in aggregate form only, without identifying any individual participants. By choosing to participate in this survey and completing the questions, you are providing your consent for your responses to be used in this research. A completely submitted survey will be a due consideration hearted wholehearted participation in this Survey exercise. Thank you for your participation."

The following section outlines the process of structuring the survey questions, which are systematically categorized into distinct themes to ensure comprehensive data collection. The questions are designated as Q1 to Q25, with their corresponding themes labelled from A to F. This structured approach allows for a detailed examination of the participants' perspectives on various aspects of organic solvent usage and sustainability in pharmaceutical manufacturing.

The first theme, Demography (A), encompasses basic participant characteristics such as gender (Q1), age (Q2), and professional background (Q3), ensuring a diverse representation of students and pharmaceutical professionals. Additionally, Q4 assesses prior exposure to projects exploring alternatives to organic solvents. Collecting demographic information is fundamental in understanding the diversity of the participants as respondents. A clear example of how demographic data, such as gender and age, can be integrated into sustainability research as can be observed in the assessment performed in the research by (Al-Nuaimi and Al-Ghamdi, 2022).

The next theme Awareness and Understanding (B) gauges participants' familiarity with the environmental (Q5) and health (Q6) impacts of organic solvents, regulatory norms (Q7), and knowledge of available alternatives (Q8) and aims to establish baseline awareness levels across different respondent groups. Evaluating participants' awareness of environmental and health impacts, regulatory norms, and knowledge of alternatives is crucial as evidenced in the paper "Overcoming Barriers to Green Chemistry in the Pharmaceutical Industry – the Green Aspiration Level™ Concept" which discusses the importance of awareness in adopting green chemistry practices. (F. Roschangar et al., 2015).

Theme Motivation towards Alternatives (C) explores individual attitudes toward sustainability and the reduction of organic solvents. It measures personal importance (Q9), perceived significance in pharmaceutical manufacturing (Q10), concerns regarding long-term environmental effects (Q11), and motivation to adopt sustainable practices (Q12) as also evidenced in the research by (Al-Nuaimi and Al-Ghamdi, 2022).

The next concept Alternatives Study (D) focuses on the practical application of alternative methods. It includes inquiries about the extent of organic solvent use in manufacturing (Q13), prior experimentation with alternatives (Q14), perceived effectiveness in terms of quality and yield (Q15), cost implications (Q16), and the frequency of considering alternative methods based on their impact (Q17-Q18). Exploring the practical application of alternative methods involves understanding the extent of organic solvent use and prior experimentation with alternatives. The paper "Challenges in Implementation of Green Chemistry in Indian Pharmaceutical Sector" identifies economic, financial, and regulatory barriers to adopting green technology in pharmaceuticals. (Kapoor and Mehendale, 2021).

The fifth theme, Industry and Compliance (E) investigates regulatory challenges and institutional support for sustainability. This theme examines compliance difficulties (Q19), organizational encouragement for solvent-free methods (Q20), the practicality of existing regulations (Q21), industry-wide compliance levels (Q22), and the role of education in promoting sustainability (Q23-Q24). Investigating regulatory challenges and institutional support for sustainability is essential. The study "Barriers to the Implementation of Green Chemistry in the United States" highlights various obstacles, including regulatory and organizational challenges, that hinder the adoption of green chemistry practices (Matus et al., 2012).

Lastly, Barriers to Sustainable Alternatives (F) captures the perceived obstacles in transitioning from traditional solvent-based methods to eco-friendly practices (Q25). This open-ended question provides critical insights into challenges faced by professionals and students in implementing sustainable solutions. Identifying perceived obstacles in transitioning to eco-friendly practices is critical. The paper "Challenges in Implementation of Green Chemistry in Indian Pharmaceutical Sector" (Kapoor and Mehendale, 2021) discusses major barriers, such as economic and regulatory challenges, to implementing green chemistry in the pharmaceutical sector.

By systematically structuring the survey across these themes, this study provides a comprehensive analysis of participants' awareness, attitudes, experiences, and perceived challenges related to organic solvent usage and sustainable alternatives in pharmaceutical manufacturing. The survey questionnaire, consisting of 25 questions, is included in the Appendix of this thesis.

The development of this questionnaire on the sustainable use of organic solvents in pharmaceutical manufacturing involved a systematic process, emphasizing clarity, relevance, and structure to ensure meaningful data collection. The questionnaire was structured to address key themes as explained in this section, including demographics, awareness, motivation, alternatives, industry-compliance, and barriers to sustainable practices, creating a comprehensive assessment aligned with the research objectives. The following steps were undertaken for developing the Questionnaire, as shown in the figure below and detailed out further:

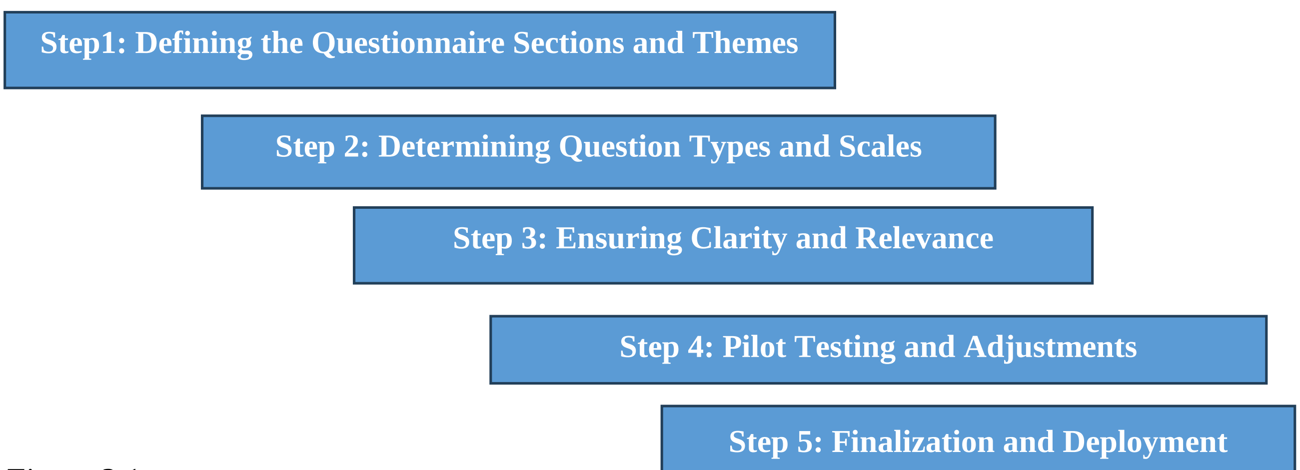

Figure 3.1
Steps for development of Questionnaire

Step 1: Defining the Questionnaire Sections and Themes

To create an effective tool for gathering data, the questionnaire was first organized into six thematic sections: Demography, Awareness and Understanding, Motivation toward Alternatives, Alternatives Study, Industry and Compliance, and Barriers to Sustainable Alternatives, which are depicted in the figure below. These categories served as overarching themes to frame the questions in a logical flow, each one targeting a different aspect of the sustainable use of organic solvents. This clear structure enables respondents to gradually transition from background information to more specific inquiries related to their professional knowledge, motivations, and challenges.

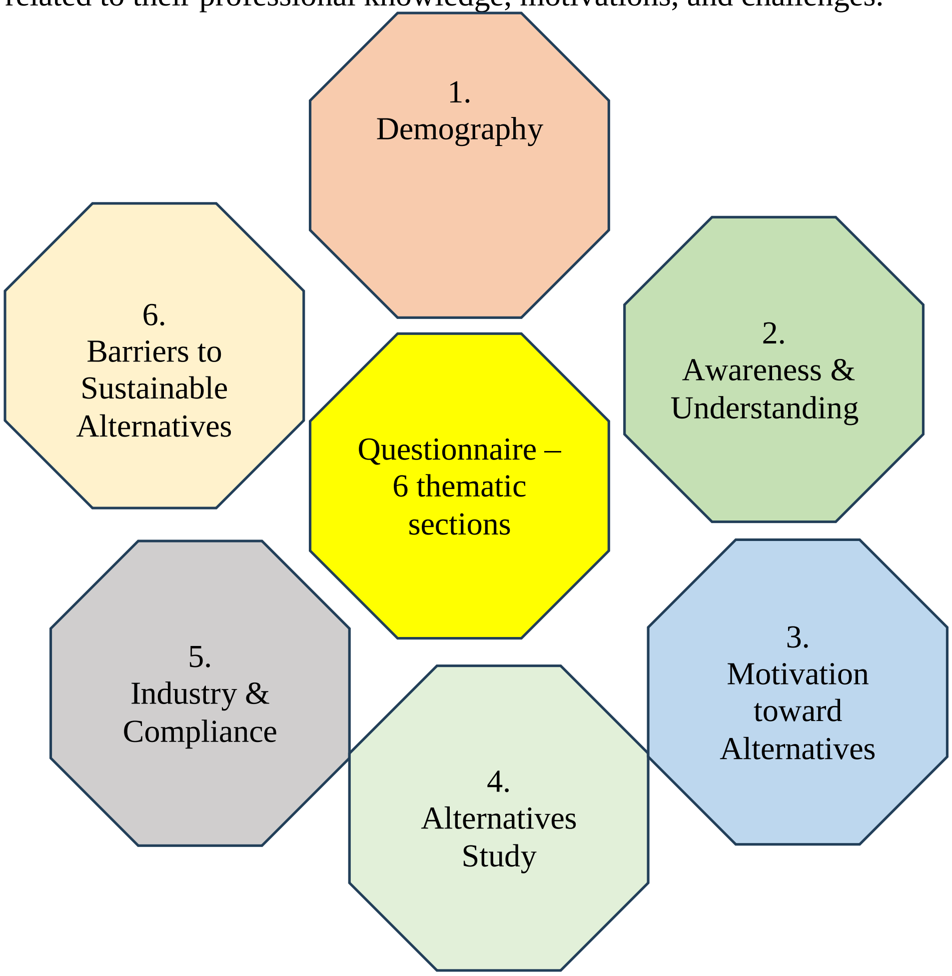

Figure 3.2
Questionnaire – Thematic sections

The Thematic sections of the Questionnaire stated in the Figure above are detailed out below:

Demography: This section was designed to gather essential information on respondents' backgrounds, such as gender, age, and whether they are professionals or students. Questions also sought to understand respondents' prior exposure to research or projects related to organic solvents, laying the foundation for understanding the diversity in perspectives.

Awareness and Understanding: Questions in this section assess the level of awareness regarding the environmental and health impacts of organic solvents. Recognizing knowledge gaps or strengths helps to understand the respondents' foundational knowledge, enabling deeper insights when interpreting their views on sustainability.

Motivation toward Alternatives: To gauge personal commitment to sustainability, this section included questions on respondents' motivations and attitudes towards reducing organic solvents in manufacturing. A Likert scale was used here to capture degrees of importance, concern, and motivation, allowing the nuanced understanding of respondents' attitudes.

Alternatives Study: Here, the focus was on the respondent's practical experience with organic solvents and alternative methods. Questions explore how often these alternatives are considered, their perceived effectiveness, and any associated cost implications. This section serves as a crucial indicator of industry practices and openness to change.

Industry and Compliance: Compliance with regulatory norms is vital in the pharmaceutical industry, particularly concerning environmental standards. Questions here address the support from organizations and institutions, the practicality of regulations, and the perceived compliance across the industry.

Barriers to Sustainable Alternatives: Finally, respondents were asked to identify potential obstacles they face or foresee in adopting sustainable practices. Understanding barriers is critical for developing feasible solutions and actionable recommendations.

Step 2: Determining question types and scales

To accurately capture data, the questionnaire included both close-ended and Likert scale questions, allowing a mix of quantitative and qualitative insights:

Close-Ended Questions: Some questions, especially those under Demography, were designed to obtain specific, straightforward data. For instance, "Have you participated in any projects or assignments that explore alternatives to organic solvents?" simply requires a yes or no answer, ensuring quick, focused responses that categorize the sample.

Likert Scale Questions: Many questions used a 1-to-5 Likert scale to measure respondents' attitudes, perceptions, and experiences. This scale provides flexibility, allowing participants to express varying levels of agreement or concern. For example, questions like "How important do you think sustainability is in the context of pharmaceutical manufacturing?" and "How motivated are you to incorporate sustainable practices in your future professional work?" help quantify subjective attitudes.

Open-Ended Question on Barriers: An open-ended question on anticipated barriers was included to allow respondents to elaborate on specific obstacles they perceive in transitioning to sustainable alternatives. This format encourages nuanced answers, offering insights into challenges that might not emerge from close-ended questions alone.

Step 3: Ensuring clarity and relevance

Ensuring clarity was essential, as ambiguity in questions could lead to varied interpretations and potentially unreliable data. Each question was reviewed to ensure it was straightforward, avoiding technical jargon where possible to accommodate a range of respondents, from students to seasoned professionals.

Step 4: Pilot testing and adjustments

A small sample in the target population was used for pilot testing to improve the questionnaire. This process yielded insightful comments regarding the survey's time requirements, question clarity, or any areas of ambiguity. Based on responses, minor adjustments were made, particularly in the phrasing of certain questions to enhance comprehension and the logical flow of sections.

Step 5: Finalization and deployment

After incorporating feedback, the final questionnaire was deployed using Google Forms to facilitate easy access and efficient data collection. This online format allowed for convenient distribution to a larger audience, maximizing response rates and enabling automated data aggregation for further analysis.

By following this structured approach, the questionnaire became a reliable tool for gathering insights into the perceptions, motivations, and challenges regarding the sustainable use of organic solvents in pharmaceutical manufacturing. This process emphasized the importance of systematic design to ensure that data collected would be both relevant to the research objectives and actionable for future studies and recommendations.

3.8 Data Collection Procedures

The study's data collection methods for long-term utilization of organic solvents during pharmaceutical manufacturing were created to guarantee the precision, applicability, and thoroughness of the information acquired. This process aimed to reach a well-represented sample of participants, maintain consistency in responses, and uphold ethical standards. The following steps were followed here:

Step 1: Identifying the target population and sample size

The first step was to define the target population, which included pharmaceutical professionals and students, as they are directly affected by the industry’s practices regarding organic solvents. The inclusion of students was strategic, given their potential to contribute to sustainable practices as future industry professionals. Aiming to gather data from around 300 to 350 participants, the sample size has been chosen to yield a wide variety of insights while yet being feasible for in-depth examination sample size was selected to yield a wide variety of insights while yet being feasible for in-depth examination.

To ensure the data represented a broad spectrum of views, a mix of pharmaceutical professionals and students aged 15 to above 45 were included. This age range encompasses individuals who are either actively involved in manufacturing or training & educational student programs, allowing for a variety of perspectives on current practices and future outlooks.

Step 2: Selection of data collection method

A survey approach was used as the main means of gathering data for this study. Surveys are very helpful for collecting uniform information regarding a large number many participants. For exploring knowledge, attitudes, and practices. Given the study's focus on perceptions and motivations toward sustainable practices, the survey method provided a structured way to capture data on individual awareness, motivations, and observed barriers.

The survey was created using Google Forms, a versatile and widely accessible platform that facilitates online distribution and data organization. The decision to use Google Forms was influenced by its accessibility for participants, ease of sharing links via email or messaging apps, and automatic aggregation of responses for analysis.

Step 3: Developing and testing the Questionnaire

As mentioned and described in the previous section, the questionnaire design was tailored to meet the objectives of the study, with questions divided into six key sections (Demography, Awareness, Motivation, Alternatives, Industry Compliance, and Barriers). Each section aimed to gather specific information related to sustainable practices and the use of organic solvents.

A small sample group that was typical of the desired population participated in a pilot test. This testing phase allowed for adjustments based on feedback regarding clarity, question length, and any ambiguity in wording. The pilot test helped ensure the final survey would be straightforward and engaging for participants, minimizing drop-offs and encouraging thorough responses.

Step 4: Data collection execution

With the final questionnaire prepared, a link to the Google Form was distributed to potential participants. The distribution was done via email and social media groups associated with pharmaceutical professionals and students. The survey was distributed electronically to participants, and responses were collected anonymously. To ensure a high response rate, follow-up reminders were sent to non-respondents. Leveraging professional and academic networks helped reach a focused audience interested in pharmaceutical manufacturing and environmental sustainability.

To encourage participation and maintain engagement, the survey was designed to be concise, requiring approximately 10-15 minutes to complete. Participants received assurances that their answers would be kept private as well as the survey would be anonymous. Used solely for research purposes. Additionally, a brief description of the research objectives and their potential implications was provided at the beginning of the survey to motivate respondents. The data collection process was conducted online using Google Forms, allowing for efficient distribution and accessibility for participants across various locations within the pharmaceutical industry & students. The survey link was shared with participants through email, industry networks, social media to ensure a broad and representative sample.

Step 5: Monitoring responses and ensuring data quality

As mentioned previously, the survey is designed to include questions that measure: Awareness levels regarding the environmental impacts of organic solvent usage, Attitudes towards sustainable solvent alternatives, Perceptions of the practicality and feasibility of adopting sustainable practices, Views on the role of government regulations and societal pressures. Questionnaire Design: The questionnaire is structured with Likert-scale, multiple-choice, and dichotomous (yes/no) questions. The Likert scale allows respondents to express their level of agreement with statements related to sustainability, while multiple-choice questions provide categorical data on awareness and perceptions. Throughout the data collection period, responses were monitored daily to track progress toward the target sample size and to identify any issues, such as incomplete submissions or potential inconsistencies. The Google Forms platform allowed for a quick review of incoming data, and any errors (e.g., duplicated entries) were flagged for further review.

Step 6: Data storage and ethical considerations

To protect participant privacy, all responses were stored securely in a password-protected Google account accessible only to the researcher. Anonymity was strictly maintained, with no identifying information collected beyond basic demographic data. Adherence to ethical guidelines was essential, ensuring The goal of the study, the participants' freedom to withdraw, & the confidentiality underlying the responses were all explained to them.

Consent was implied through voluntary participation, as participants were informed that completing and submitting the survey indicated agreement to participate. To ensure compliance with ethical standards, the study followed protocols aligned with general research guidelines, such as informed consent, anonymity, and data protection.

Step 7: Data consolidation and preparation for analysis

Once the target number of responses was achieved, the survey was closed, and data consolidation began. Google Forms facilitated the process of downloading responses into an Excel file, which was then evaluated statistically for further processing. The data was cleaned by checking for any inconsistencies, such as outliers or incomplete responses, which were either addressed or excluded from analysis. Data from closed-ended questions were coded for quantitative analysis, while responses to open-ended questions (such as perceived barriers to sustainable alternatives) were categorized to identify common themes and patterns.

Conclusion:

This structured approach to data collection helped to ensure that the data obtained were relevant, consistent, and aligned with the study's goals. By adhering to a clear process and prioritizing ethical considerations, the survey data offers a reliable foundation for analysis, providing insights into the perceptions, motivations, and challenges regarding the sustainable use of organic solvents in pharmaceutical manufacturing. This systematic data collection process is essential for drawing meaningful conclusions and developing recommendations that could positively impact industry practices.

3.9 Data Analysis

The data were summarized using descriptive conclusive statistics, which included central tendency and dispersion measures, frequencies, among percentages. The associations between the variables have been examined utilizing correlation analysis. Hypothesis testing was used to compare the responses based on the Research Questions.

In the analysis of the survey data on the sustainable use of organic solvents in pharmaceutical manufacturing, descriptive statistics, correlation analysis, and hypothesis testing were employed to draw insights from the responses. Each of these statistical methods played a distinct role in exploring the data, understanding relationships between variables, and testing the differences in responses across groups. Below is an overview of how these methods contributed to the research analysis:

IBM SPSS (Statistical Package for the Social Sciences) which is a widely used statistical software for analyzing survey and questionnaire data due to its robust features, ease of use, and advanced statistical capabilities was used. It allows researchers to efficiently manage large datasets, perform descriptive and inferential statistical tests, and generate graphical representations of data. SPSS is particularly valuable in questionnaire-based research as it enables accurate computation of measures like Margin of Error (MOE), confidence intervals, regression analysis, and hypothesis testing. Its user-friendly interface and automated statistical processes make it an essential tool for researchers analyzing survey responses in various fields, including pharmaceutical and sustainability studies.

Descriptive Statistics: Initially, descriptive statistics were used to give an overview of the information gathered, including details about the general distribution and traits of the replies. Frequencies, percentages, and metrics of dispersion (standard deviation) and central tendency (mean, median) were analyzed throughout the survey's different sections.

Frequencies and Percentages: Frequencies were calculated for categorical variables such as demographic factors, including gender, age, and the type of respondent (professional or student). This analysis provided an understanding of the composition of the sample, including the proportion of respondents from each category, which was particularly useful in determining the representation of different demographics in the survey.

Measures of Central Tendency and Dispersion: For Likert-scale responses, Measures of dispersion (standard deviation) and central tendency (mean & median) were computed to compile participants' attitudes and perceptions. For example, questions on awareness of the environmental and health impacts of organic solvents provided data on how aware respondents generally were, and the variation in responses was captured by the standard deviation. High means on questions related to sustainability awareness indicated a general understanding of the importance of sustainable practices, while larger standard deviations highlighted a divergence in awareness levels among different respondents.

Correlation Analysis: The associations between various factors were then investigated using correlation analysis particularly those that could reveal dependencies or associations. By calculating correlation coefficients, the analysis identified pairs of variables that were significantly related. For instance, correlations were explored between respondents' awareness of regulatory norms and their motivation to adopt sustainable practices, as well as between concern about long-term environmental impacts and the likelihood of experimenting with alternatives to organic solvents.

Positive Correlations: Positive correlations between variables, such as the level of awareness regarding health impacts and motivation to incorporate sustainable practices, suggested that respondents with greater awareness of the negative effects of solvents were more likely to be motivated to seek alternatives.

Negative or Weak Correlations: Conversely, weak or negative correlations helped indicate areas where awareness or concern did not necessarily translate into action or motivation. For instance, if there was no strong correlation between familiarity with regulations and the perceived feasibility of sustainable practices, it could suggest a disconnect between knowledge of regulations and their practical application.

Through correlation analysis, the study explored how various factors were interconnected, which helped in identifying key drivers of motivation and barriers to implementing sustainable practices. These insights formed the basis for developing recommendations aimed at fostering a more sustainable approach to organic solvents within the pharmaceutical industry.

Hypothesis Testing:

Hypothesis testing was the final statistical method used to compare responses. This involved formulating hypotheses based on expected differences and using statistical tests to confirm or refute these expectations.

By using hypothesis testing, the study was able to statistically validate observations regarding group differences and establish confidence in the patterns observed within the survey responses. Hypothesis testing allowed the analysis to go beyond descriptive trends, demonstrating statistically significant differences or associations that could be generalized to the broader population of professionals and students in the pharmaceutical field.

Conclusion:

The combination of descriptive statistics, correlation analysis, and hypothesis testing provided a comprehensive approach to analyzing the survey data. Descriptive statistics helped outline the general trends in responses, correlation analysis revealed important relationships between key variables, and hypothesis testing allowed for in-depth comparisons and conclusions with respect to the Reserach Questions. Together, these methods provided a nuanced understanding of the factors influencing the sustainable use of organic solvents in pharmaceutical manufacturing, supporting actionable insights and recommendations for future practices.

3.10 Research Design Limitations

As explained in the previous sections, Objectives of the Research were as listed below:

Assess awareness and understanding:

Compare the awareness of the environmental impacts of organic solvents between students and pharmaceutical professionals. Evaluate the understanding of the regulatory norms governing the use of organic solvents among both groups.

Identify barriers to sustainable practices:

Determine the perceived barriers to transitioning from traditional solvent-based methods to more sustainable alternatives. Assess the effectiveness of current educational programs in addressing the sustainability of organic solvents.

Explore the feasibility of avoiding organic solvents:

Evaluate the feasibility of entirely avoiding organic solvents in the manufacture of pharmaceutical dosage forms. Analyze the potential impact of such a transition on the regulatory landscape and industry practices.

Examine the adoption of green alternatives:

Assess the awareness and adoption of green, sustainable alternatives to organic solvents in the pharmaceutical industry. Identify factors influencing the adoption of these alternatives, such as economic considerations, technical feasibility, and regulatory requirements.

Investigate the relationship between awareness and action:

Examine the correlation between awareness of the negative environmental impacts of organic solvent usage and the actions taken by pharmaceutical companies to reduce or replace them. Identify potential factors influencing the translation of awareness into action, such as organizational culture, resource availability, and industry trends.

While the survey-based approach provides broad insights, some limitations exist:

Response Bias: Social desirability bias may have an impact on the survey's self-reported findings. Respondents may provide responses that they feel conform to socially acceptable standards for sustainability and environmental consciousness.

Limited Depth of Responses: As a quantitative method, the survey may lack the depth of insights that qualitative methods, such as interviews, can provide. The structured questions may limit participants' ability to fully express complex views or nuanced challenges.

Sampling Constraints: Although efforts are made to ensure a representative sample, findings may still be limited by the sampling technique, as some specific industry sub-sectors or geographical regions may be underrepresented.

Conclusion:

Recognizing and addressing research design limitations strengthens the credibility of the study on sustainable practices in pharmaceutical manufacturing. Sampling, measurement, methodological, external validity, and analytical constraints collectively influence the scope and accuracy of the findings. Future research may potentially overcome these constraints by using mixed-method approaches, longer-term research that documents changing industry patterns, and larger and more varied samples. Acknowledging these limitations is critical to providing a balanced interpretation of the data, ensuring that the insights gained can meaningfully contribute to sustainable practices in pharmaceutical manufacturing.

3.11 Conclusion

This chapter outlines the survey-based research design used to explore sustainable practices regarding organic solvent usage in pharmaceutical manufacturing. By focusing on a standardized approach, the survey enables systematic data collection across a broad sample, allowing for reliable quantitative analysis. The design considers ethical practices, data analysis techniques, and potential limitations to ensure a transparent and robust foundation for interpreting the findings in subsequent chapters.

CHAPTER IV:

RESULTS

This chapter summarizes the results using the survey on the usage of organic solvents and sustainable practices in the pharmaceutical industry. The survey gathered data from a diverse sample of industry professionals and students, focusing on various aspects such as awareness of organic solvents' environmental and health impacts, motivation toward sustainable practices, and perceived barriers in transitioning from organic solvents to more sustainable alternatives. The results are presented in the below section based on each of the Research questions (in the Google form questionnaire) and the respondent's outcomes (responses to the google form questionnaire), using the output from Google forms responses as graphs and tabulation outputs from SPSS Software. The respondents output from the Survey, was also subjected to detailed statistical evalaution using SPSS software and thes results are presented in this section.

Results of Questionnaire based Survey:

A) This section provides the results (as responses) of each of the 25 Survey Questions of the Questionnaire as listed below:

Question 1: Gender: The survey sample comprised 79.9% male and 20.1% female respondents, indicating a male-dominated respondent base, however not much needs to be construed from this skewed ratio as considering gender-neutral roles in the industry, it may seem as if one gender is lesser than the other, however, the pharmaceutical industry discriminates between none, and is known for its unbiased gender neutral work profiles, all having equal opportunities of work, research, projects, etc. Refer the table and figure below for the Gender distribution data and graphics.

Table 4.1
Responses data on Gender

1) Gender

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Female	65	20.1	20.1	20.1
	Male	258	79.9	79.9	100.0
	Total	323	100.0	100.0	

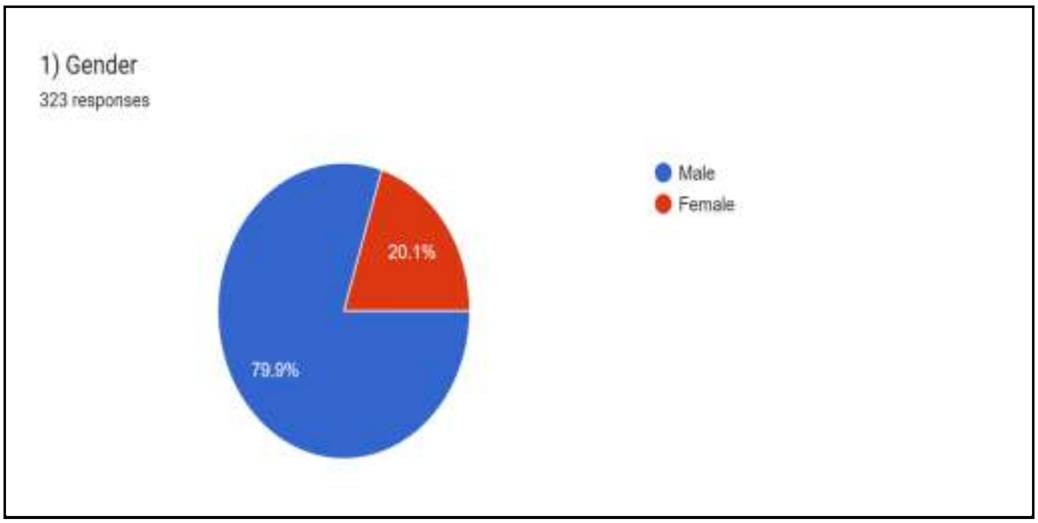

Figure 4.1
Graph of Responses data on Gender

Question 2: Age: The age distribution of respondents shows a strong representation from the 36-45 age group (39%), followed by the 15-25 group (23.8%), which is only slightly more than 45 age group (20.1%) and the smallest group being 26-35 (17%) as can be observed from the data table and graph below. Refer the table and figure below for the Gender distribution data and graphics.

Table 4.2
Responses data on Age

2) Age					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	15-25	77	23.8	23.8	23.8
	26-35	55	17.0	17.0	40.9
	36-45	126	39.0	39.0	79.9
	Above 45	65	20.1	20.1	100.0
	Total	323	100.0	100.0	

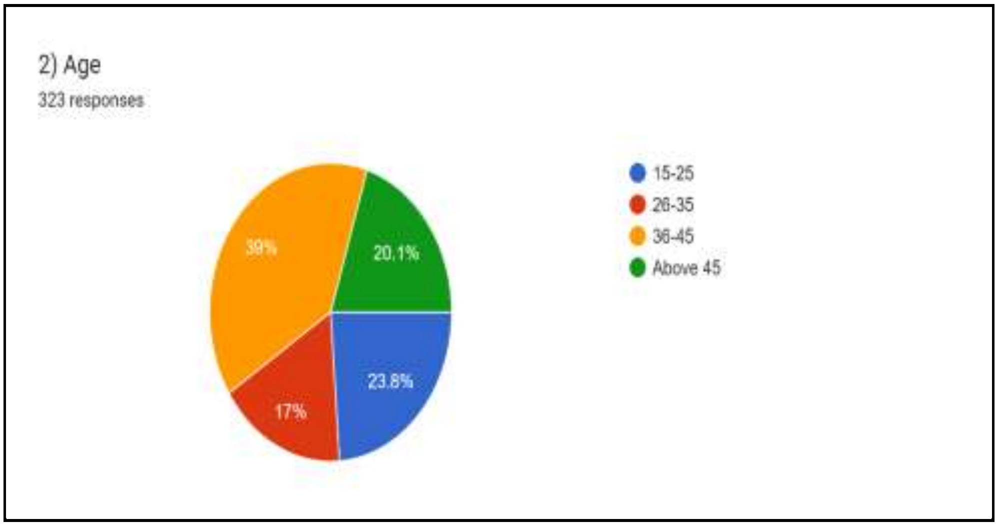

Figure 4.2
Graph of Responses data on Age

Question 3: Pharmaceutical professional or student: Respondents included a significant proportion of pharmaceutical professionals (67.2%) and students (32.8%). This split allows for a meaningful comparison between current industry practitioners and those still in the educational pipeline regarding awareness levels of solvent impacts.

Table 4.3
Responses data on Pharma professional or student

3) Pharma professional or a student, please choose below					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Pharma professional	217	67.2	67.2	67.2
	Student	106	32.8	32.8	100.0
	Total	323	100.0	100.0	

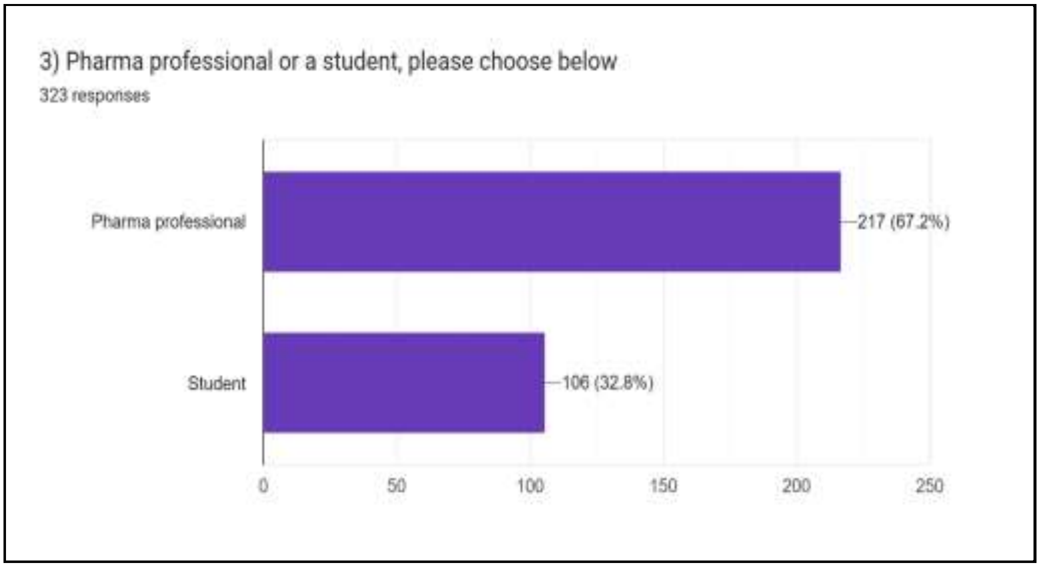

Figure 4.3
Graph of Responses data on Pharma professional or student

Question 4: Have you participated in any projects or assignments that explore alternatives to organic solvents? : The data indicates that 60.1% of respondents have been directly involved in projects or assignments exploring organic solvents, while 39.9% have had no such exposure. Just as participation improves knowledge about any project in any other field, participation in environmentally focused projects significantly contributes to awareness and often enhances practical knowledge of the environmental implications of specific practices. Educational programs and curricula that encourage the inclusion of youngsters in student-centric projects focused on sustainable or alternative solvent solutions tend to have the students develop a strong sense of understanding of these issues, potentially influencing their readiness to adopt or advocate for alternative practices. The 39.9% of respondents who have not been involved and had such exposure would surely benefit from any targeted educational initiatives that increase their familiarity with sustainability-related practices in pharmaceuticals.

Table 4.4
Responses data on participation in projects, assignments that explore alternatives

4) Have you participated in any projects or assignments that explore alternatives to organic solvents?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	129	39.9	39.9	39.9
	Yes	194	60.1	60.1	100.0
	Total	323	100.0	100.0	

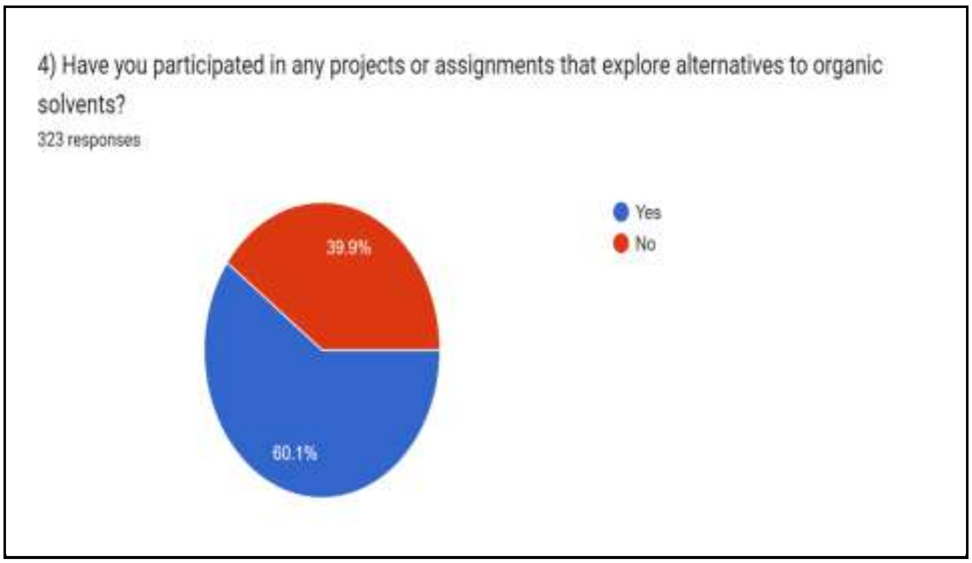

Figure 4.4
Graph of Responses data on participation in projects, assignments that explore alternatives

Question 5: How aware are you of the environmental impacts of using organic solvents? : The survey reveals that 13% of respondents are not aware of the environmental impacts of organic solvents, 50.2% are somewhat aware, and 36.8% are very aware. Awareness of environmental impacts can vary widely based on the participant's educational background, the role in which the participant is in his official pharma capacity and the pharma industry in which he is employed, his prior exposure to sustainability practices, and his daily practical activities at his workplace pharma projects. The distribution thrown up by the survey suggests that while a significant proportion of respondents have a fundamental or advanced understanding of the environmental risks associated with organic solvents, there remains another segment that lacks much awareness of sustainability and organic solvents and their environmental impacts. This gap presents an opportunity for increased educational and awareness programs tailored for individuals in the pharmaceutical sector. As can be stated, environmental awareness can surely lead to better understanding of environmental issues, sustainability, harmful effects of solvents, depletion of natural resources, short-term and long-term gaps in dealing with sustainability outcomes for our future generations, etc. Without awareness, there would be complete ignorance from participants belonging to the segment who are unaware of such issues.

Table 4.5
Responses data on awareness score - environmental impact

5) How aware are you of the environmental impacts of using organic solvents?"

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not aware	42	13.0	13.0	13.0
	Somewhat aware	162	50.2	50.2	63.2
	Very aware	119	36.8	36.8	100.0
	Total	323	100.0	100.0	

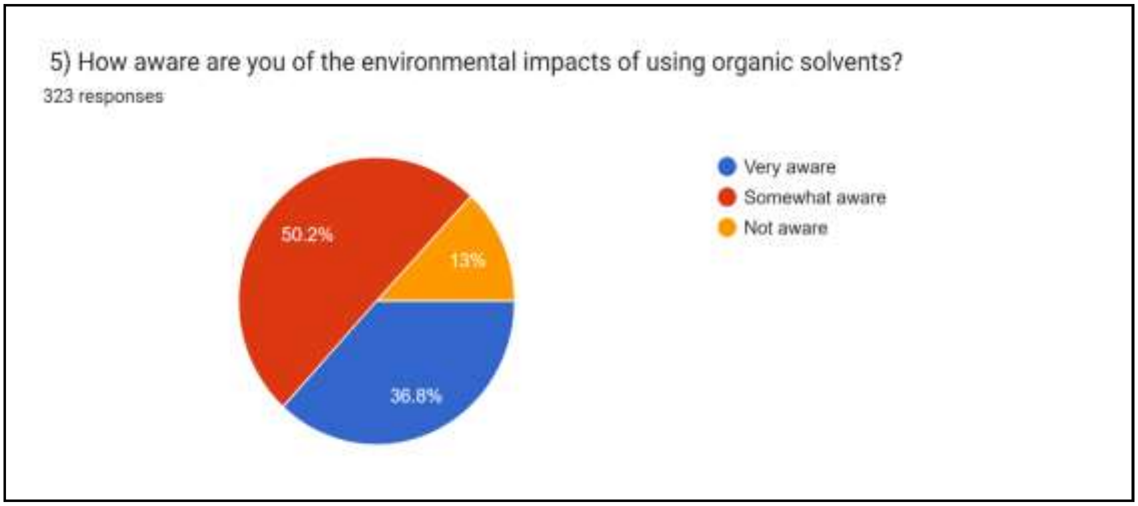

Figure 4.5
Graph of Responses data on awareness score - environmental impact

Question 6: How aware are you of the health impacts of using organic solvents? Regarding health impacts, 12.4% of respondents report no awareness, 55.1% are somewhat aware, and 32.5% are very aware. Awareness of the health risks associated with organic solvents, such as respiratory issues and potential toxicity, is essential for fostering a workplace culture that values safe practices in occupational environments, higher awareness of health implications can improve compliance with safety protocols and motivate personnel to adopt safer alternatives.

Table 4.6
Responses data on awareness score – health impacts

6) How aware are you of the health impacts of using organic solvents?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not aware	40	12.4	12.4	12.4
	Somewhat aware	178	55.1	55.1	67.5
	Very aware	105	32.5	32.5	100.0
	Total	323	100.0	100.0	

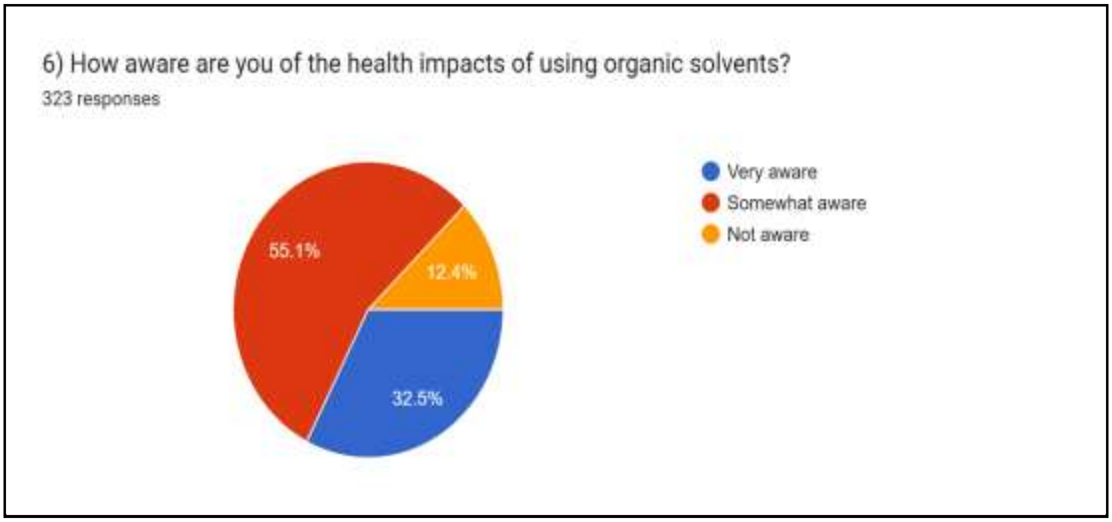

Figure 4.6
Graph of Responses data on awareness score – health impacts

Question 7: How familiar are you with the regulatory norms governing the usage of organic solvents in pharmaceutical manufacturing? : Awareness of regulatory guidelines among respondents varied significantly, with one-third (33.4%) of respondents unfamiliar with the regulatory norms for organic solvents. Nearly half (47.4%) were somewhat familiar, indicating they had a basic or moderate understanding of regulatory norms. A smaller group (19.2%) were very familiar with regulatory norms thus demonstrating a strong awareness of these regulations. This does indicate a persistent gap in the dissemination and understanding of regulatory guidelines, which could limit their effective implementation across the industry.

Table 4.7
Responses data on awareness score – regulatory norms

7) How familiar are you with the regulatory norms governing the usage of organic solvents in pharmaceutical manufacturing?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not familiar	108	33.4	33.4	33.4
	Somewhat Familiar	153	47.4	47.4	80.8
	Very Famiilar	62	19.2	19.2	100.0
	Total	323	100.0	100.0	

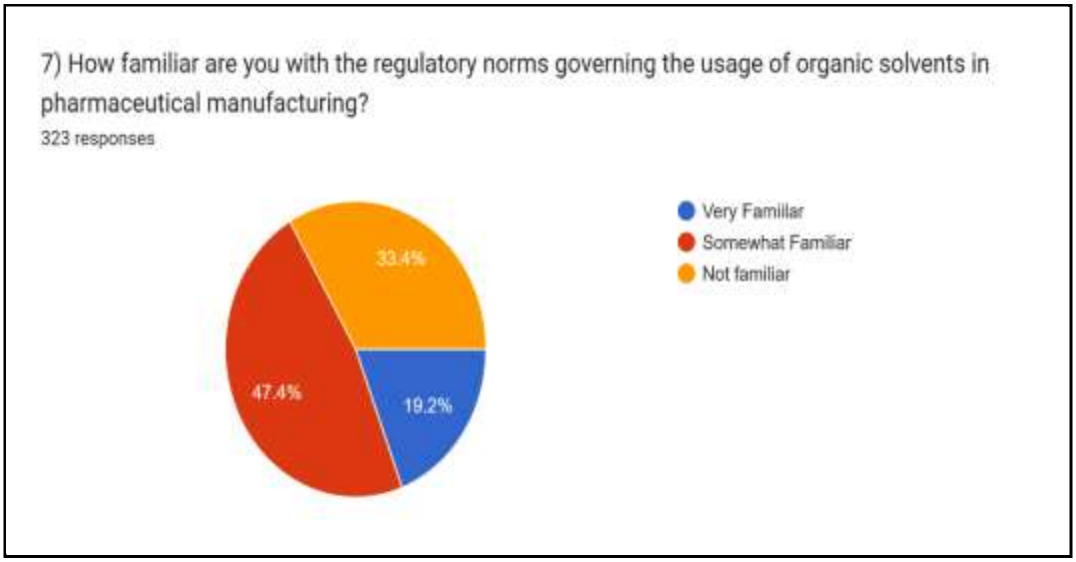

Figure 4.7
Graph of Responses data on awareness score – regulatory norms

Question 8: How aware are you of any alternatives to organic solvents in pharmaceutical manufacturing? : Amongst the full set of respondents, 15.8% were not at all aware of the existence of alternatives to organic solvent, 27.9 % had a substantial awareness score whilst 56.3% were somewhat aware. This indicates that a majority of the population does have awareness of alternatives but just by having knowledge of alternatives existing, does not mean this ensures adoption of these alternatives.

Table 4.8
Responses data on awareness score – alternatives

8) How aware are you of any alternatives to organic solvents in pharmaceutical manufacturing?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not aware	51	15.8	15.8	15.8
	Somewhat aware	182	56.3	56.3	72.1
	Very aware	90	27.9	27.9	100.0
	Total	323	100.0	100.0	

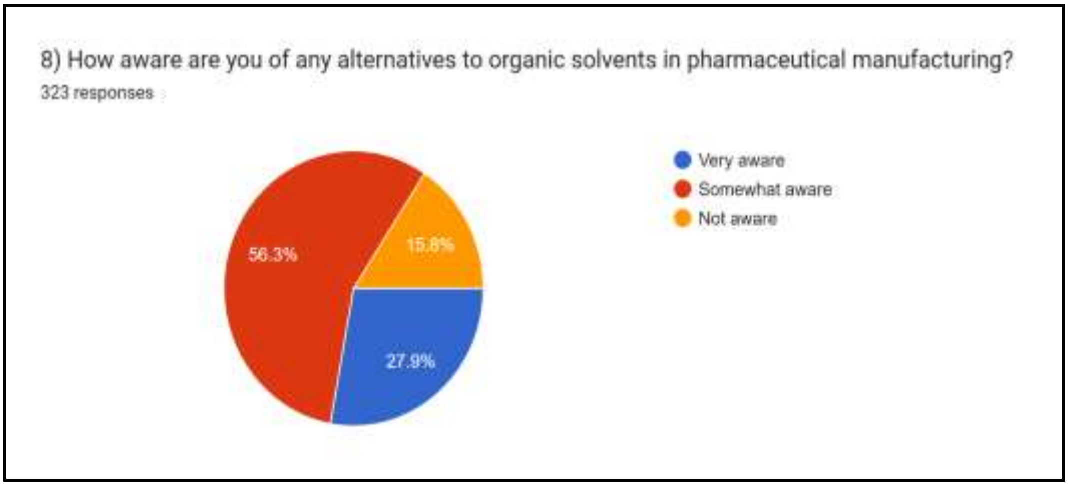

Figure 4.8
Graph of Responses data on awareness score – alternatives

Question 9: How important is it to you personally to reduce the usage of organic solvents in your work? (Likert Scale: 1-5) : This question gauges the personal thinking and choice of the participants pertaining to the reduction or avoiding usage of organic solvents. Only 5.9% of the participants felt the importance of organic solvents reduction, 11.1 % were not in the least indicative about any importance. 18% did feel deeply about the importance whilst a majority of about 65% were in median range of the Likert scale rating either slightly or moderately important. Thus, majority of the participants were on the middle scale of importance for reducing usage of organic solvents whist only about

5.9% felt it to be really important. This shows that increasing awareness is needed to bring about a change in personal thinking.

Table 4.9
Responses data on importance of reducing usage of organic solvents

9) How important is it to you personally to reduce the usage of organic solvents in your work? (Likert Scale: 1-5)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	36	11.1	11.1	11.1
	2	107	33.1	33.1	44.3
	3	103	31.9	31.9	76.2
	4	58	18.0	18.0	94.1
	5	19	5.9	5.9	100.0
	Total	323	100.0	100.0	

Likert scale:

1: Not important

2: Slightly important

3: Moderately important

4: Important

5: Very important

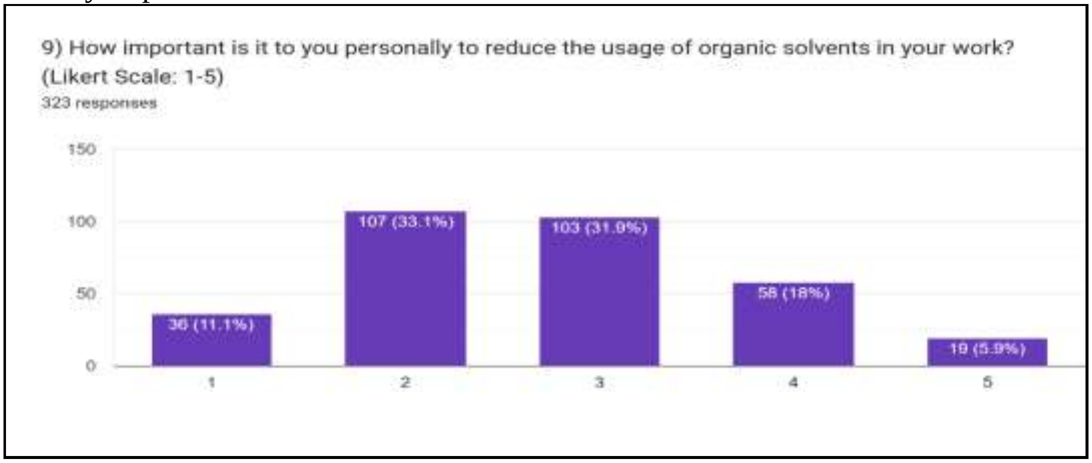

Figure 4.9
Graph of importance of reducing usage of organic solvents

Question 10: How important do you think sustainability is in the context of pharmaceutical manufacturing? (Likert Scale: 1-5): Sustainability as a concept for pharmaceutical manufacturing is rated at slightly important and moderately important by almost equal number of participants at 30.3% and 27.6% respectively whilst only 8% felt its significance clearly and 19.8% agreed on its importance. 14.2 % were indifferent and felt Sustainability did not really matter,

Table 4.10
Responses data on importance of sustainability in pharmaceutical manufacturing

10) How important do you think sustainability is in the context of pharmaceutical manufacturing? (Likert Scale: 1-5)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	46	14.2	14.2	14.2
	2	98	30.3	30.3	44.6
	3	89	27.6	27.6	72.1
	4	64	19.8	19.8	92.0
	5	26	8.0	8.0	100.0
	Total	323	100.0	100.0	

Likert scale:

1: Not important

2: Slightly important

3: Moderately important

4: Important

5: Very important

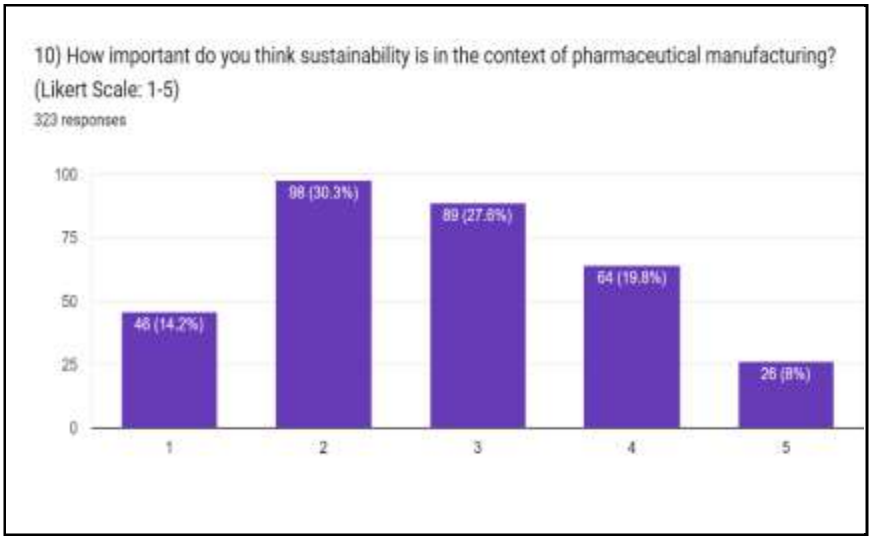

Figure 4.10
Graph of importance of sustainability in pharmaceutical manufacturing

Question 11: What is your level of concern regarding the long-term environmental impact of using organic solvents? (Likert Scale: 1-5): The responses to Question 11, which assessed concern regarding the long-term environmental impact of using organic solvents on a Likert scale (1-5), indicate that a majority of respondents (52.7%) selected moderate to high concern levels (3 and 4), suggesting that environmental impact is an important consideration for them. A smaller proportion of respondents—14.6% chose 1 (Not concerned) and 24.5% selected 2 (Slightly concerned)—indicating that minimal concern is relatively uncommon. The distribution of responses, as illustrated in Figure 4.11, highlights that only 8.4% of respondents selected 5 (Very concerned), showing a somewhat mixed but leaning-toward-concerned perspective on the issue. These findings reinforce the need for greater awareness and sustainable alternatives in pharmaceutical manufacturing.

Table 4.11
Responses data on level of concern for long term environmental impacts of using organic solvents

11) What is your level of concern regarding the long-term environmental impact of using organic solvents? (Likert Scale: 1-5)					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	47	14.6	14.6	14.6
	2	79	24.5	24.5	39.0
	3	100	31.0	31.0	70.0
	4	70	21.7	21.7	91.6
	5	27	8.4	8.4	100.0
	Total	323	100.0	100.0	

Likert scale:

1: Not concerned

2: Slightly concerned

3: Moderately concerned

4: Concerned

5: Very concerned

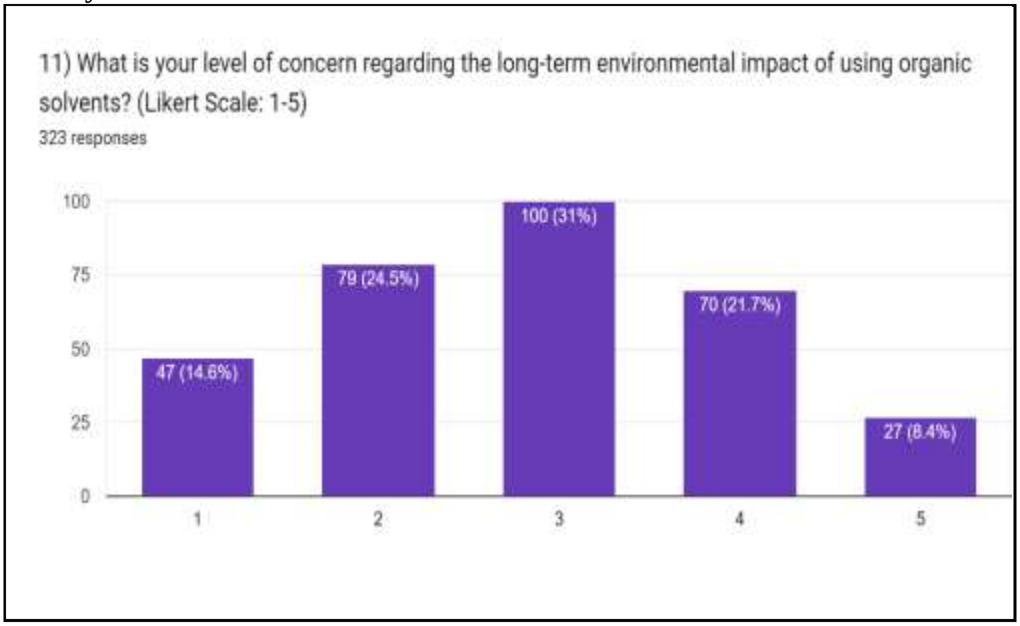

Figure 4.11
Graph of level of concern for long term environmental impacts of using organic solvents

Question 12: How motivated are you to incorporate sustainable practices in your future professional work? (Likert Scale: 1-5): The responses to Question 12, which assessed motivation to incorporate sustainable practices in future professional work on a Likert scale (1-5), indicate a generally positive outlook toward sustainability. A majority of respondents selected moderate to high motivation levels (3, 4, and 5), suggesting a strong willingness to adopt environmentally conscious practices. A smaller proportion of respondents chose 1 (Not motivated) or 2 (Slightly motivated), indicating that a lack of motivation is uncommon. The distribution of responses, as illustrated in Figure 4.12, highlights a promising trend toward sustainable initiatives in professional settings, reinforcing the growing awareness and commitment to eco-friendly practices in the industry. About 9.9% were really motivated about sustainable practices.

Table 4.12
Responses data on motivation for sustainable practices

12) How motivated are you to incorporate sustainable practices in your future professional work? (Likert Scale: 1-5)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	41	12.7	12.7	12.7
	2	104	32.2	32.2	44.9
	3	91	28.2	28.2	73.1
	4	55	17.0	17.0	90.1
	5	32	9.9	9.9	100.0
	Total	323	100.0	100.0	

Likert scale:

1: Not motivated

2: Slightly motivated

3: Moderately motivated

4: Motivated

5: Highly motivated

Figure 4.12
Graph of motivation for sustainable practices

Question 13: What percentage of your manufacturing processes currently involve organic solvents? The responses to Question 13, which assessed the percentage of manufacturing processes currently involving organic solvents, indicate that the majority of respondents (68.4%) reported a moderate usage range (26-75%), highlighting the continued reliance on organic solvents in pharmaceutical manufacturing. Specifically, 38.1% of respondents indicated that 26-50% of their processes use organic solvents, while 30.3% reported a higher usage of 51-75%. Meanwhile, 29.4% of respondents reported minimal usage (0-25%), suggesting that some manufacturers have already taken steps toward reducing solvent dependency. Only 2.2% of respondents indicated very high usage levels (76-100%), reflecting a small but persistent segment with significant reliance on organic solvents. The distribution of responses, as illustrated in Figure 4.13, underscores the need for continued efforts toward sustainable manufacturing practices, particularly for industries operating in the mid-to-high solvent usage range.

Table 4.13
Responses data on percentage of manufacturing processes using organic solvents

13) What percentage of your manufacturing processes currently involve organic solvents?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0-25%	95	29.4	29.4	29.4
	26-50%	123	38.1	38.1	67.5
	51-75%	98	30.3	30.3	97.8
	76-100%	7	2.2	2.2	100.0
	Total	323	100.0	100.0	

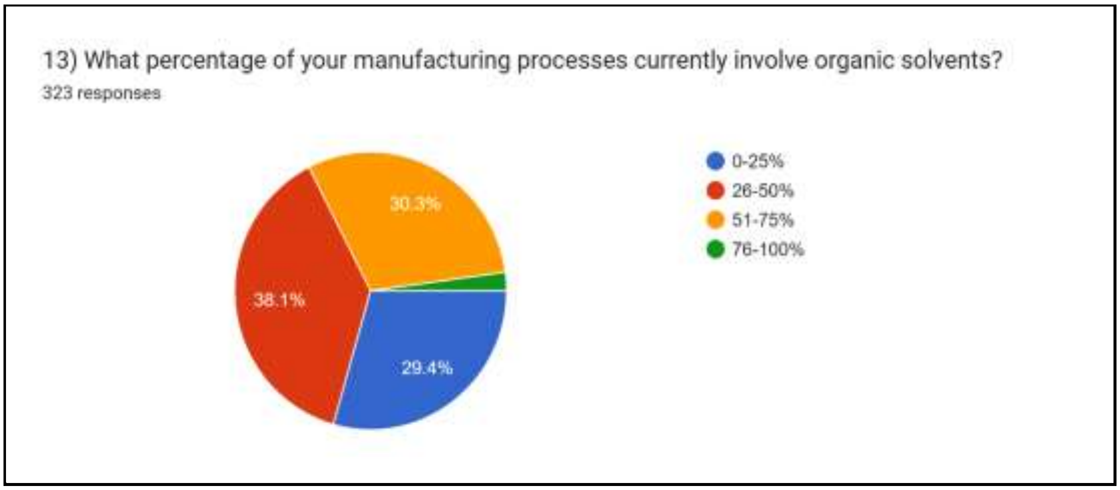

Figure 4.13
Graph on percentage of manufacturing processes using organic solvents

Question 14: Have you experimented with or studied alternative methods that do not involve organic solvents? The responses to Question 14 indicate a growing interest and engagement in alternative methods that do not involve organic solvents. A majority (56.1%) have experimented with such methods, with 44.0% having explored them "somewhat" and 12.1% reporting extensive experience. Additionally, 36.2% have not experimented but expressed interest, indicating a strong potential for future adoption of solvent-free methods. However, 7.7% of respondents stated that they are not interested in alternatives, suggesting some resistance to change. The distribution of responses, as illustrated in Figure 4.14, highlights both current engagement with sustainable practices and the need for further encouragement and awareness to drive broader adoption of solvent-free technologies in pharmaceutical manufacturing.

Table 4.14
Responses data on experience with alternatives

14) Have you experimented with or studied alternative methods that do not involve organic solvents?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No, but interested	117	36.2	36.2	36.2
	No, not interested	25	7.7	7.7	44.0
	Yes, extensively	39	12.1	12.1	56.0
	Yes, somewhat	142	44.0	44.0	100.0
	Total	323	100.0	100.0	

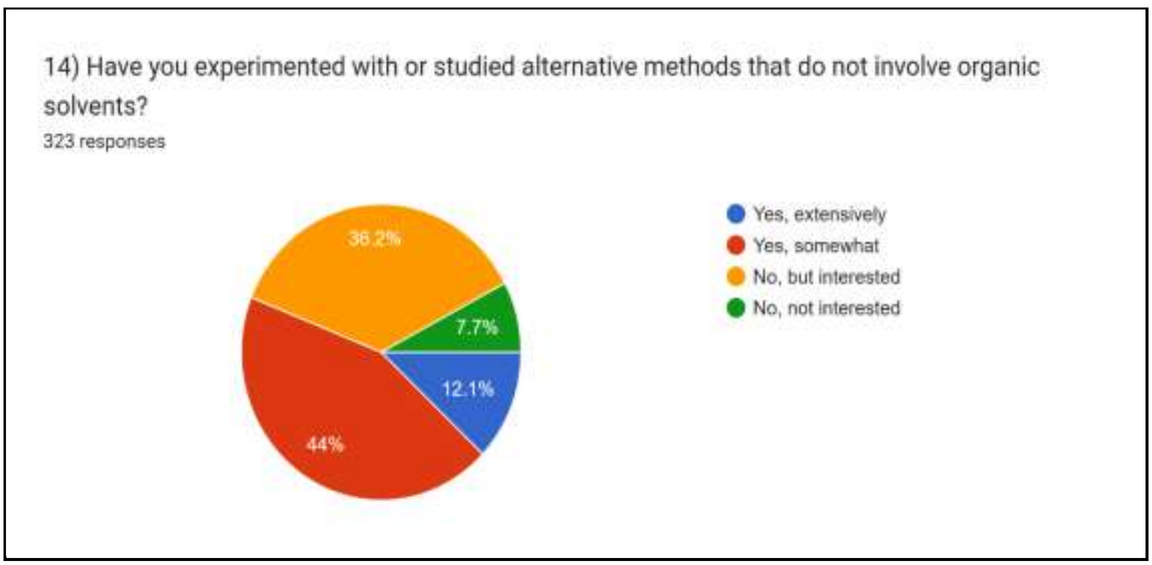

Figure 4.14
Graph on experience with alternatives

Question 15: How effective do you find the alternatives to organic solvents in terms of quality and yield? (Likert Scale: 1-5). The responses to Question 15, which assessed the perceived effectiveness of alternatives to organic solvents in terms of quality and yield on a Likert scale (1-5), indicate that most respondents view these alternatives as moderately effective. The majority (42.4%) rated them as "moderately effective" (3), while 22.0% considered them "effective" (4). However, 22.6% of respondents found them only "slightly effective" (2), and 8.0% perceived them as "not effective" (1). A small percentage (5.0%) rated these alternatives as "most effective" (5). The distribution of responses, as illustrated in Figure 4.15, suggests that while there is moderate confidence in the effectiveness of alternative methods, there remains some skepticism regarding their ability to fully match the quality and yield of traditional solvent-based processes. These findings highlight the need for further research and process optimization to enhance the acceptance and reliability of sustainable manufacturing alternatives.

Table 4.15
Responses data on effectiveness of alternatives

15) How effective do you find the alternatives to organic solvents in terms of quality and yield? (Likert Scale: 1-5)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	26	8.0	8.0	8.0
	2	73	22.6	22.6	30.7
	3	137	42.4	42.4	73.1
	4	71	22.0	22.0	95.0
	5	16	5.0	5.0	100.0
	Total	323	100.0	100.0	

Likert scale:

1: Not effective

2: Slightly effective

3: Moderately effective

4: Effective

5: Most effective

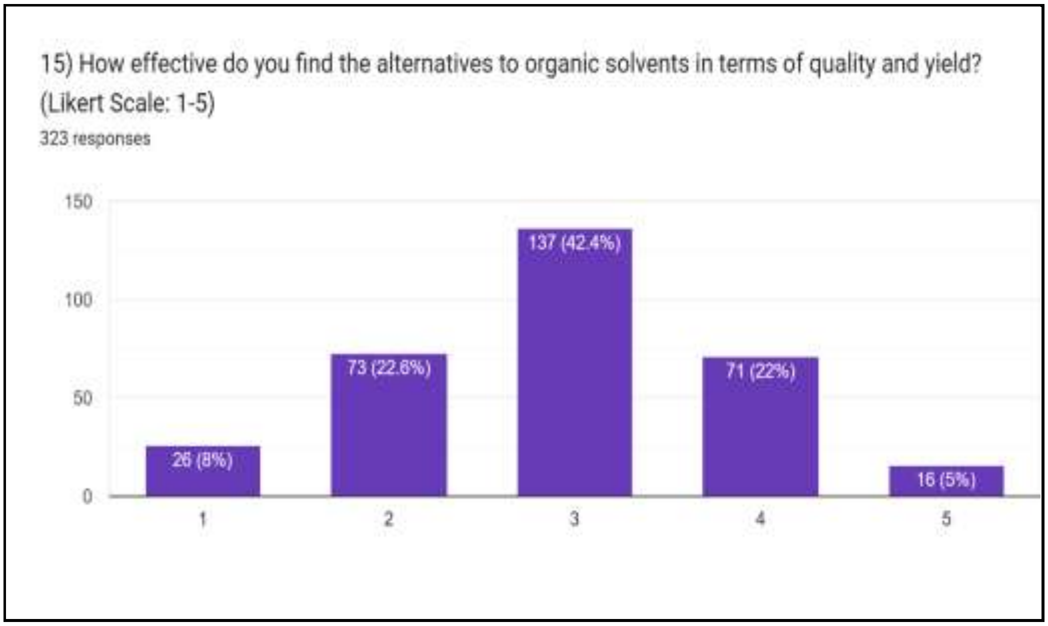

Figure 4.15
Graph on effectiveness of alternatives

Question 16: Have you noticed any changes in production costs when using alternatives to organic solvents? The responses to Question 16, which examined changes in production costs and thus an impact on the cost of goods, when using alternatives to organic solvents, reveal mixed perceptions regarding cost implications. A significant proportion (46.7%) reported an increase in production costs, indicating that alternative methods may currently be perceived as financially burdensome. However, 38.1% of respondents observed a decrease in costs, suggesting that for some, solvent-free alternatives may offer economic benefits. A small percentage (5.9%) noted no significant change in costs, while 9.3% marked this question as not applicable, possibly indicating a lack of direct experience with these alternatives. The distribution of responses, as illustrated in Figure 4.16, suggests that while cost concerns remain a challenge, there is also potential for cost-saving opportunities with optimized solvent-free processes. These findings highlight the need for further evaluation of cost-effectiveness and efficiency improvements in sustainable manufacturing practices.

Table 4.16
Responses data on costs of alternatives

16) Have you noticed any changes in production costs when using alternatives to organic solvents?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not applicable	30	9.3	9.3	9.3
	Yes, costs decreased	123	38.1	38.1	47.4
	No significant change	19	5.9	5.9	53.3
	Yes, costs increased	151	46.7	46.7	100.0
	Total	323	100.0	100.0	

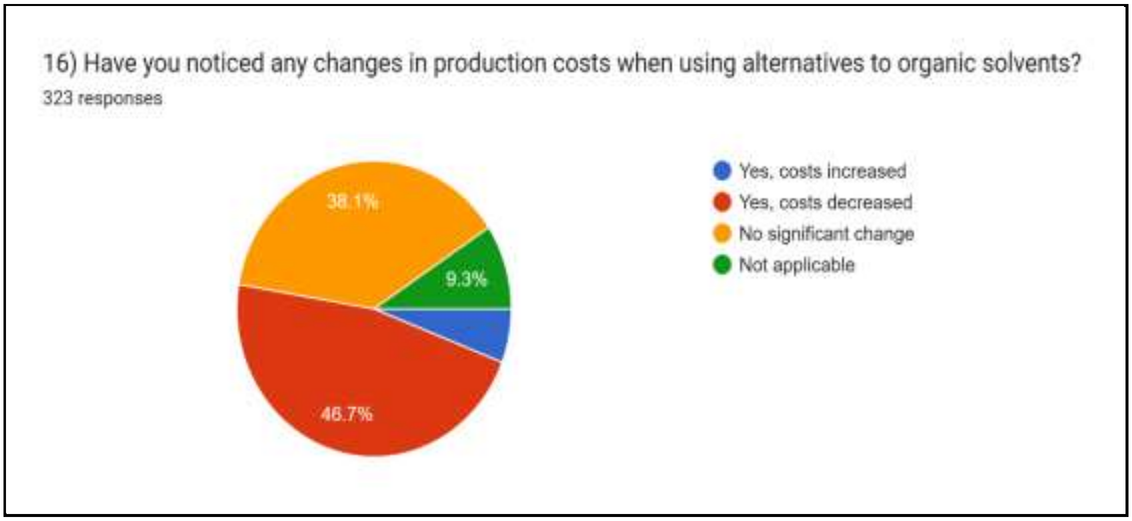

Figure 4.16
Graph on costs of alternatives

Question 17: How often do you seek alternatives to organic solvents based on their negative impacts? The responses to Question 17, which assessed how frequently respondents seek alternatives to organic solvents due to their negative impacts, reveal that the majority (52.3%) do so only occasionally. Additionally, 27.9% stated they rarely seek alternatives, while 10.2% indicated they never consider alternatives, suggesting that for a significant portion, the search for solvent-free solutions is not a priority. In contrast, only 9.6% reported frequently seeking alternatives, highlighting a relatively low level of proactive efforts in this area. The distribution of responses, as shown in Figure 4.17, suggests that while awareness exists, stronger incentives or regulatory pressures may be needed to drive consistent adoption of sustainable practices.

Table 4.17
Responses data on seeking alternatives

17) How often do you seek alternatives to organic solvents based on their negative impacts?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Never	33	10.2	10.2	10.2
	Rarely	90	27.9	27.9	38.1
	Occasionally	169	52.3	52.3	90.4
	Frequently	31	9.6	9.6	100.0
	Total	323	100.0	100.0	

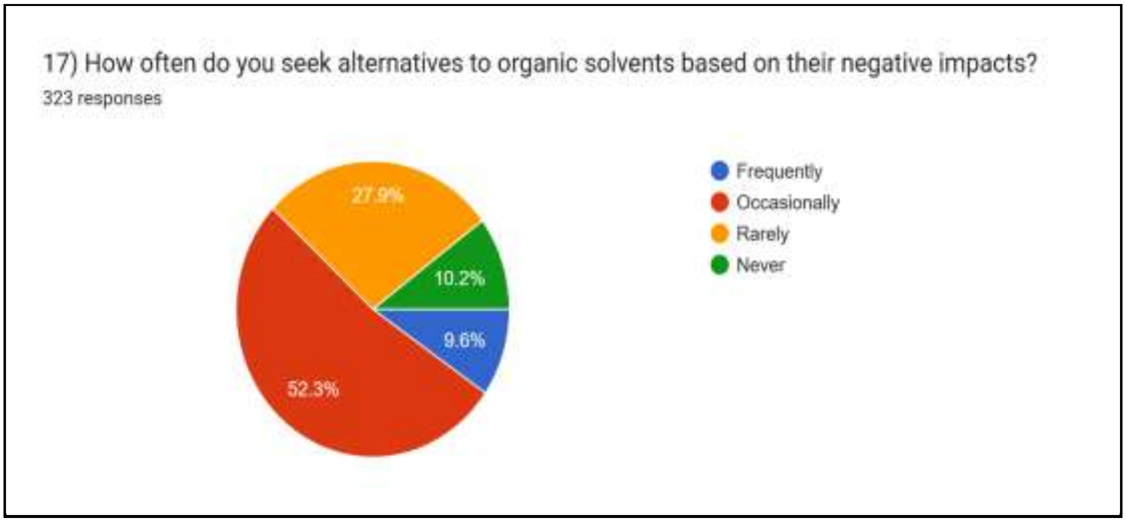

Figure 4.17
Graph on seeking alternatives

Question 18: Do you consider the negative impacts of solvents when choosing manufacturing methods? The responses to Question 18, which explored whether respondents consider the negative impacts of solvents when choosing manufacturing methods, indicate that a majority (51.4%) take these factors into account sometimes. Meanwhile, 22.0% reported often considering solvent impacts, and 5.3% stated they always factor them in, demonstrating that a smaller portion consistently integrates sustainability into their decision-making. On the other hand, 13.6% rarely consider these impacts, while 7.7% never do, suggesting that awareness and concern are not universal. The results, illustrated in Figure 4.18, highlight that while solvent-related concerns are acknowledged by many, there remains room for improvement in making sustainability a core consideration in manufacturing choices.

Table 4.18
Responses data on considering the negative impacts of solvents when choosing manufacturing methods

18) Do you consider the negative impacts of solvents when choosing manufacturing methods?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Never	25	7.7	7.7	7.7
	Rarely	44	13.6	13.6	21.4
	Sometimes	166	51.4	51.4	72.8
	Often	71	22.0	22.0	94.7
	Always	17	5.3	5.3	100.0
	Total	323	100.0	100.0	

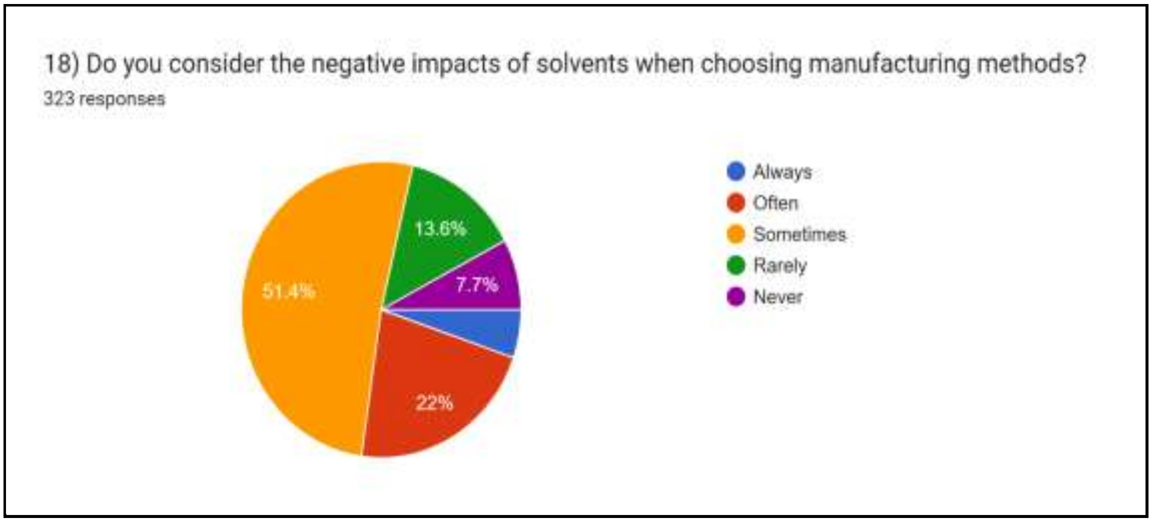

Figure 4.18
Graph on considering the negative impacts of solvents when choosing manufacturing methods

Question 19: How often do you face challenges in complying with these regulatory norms? The respondents to Question 19, have indicated that half (50.2%) occasionally encounter difficulties, while 32.2% rarely face such issues. Only 7.4% reported frequent challenges, and 10.2% stated they never experience difficulties in compliance. These findings, illustrated in Figure 4.19, suggest that while regulatory compliance is a manageable issue for most, occasional hurdles remain a concern for a significant portion of respondents.

Table 4.19
Responses data on challenges in complying with regulatory norms

19) How often do you face challenges in complying with these regulatory norms?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Never	33	10.2	10.2	10.2
	Rarely	104	32.2	32.2	42.4
	Occasionally	162	50.2	50.2	92.6
	Frequently	24	7.4	7.4	100.0
	Total	323	100.0	100.0	

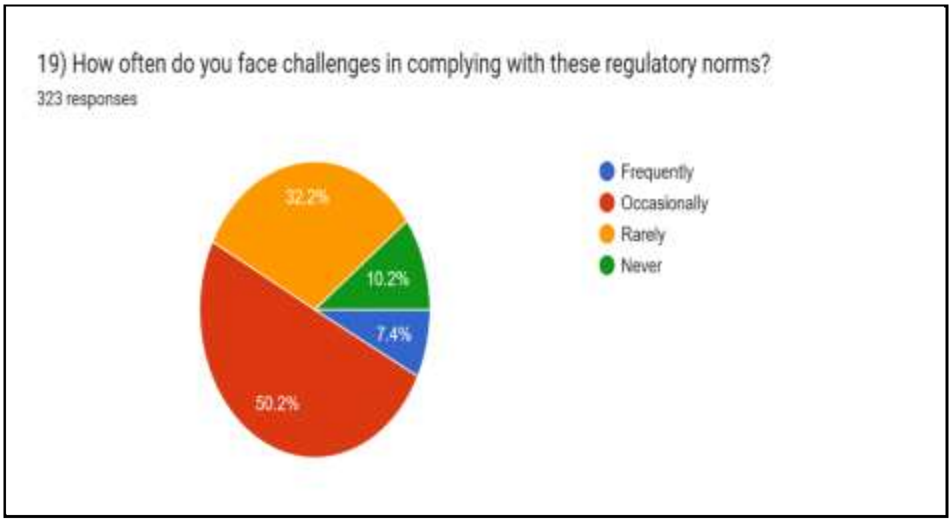

Figure 4.19
Graph on challenges in complying with regulatory norms

Question 20: How supportive is your organization/institution in implementing solvent-free manufacturing methods? (Likert Scale: 1-5). Based on the responses to Question 20, which evaluated how supportive organizations or institutions are in implementing solvent-free manufacturing methods, data indicates that 37.5% of respondents rated their organization as moderately supportive, while 27.2% perceived only slight support. Meanwhile, 20.7% found their organization to be supportive, and 5.3% felt their institution was highly supportive. However, 9.3% reported no support at all. These findings, illustrated in Figure 4.20, suggest that while a moderate level of support exists, there is still room for improvement in fostering organizational backing for solvent-free manufacturing.

Table 4.20
Responses data on support from organization/institution in implementing solvent-free manufacturing methods

20) How supportive is your organization/insitution in implementing solvent-free manufacturing methods? (Likert Scale: 1-5)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	30	9.3	9.3	9.3
	2	88	27.2	27.2	36.5
	3	121	37.5	37.5	74.0
	4	67	20.7	20.7	94.7
	5	17	5.3	5.3	100.0
	Total	323	100.0	100.0	

Likert scale:

1: Not supportive

2: Slightly supportive

3: Moderately supportive

4: Supportive

5: Most supportive

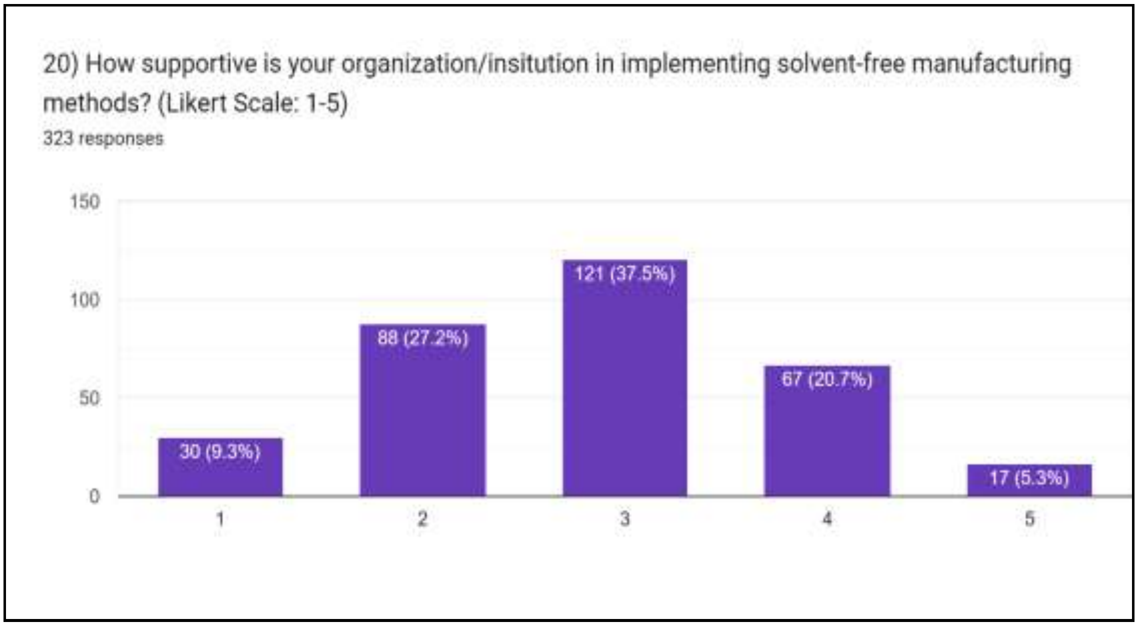

Figure 4.20
Graph on support from organization/institution in implementing solvent-free manufacturing methods

Question 21: To what extent do you think these regulations are practical in real-world manufacturing settings? (Likert Scale: 1-5). The responses to Question 21, which assessed the practicality of regulations in real-world manufacturing settings, show that 36.2% of respondents found them moderately practical, while 27.2% considered them only slightly practical. 18.6% believed these regulations were practical, and 4.3% found them highly practical. However, 13.6% viewed them as impractical. These results, as seen in Figure 4.21, indicate that while most respondents acknowledge some level of practicality, there remains a significant perception that regulatory norms pose real-world challenges.

Table 4.21
Responses data on practicality of regulations

21) To what extent do you think these regulations are practical in real-world manufacturing settings? (Likert Scale: 1-5)					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	44	13.6	13.6	13.6
	2	88	27.2	27.2	40.9
	3	117	36.2	36.2	77.1
	4	60	18.6	18.6	95.7
	5	14	4.3	4.3	100.0
	Total	323	100.0	100.0	

Likert scale:

1: Not practical

2: Slightly practical

3: Moderately practical

4: Practical

5: Most practical

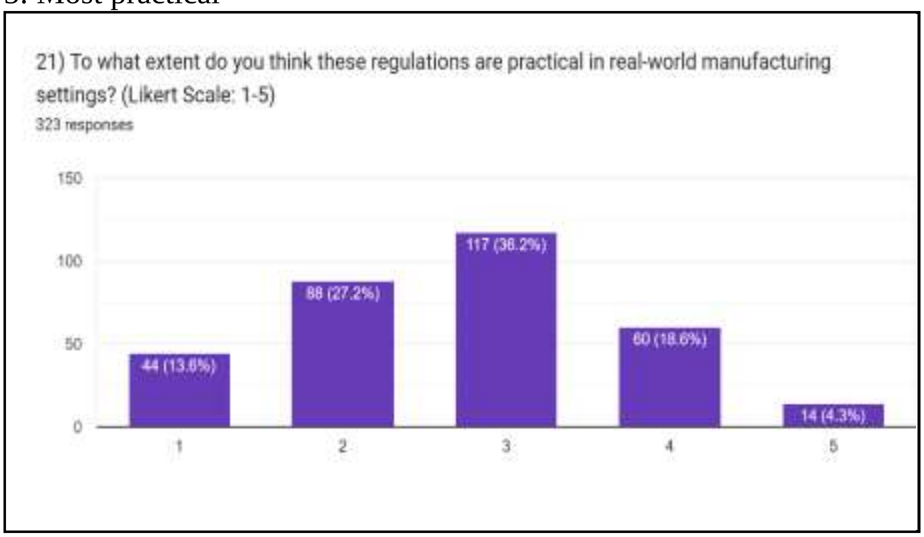

Figure 4.21
Graph on practicality of regulations

Question 22: How well do you think the industry as a whole is complying with the regulatory norms regarding organic solvents? (Likert Scale: 1-5). The survey results provide insights into how professionals perceive the compliance of the pharmaceutical industry with regulatory norms concerning organic solvents. 39.3% of respondents (127 out of 323) believe the industry complies moderately well with the regulations. This suggests that while some measures are in place to adhere to regulations, there may still be gaps or inconsistencies in implementation. 27.6% (89 respondents) feel that compliance is only slightly well. This significant proportion indicates a perception that the industry is making efforts but falls short of meeting full regulatory expectations. 17.0% (55 respondents) think the industry is complying well enough, reflecting a more optimistic view that regulatory norms are largely being followed, albeit with some challenges. 4.3% (14 respondents) rate industry compliance as very well, indicating a small group that believes the sector is fully aligned with regulatory expectations. On the other hand, 11.8% (38 respondents) perceive compliance as not well enough, indicating concerns about inadequate adherence to solvent-related regulations.

Table 4.22
Responses data on regulatory compliances

22) How well do you think the industry as a whole is complying with the regulatory norms regarding organic solvents? (Likert Scale: 1-5)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	38	11.8	11.8	11.8
	2	89	27.6	27.6	39.3
	3	127	39.3	39.3	78.6
	4	55	17.0	17.0	95.7
	5	14	4.3	4.3	100.0
	Total	323	100.0	100.0	

Likert scale:

1: Not well enough

2: Slightly well

3: Moderately well

4: Well enough

5: Very well

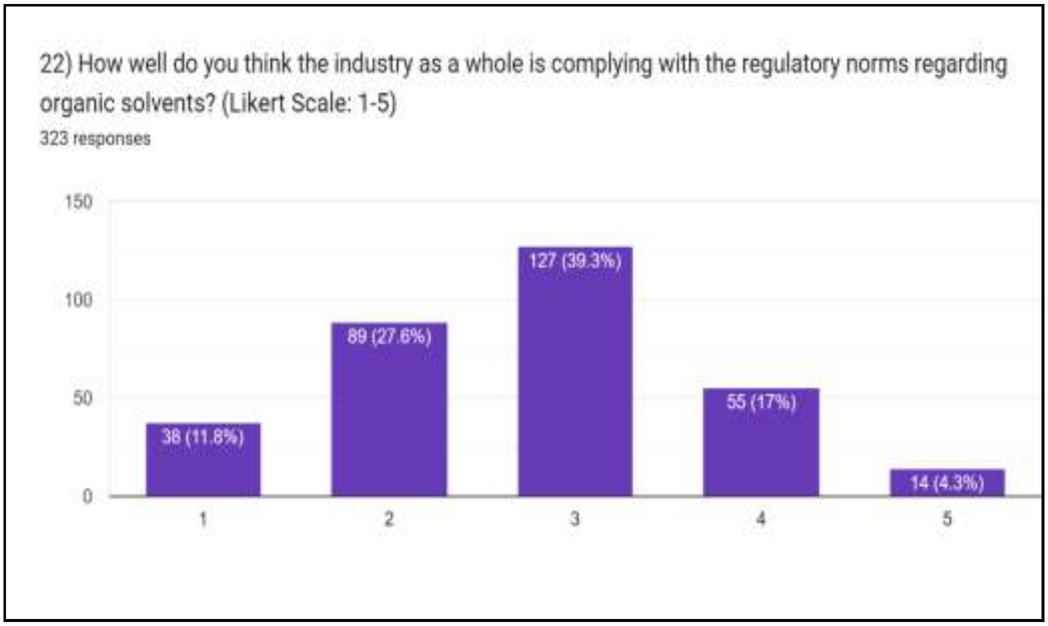

Figure 4.22
Graph on regulatory compliances

Question 23: How important do you think it is for your curriculum to include information about the sustainable use of organic solvents? (Likert Scale: 1-5). This question assesses the importance of including sustainable solvent use in the curriculum as the perception of students and professionals regarding the necessity of incorporating information about sustainable solvent use into their educational curriculum. The Key findings indicate 33.7% (109 respondents) consider it "moderately important," indicating a general acknowledgment of its relevance but possibly suggesting competing priorities in the curriculum. 31.9% (103 respondents) rate it as "slightly important," implying that while some see value, they may not perceive it as a critical component of their education. 19.8%

(64 respondents) regard it as "important," showing a solid portion of respondents advocating for more emphasis on sustainability in education. 8.0% (26 respondents) consider it "very important," highlighting a small but strong segment that believes sustainability in solvent use should be a key focus. 6.5% (21 respondents) see it as "not important," possibly indicating a lack of awareness or perceived relevance to their specific field or career.

Table 4.23
Responses data on curriculum to include information about the sustainable use of organic solvents

23) How important do you think it is for your curriculum to include information about the sustainable use of organic solvents? (Likert Scale: 1-5)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	21	6.5	6.5	6.5
	2	103	31.9	31.9	38.4
	3	109	33.7	33.7	72.1
	4	64	19.8	19.8	92.0
	5	26	8.0	8.0	100.0
	Total	323	100.0	100.0	

Likert scale:

1: Not important

2: Slightly important

3: Moderately important

4: Important

5: Very important

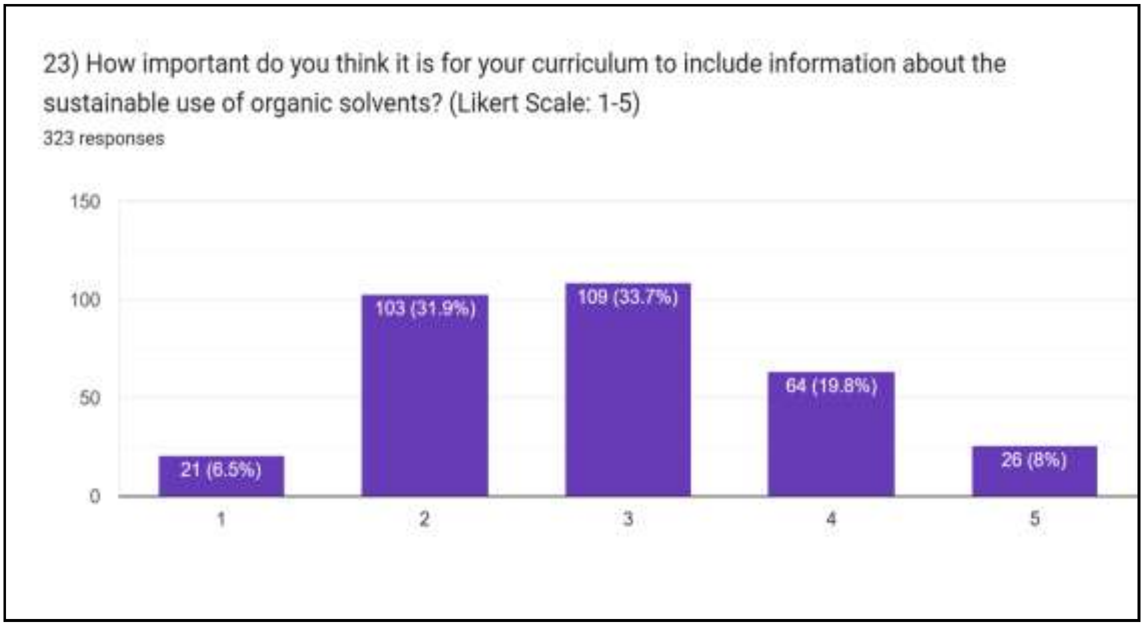

Figure 4.23
Graph on curriculum to include information about the sustainable use of organic solvents

Question 24: How effective do you believe current educational programs are in addressing the sustainability of organic solvents? (Likert Scale: 1-5). This question evaluates the perception of respondents regarding how well current educational programs cover sustainability aspects related to organic solvents. 37.2% (120 respondents) rated the programs as "moderately effective," suggesting that while there is some coverage, there is still room for improvement. 28.5% (92 respondents) found them "slightly effective," indicating that a significant portion believes the current curriculum does not adequately address sustainability. 20.7% (67 respondents) consider the programs "effective," meaning some respondents recognize a solid effort toward sustainability education. 4.0% (13 respondents) think the programs are "very effective," implying that a small group finds the education system sufficient in addressing sustainability concerns. 9.6% (31 respondents) rated them as "not effective," highlighting dissatisfaction with the current curriculum.

Table 4.24
Responses data on effectiveness of current educational programs in addressing the sustainability of organic solvents

24) How effective do you believe current educational programs are in addressing the sustainability of organic solvents? (Likert Scale: 1-5)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	31	9.6	9.6	9.6
	2	92	28.5	28.5	38.1
	3	120	37.2	37.2	75.2
	4	67	20.7	20.7	96.0
	5	13	4.0	4.0	100.0
	Total	323	100.0	100.0	

Likert scale:

1: Not effective

2: Slightly effective

3: Moderately effective

4: Effective

5: Very effective

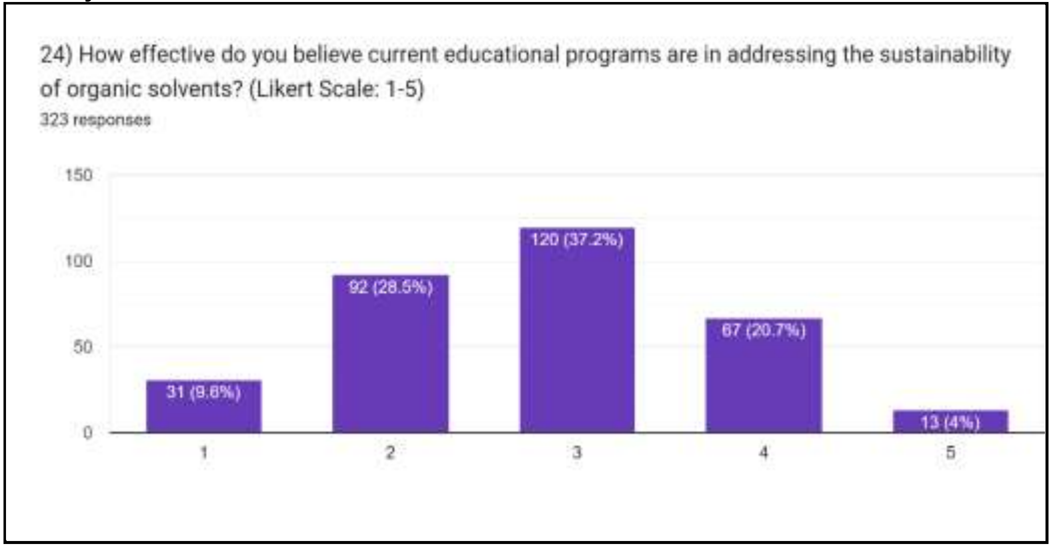

Figure 4.24
Graph on effectiveness of current educational programs in addressing the sustainability of organic solvents

Question 25: What barriers do you foresee in the transition from traditional solvent-based methods to more sustainable alternatives? As observed from the responses to the Barriers to Transitioning from Traditional Solvent-Based Methods to Sustainable Alternatives, the responses from 323 participants indicate several key barriers to adopting sustainable alternatives in solvent-based manufacturing. Lack of Awareness and Expertise (27.2%) emerged as the most significant challenge, suggesting a need for better training, education, and knowledge dissemination. Technical Challenges (22.3%) ranked second, indicating that current sustainable alternatives may require further research and technological advancements. Supply Chain Issues (16.4%) and Risk Aversion (16.1%) were also notable concerns, reflecting potential hesitancy from stakeholders and logistical difficulties in sourcing sustainable materials. Resistance to Change (15.2%) and Cost & Economic Feasibility (14.9%) were cited at similar levels, highlighting financial and psychological barriers to shifting away from traditional methods. Market Demand (13.6%) was seen as a relatively minor obstacle, implying that there is at least some level of interest in sustainable practices. Regulatory Compliance (11.5%) was the least cited barrier, suggesting that existing policies may not be a major hindrance, or that compliance processes are already well understood.

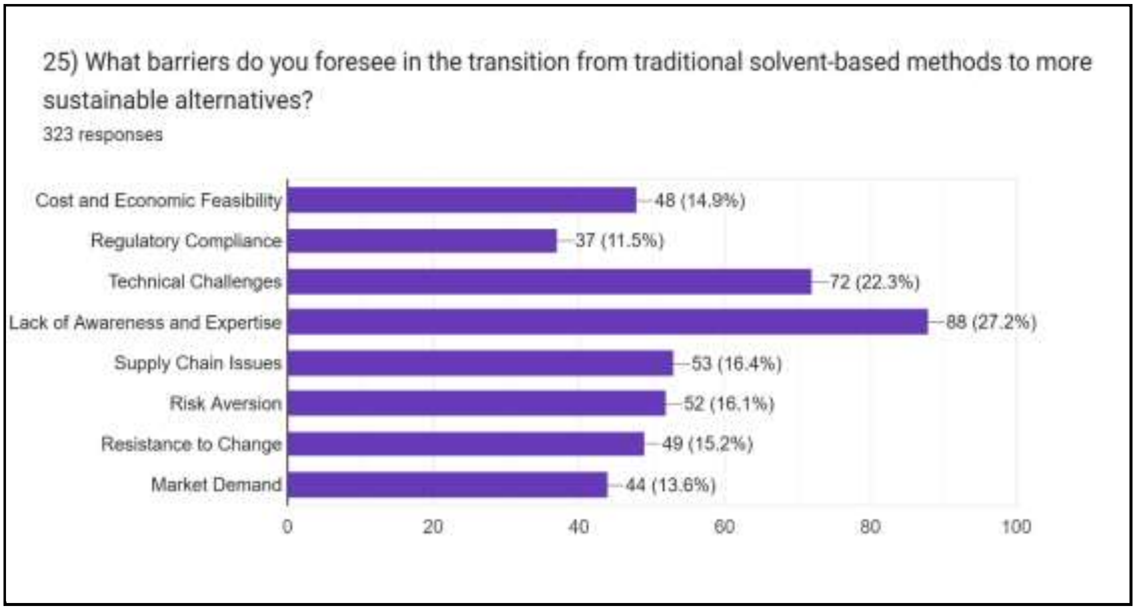

Figure 4.25
Graph on foreseen barriers

B) Margin of Error-Statistical evaluation of data:

The results obtained in the survey study were further subjected to statistical analysis using SPSS software and correlation analysis which revealed significant relationships between the variables investigated in the survey as have been discussed in the previous sections. In Descriptive Statistics the Margin of error was checked, Margin of Error (MOE) being a crucial statistical measure in data analysis, particularly in survey-based research, as it quantifies the level of uncertainty in sample estimates. Since data is collected from a subset of the population rather than the entire group, MOE helps determine how closely the sample responses represent the true population values. A lower MOE indicates higher reliability, while a higher MOE suggests greater variability. By calculating MOE, confidence intervals can be established, ensuring that findings are statistically sound and minimizing the risk of misleading conclusions. In this study, MOE has been applied to assess the precision of responses, validating the dataset's reliability for further interpretation and decision-making.

Bootstrapping method was used to provide more accurate MoE and confidence intervals by accounting for variability, sample size effects, and deviations from normality (Non normal data). It makes the results more reliable, especially for survey-based research. Bootstrapping helps when the Sample Size is of a Moderate size like n=323 for this survey. Traditional margin of error formulae assumes a perfectly normal distribution, which may not always hold true. Bootstrapping resamples the dataset many times (in this case, 1000 resamples) to better approximate the true sampling distribution and provide more accurate confidence intervals.

Bootstrapping in SPSS is a resampling technique that estimates the sampling distribution of a statistic by repeatedly drawing random samples (with replacement) from the original data. This process helps generate more robust confidence intervals and standard errors, especially when the data is non-normal or has a small sample size. The subsequent section provides details of Margin of Error for the responses to each of the 25 questions in the Survey.

Table 4.25
Margin of Error for Responses to Question 1

Criteria-Gender	Frequency	Percent	Valid Percent	Cumulative percent	Bootstrap for percent*				Margin of Error (%)	Valid percentage (Mean)
					Bias	Std Error	95% Confidence Interval			
							Lower	Upper		
Female	65	20.1	20.1	20.1	0.1	2.3	15.8	24.8	4.64	20.123839
Male	258	79.9	79.9	100.0	-0.1	2.3	75.2	84.2	4.33	79.876161
Total	323	100.0	100.0		0.0	0.0	100.0	100.0		

* Bootstrap results are based on 1000 bootstrap samples

As depicted in the above table, the survey data indicates that 20.1% of respondents were female (n=65) and 79.9% were male (n=258), with a total sample size of 323. The Margin of Error (MOE) is 4.64 for females and 4.33 for males, indicating high reliability with minimal deviation. The 95% Confidence Interval (CI) for females ranges between 15.8% and 24.8%, while for males, it ranges between 75.2% and 84.2%. These results suggest that the gender distribution in the sample is statistically stable and representative within the given confidence limits.

Table 4.26
Margin of Error for Responses to Question 2

Criteria-Age group	Frequency	Percent	Valid Percent	Cumulative percent	Bootstrap for percent*				Margin of Error (%)	Valid percentage (Mean)
					Bias	Std Error	95% Confidence Interval			
							Lower	Upper		
15-25	77	23.8	23.8	23.8	0.0	2.4	19.2	28.8	4.95	23.839009
26-35	55	17.0	17.0	40.9	-0.1	2.2	12.7	21.1	4.02	17.027864
36-45	126	39.0	39.0	79.9	0.1	2.7	33.7	44.6	5.57	39.009288
Above 45	65	20.1	20.1	100.0	0.0	2.2	16.1	25.1	4.95	20.123839
Total	323	100.0	100.0		0.0	0.0	100.0	100.0		

* Bootstrap results are based on 1000 bootstrap samples

The survey respondents are distributed across four age groups:

15-25 years: 23.8% (n=77), MOE = 4.95, 95% CI: 19.2% - 28.8%

26-35 years: 17.0% (n=55), MOE = 4.02, 95% CI: 12.7% - 21.1%

36-45 years: 39.0% (n=126), MOE = 5.57, 95% CI: 33.7% - 44.6%

Above 45 years: 20.1% (n=65), MOE = 4.95, 95% CI: 16.1% - 25.1%

The Margin of Error (MOE) indicates that the data is highly reliable across all age groups except for the 36-45 age group, which has a slightly higher MOE (5.57), making it acceptable but with slightly more deviation. The confidence intervals confirm that the data distribution is stable, ensuring reliable age group representation in the survey.

Table 4.27
Margin of Error for Responses to Question 3

Criteria-Pharma professional or Student	Frequency	Percent	Valid Percent	Cumulative percent	Bootstrap for percent				Margin of Error (%)	Valid percentage (Mean)
					Bias	Std Error	95% Confidence Interval			
							Lower	Upper		
Pharma professional	217	67.2	67.2	67.2	0.0	2.6	61.6	72.4	5.26	67.182663
Student	106	32.8	32.8	100.0	0.0	2.6	27.6	38.4	5.56	32.817337
Total	323	100.0	100.0		0.0	0.0	100.0	100.0		

* Bootstrap results are based on 1000 bootstrap samples

The survey respondents are categorized into two groups:

Pharma Professionals: 67.2% (n=217), MOE = 5.26, 95% CI: 61.6% - 72.4%

Students: 32.8% (n=106), MOE = 5.56, 95% CI: 27.6% - 38.4%

The Margin of Error (MOE) indicates that the data is acceptable with minimal deviation. The confidence intervals confirm that the data distribution is stable and reliable. The proportion of pharma professionals is significantly higher than that of students, reflecting the primary focus of the research on professionals while still incorporating student perspectives.

Table 4.28
Margin of Error for Responses to Question 4

Criteria-Participation	Frequency	Percent	Valid Percent	Cumulative percent	Bootstrap for percent				Margin of Error (%)	Valid percentage (Mean)
					Bias	Std Error	95% Confidence Interval			
							Lower	Upper		
No	129	39.9	39.9	39.9	0.0	2.7	34.4	45.2	5.26	39.93808
Yes	194	60.1	60.1	100.0	0.0	2.7	54.8	65.6	5.57	60.06192
Total	323	100.0	100.0		0.0	0.0	100.0	100.0		

* Bootstrap results are based on 1000 bootstrap samples

The margin of error (MOE) for this question on participation is 5.26% for "No" responses and 5.57% for "Yes" responses, indicating minimal deviation. The 95% confidence interval shows that the true proportion of respondents who participated in such projects is likely between 54.8% and 65.6%, while those who did not fall between 34.4% and 45.2%. Since the intervals do not overlap, a majority have engaged in such projects. The MOE values confirm data reliability, making it suitable for further analysis.

Table 4.29
Margin of Error for Responses to Question 5

Criteria- How aware are you of the environmental impacts of using organic solvents?	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.24	0.037	0.00	0.04	2.16	2.31	7.58
95% Confidence Interval for Mean, Lower Bound	2.17						
95% Confidence Interval for	2.31						

Mean, Upper Bound							
5% Trimmed Mean	2.26		0.00	0.04	2.18	2.35	
Median	2.00		0.00	0.00	2.00	2.00	
Variance	0.443		-0.001	0.026	0.390	0.494	
Std. Deviation	0.666		-0.001	0.020	0.625	0.703	
Minimum	1						
Maximum	3						
Range	2						
Interquartile Range	1		0	0	1	1	
Skewness	-0.311	0.136	0.005	0.065	-0.441	-0.185	
Kurtosis	-0.782	0.271	0.007	0.085	-0.941	-0.602	

For this question, the response options of not aware/somewhat aware/very aware are converted to a numerical scale of 1, 2, and 3, based on which the Mean has been calculated as 2.24. Further statistical evaluation resulted in a Margin of Error (MOE) of 7.58%. The Mean Awareness Score with a Mean = 2.24 (on a 1-3 scale), with a 95% confidence interval (2.17 – 2.31) and the 5% trimmed mean (2.26), is close to the mean, indicating minimal impact from outliers.

The Spread & Dispersion at Standard Deviation = 0.666 (moderate variation) and Variance = 0.443 is slightly higher than the variance in awareness of health impacts (0.410). The Distribution Shape with Skewness = -0.311 (slightly negative) suggests that responses are somewhat skewed toward higher awareness, while Kurtosis = -0.782 indicates a relatively flat distribution.

The Margin of Error (MOE) at 7.58% suggests that the awareness of the environmental impacts of organic solvents is estimated with a moderate level of precision. While the reported mean (2.24) is a reliable reflection of the overall awareness, the slightly higher MOE suggests a moderate level of uncertainty compared to awareness of health impacts.

Overall, respondents show a moderate level of awareness regarding the environmental impacts of organic solvents. The negative skew suggests that more respondents lean toward awareness rather than lack of awareness, but there remains an opportunity for further improvement in knowledge and understanding.

Table 4.30
Margin of Error for Responses to Question 6

Criteria- How aware are you of the health impacts of using organic solvents?	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.20	0.036	0.00	0.04	2.13	2.27	6.97
95% Confidence Interval for Mean, Lower Bound	2.13						
95% Confidence Interval for Mean, Upper Bound	2.27						
5% Trimmed Mean	2.22		0.00	0.04	2.14	2.30	
Median	2.00		0.00	0.00	2.00	2.00	
Variance	0.410		-0.001	0.027	0.357	0.459	
Std. Deviation	0.640		-0.001	0.021	0.597	0.678	
Minimum	1						
Maximum	3						
Range	2						
Interquartile Range	1		0	0	1	1	
Skewness	-0.206	0.136	0.007	0.058	-0.324	-0.088	
Kurtosis	-0.647	0.271	0.009	0.108	-0.833	-0.401	

For this question the responses options of not aware/somewhat aware/very aware are converted to numerical scale of 1,2,3 based on which the Mean has been calculated as

2.20 and with further statistical evaluation leading to an MOE of 6.97%. The Mean Awareness Score with a Mean = 2.20 (on a 1-3 scale), with a 95% confidence interval (2.13 – 2.27) and the 5% trimmed mean (2.22) is close to the mean, indicating minimal impact from outliers. The Spread & Dispersion at Standard Deviation = 0.640 (moderate variation) and Variance = 0.410, slightly lower than the variance in familiarity with regulations (0.508). The Distribution Shape with Skewness = -0.206 (slightly negative), meaning responses are slightly skewed toward higher awareness and Kurtosis = -0.647, suggesting a relatively flat distribution. The Margin of Error (MOE) at 6.97%, the awareness of health impacts of organic solvents is estimated with a relatively high level of precision. The low MOE indicates that the reported mean (2.20) is a reliable reflection of the overall awareness in the surveyed population, with minimal uncertainty.

Respondents are relatively aware of the health impacts of organic solvents, but there is still room for improvement. The negative skew suggests that a higher proportion of respondents lean toward awareness rather than lack of awareness.

Table 4.31
Margin of Error for Responses to Question 7

Criteria- How familiar are you with the regulatory norms governing the usage of organic solvents in pharmaceutical manufacturing?	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	1.86	0.040	0.00	0.04	1.78	1.93	7.89
95% Confidence Interval for Mean, Lower Bound	1.78						
95% Confidence Interval for	1.94						

Mean, Upper Bound							
5% Trimmed Mean	1.84		0.00	0.04	1.75	1.93	
Median	2.00		0.00	0.00	2.00	2.00	
Variance	0.508		-0.002	0.027	0.453	0.558	
Std. Deviation	0.712		-0.001	0.019	0.673	0.747	
Minimum	1						
Maximum	3						
Range	2						
Interquartile Range	1		0	0	1	1	
Skewness	0.214	0.136	0.002	0.065	0.095	0.346	
Kurtosis	-1.013	0.271	0.012	0.096	-1.176	-0.808	

For this question the responses options of not familiar/somewhat familiar/very familiar are converted to numerical scale of 1,2,3 based on which the Mean has been calculated as 1.86 and with further statistical evaluation leading to an MOE of 7.89%.

This dataset represents the familiarity of respondents with regulatory norms governing the usage of organic solvents in pharmaceutical manufacturing. Mean Familiarity Score: The mean is 1.86, with a 95% confidence interval of (1.78 to 1.94). The 5% trimmed mean (1.84) is close to the mean, suggesting minimal influence from extreme values. Central Tendency & Distribution: Median = 2.00, meaning half of the respondents scored ≤2. The data is on a 3-point scale (1-3). Variance = 0.508 and Standard Deviation = 0.712, indicating moderate dispersion.

Distribution Shape: Skewness = 0.214 (slightly positive), meaning a small tendency for responses to cluster towards the lower end (less familiarity). Kurtosis = -1.013 (platykurtic), suggesting the distribution is flatter than a normal curve.

Margin of Error (MOE): 7.89%, indicating a reasonable level of precision in the estimate. Respondents reported low familiarity with regulatory norms. The slightly positive skew suggests that while some individuals are familiar with the regulations, many lack knowledge.

Table 4.32
Margin of Error for Responses to Question 8

Criteria- How aware are you of any alternatives to organic solvents in pharmaceutical manufacturing?	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.12	0.036	0.00	0.04	2.05	2.19	7.12
95% Confidence Interval for Mean, Lower Bound	2.05						
95% Confidence Interval for Mean, Upper Bound	2.19						
5% Trimmed Mean	2.13		0.00	0.04	2.06	2.21	
Median	2.00		0.00	0.00	2.00	2.00	
Variance	0.423		-0.001	0.027	0.371	0.476	
Std. Deviation	0.651		-0.001	0.021	0.609	0.690	
Minimum	1						
Maximum	3						
Range	2						
Interquartile Range	1		0	0	0	1	
Skewness	-0.124	0.136	0.002	0.047	-0.222	-0.038	
Kurtosis	-0.656	0.271	0.010	0.138	-0.893	-0.361	

This data summarizes the awareness of alternatives to organic solvents in pharmaceutical manufacturing. The Mean Awareness Level, the mean awareness score is 2.12. The data ranges from 1 (minimum) to 3 (maximum), with a 95% confidence interval ranging from 2.05 to 2.19. A 5% trimmed mean of 2.13 indicates that extreme values did not significantly impact the average.

Central Tendency & Distribution: The median score is 2.00, suggesting that the central tendency is slightly lower than the mean. The variance (0.423) and standard deviation (0.651) suggest moderate spread in responses. The interquartile range (IQR) is 1, meaning 50% of respondents scored between 1 and 2 or 2 and 3.

Distribution Shape: Skewness (-0.124): Slight negative skew, meaning slightly more responses lean towards higher awareness. Kurtosis (-0.656): The distribution is slightly platykurtic (flatter than a normal distribution).

Margin of Error (MOE): The margin of error is 7.12%, which is reasonable but suggests that awareness levels could slightly fluctuate if sampled again.

The responses indicate low to moderate awareness of alternatives to organic solvents. The slight negative skew suggests that while most respondents fall in the lower to mid-range of awareness, a small portion might have relatively higher awareness. The confidence interval confirms that the true mean awareness level is likely around 2.12, meaning there is room for improvement in awareness levels.

Table 4.33
Margin of Error for Responses to Question 9

Criteria- How important is it to you personally to reduce the usage of organic solvents in your work? (Likert Scale: 1-5)	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.74	0.059	0.00	0.06	2.63	2.86	11.29
95% Confidence Interval for	2.63						

Mean, Lower Bound							
95% Confidence Interval for Mean, Upper Bound	2.86						
5% Trimmed Mean	2.71		0.00	0.06	2.60	2.84	
Median	3.00		-0.02	0.14	3.00	3.00	
Variance	1.129		-0.003	0.078	0.975	1.281	
Std. Deviation	1.063		-0.002	0.037	0.987	1.132	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	1		0	0	1	2	
Skewness	0.263	0.136	-0.003	0.082	0.093	0.426	
Kurtosis	-0.540	0.271	-0.003	0.124	-0.761	-0.265	

For the question on how personally important it is to reduce organic solvent usage in work (Likert scale 1-5), Mean response is 2.74, with a 95% confidence interval of 2.63 to 2.86. Margin of error (MOE) is 11.29%, indicating a relatively stable response distribution. Median score is 3.00, suggesting that most respondents have a neutral-to-moderate stance on reducing organic solvent use. Standard deviation (1.063) and variance (1.129) indicate moderate variability, meaning opinions on this topic are somewhat spread out. Skewness (0.263) suggests a slight positive skew, meaning a few respondents might have rated the importance higher. Kurtosis (-0.540) suggests a flatter distribution, indicating that responses are spread across multiple values rather than clustering around a single number.

These results indicate that reducing organic solvent usage is personally important to many respondents but not overwhelmingly so. The neutral-to-moderate mean score (2.74) and median (3.00) show that while some respondents recognize its significance, it is not a strong priority for all.

Lack of Strong Commitment: The relatively low mean and moderate skewness suggest that respondents might not feel a strong personal drive to reduce solvent use, possibly due to industry constraints, lack of alternatives, or limited awareness.

Potential for Awareness Programs: Organizations and regulatory bodies could benefit from educational initiatives that highlight the benefits of solvent reduction in terms of safety, compliance, and sustainability.

Need for Practical Solutions: If practical alternatives to organic solvents are not readily available, professionals may be less motivated to make changes. This suggests an opportunity for further research and investment into green solvent alternatives.

While reducing organic solvents is somewhat important to respondents, it is not a top personal priority. Targeted awareness efforts and viable sustainable alternatives could enhance motivation and adoption in the pharmaceutical industry.

Table 4.34
Margin of Error for Responses to Question 10

Criteria- 10) How important do you think sustainability is in the context of pharmaceutical manufacturing? (Likert Scale: 1-5)	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.77	0.065	0.00	0.06	2.64	2.90	12.85
95% Confidence Interval for Mean, Lower Bound	2.64						
95% Confidence Interval for Mean, Upper Bound	2.90						

5% Trimmed Mean	2.75		0.00	0.07	2.60	2.89	
Median	3.00		-0.03	0.17	2.00	3.00	
Variance	1.345		-0.005	0.082	1.185	1.504	
Std. Deviation	1.160		-0.003	0.035	1.089	1.226	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	2		0	0	1	2	
Skewness	0.215	0.136	-0.001	0.079	0.064	0.366	
Kurtosis	-0.797	0.271	0.004	0.095	-0.963	-0.595	

For this question on the perceived Importance of Sustainability in Pharmaceutical Manufacturing with Likert scale 1-5, Mean response is 2.77, with a 95% confidence interval of 2.64 to 2.90. Margin of error (MOE) is 12.85%, which indicates moderate variability in responses. Median score is 3.00, meaning most respondents perceive sustainability as moderately important.

Standard deviation (1.160) and variance (1.345) show a wide spread of responses, indicating some level of disagreement. Skewness (0.215) suggests a slight positive skew, meaning a small number of respondents may place more importance on sustainability. Kurtosis (-0.797) suggests a relatively flat distribution, meaning responses are not concentrated around any single category.

These results suggest that while sustainability is seen as important, it is not a top priority for all respondents. The neutral-to-moderate mean score (2.77) and median (3.00) indicate that many respondents acknowledge sustainability's relevance but do not strongly advocate for it.

Potential Gaps in Sustainability Awareness, where the moderate response suggests that awareness campaigns and educational efforts may be needed to emphasize sustainability's role in pharmaceutical manufacturing. Sustainability in pharmaceutical manufacturing is moderately valued, but not yet a major concern for all respondents. There is room for improvement in driving awareness and integrating sustainable practices into industry norms.

Table 4.35
Margin of Error for Responses to Question 11

Criteria- 11) What is your level of concern regarding the long-term environmental impact of using organic solvents? (Likert Scale: 1-5)	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.85	0.065	0.00	0.07	2.71	2.98	13.62
95% Confidence Interval for Mean, Lower Bound	2.72						
95% Confidence Interval for Mean, Upper Bound	2.98						
5% Trimmed Mean	2.83		0.00	0.07	2.68	2.98	
Median	3.00		0.00	0.00	3.00	3.00	
Variance	1.359		-0.005	0.081	1.194	1.507	
Std. Deviation	1.166		-0.003	0.035	1.092	1.227	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	2		0	0	1	2	
Skewness	0.062	0.136	-0.001	0.076	-0.088	0.210	
Kurtosis	-0.815	0.271	0.006	0.092	-0.972	-0.610	

As regards Concern About Environmental Impact of Organic Solvents on a Likert scale 1-5, Mean response is 2.85, with a 95% confidence interval ranging from 2.72 to 2.98. Margin of error (MOE) is 13.62%, indicating a relatively high variability in responses. The median score is 3.00, showing that most respondents have a neutral-to-moderate level of concern.

Standard deviation is 1.166, and variance is 1.359, indicating broad dispersion in responses. Skewness (0.062) is close to zero, meaning the distribution is almost symmetric, suggesting that concern is fairly evenly distributed across respondents. Kurtosis (-0.815) suggests a slightly flatter distribution, meaning responses do not strongly cluster around any single value.

The results suggest that respondents are not strongly polarized in their views on the long-term environmental impact of organic solvents. While some express high concern, others remain neutral or less worried. Given that the mean is below 3.00, concern is not particularly strong, though not absent either.

Need for Awareness Initiatives: If reducing solvent use is a priority, increased awareness campaigns may be needed to emphasize long-term environmental risks. Overall, this finding suggests room for improvement in driving awareness and concern about the environmental impact of organic solvents in the pharmaceutical industry.

Table 4.36
Margin of Error for Responses to Question 12

Criteria- 11) What is your level of concern regarding the long-term environmental impact of using organic solvents?	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	

(Likert Scale: 1-5)							
Mean	2.79	0.065	0.00	0.06	2.67	2.92	12.54
95% Confidence Interval for Mean, Lower Bound	2.67						
95% Confidence Interval for Mean, Upper Bound	2.92						
5% Trimmed Mean	2.77		0.00	0.07	2.63	2.91	
Median	3.00		-0.03	0.17	2.00	3.00	
Variance	1.357		-0.005	0.082	1.197	1.520	
Std. Deviation	1.165		-0.003	0.035	1.094	1.233	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	2		0	0	1	2	
Skewness	0.304	0.136	0.001	0.077	0.151	0.451	
Kurtosis	-0.725	0.271	0.008	0.110	-0.910	-0.481	

For the question on motivation to incorporate sustainable practices in future professional work (Likert scale 1-5), the mean response is 2.79, with a 95% confidence interval ranging from 2.67 to 2.92. The margin of error (MOE) is 12.54%, indicating a relatively broad range, suggesting some variability in responses. The median score is 3.00, implying that most respondents fall around the neutral-to-moderate motivation level. The standard deviation is 1.165, and the variance is 1.357, indicating high dispersion in responses, meaning that motivation levels are widely spread across the Likert scale.

Skewness (0.304) suggests a slight positive skew, meaning there are more responses on the lower end but with some higher responses as well. Kurtosis (-0.725) suggests a flatter distribution, indicating that responses do not cluster tightly around a particular value but are spread out.

The findings suggest that motivation to adopt sustainable practices in professional work is mixed, with a slight tendency toward moderate motivation. Since the mean is below 3.00, some respondents may not strongly prioritize sustainability yet. The high standard deviation and interquartile range indicate diverse opinions, possibly due to different levels of awareness, exposure, or constraints in adopting sustainability in professional settings.

Efforts should be made to increase awareness and emphasize the benefits of sustainability, as motivation levels are not very high. Some professionals may lack the necessary resources, incentives, or organizational support, which could be influencing their moderate motivation levels. A deeper look into the reasons for lower motivation scores could help tailor sustainability initiatives to address specific concerns or barriers within the industry.

Table 4.37
Margin of Error for Responses to Question 13

Criteria: What percentage of your manufacturing processes currently involve organic solvents?	Frequency	Percent	Valid Percent	Cumulative percent	Bootstrap for percent*				Margin of Error (%)	Valid percentage (Mean)
					Bias	Std Error	95% Confidence Interval			
							Lower	Upper		
0-25%	95	29.4	29.4	29.4	-0.1	2.6	24.5	34.4	4.95	29.411765
26-50%	123	38.1	38.1	67.5	0.0	2.7	32.8	43.6	5.56	38.080495
51-75%	98	30.3	30.3	97.8	0.1	2.5	25.4	35.6	5.26	30.340557

76-100%	7	2.2	2.2	100.0	0.0	0.8	0.9	4.0	1.85	2.1671827
Total	323	100.0	100.0		0.0	0.0	100.0	100.0		

* Bootstrap results are based on 1000 bootstrap samples

Respondents were asked what percentage of their manufacturing processes currently involve organic solvents. The survey results indicate that most respondents (67.5%) use solvents in 50% or less of their processes. Specifically, 29.4% report a usage rate of 0-25%, with a margin of error (MOE) of 4.95 and a 95% confidence interval (CI) of 24.5% to 34.4%, making the data highly reliable with minimal deviation. The largest group, 38.1%, falls within the 26-50% usage range, with an MOE of 5.56 and a 95% CI of 32.8% to 43.6%, indicating acceptable reliability with some deviation. Another 30.3% of respondents report solvent usage between 51-75%, with an MOE of 5.26 and a 95% CI of 25.4% to 35.6%, also considered acceptable in reliability. Only 2.2% of respondents indicate heavy reliance on solvents (76-100%), with an MOE of 1.85 and a 95% CI of 0.9% to 4.0%, making this data highly reliable with minimal deviation. The overall findings suggest a trend toward reduced solvent use or the adoption of sustainable practices in pharmaceutical manufacturing.

Table 4.38
Margin of Error for Responses to Question 14

Criteria- 14) Have you experimented with or studied alternative methods that do not involve organic solvents?	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.60	0.044	0.00	0.04	2.52	2.69	8.36
95% Confidence	2.52						

Interval for Mean, Lower Bound							
95% Confidence Interval for Mean, Upper Bound	2.69						
5% Trimmed Mean	2.62		0.00	0.05	2.53	2.71	
Median	3.00		-0.01	0.08	3.00	3.00	
Variance	0.638		-0.002	0.046	0.548	0.726	
Std. Deviation	0.798		-0.002	0.029	0.740	0.852	
Minimum	1						
Maximum	4						
Range	3						
Interquartile Range	1		0	0	1	1	
Skewness	-0.085	0.136	0.001	0.085	-0.249	0.082	
Kurtosis	-0.438	0.271	0.003	0.096	-0.612	-0.242	

For the question on whether respondents have experimented with or studied alternative methods that do not involve organic solvents, the mean response is 2.60, with a 95% confidence interval ranging from 2.52 to 2.69. The margin of error (MOE) is 8.36%, indicating moderate precision. The median score is 3.00, suggesting that most respondents leaned towards agreeing that they have explored alternative methods.

The standard deviation of 0.798 and variance of 0.638 indicate moderate variability in responses. Skewness (-0.085) is close to zero, indicating a fairly symmetrical distribution of responses. Kurtosis (-0.438) suggests a relatively flat distribution, meaning responses are somewhat spread out rather than clustering tightly around the mean.

The results suggest that many respondents have engaged with or studied alternative methods that avoid organic solvents. However, since the mean is not very high (closer to neutral at 2.60 rather than strongly affirmative at 4.00), it implies that while some have explored these methods, a significant portion may still be hesitant or lack exposure to alternative techniques. This indicates a need for further education, training, or incentives to encourage broader adoption of sustainable manufacturing practices.

Table 4.39
Margin of Error for Responses to Question 15

Criteria- How effective do you find the alternatives to organic solvents in terms of quality and yield? (Likert Scale: 1-5)	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.93	0.055	0.00	0.06	2.82	3.03	10.68
95% Confidence Interval for Mean, Lower Bound	2.82						
95% Confidence Interval for Mean, Upper Bound	3.04						
5% Trimmed Mean	2.92		0.01	0.06	2.81	3.04	
Median	3.00		0.00	0.00	3.00	3.00	
Variance	0.964		-0.006	0.070	0.820	1.096	
Std. Deviation	0.982		-0.004	0.036	0.905	1.047	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	2		0	0	1	2	
Skewness	-0.061	0.136	-0.001	0.091	-0.241	0.123	
Kurtosis	-0.298	0.271	0.006	0.139	-0.531	0.009	

For Question 15, the margin of error (MOE) calculated from the confidence interval is 10.68%, with the mean effectiveness rating at 2.93. The 95% confidence interval for the mean falls within 2.82 to 3.04, indicating that respondents generally perceive alternatives to organic solvents as moderately effective in maintaining quality and yield. The relatively small confidence interval suggests that the responses are consistent, though with some variation in perceptions.

The bootstrap method further confirms the reliability of these estimates, accounting for the variability in responses. The interquartile range of 2 and a standard deviation of 0.982 highlight some spread in the data, but the median of 3.00 aligns closely with the mean. This approach reinforces that the perceived effectiveness of alternatives is somewhat neutral, with neither strong agreement nor strong disagreement dominating the responses.

Table 4.40
Margin of Error for Responses to Question 16

Criteria: Cost score	Frequency	Percent	Valid Percent	Cumulative percent	Bootstrap for percent*				Margin of Error (%)	Valid percentage (Mean)
					Bias	Std Error	95% Confidence Interval			
							Lower	Upper		
0	30	9.3	9.3	9.3	-0.1	1.7	6.2	12.7	3.41	9.2879257
2	123	38.1	38.1	47.4	0.1	2.8	32.5	43.7	5.57	38.080495
4	19	5.9	5.9	53.3	0.0	1.3	3.4	8.7	2.79	5.8823529
6	151	46.7	46.7	100.0	0.0	2.8	41.2	52.3	5.57	46.749226
Total	323	100.0	100.0		0.0	0.0	100.0	100.0		

* Bootstrap results are based on 1000 bootstrap samples

The cost score distribution indicates that 46.7% of respondents perceive a high-cost impact (score 6), while 38.1% consider the impact to be moderate (score 2). A smaller portion, 9.3%, views the cost impact as low (score 0), and only 5.9% rated it as minor (score 4). Overall, 47.4% of responses fall within the low to moderate cost range (scores 0-2). The data is reliable, with minimal margin of error, suggesting consistent responses across the sample.

Table 4.41

Margin of Error for Responses to Question 17

Criteria- How often do you seek alternatives to organic solvents based on their negative impacts?	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.61	0.044	0.00	0.04	2.53	2.70	8.51
95% Confidence Interval for Mean, Lower Bound	2.53						
95% Confidence Interval for Mean, Upper Bound	2.70						
5% Trimmed Mean	2.63		0.00	0.05	2.53	2.72	
Median	3.00		0.00	0.00	3.00	3.00	
Variance	0.635		-0.003	0.047	0.545	0.729	
Std. Deviation	0.797		-0.003	0.030	0.738	0.854	
Minimum	1						
Maximum	4						
Range	3						
Interquartile Range	1		0	0	1	1	
Skewness	-0.412	0.136	-0.004	0.091	-0.588	-0.237	
Kurtosis	-0.250	0.271	0.011	0.153	-0.514	0.099	

This survey question assessed how often respondents seek alternatives to organic solvents due to their negative impacts. The mean response was 2.61, with a margin of error (MOE) of 8.51% and a 95% confidence interval ranging from 2.53 to 2.70. The 5% trimmed mean of 2.63 is close to the mean, indicating that extreme values did not significantly affect the average. The median response was 3.00, suggesting a central tendency slightly higher than the mean.

The variance was 0.635, and the standard deviation was 0.797, indicating moderate variability in responses. The minimum value was 1, and the maximum was 4, resulting in a range of 3. The interquartile range was 1, meaning responses were relatively clustered around the median.

A skewness value of -0.412 suggests a slight left skew, meaning more respondents selected higher values. The kurtosis value of -0.250 indicates a relatively flat distribution, suggesting a lack of extreme outliers. These findings indicate that while some respondents actively seek alternatives to organic solvents, the frequency varies, with many showing only moderate or occasional interest in doing so.

Table 4.42
Margin of Error for Responses to Question 18

Criteria- Do you consider the negative impacts of solvents when choosing manufacturing methods?	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	3.03	0.052	0.00	0.05	2.93	3.14	10.22
95% Confidence Interval for Mean, Lower Bound	2.93						

95% Confidence Interval for Mean, Upper Bound	3.14						
5% Trimmed Mean	3.04		0.00	0.05	2.93	3.15	
Median	3.00		0.00	0.00	3.00	3.00	
Variance	0.878		-0.005	0.073	0.733	1.016	
Std. Deviation	0.937		-0.004	0.039	0.856	1.008	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	1		0	0	0	2	
Skewness	-0.250	0.136	-0.005	0.093	-0.444	-0.076	
Kurtosis	0.233	0.271	0.011	0.202	-0.121	0.685	

This survey question assessed whether respondents consider the negative impacts of solvents when choosing manufacturing methods, using a Likert scale (1-5). The mean response was 3.03, with a margin of error (MOE) of 10.22%, and a 95% confidence interval ranging from 2.93 to 3.14. The 5% trimmed mean was 3.04, closely aligning with the median of 3.00, indicating that extreme values had little influence on the overall mean.

The variance was 0.878, with a standard deviation of 0.937, suggesting moderate variability in responses. The minimum response was 1, and the maximum was 5, giving a range of 4. The interquartile range was 1, implying that most responses were clustered around the median.

A slight negative skewness (-0.250) suggests that responses were slightly more concentrated on the higher end of the scale, while the kurtosis value (0.233) indicates a distribution close to normal. These results suggest that respondents generally consider the negative impacts of solvents when selecting manufacturing methods, but opinions vary.

Table 4.43
Margin of Error for Responses to Question 19

Criteria- How often do you face challenges in complying with these regulatory norms?	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.55	0.043	0.00	0.04	2.47	2.63	8.05
95% Confidence Interval for Mean, Lower Bound	2.46						
95% Confidence Interval for Mean, Upper Bound	2.63						
5% Trimmed Mean	2.55		0.00	0.05	2.47	2.65	
Median	3.00		0.00	0.05	3.00	3.00	
Variance	0.603		-0.003	0.044	0.515	0.684	
Std. Deviation	0.776		-0.003	0.028	0.717	0.827	
Minimum	1						
Maximum	4						
Range	3						
Interquartile Range	1		0	0	1	1	
Skewness	-0.341	0.136	-0.001	0.095	-0.540	-0.162	
Kurtosis	-0.306	0.271	0.006	0.125	-0.526	-0.038	

The survey examined how often respondents face challenges in complying with regulatory norms using a Likert scale (1-5). The mean response was 2.55, with a margin of error (MOE) of 8.05% and a 95% confidence interval ranging from 2.46 to 2.63. The 5% trimmed mean was also 2.55, closely matching the median of 3.00. The variance was 0.603, and the standard deviation was 0.776, indicating moderate dispersion in responses. The minimum response was 1, while the maximum was 4, resulting in a range of 3. The interquartile range was 1, suggesting that most responses were clustered around the median. The negative skewness (-0.341) indicates a slight leftward distribution, meaning more responses leaned towards the higher values. The kurtosis value (-0.306) suggests a slightly flatter-than-normal distribution. These results imply that respondents experience regulatory compliance challenges at a moderate frequency, with some variability in their responses.

Table 4.44
Margin of Error for Responses to Question 20

Criteria- How supportive is your organization/institution in implementing solvent-free manufacturing methods? (Likert Scale: 1-5)	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.85	0.057	0.00	0.06	2.74	2.97	11.46
95% Confidence Interval for Mean, Lower Bound	2.74						
95% Confidence Interval for Mean, Upper Bound	2.97						
5% Trimmed Mean	2.84		0.00	0.06	2.72	2.97	
Median	3.00		0.00	0.00	3.00	3.00	
Variance	1.044		-0.005	0.071	0.904	1.183	
Std. Deviation	1.022		-0.003	0.035	0.951	1.088	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	2		0	0	1	2	
Skewness	0.067	0.136	-0.006	0.090	-0.108	0.238	
Kurtosis	-0.481	0.271	-0.002	0.114	-0.687	-0.243	

The survey assessed how supportive organizations or institutions are in implementing solvent-free manufacturing methods using a Likert scale (1-5). The mean response was 2.85, with a margin of error (MOE) of 11.46% and a 95% confidence interval ranging from 2.74 to 2.97. The 5% trimmed mean was 2.84, closely matching the median of 3.00. The variance was 1.044, and the standard deviation was 1.022, indicating moderate variability in responses. The response range was from 1 to 5, with an interquartile range of 2, suggesting a somewhat dispersed distribution. Skewness (0.067) and kurtosis (-0.481) indicate a near-symmetrical but slightly flatter-than-normal distribution. These findings suggest that respondents perceive institutional support for solvent-free manufacturing as moderate, with some variation in responses.

Table 4.45
Margin of Error for Responses to Question 21

Criteria- To what extent do you think these regulations are practical in real-world manufacturing settings? (Likert Scale: 1-5)	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.73	0.059	0.00	0.06	2.62	2.84	11.15
95% Confidence Interval for Mean, Lower Bound	2.61						
95% Confidence Interval for Mean, Upper Bound	2.84						
5% Trimmed Mean	2.70		0.00	0.06	2.59	2.82	

Median	3.00		0.00	0.00	3.00	3.00	
Variance	1.106		-0.003	0.075	0.962	1.252	
Std. Deviation	1.052		-0.002	0.036	0.981	1.119	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	1		0	0	1	2	
Skewness	0.079	0.136	-0.005	0.081	-0.081	0.235	
Kurtosis	-0.575	0.271	-0.004	0.122	-0.802	-0.308	

The survey examined perceptions of the practicality of regulatory norms in real-world pharmaceutical manufacturing settings using a Likert scale (1-5). The mean response was 2.73, with a margin of error (MOE) of 11.15% and a 95% confidence interval ranging from 2.61 to 2.84. The 5% trimmed mean was 2.70, closely aligning with the median of 3.00. The variance was 1.106, and the standard deviation was 1.052, indicating moderate variability in responses. The response range was from 1 to 5, with an interquartile range of 1, suggesting a relatively concentrated distribution. Skewness (0.079) and kurtosis (-0.575) indicate a near-symmetrical but slightly flatter-than-normal distribution. These findings suggest that respondents view the practicality of these regulations as moderate, with some uncertainty and variability in opinions.

Table 4.46
Margin of Error for Responses to Question 22

Criteria- How well do you think the industry as a whole is complying with the regulatory norms regarding organic solvents?	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	

(Likert Scale: 1-5)							
Mean	2.75	0.056	0.00	0.06	2.64	2.87	11.46
95% Confidence Interval for Mean, Lower Bound	2.64						
95% Confidence Interval for Mean, Upper Bound	2.86						
5% Trimmed Mean	2.73		0.01	0.06	2.61	2.86	
Median	3.00		0.00	0.00	3.00	3.00	
Variance	1.029		-0.005	0.074	0.887	1.179	
Std. Deviation	1.014		-0.003	0.036	0.942	1.086	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	1		0	0	1	2	
Skewness	0.094	0.136	-0.005	0.086	-0.082	0.252	
Kurtosis	-0.400	0.271	-0.001	0.132	-0.641	-0.131	

The survey assessed perceptions of how well the industry complies with regulatory norms regarding organic solvents, using a Likert scale (1-5). The mean response was 2.75, with a margin of error (MOE) of 11.46% and a 95% confidence interval between 2.64 and 2.86. The 5% trimmed mean was 2.73, closely aligning with the median of 3.00. The variance was 1.029, and the standard deviation was 1.014, indicating moderate variability in responses. The scores ranged from 1 to 5, with an interquartile range of 1, suggesting a more concentrated distribution of responses. Skewness (0.094) and kurtosis (-0.400) indicate a relatively symmetrical and slightly flatter-than-normal distribution. These findings suggest that respondents perceive industry compliance with regulations as moderate, with some degree of uncertainty in opinions.

Table 4.47
Margin of Error for Responses to Question 23

Criteria- How important do you think it is for your curriculum to include information about the sustainable use of organic solvents? (Likert Scale: 1-5)	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.91	0.058	0.00	0.06	2.80	3.02	11.14
95% Confidence Interval for Mean, Lower Bound	2.80						
95% Confidence Interval for Mean, Upper Bound	3.02						
5% Trimmed Mean	2.90		0.00	0.06	2.78	3.02	
Median	3.00		0.00	0.00	3.00	3.00	
Variance	1.094		-0.002	0.074	0.956	1.245	
Std. Deviation	1.046		-0.002	0.035	0.978	1.116	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	2		0	0	1	2	
Skewness	0.262	0.136	-0.004	0.086	0.099	0.436	
Kurtosis	-0.554	0.271	0.000	0.116	-0.766	-0.299	

The survey evaluated the perceived importance of including information about the sustainable use of organic solvents in the curriculum, using a Likert scale (1-5). The mean response was 2.91, with a margin of error (MOE) of 11.14% and a 95% confidence interval ranging from 2.80 to 3.02. The 5% trimmed mean was 2.90, closely matching the median of 3.00. The variance was 1.094, and the standard deviation was 1.046, indicating moderate variability in responses. The scores ranged from 1 to 5, with an interquartile range of 2, suggesting a slightly wider spread of opinions. Skewness (0.262) and kurtosis (-0.554) indicate a slight positive skew with a flatter-than-normal distribution. These results suggest that while respondents recognize the importance of including sustainability topics in the curriculum, opinions vary, and the overall perceived necessity remains moderate.

Table 4.48
Margin of Error for Responses to Question 24

Criteria- How effective do you believe current educational programs are in addressing the sustainability of organic solvents? (Likert Scale: 1-5)	Statistic	Std. Error	Bootstrap for percent				Margin of Error (%)
			Bias	Std Error	95% Confidence Interval		
					Lower	Upper	
Mean	2.81	0.056	0.00	0.06	2.70	2.93	11.29
95% Confidence Interval for Mean, Lower Bound	2.70						
95% Confidence Interval for Mean, Upper Bound	2.92						

5% Trimmed Mean	2.80		0.00	0.06	2.69	2.92	
Median	3.00		0.00	0.00	3.00	3.00	
Variance	1.005		-0.002	0.069	0.870	1.140	
Std. Deviation	1.002		-0.002	0.034	0.933	1.068	
Minimum	1						
Maximum	5						
Range	4						
Interquartile Range	1		0	1	1	2	
Skewness	0.051	0.136	-0.003	0.088	-0.139	0.215	
Kurtosis	-0.502	0.271	0.001	0.118	-0.717	-0.259	

The survey assessed perceptions of the effectiveness of current educational programs in promoting the sustainability of organic solvents, using a Likert scale (1-5). The mean response was 2.81, with a margin of error (MOE) of 11.29% and a 95% confidence interval ranging from 2.70 to 2.92. The 5% trimmed mean was 2.80, closely aligning with the median of 3.00. Variance and standard deviation were 1.005 and 1.002, respectively, indicating moderate dispersion of responses. Scores ranged from 1 to 5, with an interquartile range of 1, suggesting that most responses clustered around the middle values. Skewness (0.051) and kurtosis (-0.502) indicate a relatively normal distribution, though slightly flatter than a standard normal curve. Overall, the findings suggest that respondents perceive current educational programs as only moderately effective in addressing sustainability concerns related to organic solvents.

Question 25, on barriers for transitioning from traditional solvent based methods to more sustainable alternatives, the respondents were to choose from the 8 suggestions listed, viz. Cost and Economic Feasibility, Regulatory Compliance, Technical Challenges, Lack of Awareness and Expertise, Supply Chain Issues, Risk Aversion, Resistance to Change and Market Demand. Since there was no measurable scale here, due to one or more responses by each respondent, here the MOE was derived based on the total number of responses for each of the 8 suggestions as Margin of Error (MOE) for proportions using the Frequencies procedure .and the data is listed in the Table below.

Table 4.49
Margin of Error for Responses to Question 25

Barrier Type	Count of responses	Proportion (%)	Standard Error (SE)	Margin of Error (MOE)	95% Confidence Interval (Lower - Upper)
Cost and Economic Feasibility	48	14.9%	0.0204	4.00%	10.9% - 18.9%
Regulatory Compliance	37	11.5%	0.0180	3.52%	8.0% - 15.0%
Technical Challenges	72	22.3%	0.0235	4.61%	17.7% - 26.9%
Lack of Awareness and Expertise	88	27.2%	0.0250	4.90%	22.3% - 32.1%
Supply Chain Issues	53	16.4%	0.0214	4.19%	12.2% - 20.6%
Risk Aversion	52	16.1%	0.0212	4.16%	12.0% - 20.3%

Lack of Awareness and Expertise (27.2%) is the most frequently cited barrier, with a confidence range of 22.3% to 32.1%, meaning that in repeated surveys, the true proportion of concern would likely fall within this range.

Technical Challenges (22.3%) also show a significant presence, with a margin of error of ±4.61%, suggesting a range of 17.7% to 26.9%.

Cost and Economic Feasibility (14.9%) has an MOE of ±4.00%, indicating that real concerns around this issue are likely between 10.9% and 18.9%.

Regulatory Compliance (11.5%) is the least cited barrier but still has a significant presence, with a confidence range of 8.0% to 15.0%.

The survey results indicate that the biggest challenges in transitioning to sustainable alternatives are Lack of Awareness & Expertise (27.2%) and Technical Challenges (22.3%). The calculated margin of error (MOE) ensures that the findings are statistically reliable within a 95% confidence level. This data can be used to formulate strategic plans addressing the most critical barriers in sustainability adoption.

The Margin of Error -Statistical analysis for the responses in the Survey is discussed in the next Chapter, Chapter 5.

4.1 Research Question One

Awareness of the negative impacts of solvents usage in Pharmaceutical Personnel as well as Students.

Research question one aims to assess the level of awareness among pharmaceutical professionals and students regarding the negative impacts of solvents usage , which could be environmental as well as health impacts. Based on a review of the responses obtained for the relevant questions, the key findings are reported below:

Awareness of environmental impacts (Q5): 36.8% of respondents are very aware of the environmental impacts of organic solvents, while 50.2% are somewhat aware. However, 13% are not aware, indicating a significant gap in awareness. This suggests that while a majority have some understanding of environmental risks, a notable portion lacks sufficient awareness, highlighting the need for targeted educational programs.

Awareness of health impacts (Q6): 32.5% are very aware of the health impacts, and 55.1% are somewhat aware. However, 12.4% are not aware. This indicates that while most respondents recognize the health risks associated with solvents, there is still a segment that lacks awareness, which could hinder the adoption of safer practices.

Familiarity with regulatory norms (Q7): Only 19.2% are very familiar with regulatory norms, while 47.4% are somewhat familiar. A significant 33.4% are not familiar. This suggests a gap in regulatory knowledge, which could limit effective implementation of solvent-related guidelines.

Awareness of alternatives (Q8): 56.3% are somewhat aware of alternatives to organic solvents, while 27.9% have substantial awareness. However, 15.8% are not aware. This indicates that while most respondents know about alternatives, a significant minority lacks awareness, which could hinder the adoption of sustainable practices.

Participation in projects (Q4): 60.1% of respondents have participated in projects exploring alternatives to organic solvents, while 39.9% have not. Participation in such projects likely enhances awareness and practical knowledge, suggesting that educational initiatives should encourage more hands-on involvement.

Demography (Q1, Q2): The demographic characteristics of respondents for this research question provide key insights into how awareness of the negative impacts of solvent usage might vary across different groups. The results of demographic analysis help frame subsequent interpretations of awareness-related responses and highlight specific areas where interventions may be required to enhance awareness in the pharmaceutical sector.

Gender distribution: The survey sample comprised 79.9% male and 20.1% female respondents, indicating a male-dominated respondent base, however not much needs to be construed from this skewed ratio as considering gender-neutral roles in the industry, it may seem as if one gender is lesser than the other, however, the pharmaceutical industry discriminates between none, and is known for its unbiased gender neutral work profiles, all having equal opportunities of work, research, projects, etc.

Age distribution: The age distribution of respondents shows a strong representation from the 36-45 age group (39%), followed by the 15-25 group (23.8%), which is only slightly more than 45 age group (20.1%) and the smallest group being 26-35 (17%) as can be observed from the data table and graph below.

Young adults (15-25): The younger demographic likely includes students or early-career professionals who are more exposed to recent advancements in sustainable practices and may have studied environmental topics in their education. Consequently, they might have higher baseline awareness of the environmental impacts of solvents and be more open to sustainable alternatives.

Early to mid-career professionals (26-35): Though a smaller segment in this survey, this group often serves as a bridge between the younger and older groups in terms of experience and perspective. Their training and experience enable them to appreciate both the operational demands of the industry and the need for sustainable practices, positioning them well to lead or advocate for awareness initiatives in their workplaces.

Mid-career professionals (36-45): This age group, often more established in their careers, may prioritize efficiency and regulatory compliance over sustainability due to their practical experience in the field. However, as they hold substantial industry experience, these professionals are in a position to influence policy and practice within their organizations. Targeting awareness efforts at mid-career professionals could therefore encourage the promotion of sustainability among influential industry members.

Professional background: Respondents included a significant proportion of pharmaceutical professionals (67.2%) and students (32.8%). This split allows for a meaningful comparison between current industry practitioners and those still in the educational pipeline regarding awareness levels of solvent impacts.

Pharmaceutical professionals: With a majority of professionals in the sample, the findings may largely reflect the awareness, attitudes, and knowledge of those actively working within pharmaceutical environments. Professionals in regulated sectors like pharmaceuticals often possess a strong understanding of regulations but may have limited awareness of newer sustainable practices due to established standard operating procedures. This group's responses may indicate whether awareness of solvent impacts has permeated operational knowledge or if professionals primarily view solvents through a regulatory compliance lens.

Students: Representing one-third of the sample, students likely have a more theoretical and evolving understanding of environmental sustainability. Educational institutions often include recent advancements in their curricula, which could contribute to higher awareness levels in this group regarding the health and environmental impacts of solvents. If students demonstrate notably higher awareness, it might suggest that current industry professionals could benefit from continued education programs to keep pace with emerging knowledge in sustainability practices.

Implications of demographic analysis for awareness levels: The demographic analysis indicates that a predominantly male, mid-career professional group represents the survey sample, with students constituting a significant minority. This demographic profile implies that while there may be a solid foundation of operational and regulatory knowledge among respondents, awareness of the broader environmental and health impacts of solvents may vary significantly, particularly between students and industry professionals. For example, students may possess up-to-date information on solvent alternatives, while professionals might prioritize compliance and production efficiency. The demographic diversity also points to potential challenges in promoting sustainable practices. Industry professionals who have worked for years with solvent-based processes may require more robust training to develop a mindset shift toward sustainable alternatives. Conversely, younger respondents and students might more readily adopt and advocate for these practices. Recognizing these demographic patterns allows policymakers, educational institutions, and industry leaders to tailor awareness campaigns and training programs to the specific needs and mindsets of different groups, ultimately fostering a more informed and sustainability-conscious pharmaceutical industry.

Conclusion for Research Question 1:

There is a moderate to high level of awareness among pharmaceutical professionals and students regarding the negative impacts of organic solvents. However, a significant minority lacks awareness, particularly regarding regulatory norms and alternatives. This gap presents an opportunity for targeted educational programs and awareness campaigns to improve understanding and promote sustainable practices. The survey sample comprised majority male respondents, however, the pharmaceutical industry is known for its gender-neutral roles, and this skew does not imply bias in opportunities or awareness. The Young Adults age group is likely more exposed to recent advancements in sustainability, this group may have higher baseline awareness of environmental impacts and be more open to alternatives. With substantial industry experience, the mid-career group can influence policy and practice but may prioritize efficiency over sustainability. Targeted awareness efforts could encourage them to promote sustainable practices. Respondents included majorly pharmaceutical professionals over students, professionals would mostly prioritize regulatory compliance and operational efficiency, which may limit their awareness of newer sustainable practices.

4.2 Research Question Two

The practical applicability of the Regulatory norms that govern the usage of Organic solvents

To evaluate the perceived practicality and applicability of regulatory norms governing organic solvent usage in the pharmaceutical industry, the following responses were found to be significant:

Challenges in compliance (Q19): 50.2% of respondents occasionally face challenges in complying with regulatory norms, while 32.2% rarely face such issues. Only 7.4% face frequent challenges, and 10.2% never face difficulties. This suggests that while compliance is manageable for most, occasional hurdles remain a concern for a significant portion of the industry.

Perceived practicality of regulations (Q21): 36.2% find regulations moderately practical, while 27.2% find them slightly practical. However, 13.6% consider them impractical. This indicates that while most respondents acknowledge some level of practicality, there is a perception that regulatory norms pose real-world challenges.

Industry compliance (Q22): 39.3% believe the industry complies moderately well with regulations, while 27.6% feel compliance is only slightly well. Only 4.3% think the industry complies very well, and 11.8% believe compliance is not well enough. This suggests that while some efforts are being made, there are gaps in full regulatory adherence.

Support from Organizations (Q20): 37.5% perceive their organizations as moderately supportive of solvent-free methods, while 27.2% report only slight support. Only 5.3% feel their organizations are highly supportive, and 9.3% report no support. This indicates that while there is some organizational support, stronger backing is needed to drive the adoption of sustainable practices.

Conclusion for Research Question 2:

Regulatory norms are perceived as moderately practical, but there are significant challenges in compliance and implementation. The industry is making efforts to adhere to regulations, but gaps remain. Organizations need to provide greater support to facilitate the transition to solvent-free methods and improve regulatory compliance.

4.3 Research Question Three

The last Research question pertained to whether **usage of organic solvents can be avoided in the manufacture of Pharmaceutical dosage forms,** for which the following responses were found to be significant:

Feasibility of avoiding solvents (Q13, Q14, Q15): 68.4% of respondents report moderate to high usage of organic solvents (26-75% of processes), while 29.4% report low usage (0-25%). 56.1% have experimented with or studied alternatives, with 12.1% reporting extensive experience. However, 7.7% are not interested in alternatives. 42.4% find alternatives moderately effective, while 22.6% find them only slightly effective, and 8% find them not effective. This suggests that while alternatives exist, their effectiveness and adoption are still limited.

Cost implications (Q16): 46.7% report increased production costs when using alternatives, while 38.1% report decreased costs. This indicates mixed perceptions about the economic feasibility of solvent-free methods.

Barriers to transition (Q25): The primary barriers include lack of awareness and expertise (27.2%), technical challenges (22.3%), and supply chain issues (16.4%). Other barriers include risk aversion (16.1%), resistance to change (15.2%), and cost concerns (14.9%). These barriers highlight the need for better training, technological advancements, and economic incentives to facilitate the transition.

Motivation for sustainable practices (Q12): 52.7% of respondents are moderately to highly motivated to incorporate sustainable practices, while 44.9% are slightly or not motivated. This suggests that while there is some motivation to adopt sustainable practices, stronger incentives are needed to drive widespread adoption.

Conclusion for Research Question 3:

While it is feasible to reduce or avoid the use of organic solvents in pharmaceutical manufacturing, significant barriers remain, including technical challenges, cost concerns, and lack of awareness. The industry needs greater support in terms of research, training, and economic incentives to facilitate the transition to sustainable alternatives.

4.4 Summary of Findings

As observed in the previous section, the survey conducted to gauge the awareness levels of Pharmaceutical personnel and students about the usage of Organic solvents in the Pharmaceutical industry as per Research question one, which was regarding Awareness of the negative impacts of solvents usage in Pharmaceutical Personnel as well as Students. This question was depicted in the Survey Questionnaire through the concepts of Demography and Awareness and Understanding. The next question Research question two, questioned the practical applicability of the Regulatory norms that govern the usage of Organic solvents and this question was depicted in the Survey Questionnaire through the concepts of Motivation towards Alternatives, Alternatives Study, and Awareness of Regulatory norms. The third and last question was about whether the usage of organic solvents can be avoided in the manufacture of Pharmaceutical dosage forms. This question was depicted in the Survey Questionnaire through the concepts of Awareness of Regulatory norms (Industry and Compliance), Barriers to Sustainable Alternatives. As can be observed, the concept of Awareness of Regulatory norms (Industry and Compliance) was common with Research Question Two as well.

The learnings from the Study responses could be summarized as stated below:

Awareness of the negative impacts of solvent usage: The study found that professionals in the pharmaceutical industry have a fair understanding of the environmental and health issues related to organic solvents. However, students showed less awareness, pointing to a gap in education about sustainable practices. Many professionals acknowledged the need to reduce solvent use but lacked detailed knowledge about alternatives, highlighting the importance of targeted awareness efforts and updates in academic programs.

Practicality of regulatory norms for organic solvent usage: Participants had mixed views on the practicality of current rules for managing organic solvents. While many professionals agreed that the regulations are essential for safety and environmental reasons, they also noted challenges like increased costs, operational difficulties, and limited availability of substitutes. Students had less familiarity with these rules, suggesting a need to include regulatory education in training programs. Although the regulations were generally seen as valuable, their application was considered resource-intensive.

Feasibility of avoiding organic solvents in pharmaceutical manufacturing: Opinions were divided on whether organic solvents can be completely avoided in pharmaceutical manufacturing. Many professionals believe that complete elimination is not feasible with existing technologies, especially for products requiring high precision. However, some alternatives, such as water-based or innovative solvent systems, were identified as potential solutions for specific processes. The adoption of these alternatives is currently limited by technical and cost-related challenges, indicating the need for gradual changes supported by further innovation and research.

4.5 Conclusion

This report presents a comprehensive analysis of the survey data collected on organic solutions and sustainable practices within the pharmaceutical industry. The survey aimed to gain insights into the current state of organic solutions usage, awareness of environmental and health impacts, motivations for sustainable practices, and barriers to transitioning from organic solutions to sustainable alternatives. For researchers, politicians, and industry stakeholders looking to encourage sustainable practices also lessen the pharmaceutical industry's environmental effect, the findings offer useful information.

Based on the Demographic Analysis conducted, the survey data collected revealed a clear and significant majority of male respondents with the rest being female. Pharmaceutical professionals constituted the majority of respondents, followed by students. A relatively large percentage of respondents belonged to the younger age groups.

A significant portion of respondents have experience with organic solutions projects. Despite participation, there are still gaps in awareness regarding environmental and health impacts, as well as regulatory norms and alternatives. The majority of respondents who are aware of the impacts of organic solutions have a positive perception.

While a significant portion of respondents considered reducing organic solution usage to be important, there were also a considerable number who viewed it as less of a priority. A majority of respondents recognized the significance of environmentally friendly procedures in the pharmaceutical sector, with a significant proportion rating it as high or very high importance.

Environmental impacts were a moderate concern for most respondents, with a smaller group expressing higher levels of concern. Motivation towards sustainable practices varied widely, with a significant portion of respondents demonstrating low or medium motivation.

Widespread presence of Organic Solutions, since Organic solutions are prevalent in the supply chains of most firms in the industry and many firms engage in some level of research on alternatives, but a significant portion have limited or no interest. While some respondents are optimistic about the effectiveness of alternatives, others remain skeptical.

Changes in production costs for alternatives are generally not considered significant. A significant portion of respondents actively seek alternatives to organic solutions.

Most respondents are moderately concerned about the negative impacts of organic solutions. Challenges with Government Norms are faced by a significant portion of respondents frequently or occasionally face challenges with government norms thus for a majority, compliance with government regulations is a significant concern.

A small group of respondents never received support from their organizations during implementation, while a majority reported receiving some level of support, which suggests that organizations are generally supportive of their employees' efforts to comply with government norms.

Practicality of Government Regulations was agreed upon by a significant portion of respondents who considered government regulations to be at least somewhat practical. However, a small group perceived regulations as low or very low in practicality, indicating that there are areas where regulations may be challenging or impractical to implement.

A majority of respondents assessed the extent of compliance in the industry as at least somewhat high and only a few of them perceived compliance as low or very low, suggesting that the industry is generally compliant with government norms. A significant majority of respondents considered the inclusion of sustainable organic solutions in curricula to be important or very important and only some viewed it as low or very low importance, indicating a strong belief in the value of incorporating sustainable practices into education.

While few of the respondents rated the effectiveness of educational programs in addressing sustainability of organic solutions as very low, a majority considered them to be at least somewhat effective, suggesting that educational efforts are generally contributing to improved sustainability practices.

Further salient features from the outcomes of the Survey and the applicability, learnings as well as gaps will be discussed in the upcoming chapter.

CHAPTER V:

DISCUSSION

5.1 Discussion of Results

The study's conclusions offer insightful information about the present situation of organic solvent use in the pharmaceutical sector and the factors influencing the adoption of sustainable alternatives. The study confirms the existence of significant barriers to transition, including cost, technical challenges, and regulatory compliance.

The findings also emphasize how critical it is to spread knowledge about the harm that organic solvents cause to the environment and to encourage the creation and use of sustainable substitutes. By taking care of these obstacles while taking advantage of the chances provided by sustainable practices, the pharmaceutical industry can contribute to a more sustainable and environmentally friendly future.

Discussion on Margin of Error-Statistical analysis of all Survey responses:

The survey findings across all 25 questions demonstrate varying levels of precision, as reflected in their margins of error (MOE). Demographic data (e.g., gender, age) showed high reliability, with MOEs ranging from 4.33% to 5.57%, confirming stable sample representation. Awareness and familiarity questions (e.g., environmental/health impacts, regulatory norms) exhibited moderate MOEs (5.26%–7.89%), suggesting consistent but slightly variable perceptions. Likert-scale questions on importance, motivation, and organizational support (Q9–Q24) had higher MOEs (6.97%–13.62%), indicating greater response variability, particularly for subjective topics like sustainability prioritization and institutional backing. Key barriers to sustainable practices (Q25), such as Lack of Awareness (27.2% ±4.90%) and Technical Challenges (22.3% ±4.61%), were identified with reliable precision, underscoring actionable focus areas. While the 95% confidence intervals validate the data's robustness for strategic decision-making, the variability in attitudinal responses highlights nuanced stakeholder perspectives. Overall, the MOEs affirm the survey's credibility within defined limits, supporting targeted interventions in awareness, education, and technical solutions while acknowledging areas where expanded sampling could refine insights.

The analysis of the 25 MOEs provides insight into the reliability of survey data collected on the sustainable usage of organic solvents in pharmaceutical manufacturing and indicate a reasonable level of precision, ensuring that the survey responses are representative of the larger population. While awareness of the adverse impacts of organic solvent usage is evident, the data reliability confirms that these insights can be used to guide industry decisions. However, variations in MOE across different survey questions highlight areas where additional data collection or validation may strengthen conclusions. Overall, the study confirms that the survey results are statistically reliable, supporting meaningful discussions on the feasibility of transitioning to sustainable solvent alternatives, regulatory compliance challenges, and industry adoption of greener practices.

5.2 Discussion of Research Question One

Research question one as stated in the previous sections deals with Awareness of the negative impacts of solvents usage in Pharmaceutical Personnel as well as Students.

Based on this Research question and on the premise that Awareness positively influences willingness to adopt solvent-free methods, the hypothesis tested was:

Statement of Hypotheses:

Null Hypothesis (H_0): There is no significant relationship between awareness of organic solvent impacts and the adoption of sustainable alternatives.

Alternative Hypothesis (H_1): Higher awareness of organic solvent impacts increases the adoption of sustainable alternatives.

Variables for testing:

This Hypothesis investigates the relationship between awareness of the environmental impacts of organic solvents and various factors influencing the adoption of alternative solvents. The variables chosen were,

Independent Variable: Awareness of environmental impacts (Q5).

Dependent Variables:

Frequency of seeking alternatives (Q17).

Perceived effectiveness of alternatives (Q15).

Changes in production costs (Q16).

Organizational support (Q20).

Statistical Test Selection:

Since the data consists of Likert scale responses (ordinal data) and non-parametric correlation analysis, Spearman's Rank Correlation (ρ) is the appropriate test. This method measures the strength and direction of association between awareness and adoption. Spearman's Rank-Order Correlation (rho) was used to examine the relationships between key variables because: Variables include Likert-scale ordinal data (e.g., Q15, Q20, Q17) and ordinal/non-normal data (Q16). Spearman's rho is non-parametric and measures monotonic relationships, making it suitable for ordinal data.

Significance Level (α):

A significance level (α) of 0.01 (1%) is used as the threshold to determine statistical significance.

If $p \leq 0.01$, reject H_0 (evidence supports a significant relationship).

If $p > 0.01$, fail to reject H_0 (no sufficient evidence of a relationship).

SPSS Analysis & Interpretation:

Pairwise correlations computed for all variables. The SPSS output data is presented in the figure below The Spearman's correlation matrix in the provided table:

Correlations

			5) How aware are you of the environmental impacts of using organic solvents?"	15) How effective do you find the alternatives to organic solvents in terms of quality and yield? (Likert Scale: 1-5)	16) Have you noticed any changes in production costs when using alternatives to organic solvents?	20) How supportive is your organization/insitution in implementing solvent-free manufacturing methods? (Likert Scale: 1-5)	17) How often do you seek alternatives to organic solvents based on their negative impacts?
Spearman's rho	5) How aware are you of the environmental impacts of using organic solvents?"	Correlation Coefficient	1.000	.185**	.255**	.165**	.277**
		Sig. (2-tailed)	.	<.001	<.001	.003	<.001
		N	323	323	323	323	323
	15) How effective do you find the alternatives to organic solvents in terms of quality and yield? (Likert Scale: 1-5)	Correlation Coefficient	.185**	1.000	.106	.447**	.200**
		Sig. (2-tailed)	<.001	.	.057	<.001	<.001
		N	323	323	323	323	323
	16) Have you noticed any changes in production costs when using alternatives to organic solvents?	Correlation Coefficient	.255**	.106	1.000	.073	.382**
		Sig. (2-tailed)	<.001	.057	.	.192	<.001
		N	323	323	323	323	323
	20) How supportive is your organization/insitution in implementing solvent-free manufacturing methods? (Likert Scale: 1-5)	Correlation Coefficient	.165**	.447**	.073	1.000	.208**
		Sig. (2-tailed)	.003	<.001	.192	.	<.001
		N	323	323	323	323	323
	17) How often do you seek alternatives to organic solvents based on their negative impacts?	Correlation Coefficient	.277**	.200**	.382**	.208**	1.000
		Sig. (2-tailed)	<.001	<.001	<.001	<.001	.
		N	323	323	323	323	323

**. Correlation is significant at the 0.01 level (2-tailed).

Figure 5.1
SPSS output data on Correlations

Table 5.1
Spearman's Correlation Matrix

Variable Pair	Spearman's ρ	p-value	Interpretation

Awareness of environmental impacts ↔ Effectiveness of alternatives	0.185	<0.001	Weak but significant positive correlation. More awareness leads to better perception of alternatives.
Awareness of environmental impacts ↔ Production cost changes	0.255	<0.001	Moderate correlation. Those aware of environmental impacts also report cost changes.
Awareness of environmental impacts ↔ Organizational/Institutional support	0.165	0.003	Weak positive correlation. Higher awareness is linked to organizations supporting greener methods.
Awareness of environmental impacts ↔ Seeking alternatives	0.277	<0.001	Moderate correlation. More awareness leads to frequent seeking of solvent-free methods.
Effectiveness of alternatives ↔ Institutional support	0.447	<0.001	Strong positive correlation. Organizations supporting green methods lead to a better perception of alternatives.
Production cost changes ↔ Seeking alternatives	0.382	<0.001	Moderate positive correlation. Cost changes impact willingness to seek alternatives.

Conclusion:

Since $p < 0.01$, the correlation is statistically significant, indicating that higher awareness is associated with an increased likelihood of adopting alternatives. Awareness positively correlates with all major variables, meaning that the more people understand the environmental impact of organic solvents, the more they explore and adopt greener alternatives. This suggests that individuals more aware of environmental impacts are more likely to perceive alternatives as effective, recognize cost changes, seek alternatives frequently, and experience organizational support.

Since all significant correlations are positive, this supports Hypothesis 1: Higher awareness of organic solvent impacts increases the adoption of sustainable alternatives.

Regression Analysis:

To further examine the influence of key predictors on the dependent variable, multiple linear regression analysis was conducted.

The **Dependent variable** chosen for this analysis was:

- How often do you seek alternatives to organic solvents based on their negative impacts?

The **independent variables (predictors)** included:

- Support from organization/institution in implementing solvent-free manufacturing methods.
- Awareness of environmental impacts of organic solvents.
- Perceived changes in production costs when using alternative solvents.
- Effectiveness of alternatives to organic solvents in terms of quality and yield.

Regression Model Summary:

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.506[a]	.256	.247	.692

a. Predictors: (Constant), 20) How supportive is your organization/insitution in implementing solvent-free manufacturing methods? (Likert Scale: 1-5), 16) Have you noticed any changes in production costs when using alternatives to organic solvents?, 5) How aware are you of the environmental impacts of using organic solvents?", 15) How effective do you find the alternatives to organic solvents in terms of quality and yield? (Likert Scale: 1-5)

b. Dependent Variable: 17) How often do you seek alternatives to organic solvents based on their negative impacts?

Figure 5.2
Regression Model Summary

As observed from the Regression model summary, the Statistical findings are summarized as:

1. **R (Correlation Coefficient), 0.506**
    - Indicates a moderate positive correlation between the predictors and the dependent variable.
    - This suggests that the selected predictors collectively explain variations in seeking alternatives to organic solvents.
2. **R-Square (Coefficient of Determination), 0.256**
    - This means that 25.6% of the variation in seeking alternatives to organic solvents is explained by the independent variables.
    - While this is a reasonable explanatory power, other factors not included in this model may also influence the decision to seek alternatives.
3. **Adjusted R-Square, 0.247**
    - The adjusted R-square corrects for the number of predictors in the model.
    - Since it's close to R-square, it suggests that the model does not suffer significantly from overfitting.
4. **Standard Error of the Estimate, 0.692**
    - This represents the average deviation of observed values from the predicted regression line.
    - A lower value would indicate a better fit, but 0.692 suggests some degree of variability remains unexplained by the model.

ANOVA Testing:

To assess the overall significance of the regression model, an ANOVA test was performed. Analysis of Variance (ANOVA) is used to test whether the overall regression model is statistically significant, meaning that at least one of the independent variables significantly predicts the dependent variable. The results are summarized in the table below:

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	52.385	4	13.096	27.356	<.001[b]
	Residual	152.240	318	.479		
	Total	204.625	322			

a. Dependent Variable: 17) How often do you seek alternatives to organic solvents based on their negative impacts?

b. Predictors: (Constant), 20) How supportive is your organization/insitution in implementing solvent-free manufacturing methods? (Likert Scale: 1-5), 16) Have you noticed any changes in production costs when using alternatives to organic solvents?, 5) How aware are you of the environmental impacts of using organic solvents?", 15) How effective do you find the alternatives to organic solvents in terms of quality and yield? (Likert Scale: 1-5)

Figure 5.3
Anova Summary

As observed from the Anova summary, the statistically significant F-value (27.356, $p < 0.001$) confirms that the regression model is valid and that the independent variables (awareness, cost, organizational support, effectiveness) together explain a significant portion of the variation in seeking alternatives to organic solvents.

Summary of statistical analysis:

Correlation analysis confirmed significant relationships between awareness, institutional support, and willingness to seek alternatives. Thus, significant relationship between awareness of organic solvent impacts and the adoption of sustainable alternatives is confirmed. Regression analysis identified that approximately 25.6% of the variation in seeking alternatives is explained by key predictors. ANOVA results validated the overall significance of the regression model. These findings collectively support the hypothesis that awareness, cost considerations, and organizational support influence the decision to seek alternatives to organic solvents.

5.3 Discussion of Research Question Two

The following study question pertained to ***the practical applicability of the Regulatory norms that govern the usage of Organic solvents.***

Variables for testing

This Hypothesis investigates the relationship between regulatory challenges (and thereby practical applicability) and various factors influencing the adoption of alternative solvents. The variables chosen were,

Dependent Variable:

Q21 - "To what extent do you think these regulations are practical in real-world manufacturing settings?" (Likert Scale: 1 = Strongly Impractical, 5 = Strongly Practical)

Independent Variables:

Based on the different questions in the questionnaire, various variables were chosen as stated below:

Awareness & Knowledge Variables:

Q5: Awareness of environmental impacts of organic solvents

Q6: Awareness of health impacts of organic solvents

Q7: Familiarity with regulatory norms

Experience & Practice Variables:

Q14: Experimentation with alternatives to organic solvents

Q15: Effectiveness of alternatives in terms of quality & yield

Compliance & Institutional Support Variables:

Q19: Frequency of challenges in complying with regulations

Q20: Support from organization/institution in implementing solvent-free manufacturing methods

Q22: Perception of how well the industry complies with regulations

Hypothesis Statements:

The below table lists out the Hypothesis statements based on the chosen variables

Table 5.2
Table with Hypothesis statements

Independent Variable	**Null Hypothesis (H_0)**	**Alternative Hypothesis (H_1)**
Q5 - Environmental Awareness	There is no significant relationship between environmental awareness and perceived practicality of regulations.	Higher environmental awareness leads to a higher perception of regulatory practicality.
Q6 - Health Awareness	There is no significant relationship between health awareness and perceived practicality of regulations.	Higher health awareness leads to a higher perception of regulatory practicality.
Q7 - Familiarity with Regulations	There is no significant relationship between familiarity with regulations and perceived practicality.	Greater familiarity with regulations increases the perception of regulatory practicality.
Q14 - Experience with Alternatives	There is no significant relationship between experience with alternatives and perceived practicality.	More experience with alternatives increases the perception of regulatory practicality.
Q15 - Effectiveness of Alternatives	There is no significant relationship between perceived effectiveness of alternatives and regulatory practicality.	Higher effectiveness of alternatives leads to higher perceived practicality.

Q19 - Compliance Challenges	There is no significant relationship between compliance challenges and perceived practicality.	More compliance challenges lower the perception of regulatory practicality.
Q20 - Organizational Support	There is no significant relationship between organizational support and perceived practicality.	Higher organizational support increases the perception of regulatory practicality.
Q22 - Industry Compliance	There is no significant relationship between industry compliance and perceived practicality.	Greater industry compliance leads to a higher perception of regulatory practicality.

Choice of Statistical method:

Ordinal Logistic Regression (OLR): OLR was used here since:

- Dependent Variable (Q21: perceived practicality of regulations) is Ordinal (Likert scale from 1 to 5).
- Independent variables (Predictors) are a mix of both categorical and continuous predictors.
- The assumption of proportional odds holds, making OLR the best alternative.

SPSS PLUM Model (Polytomous Universal Model): This is a cumulative logit model used to analyze the influence of predictor variables on ordinal categories of the dependent variable.

Results & Hypothesis Testing:

Each independent variable was tested to see if it significantly influences the perception of regulatory practicality. The below table lists out the Results and Hypothesis Testing based on the chosen variables

Table 5.3

Table with Results and Hypothesis Testing

Independent Variable	Estimate (β)	p-value	Decision on H_0	Interpretation
Q5 - Environmental Awareness	0.548	0.010	Reject H_0	Higher environmental awareness increases

				perceived practicality of regulations.
Q6 - Health Awareness	-0.286	0.230	Fail to Reject H_0	No significant effect.
Q7 - Familiarity with Regulations	-0.065	0.738	Fail to Reject H_0	No significant effect.
Q14 - Experience with Alternatives	0.075	0.630	Fail to Reject H_0	No significant effect.
Q15 - Effectiveness of Alternatives	0.182	0.148	Fail to Reject H_0	No significant effect.
Q19 - Compliance Challenges	-0.008	0.958	Fail to Reject H_0	No significant effect.
Q20 - Organizational Support	1.100	<0.001	Reject H_0	Higher organizational support strongly increases perceived practicality of regulations.
Q22 - Industry Compliance	0.712	<0.001	Reject H_0	Greater industry compliance significantly increases perceived practicality.

The Impact of Predictor Variables is also presented below, shows which factors significantly influence perceptions of solvent regulations. Significant predictors include awareness of environmental impacts ($p = 0.010$), organizational support ($p < 0.001$), and industry compliance ($p < 0.001$), suggesting these factors strongly influence perceptions of solvent regulation implementation.

Parameter Estimates

		Estimate	Std. Error	Wald	df	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Threshold	[@21Towhatextentdoyouthinktheseregulationsarepracticalinrealworld = 1]	3.594	.593	36.676	1	<.001	2.431	4.757
	[@21Towhatextentdoyouthinktheseregulationsarepracticalinrealworld = 2]	5.679	.634	80.176	1	<.001	4.436	6.922
	[@21Towhatextentdoyouthinktheseregulationsarepracticalinrealworld = 3]	8.055	.707	129.707	1	<.001	6.669	9.442
	[@21Towhatextentdoyouthinktheseregulationsarepracticalinrealworld = 4]	10.713	.827	167.832	1	<.001	9.092	12.334
Location	@5Howawareareyouoftheenvironmentalimpactsofusingorganicsolvents	.548	.213	6.650	1	.010	.132	.965
	@6Howawareareyouofthehealthimpactsofusingorganicsolvents	-.286	.238	1.443	1	.230	-.752	.181
	@7Howfamiliarareyouwiththeregulatorynormsgoverningtheusageoforga	-.065	.195	.112	1	.738	-.448	.317
	@14Haveyouexperimentedwithorstudiedalternativemethodsthatdonotin	.075	.155	.231	1	.630	-.229	.378
	@15Howeffectivedoyoufindthealternativestoorganicsolventsintermso	.182	.126	2.096	1	.148	-.064	.428
	@19Howoftendoyoufacechallengesincomplyingwiththeseregulatorynorm	-.008	.158	.003	1	.958	-.319	.302
	@20Howsupportiveisyourorganizationinsitutioninimplementingsolven	1.100	.143	58.820	1	<.001	.819	1.381
	@22Howwelldoyouthinktheindustryasawholeiscomplyingwiththeregulat	.712	.133	28.636	1	<.001	.451	.973

Link function: Logit.

Figure 5.4
Parameter estimates

Conclusion:

- **Significant Predictors:**

Organizational Support (Q20) is the strongest predictor ($\beta = 1.100$, $p < 0.001$). Companies that support solvent-free manufacturing significantly influence how practical employees find the regulations.

Perceived Industry Compliance (Q22) is also highly significant ($\beta = 0.712$, $p < 0.001$). If the industry is seen as compliant, respondents are more likely to believe that regulations are practical.

Environmental Awareness (Q5) is significant ($\beta = 0.548$, $p = 0.010$). Greater awareness of environmental impact correlates with higher acceptance of regulations.

- **Non-Significant Predictors:**

Health awareness (Q6), familiarity with regulations (Q7), experience with alternatives (Q14), effectiveness of alternatives (Q15), and compliance challenges (Q19) do not significantly influence perceived practicality.

Surprisingly, familiarity with regulations (Q7) is not a significant predictor, meaning that just knowing the rules does not necessarily lead to perceiving them as practical.

These findings emphasize that organizational support, industry compliance, and environmental awareness are the key drivers of how practical people perceive solvent-related regulations. Future interventions should focus on these areas to enhance regulatory acceptance.

Thus, the null hypothesis is rejected for:

Q5 (Environmental Awareness), Higher environmental awareness leads to a greater perception that regulations are practical.

Q20 (Organizational Support), Organizations that actively support solvent-free manufacturing significantly influence perceived regulatory practicality.

Q22 (Industry Compliance Perception), If respondents believe that the industry complies with regulations, they are more likely to see them as practical.

Fail to reject the null hypothesis for:

Health awareness, familiarity with regulations, experience with alternatives, effectiveness of alternatives, and compliance challenges, these factors do not have a statistically significant effect on how practical respondents perceive regulations to be.

Model fit:

The Model performance is presented below, where the Model fit shows how well the logistic regression model fits the data. The Chi-Square test (198.616, $p < 0.001$) confirms that the model significantly improves over the intercept-only model. This essentially justifies the statistical model choice.

Model Fitting Information

Model	-2 Log Likelihood	Chi-Square	df	Sig.
Intercept Only	905.780			
Final	707.164	198.616	8	<.001

Link function: Logit.

Figure 5.5
Model fitting information

Also, the Goodness-of-fit demonstrates that the model adequately fits the data. Pearson Chi-Square ($p = 0.998$) and Deviance ($p = 1.000$) indicate no significant lack of fit. High p-values suggest that the model does not significantly misfit the data, supporting its adequacy.

Goodness-of-Fit

	Chi-Square	df	Sig.
Pearson	1007.778	1144	.998
Deviance	682.890	1144	1.000

Link function: Logit.

Figure 5.6
Goodness-of-fit

The Model Explanation is presented below, which indicates the explanatory power of the model. Nagelkerke's $R^2 = 0.486$ suggests the model explains about 48.6% of the variability in the dependent variable. This demonstrates how well the independent variables explain perceptions of solvent regulations.

Pseudo R-Square

Cox and Snell	.459
Nagelkerke	.486
McFadden	.213

Link function: Logit.

Figure 5.7
Pseudo R-Square

Hypothesis Testing Conclusion

H_1 Accepted (Significant Factors):

Higher environmental awareness (Q5), greater organizational support (Q20), and a stronger belief in industry compliance (Q22) significantly increase the perceived practicality of regulations.

H_0 Retained (Non-Significant Factors):

Health awareness, familiarity with regulations, experience with alternatives, compliance challenges, and alternative effectiveness do not significantly impact perceptions of regulatory practicality.

5.4 Discussion of Research Question Three

The third and last question probed if the usage of Organic solvents can be avoided in the manufacture of pharmaceutical dosage forms. For testing whether the usage of organic solvents can be avoided in pharmaceutical manufacturing, the research question focuses on cost implications. Further based on the assumption that if organic solvent alternatives were cost-prohibitive, a majority of responses would indicate an increase in production costs. Conversely, rejecting this assumption would suggest that the cost perception is significantly different (either reduced or unchanged). Specifically, Question 16 of the survey, "Have you noticed any changes in production costs when using alternatives to organic solvents?", addresses the cost issue.

To analyse the responses, we define the following hypotheses:

- **Null Hypothesis (H_0):** There is no significant difference in production costs when using alternatives to organic solvents.
- **Alternative Hypothesis (H_1):** There is a significant difference in production costs when using alternatives to organic solvents.

Choice of Statistical Method:

Considering that the data for Question 16 consists of categorical responses with ordinal cost scores (0, 2, 4, and 6), non-parametric testing is appropriate. The **Wilcoxon Signed-Rank Test** was chosen to compare the observed median response against the expected median. Justification for the Wilcoxon Signed-Rank Test:

- The data represents ordinal responses rather than continuous values.
- The test is robust for non-normally distributed data.
- It is appropriate for testing whether the observed median significantly deviates from a hypothesized central value.

Calculation of the Median Cost Score

To determine the central tendency of responses, the response categories were transformed numerically as, Not applicable = 0

Yes, costs decreased = 2

No significant change = 4

Yes, costs increased = 6

Further the median cost score was determined to be 6, based on the data as stated in the below Table:

- Frequency Distribution: The most frequent response was 6 (151 responses, 46.7%).
- Cumulative Percentage: The cumulative percentage for cost scores ≤4 was 53.3%, making 6 the central tendency.
- Bootstrap Confidence Interval: The bootstrap mean for Cost Score 6 is 46.75%, confirming it as the median assumption.

Table 5.4
Margin of Error for Responses to Question 16

Criteria: Cost score	Frequency	Percent	Valid Percent	Cumulative percent	Bootstrap for percent*				Margin of Error (%)	Valid percentage (Mean)
					Bias	Std Error	95% Confidence Interval			
							Lower	Upper		
Not applicable = 0	30	9.3	9.3	9.3	-0.1	1.7	6.2	12.7	3.41	9.2879257
Yes, costs decreased = 2	123	38.1	38.1	47.4	0.1	2.8	32.5	43.7	5.57	38.080495
No significant change = 4	19	5.9	5.9	53.3	0.0	1.3	3.4	8.7	2.79	5.8823529
Yes, costs	151	46.7	46.7	100.0	0.0	2.8	41.2	52.3	5.57	46.749226

increased = 6										
Total	323	100.0	100.0		0.0	0.0	100.0	100.0		

* Bootstrap results are based on 1000 bootstrap samples

The **Wilcoxon Signed-Rank Test** was applied using the assumed median of 6 as the expected value. The test results determine whether the cost impact of switching from organic solvents is statistically significant. If the p-value < 0.05, it indicates that production costs are significantly different (higher or lower) than the assumed median. If p > 0.05, it suggests that cost variations are not significantly different from the expected distribution. Thus, this statistical approach ensures that the cost impact of avoiding organic solvents is rigorously assessed using valid non-parametric methods. The test evaluates whether the observed median differs significantly from the hypothetical median value (6), aligning with the research hypothesis. Accordingly the hypotheses were restructured as follows:

- **Null Hypothesis (H_0):** The median response for production cost changes when using alternatives to organic solvents is equal to 6 (meaning costs have increased).
- **Alternative Hypothesis (H_1):** The median response is significantly different from 6.

Statistical Analysis and Interpretation:

Wilcoxon Signed-Rank Test Results:

One-Sample Wilcoxon Signed Rank Test Summary

Total N	323
Test Statistic	.000
Standard Error	623.115
Standardized Test Statistic	-11.938
Asymptotic Sig.(2-sided test)	<.001

Figure 5.8
Wilcoxon Signed-Rank Test Summary

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.[a,b]	Decision
1	The median of 16) Have you noticed any changes in production costs when using alternatives to organic solvents? equals 6.	One-Sample Wilcoxon Signed Rank Test	<.001	Reject the null hypothesis.

a. The significance level is .050.

b. Asymptotic significance is displayed.

Figure 5.9
Hypothesis Test Summary

Decision Rule: Since the p-value < 0.001, which is much lower than the significance level (α =0.05), we reject the null hypothesis (H_0). This means that the median response is significantly different from 6.

Graphical Analysis-Histogram with Medians:

The hypothetical median (6) is represented in green. The observed median (4) is represented in blue. Since the observed median is lower than 6, it suggests that the cost has not increased as much as expected.

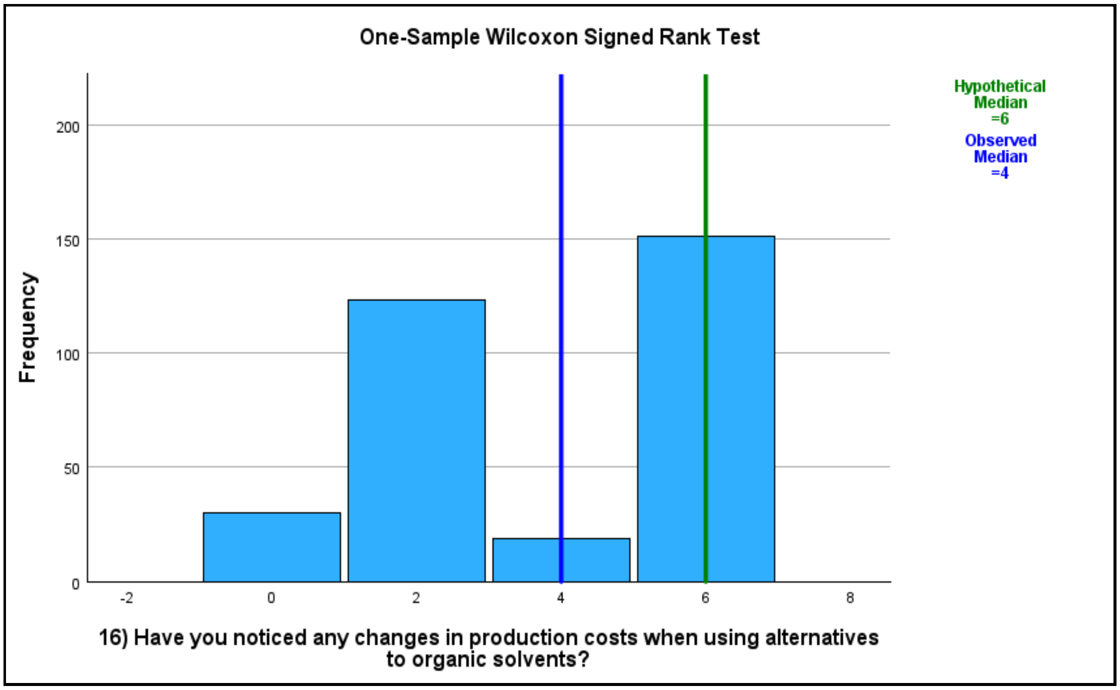

Figure 5.10
Wilcoxon Signed-Rank Test Graph

Categorical Distribution:

A large number of responses indicate that costs decreased or remained unchanged. The number of responses for "costs increased (6)" is significant but does not dominate the dataset.

Final Conclusion:

Since the null hypothesis was rejected, the median production cost change is significantly lower than 6. This suggests that costs have either decreased or remained the same for most respondents, rather than increasing. The increase in costs is not the majority perception, indicating that alternatives to organic solvents may not necessarily lead to higher costs in pharmaceutical manufacturing.

The Wilcoxon Signed-Rank Test results confirm that production costs have not increased significantly with the use of alternative solvents. This finding supports the feasibility of avoiding organic solvents in pharmaceutical manufacturing without substantial financial burden, reinforcing the potential for sustainable practices in the industry.

CHAPTER VI:

SUMMARY, IMPLICATIONS, AND RECOMMENDATIONS

6.1 Summary

The survey findings offer valuable insights into respondents' attitudes and perceptions regarding the use of organic solvents in the pharmaceutical industry. This study demonstrates that while awareness of solvent-related environmental and health impacts is moderate to high, regulatory compliance remains challenging, and the transition to solvent-free manufacturing is hindered by technical and economic constraints. Strengthening education, regulatory frameworks, and industry support is crucial for achieving sustainable pharmaceutical manufacturing. The following sections summarize key observations and lessons derived from the survey results for each of the three research questions.

A) Awareness of the Negative Impacts of Solvent Usage in Pharmaceutical Personnel and Students:

The study reveals a moderate to high level of awareness among both pharmaceutical professionals and students regarding the environmental and health impacts of organic solvents.

Environmental impacts awareness: While 50.2% of respondents are somewhat aware, and 36.8% are very aware of the negative environmental effects of solvents, 13% lack awareness. This indicates a gap in education and training programs that could be improved.

Health impacts awareness: 55.1% are somewhat aware, and 32.5% are very aware of the health risks. However, 12.4% have little to no awareness, which is concerning given the occupational hazards.

Regulatory awareness: Only 19.2% of respondents are very familiar with regulatory norms, while 47.4% have some knowledge. A significant 33.4% are unfamiliar with regulations, highlighting the need for better dissemination of regulatory information.

Participation in sustainable projects: 60.1% have been involved in projects exploring alternatives to organic solvents, which has positively influenced awareness levels.

Statistical evaluation: Correlation analysis confirmed significant relationships between awareness, institutional support, and willingness to seek alternatives Thus significant relationship between awareness of organic solvent impacts and the adoption of sustainable alternatives is confirmed. Regression and ANOVA collectively supported the hypothesis that awareness, cost considerations, and organizational support influence the decision to seek alternatives to organic solvents.

Thus, although awareness is relatively high, the study identifies a need for targeted education, regulatory training, and industry-wide initiatives to bridge knowledge gaps, particularly among those unfamiliar with the regulations and alternative solutions.

B) Practical applicability of regulatory norms governing organic solvent usage:

Perception of regulatory compliance: The survey suggests that while 39.3% believe the pharmaceutical industry complies moderately well with regulations, 27.6% perceive compliance as only slightly adequate, and 11.8% believe compliance is insufficient.

Challenges in compliance: 50.2% of respondents occasionally face difficulties adhering to regulatory norms, while 7.4% report frequent challenges.

Perceived practicality of regulations: 36.2% find regulations moderately practical, but 13.6% perceive them as impractical in real-world settings.

Organisational/Institutional support: Organizational support for implementing solvent-free methods remains limited, with only 5.3% finding their institution highly supportive and 9.3% reporting no support.

Statistical evaluation: Based on the Hypothesis Testing Conclusion, Significant Factors like higher environmental awareness (Q5), greater organizational support (Q20), and a stronger belief in industry compliance (Q22) significantly increase the perceived practicality of regulations. Non-Significant Factors like Health awareness, familiarity with regulations, experience with alternatives, compliance challenges, and alternative effectiveness do not significantly impact perceptions of regulatory practicality.

Thus, Regulatory norms are recognized as essential but are often seen as challenging to implement in real-world pharmaceutical manufacturing. More industry support and regulatory simplifications could enhance compliance and practical applicability.

C) Can the Usage of Organic Solvents Be Avoided in Pharmaceutical Manufacturing?

Current dependence on organic solvents: 68.4% of respondents report that organic solvents are used in 26-75% of their manufacturing processes, highlighting significant reliance.

Awareness of alternatives: 56.3% are somewhat aware of solvent-free alternatives, but only 27.9% have substantial awareness.

Experimentation with alternatives: 56.1% have experimented with solvent-free methods, while 36.2% are interested but have not explored them yet.

Effectiveness of alternatives: While 42.4% find them moderately effective and 22% consider them effective, 22.6% find them only slightly effective, and 8% believe they are not effective at all.

Cost concerns: 46.7% report an increase in production costs when using alternatives, while 38.1% observed cost savings.

Barriers to adoption: The most significant barriers identified include lack of awareness (27.2%), technical challenges (22.3%), supply chain limitations (16.4%), and resistance to change (15.2%).

Statistical evaluation: Based on the hypothesis testing, the increase in costs is not the major perception, indicating that alternatives to organic solvents may not necessarily lead to higher costs in pharmaceutical manufacturing. The Wilcoxon Signed-Rank Test results confirm that production costs have not increased significantly with the use of alternative solvents. This finding supports the feasibility of avoiding organic solvents in pharmaceutical manufacturing without substantial financial burden, reinforcing the potential for sustainable practices in the industry.

Thus while solvent-free manufacturing is possible, practical limitations—including cost, technical feasibility, and awareness gaps—may hinder its widespread adoption. More research, technological advancements, and regulatory incentives are needed to make sustainable alternatives viable for the industry.

6.2 Implications

The survey findings could have several implications for the pharmaceutical industry, Regulatory norms, Sustainability initiatives based on the insights from respondents' attitudes and perceptions regarding the use of organic solvents in the pharmaceutical industry. This study provides valuable insights for academia, industry, regulatory bodies, and policymakers to drive sustainability in pharmaceutical manufacturing. By addressing knowledge gaps, regulatory challenges, technical limitations, and cost concerns, the industry can transition toward greener practices with practical, scalable solutions. The following sections summarize some of the implications.

1. Implications for the Pharmaceutical Industry

a) Need for enhanced awareness and training: The study indicates that awareness of organic solvent hazards is moderate to high among professionals but lower among students. While 50.2% of respondents are somewhat aware of environmental impacts and 55.1% are somewhat aware of health risks, a significant portion (13-15%) remains unaware.

Implication: Pharmaceutical companies should implement mandatory training programs to enhance awareness of solvent-related risks and sustainability practices among employees.

For Students: Academic curricula should integrate sustainability-focused courses to bridge the awareness gap and prepare future professionals for regulatory and environmental challenges.

b) Challenges with Regulatory Compliance: Only 19.2% of respondents are very familiar with regulatory norms, with students demonstrating a lower familiarity rate (9.8%) than professionals (25.3%). Compliance difficulties were noted by 50.2% of professionals, while students expressed uncertainty due to lack of real-world exposure.

Implication: Regulatory bodies should work closely with the industry to simplify guidelines, provide better compliance support, and ensure more accessible training programs.

For Students: Universities should collaborate with regulatory agencies to offer compliance workshops and case studies on real-world challenges.

c) Adoption of Sustainable initiatives: 63.7% of professionals are somewhat aware of alternatives, whereas students lag behind at 44.9%. Only 27.9% of total respondents had substantial awareness of alternatives, indicating that information on sustainable manufacturing is not widespread.

Implication: Increased research funding and investment in green chemistry innovations can promote the feasibility of solvent-free manufacturing. Companies should conduct pilot projects on solvent-free methods before large-scale implementation.

For Students: Exposure to alternative technologies through internships, hands-on training, and laboratory simulations can improve their readiness to adopt sustainability practices in their careers.

2. Implications for Policy and Regulation

a) Strengthening Industry-Academia Collaboration: The study highlights a gap between the regulatory understanding of students (9.8% very familiar) and professionals (25.3% very familiar). Professionals also face barriers to compliance due to cost, technical challenges, and regulatory complexity.

Implication: Regulatory authorities should collaborate with academic institutions to integrate real-world compliance training into the pharmaceutical curriculum. Industry-driven guest lectures, case studies, and workshops should be incorporated into university programs to align academic learning with regulatory expectations.

b) Policy Support for Sustainable Manufacturing: 46.7% of respondents believe alternative methods increase costs, making affordability a key concern. Cost-related challenges were ranked as a major barrier (14.9%), along with technical feasibility (22.3%).

Implication: Government incentives such as tax breaks, research grants, and subsidies for green manufacturing can help industries transition to solvent-free production without financial strain. Stricter regulatory enforcement on solvent usage could push companies toward eco-friendly alternatives while ensuring a smooth transition phase.

3. Implications for Education and Curriculum Development

a) Addressing Gaps in Sustainability Education: Only 19.8% of respondents rated sustainability education as ‘important’ or ‘very important’ in their curriculum. The majority (33.7%) consider sustainability ‘moderately important,’ while 31.9% see it as ‘slightly important’, indicating a lack of emphasis in education.

Implication: Universities must restructure pharmaceutical science curricula to emphasize sustainability. Sustainability in drug formulation, solvent-free synthesis techniques, and regulatory aspects should be made mandatory topics in pharmacy education. Interdisciplinary programs combining environmental science, pharmaceutical technology, and regulatory affairs should be introduced.

b) Expanding Research Opportunities in Green Chemistry: 56.1% of professionals have worked with solvent-free methods, whereas only 41.6% of students have explored such alternatives.

Implication: Research institutions should provide more funding and research opportunities for students to work on green chemistry innovations. Universities and pharmaceutical firms should establish joint research initiatives to develop and test solvent-free drug formulations.

4. Implications for Future Research and Innovation

a) Optimizing Cost-Effective Sustainable Alternatives: 46.7% of respondents observed increased production costs when switching to alternatives, while 38.1% found cost reductions.

Implication: Further research is needed to develop cost-effective green solvents and solvent-free manufacturing techniques that match the efficiency of traditional methods. Innovation in continuous manufacturing, automation, and green synthesis can help offset the financial challenges of transition.

b) Overcoming Technical Challenges in Solvent-Free Manufacturing: Only 47.2% of professionals found solvent-free alternatives moderately to highly effective, indicating scepticism about their viability. 22.6% rated them as slightly effective, and 8% as ineffective, reinforcing the need for technical refinement.

Implication: Pharmaceutical R&D teams must focus on process optimization to enhance solvent-free methods in terms of Drug stability, Bioavailability, Process scalability, Yield consistency.

5. Implications for Sustainability and Corporate Responsibility

a) Enhancing Workplace Sustainability Practices: 65% of respondents rated reducing solvent use as moderately to slightly important, indicating lukewarm commitment to sustainability goals. Only 9.9% were highly motivated to implement sustainability in their future work.

Implication: Companies must promote environmentally responsible policies, such as eco-certifications and sustainability performance metrics for their teams. Corporate sustainability training programs should be introduced to encourage active participation in green initiatives.

b) Encouraging a Proactive Shift in Industry Practices: 52.3% of respondents said they rarely or occasionally seek alternatives to organic solvents. Only 9.6% actively seek alternatives, suggesting a lack of initiative across the industry.

Implication: Sustainability should be incorporated into industry KPIs (Key Performance Indicators) to ensure:

- Continuous evaluation of solvent use in manufacturing.
- Investment in R&D for solvent-free processes.
- Commitment to corporate environmental responsibility goals.

6.3 Recommendations for Future Research

This Study aimed to address the gaps identified in the Literature search which were summarized as Lack of Awareness, Limited Practical Implementation of Alternatives, Absence of Long-Term Impact Studies, Regulatory Gaps and Inconsistencies, Cost impact of sustainability. The learnings from the Survey study addressing these Gaps are listed below, with recommendations for the future.

1. Addressing Lack of Awareness (Literature Gap)

Past Studies highlight the environmental and health hazards of organic solvent usage, but there is insufficient data on awareness levels among pharmaceutical professionals and students.

The current study quantified awareness gaps indicating that 13% of respondents were unaware of the environmental impacts of solvents (Q5), 33.4% were unfamiliar with regulatory norms (Q7), 15.8% were unaware of alternative solvents (Q8). Demographic disparities were observed, where Students had higher theoretical awareness but lacked practical knowledge. Professionals prioritized regulatory compliance but were less aware of sustainable alternatives.

Recommendations:

Develop Tiered Awareness Programs:

For professionals: Implement workplace training modules on solvent hazards, alternative solvents, and regulatory frameworks.

For students: Integrate sustainability-focused modules into curricula, using case studies and industry collaborations.

Create Industry-Academia Knowledge Hubs: Leverage the 60.1% of respondents who participated in projects (Q4) to develop joint academic-industry workshops for bridging the knowledge gap between theory and practice.

Regulatory Awareness Campaigns: Increase access to free online courses and certifications on solvent sustainability and regulatory standards, targeting students and early-career professionals.

2. Addressing Limited Practical Implementation of Alternatives (Literature Gap)

While alternative solvents have been extensively researched, their practical application remains low due to cost, regulatory barriers, and lack of standardized protocols.

From the current study, it was observed that 56.1% of respondents have experimented with solvent-free methods (Q14). 42.4% rated alternatives as only moderately effective (Q15). 22.6% found them slightly effective, and 8% found them not effective. Cost concerns remain a major challenge (Q16) where 46.7% reported an increase in production costs when using alternatives, 38.1% observed cost reductions, suggesting mixed industry experiences.

Recommendations:

Prioritize R&D for Scalable Alternatives: Governments should fund research on cost-effective, scalable alternatives to organic solvents, addressing technical challenges (Q25: 22.3%).

Standardize Protocols for Alternative Solvents: Regulatory bodies should establish clear industry-wide protocols for implementing solvent-free methods, helping standardize quality and efficiency expectations.

Launch Pilot Projects in Key Pharmaceutical Sectors: Target mid-career professionals (39% of respondents, Q2) to lead pilot initiatives on solvent-free manufacturing. Use real-world case studies from companies that successfully reduced costs (Q16: 38.1%) to encourage wider adoption.

3. Addressing Absence of Long-Term Impact Studies (Literature Gap)

The Gap identified that there is a lack of longitudinal studies on the environmental and health impacts of solvent usage, especially in emerging economies. Additionally, research on bioaccumulation of solvent residues in ecosystems is insufficient.

The current study provided baseline data on solvent usage, where 68.4% of respondents reported using solvents in 26–75% of their processes (Q13). The study also Identified a lack of data-driven decision-making in companies regarding sustainability.

Recommendations:

Establish Longitudinal Monitoring Frameworks: Conduct multi-year studies tracking solvent reduction progress, using your study's demographic insights as a baseline.

Collaborate with Environmental Conservation Agencies: Work with agencies to study solvent residue bioaccumulation in ecosystems, focusing on regions with weaker regulatory enforcement (Q22: 27.6% rated compliance as "slightly well").

Industry Reporting Mechanism: Require pharmaceutical companies to report long-term environmental and health impact data as part of sustainability compliance reports.

4. Addressing Regulatory Gaps and Inconsistencies (Literature Gap)

While regulations exist, compliance varies significantly across regions, especially in developing countries and the impact of international regulatory frameworks on solvent reduction strategies remains underexplored.

The current study showed that 50.2% of respondents occasionally face compliance challenges (Q19). 13.6% perceive regulations as impractical in real-world settings (Q21). Organizational support impacts regulatory compliance (Q20: 37.5% rated their company as moderately supportive).

Recommendations:

Advocate for Harmonized Global Standards: Pharmaceutical companies should advocate data on regional compliance perceptions to lobby for regulatory alignment between ICH, WHO, and local pharmaceutical frameworks.

Strengthen Compliance Incentives: Governments should provide tax breaks for companies adopting solvent-free methods, ensuring economic benefits drive compliance.

Regulatory Task Forces for Emerging Markets: Form regional task forces to evaluate barriers to compliance, particularly in developing nations where regulatory enforcement is inconsistent.

5. Addressing Cost Impact of Sustainability (Literature Gap)

More research is needed on the cost-benefit analysis of green solvent alternatives, including economic incentives and policy-driven solutions. However the current study reports that 46.7% of respondents believe alternative methods increase costs (Q16), while 38.1% observed cost reductions. Low motivation to implement sustainability is exhibited where 44.9% were slightly or not motivated to adopt greener practices (Q12).

Recommendations:

Conduct Sector-Specific Cost-Benefit Analyses: Use your cost variability data (Q16) to model long-term cost savings from solvent reduction.

Promote Economic Incentives: Advocate for government subsidies and grants for SMEs transitioning to green solvents.

Transparency in Cost Reduction Strategies: Pharmaceutical companies should publish case studies on how sustainability efforts led to cost savings over time to encourage industry-wide adoption.

Future Research Directives:

This study further identifies several critical avenues for future research:

Longitudinal and Regional Studies: Conduct multi-year analyses to track the long-term environmental and health impacts of solvent usage, particularly in emerging economies. Investigate bioaccumulation patterns of solvent residues in diverse ecosystems, as highlighted by (Joshi and Adhikari, 2019).

Cost-Benefit Frameworks: Develop economic models to evaluate the full lifecycle costs of green solvents, including hidden savings from reduced waste and compliance benefits (Parmentier et al., 2017).

Regulatory Harmonization: Explore the role of international frameworks (e.g., ICH, WHO) in bridging compliance disparities across regions, particularly in developing countries.

Educational Efficacy: Assess the impact of revised pharmaceutical curricula on students' preparedness for sustainability practices in the industry.

By addressing these areas, future researchers can amplify the momentum toward sustainable pharmaceutical practices while grounding solutions in empirical, actionable evidence.

6.4 Conclusion

This thesis set out to investigate the usage of organic solvents in the pharmaceutical industry by addressing three critical research questions: (A) What is the level of awareness among pharmaceutical professionals and students regarding the environmental and health hazards of organic solvents? (B) How practically applicable are the regulatory norms governing organic solvent usage in real-world manufacturing settings? (C) Can the use of organic solvents be avoided in pharmaceutical manufacturing through the adoption of sustainable alternatives?

Using a comprehensive survey design and rigorous statistical analysis, the study gathered insights from both industry professionals and students. The results reveal that while a majority of respondents are moderately aware of the negative impacts of organic solvents, significant gaps remain—especially among students—regarding the detailed understanding of regulatory norms and the practical feasibility of alternative, solvent-free methods. Professionals, benefiting from direct industry exposure, generally demonstrated higher awareness levels and more practical engagement with sustainability initiatives compared to their student counterparts.

The findings indicate that despite some experimentation with alternative solvents, the transition toward solvent-free manufacturing is hindered by technical challenges, cost implications, and inconsistent regulatory frameworks. These barriers underscore the need for targeted training programs, enhanced industry-academia collaboration, and policy reforms that streamline compliance and incentivize the adoption of green alternatives.

The research findings presented in this report provide valuable insights into the current state of organic solvent usage and the challenges and opportunities associated with transitioning to more sustainable alternatives within the pharmaceutical industry.

The study successfully achieved its objectives, shedding light on the following key areas:

Awareness and understanding: The research compared the awareness and understanding of environmental impacts and regulatory norms between students and pharmaceutical professionals. It found that while both groups have some level of awareness, there are notable differences in their understanding of specific aspects.

Barriers to sustainable practices: The study identified several barriers hindering the transition to sustainable alternatives, including cost, regulatory compliance, technical challenges, and market demand. It also assessed the effectiveness of educational programs, finding that while they contribute to awareness, more targeted and comprehensive programs are needed.

Feasibility of avoiding organic solvents: The research explored the feasibility of entirely avoiding organic solvents, concluding that while it may be challenging in certain applications, it is possible to reduce their usage significantly through innovative approaches and technological advancements.

The Study reported in this paper, uncovers precious knowledge on the present usage of organic solvents and the hurdles and prospects in progressing towards eco-friendly alternatives in the pharmaceutical sector. The current has shed light on these important facets:

Recognition and grasp: By comparing students and pharmaceutical experts, the study looked at how well they comprehend environmental impacts and regulation norms. Discoveries showed both groups have a form of cognizance; however, grasp of specific elements differs significantly.

Roadblocks to green methods: Certain obstacles prevent a smooth change to greener alternatives, which include expenses, regulatory legalities, technical challenges, and consumer demand. This research checked out educational programs for their effectiveness and brought to light that while they spur knowledge, more directed and all-inclusive programs are needed,

Practicability of avoiding organic solvents: The possibility of skipping organic solvents altogether was probed in this research. Although it might pose difficulties for certain applications, steps forward in innovation and technology make it conceivable to slash their usage down by a whopping amount.

Green alternatives' popularity: The analysis gauged the understanding and embrace of eco-friendly substitutes and recognized factors like financial deliberations and regulatory obligations, impacting this adoption. It highlighted a budding desire for these green replacements, but it is clear that uptake fluctuates, depending on the sector and uses within the industry.

The bridge between understanding and action: This inquiry delved into the link between comprehending environmental damages and steps taken by pharmaceutical companies. While it surfaced that awareness is a significant factor, others like company culture, access to resources, or trending industry procedures also sway how this knowledge turns into action.

Insights from this study spotlight both opportunities and stumbling blocks when shifting from organic solutions to sustainable alternatives in the pharmaceutical trade. Although a sizable group from those surveyed are accustomed to organic solutions and understand sustainable methods' importance, there are considerable lapses in realizing, learning, and eagerness. Addressing these hurdles - cost factors, adhering to regulations, technical difficulties as well as market demand - is pivotal to ensuring successful adaptation.

These insights underline the pressing need for more drives promoting eco-conscious habits through education programs, professional development initiatives, and policy measures. With dedication towards research & development, encouraging cooperation amongst stakeholders within the industry along with aiding the invention of sustainable alternatives, a significant contribution can be made towards reducing the environmental impact by pharma sector and fostering a brighter future.

In summing up, this research's outcome emphasizes an urgent collective effort required to confront issues linked to migrating from organic solvents to sustainable substitutes in the pharmaceutical arena. By pouring capital into R&D, promoting education & awareness as well as adopting conducive policies for this shift - significant strides can indeed contribute towards minimizing environmental footprints that propels us towards a more sustainable world ahead.

The survey findings highlight both the opportunities and challenges associated with transitioning from organic solutions to sustainable alternatives within the pharmaceutical industry. While a significant portion of respondents have experience with organic solutions and recognize the importance of sustainable practices, there are still gaps in awareness, knowledge, and motivation. Addressing these barriers, such as cost, regulatory compliance, technical challenges, and market demand, is crucial for facilitating a successful transition.

Lastly, the results of this study demonstrate the need for a concerted effort to address the challenges associated with transitioning from organic solvents to sustainable alternatives within the pharmaceutical industry. By investing in research and development, promoting education and awareness, and implementing supportive policies, to lessen its impact on the environment and help create a more sustainable future, the industry can play a big part.

While this study provides valuable insights into the awareness, regulatory challenges, and feasibility of solvent-free alternatives in pharmaceutical manufacturing, several areas remain unexplored and require further investigation. Longitudinal studies are needed to assess the long-term environmental and health impacts of organic solvent usage, particularly in emerging economies where regulatory enforcement may be inconsistent. Future researchers should also explore cost-benefit frameworks that provide a granular analysis of green solvent adoption, including hidden savings from waste reduction and regulatory compliance benefits. Additionally, comparative regulatory studies could assess how international guidelines (ICH, WHO, and local frameworks) influence solvent reduction strategies across different regions. Another promising area for future research is the behavioral aspects of sustainability adoption—studying how organizational culture, professional training, and financial incentives impact the willingness of pharmaceutical manufacturers to transition to solvent-free methods. Finally, interdisciplinary collaborations between pharmaceutical scientists, environmental researchers, and economists could yield data-driven policies and technological advancements to accelerate sustainable practices in the industry. By addressing these gaps, future research can build upon this study’s findings and contribute to a more sustainable and environmentally responsible pharmaceutical sector.

Furthermore, the thesis identifies several implications for the pharmaceutical industry, regulatory bodies, and educational institutions. It recommends developing tiered awareness programs, standardizing protocols for sustainable practices, and launching pilot projects to demonstrate the feasibility of alternative methods. Additionally, there is a call for longitudinal studies to assess long-term environmental and health impacts, as well as comprehensive cost-benefit analyses to support economic incentives for greener manufacturing processes.

In conclusion, this research contributes valuable empirical evidence to the literature by quantifying awareness levels, identifying practical and regulatory barriers, and suggesting actionable strategies to foster a more sustainable pharmaceutical manufacturing environment. The study not only bridges existing gaps in the literature but also sets the stage for future research aimed at achieving a more environmentally responsible and economically viable transition away from organic solvent dependency in the pharmaceutical sector.

Regulatory compliance emerges as a key challenge, with respondents citing practical difficulties in adhering to guidelines due to cost constraints, lack of institutional support, and inconsistent enforcement across regions. The study underscores the importance of harmonized global standards and the need for incentive-driven policies to enhance compliance and encourage sustainable practices.

The research also explores the feasibility of replacing organic solvents in pharmaceutical manufacturing. While some companies have experimented with solvent-free alternatives, adoption remains limited due to concerns over cost, technical viability, and production efficiency. The study highlights mixed industry perceptions, with some respondents noting cost reductions while others report increased production expenses. These findings emphasize the need for further research and investment in cost-effective green alternatives.

From an academic perspective, this research addresses gaps in the literature by providing quantitative data on awareness levels, industry perceptions, and regulatory challenges—areas previously underexplored. The study's recommendations advocate for policy reforms, R&D investment, and improved sustainability education to facilitate a smoother transition toward greener pharmaceutical practices. In conclusion, this research serves as a foundation for future studies and industry initiatives aimed at reducing organic solvent dependency, promoting regulatory alignment, and integrating sustainability into pharmaceutical manufacturing. By implementing the proposed policy, educational, and technological advancements, stakeholders can drive meaningful progress toward an environmentally responsible and sustainable pharmaceutical sector.

APPENDIX A

SURVEY COVER LETTER

APPENDIX B

INFORMED CONSENT

At the start of the Questionnaire, the following introduction with explanation of the survey purpose and enabling consent of participants as a voluntary effort was provided for ease of understanding and ethical concepts pertaining to the participants, as "Hello, I Varsha S. Choudhary, am working on a survey pertaining to the sustainable usage of Organic solvents, and for this purpose, I would be delighted if you could spend some time answering a few questions listed in this Google form. The responses will be used to gauge the current status and future prospects (if any) on the sustainable use of Organic solvents. Your response should be based on your basic knowledge and experience with Organic solvents in your field.

Participation in this survey is entirely voluntary. You are free to stop at any point, and there are no penalties or consequences for choosing not to complete the survey. All responses will be kept confidential and used solely for research purposes. Data will be reported in aggregate form only, without identifying any individual participants. By choosing to participate in this survey and completing the questions, you are providing your consent for your responses to be used in this research. A completely submitted survey will be a due consideration hearted wholehearted participation in this Survey exercise. Thank you for your participation."

APPENDIX C

INTERVIEW GUIDE

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APPENDIX A:

QUESTIONNAIRE - AS GOOGLE FORM

The following questionnaire was used to collect data for this research study on the sustainable use of organic solvents in pharmaceutical manufacturing. The survey was conducted using Google Forms and distributed to pharmaceutical professionals and students.

Feedback on the Usage of Organic Solvents

Introduction:

This survey was conducted as part of the research study on the sustainable use of organic solvents in pharmaceutical manufacturing. The responses collected were used to evaluate the current awareness levels, regulatory challenges, and the feasibility of solvent-free alternatives among pharmaceutical professionals and students.

Participation in this survey was entirely voluntary, and all responses were kept confidential and used solely for research purposes. The data collected provided key insights into industry and academic perspectives on organic solvents.

The Questionnaire was provided as Google form which had the following questions:

1. **Gender:**
    - Male
    - Female
2. **Age:**
    - 15-25
    - 26-35

- 36-45
- Above 45

3. **Pharma professional or a student, please choose below:**
    - Pharma professional
    - Student
4. **Have you participated in any projects or assignments that explore alternatives to organic solvents?**
    - Yes
    - No
5. **How aware are you of the environmental impacts of using organic solvents?**
    - Very aware
    - Somewhat aware
    - Not aware
6. **How aware are you of the health impacts of using organic solvents?**
    - Very aware
    - Somewhat aware
    - Not aware
7. **How familiar are you with the regulatory norms governing the usage of organic solvents in pharmaceutical manufacturing?**
    - Very familiar
    - Somewhat familiar
    - Not familiar
8. **How aware are you of any alternatives to organic solvents in pharmaceutical manufacturing?**
    - Very aware

- Somewhat aware
- Not aware

9. **How important is it to you personally to reduce the usage of organic solvents in your work?** *(Likert Scale: 1-5, 1 = Not important, 5 = Very important)*
10. **How important do you think sustainability is in the context of pharmaceutical manufacturing?** *(Likert Scale: 1-5, 1 = Not important, 5 = Very important)*
11. **What is your level of concern regarding the long-term environmental impact of using organic solvents?** *(Likert Scale: 1-5, 1 = Not concerned, 5 = Very concerned)*
12. **How motivated are you to incorporate sustainable practices in your future professional work?** *(Likert Scale: 1-5, 1 = Not motivated, 5 = Highly motivated)*
13. **What percentage of your manufacturing processes currently involve organic solvents?**
    - 0-25%
    - 26-50%
    - 51-75%
    - 76-100%
14. **Have you experimented with or studied alternative methods that do not involve organic solvents?**
    - Yes, extensively
    - Yes, somewhat
    - No, but interested
    - No, not interested
15. **How effective do you find the alternatives to organic solvents in terms of quality and yield?** *(Likert Scale: 1-5, 1 = Not effective, 5 = Most effective)*

16. **Have you noticed any changes in production costs when using alternatives to organic solvents?**
    - Yes, costs increased
    - Yes, costs decreased
    - No significant change
    - Not applicable
17. **How often do you seek alternatives to organic solvents based on their negative impacts?**
    - Frequently
    - Occasionally
    - Rarely
    - Never
18. **Do you consider the negative impacts of solvents when choosing manufacturing methods?**
    - Always
    - Often
    - Sometimes
    - Rarely
    - Never
19. **How often do you face challenges in complying with these regulatory norms?**
    - Frequently
    - Occasionally
    - Rarely
    - Never

20. **How supportive is your organization/institution in implementing solvent-free manufacturing methods?** *(Likert Scale: 1-5, 1 = Not supportive, 5 = Most supportive)*
21. **To what extent do you think these regulations are practical in real-world manufacturing settings?** *(Likert Scale: 1-5, 1 = Not practical, 5 = Most practical)*
22. **How well do you think the industry as a whole is complying with the regulatory norms regarding organic solvents?** *(Likert Scale: 1-5, 1 = Not well enough, 5 = Very well)*
23. **How important do you think it is for your curriculum to include information about the sustainable use of organic solvents?** *(Likert Scale: 1-5, 1 = Not important, 5 = Very important)*
24. **How effective do you believe current educational programs are in addressing the sustainability of organic solvents?** *(Likert Scale: 1-5, 1 = Not effective, 5 = Very effective)*
25. **What barriers do you foresee in the transition from traditional solvent-based methods to more sustainable alternatives?** *(Select all that apply)*
    - Cost and Economic Feasibility
    - Regulatory Compliance
    - Technical Challenges
    - Lack of Awareness and Expertise
    - Supply Chain Issues
    - Risk Aversion
    - Resistance to Change
    - Market Demand