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A REVIEW ON GREEN MANUFACTURING IN PHARMCEUTICAL INDUSTRIES

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ABSTRACT

Green manufacturing is a priority in developing sustainable and eco-friendly approaches to pharmaceutical production. This review provides an insight into the most prominent environmental issues related to the pharmaceutical manufacturing process. The main negative effects of pharmaceutical production on the environment are connected with hazardous waste, solvents, water, energy, and active pharmaceutical ingredients (API). Applying green chemistry and engineering principles in various contexts of the pharmaceutical industry can lead to significant improvements in terms of waste minimization, efficient use of resources, and reduction of hazardous materials.

The set of green chemistry and engineering metrics that can be applied to assess pharmaceutical manufacturing includes E-factor, atom economy, Process Mass Intensity (PMI), Reaction Mass Efficiency

(RME), Effective Mass Yield (EMY), green solvents, and solvent guides (for instance, GSK Solvent Guide). Proper pharmaceutical waste minimization, recycling, water and energy conservation, biocatalysis, continuous manufacturing process, and chemical engineering and process safety are the key ways to make pharmaceutical production more environmentally friendly and sustainable. The Life Cycle Assessment (LCA) is the critical tool for analyzing the potential environmental impacts of a product throughout its life cycle. The latest technologies, including Artificial Intelligence, IoT, and Process Analytical Technology, can be successfully employed to optimize and make pharmaceutical production more eco-friendly. In general, there are several ways to make the pharmaceutical industry more sustainable, profitable, safer, and competitive.

KEYWORDS: Process Mass intensity (PMI) and life cycle Assessment (LCA) are coupled here with sustainable technology and environment sustainable

INTRODUCTION

The pharmaceutical and chemical industries, along with chemist can significantly contributes to the resolution of today's environment and health issues. green chemistry has become an important approach for promoting sustainable and environmently responsible practices in the pharmaceutical industry in recent year increasing attention has been given to the use of green chemistry principle and metrics to minimize waste, reduce hazardous substance improve resource efficiency, and support more sustainable pharmaceutical manufacturing process. measurable sustainability metrics inform both process and product design and they Estabilish Beanchmarks for future enhancement life cycle assessments (LLA) as outline in the international organization for standard (ISO) standard 14.040;2006 measure the environment impact linked to all stages of a products life cycle. LLA is utilized within the bulk chemical industry, particularly of new bulk product, as well as in green and brownfield project. bulk pharmaceutical sector is also increasingly recognizing the significance of LCA. Given the rapid pace of pharmaceutical process development needed to meet clinical trial schedule and timely product launches, there is demand for tools that efficiently address environment impact. In responsible to this demand, Glaxo smith kline (Gsk) has concentrated on applying LCA in a focused manner. [1]

Green Synthesis seeks to optimize consumption, minimize energy waste, and power operations through renewable energy sources. Despite being the world's leading contributors to the economy with total revenue of 1.27 trillion U.S. dollars, pharmaceutical companies are also a primary driver of the carbon footprint, accounting for approximately 1.9 Mt CO2 [1]. Although the concept of environmental protection has been around for a decade, many initiatives failed to materialize because of a lack of collaboration from the industries. The Industrial Nations have consistently sought to manage output and identify processes to minimize their environmental impact, yet neither approach has fully satisfied these industries [2]. The objective of every pharmaceutical company has always been to ensure the delivery of revolutionary medicines that improve living standards globally. To achieve this goal in an environmentally friendly manner. kumar et,.al, (2021) [2]

The continuous increase in the demand and sales of pharmaceuticals has been driving up related environmental impacts (Kong et al., 2021; Siegert et al., 2020b). The unique aspects of pharmaceutical production encompass a series of interconnected processes, including bulk drug synthesis, pharmaceutical preparation, packaging, and transportation. These activities operate across the global economy and influence various regions and economic sectors. Similarly, pharmacy synthesis involves numerous inputs and outputs, generates toxic by-products, and requires extensive energy and resources (Ahsan et al., 2020). As complex and high-value-added products, pharmaceutical chemicals typically generate a significantly larger environmental impact per kilogram

compared to basic chemicals. This is largely due to the intricate chemistry of active pharmaceutical ingredients (APIs), which requires sophisticated multistep manufacturing processes (Belkhir and Elmeligi, 2019; Cespi et al., 2015; Debaveye et al., 2016). The cumulative energy demand (CED) of pharmaceutical chemicals is estimated to be twenty times greater than that of essential chemical goods, while their global warming impact is up to twenty-five times higher (Wernet et al., 2010). Therefore, the production of pharmaceuticals is a labor- and resource-intensive process that involves significant challenges. haque et,.al(2024)[3]

1.1 sustainability in pharmaceutical manufacturing

A comprehensive review of the exiting literature indicates that the adoption of sustainable practices in increasing across various industrial sectors worldline. Growing awareness of socio-environmental issues has encouraged manufacturing organization to incorporation environment consideration into their business strategies. Previous studies have identification waste reduction, efficient utilization of material and resources, and improvement of ecosystem as important approach for achieving sustainable manufacturing (Abdul Rashid et al., 2008; Despeise et al., 2012)

The relationship between industrial manufacturing activities and environment challenges became increasing recognize following the first united nation conference on the Human environment held in Stockholm in 1972 (IPCC,2013). This growing awareness contributes to the development of the concept of sustainability. The Brundtland Commission defined sustainability meeting present needs without limiting the ability of future generation to meet their own needs (UNDESA,1987). Over time, this concept has become an important component of industrial and corporate decision -making.[4]

In the pharmaceutical sector, sustainability involves integrating environmentally responsible practices into manufacturing process and business strategies. Increasing expectation from stakeholder have also encouraged organization to demonstrate greater accountability, transparency, and responsible governance through corporate sustainability practices (Kolk,2010). Corporate sustainability further Emphasize fulfilling the requirement of present stakeholder while maintaining the ability to address the needs of further stakeholder (Dyllick and Hockerts, 2002). Therefore, sustainable pharmaceutical manufacturing requires attention to environment protection, efficient resources utilization, and the long-term well -being of society. [5]

(example: in 2023, inspection of 162 pharmaceutical manufacturing units in India revealed several deficiencies in manufacturing practices, infrastructure, quality control and documentation, resulting in manufacturing halts and regulatory action."(Indian express) [6]

1.2 impact of pharmaceutical manufacturing on ecosystem

risks that are associated with environmental discharge from pharmaceutical manufacturing differ in several respects from those that are associated with the excretion of drugs This is primarily due to differences in exposure levels, as

effects thresholds are independent of the contamination source. Drug concentration due to excretion Since the amount of drugs contained in urban wastewater is limited, Although only a small percentage of the population uses it on a daily basis, With possible exceptions in the event of a serious infectious disease outbreak the outbreak of a pandemic. In even more countrie, each person will use a large amount of water, and as a result,Strong initial dilution of stool and urine. is increasingly recognized. Every stage of a pharmaceutical lifecycle manufacturing, application, and disposal can lead to environmental pollution. Consequently, these substance may enter our drinking water supply and fish and vegetables. Pharmaceutical residues have been detected in various environment contexts worldwide, including surface water, manure, soil, and other (pharmaceutical in the environment: Our Haleon viewpoint, Nd) .research paper indicate that medication can manifest as reproductive issues in fish, kidney failure in vulture, and inhibiting growth in certain aquatic spices (kolki-kun, J.F (2012). for the future of biopharmaceutical production, continuous manufacturing. [7]

1.3 Process mass intensity as a green manufacturing

To evaluate the efficiency of a manufacturing process, one kilogram of output material must be generated. PMI serves as an initial comparison between two similar processes, even though it does not account for all environment impacts (Kokai-kun, J.F(2022). Typically, PMIs are higher in biological manufacturing techniques utilizing fermenters or bioreactors compared to those that yield small molecules active pharmaceutical ingredients (APIs). For illustration, a monoclonal antibody (mAb) yield of one kilogram requires roughly 7,700 kilogram of input materials, whereas the standard PMI for small molecules API production between 100 and 200kg\kg. This input is composed of raw materials, extra consumables required during production, and water for media and buffers. However. it fails to consider factors such as water needed for cleaning equipment. [8]



Fig - 1.3: Environmental Impact of Pharmaceutical Industries.[9]

1.4 concept and approach of green manufacturing

while PPCPs are frequently classified as "emerging " pollutants, it is responsible to infer that their presence in water is not a recent occurrence. The visibility of PPCPs in the environment has increased since the 1990s , primarily due to advancement in chemical analysis techniques that have significantly improved detection limits of various xenobiotics in environment sample There is no evidence to suggest that any specific PPCP has not been capable of entering the environment since it was first marked or even since it was initially utilized in research or clinical studies most present -day strategies for tracking pollutants focus on a limited range of anthropogenic (and occasionally naturally occurring) toxic substance in the environment. Think about exposure only as a result of one toxicant or a small number of chemical stressors. but the big picture is starting to emerge, this is not only caused by poe's larger universe; potentially toxic substance to which living organism may be affected typically exposed at any point (Or period). it depends not point only on time but also on a host of other variables. exposure level, route of exposure (Ex, skin, intestine, lungs), exposure continues intermittent, tentative temporary or chronic nutrition, age gender, Genetic factor, and nonchemical factor (temperament). stress noise electricity magnetic radiation, pathogens, all the factor organization historical " exposed traffic " A "vector' determine the current value. understand your health and build the foundation for result current impact (vulnerability or resilience) destruction of homoeostasis. with science although our understanding of this complex is limited, Dynamic interaction of several factor, risk evaluation is necessarily limited to evaluation. impact of potential toxic effect event without a broader holistic perspective. [10]

A quick summery is as follows, structure the complete context of the organism Cumulative exposure to chemical stressors does not exist. one possibility suggested here is "toxicity" Frame-totality-tolerance-Trajectory" ("4t"., see Doton\us EPA 2003a). Take in account the total impact on the body. by previous writing, History of 3D influence and its facts the main purpose of all living thing is maintain is homeostasis (under certain condition) Resentment towards stressors. homeostasis looks like this; supported only within tolerance for biochemical protection of the body directory so, the 4Ts describe a hypothesis. calculation of the total impact of all toxic real risk reflected by the amount the total impact of all toxic anthropogenic genetic and natural though out mini monograph\ DOTON 758volume 111\ no. 5 \may2003 environment health perspective Anthropogenic pollutant nature'

The Future of Green Manufacturing Research: An In-Depth Analysis Although this study includes a dataset of 189 GMO articles. research, this subject is still poorly understood and offers a wide range of future research opportunities. Through in-depth analysis, we identified ideas that provide research opportunities for GMO scientists. we group together Questions about performance, human resources, and interdisciplinary orientation. Three future research directions are discussed here [11]

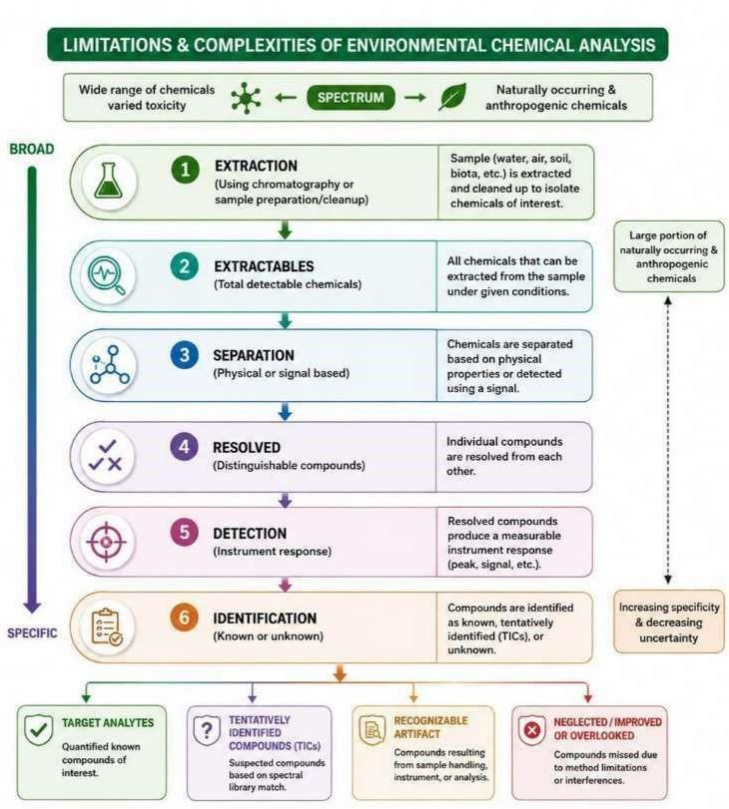


Figure 1.2: Limitation and Complication chemical Analysis.

The presence of PPCPs in the environment may have unclear implication for ecological or human health, especially given that their detected levels are extremely low, ranging from nanogram per liter (part per billion). Concern regarding possible ecological effect cannot be addressed until aquatic and computation toxicologists start examining the impacts on non- start examining the impact on non-target organism trough simultaneous, long- term exposure to various PPCPs at low concentration, as well as evaluating the importance of cumulative exposure to PPCPs that share similar mechanism of action (MOA). In fact, the therapeutic doses for target organism are often significantly higher than the concentration found in dissolved waste.

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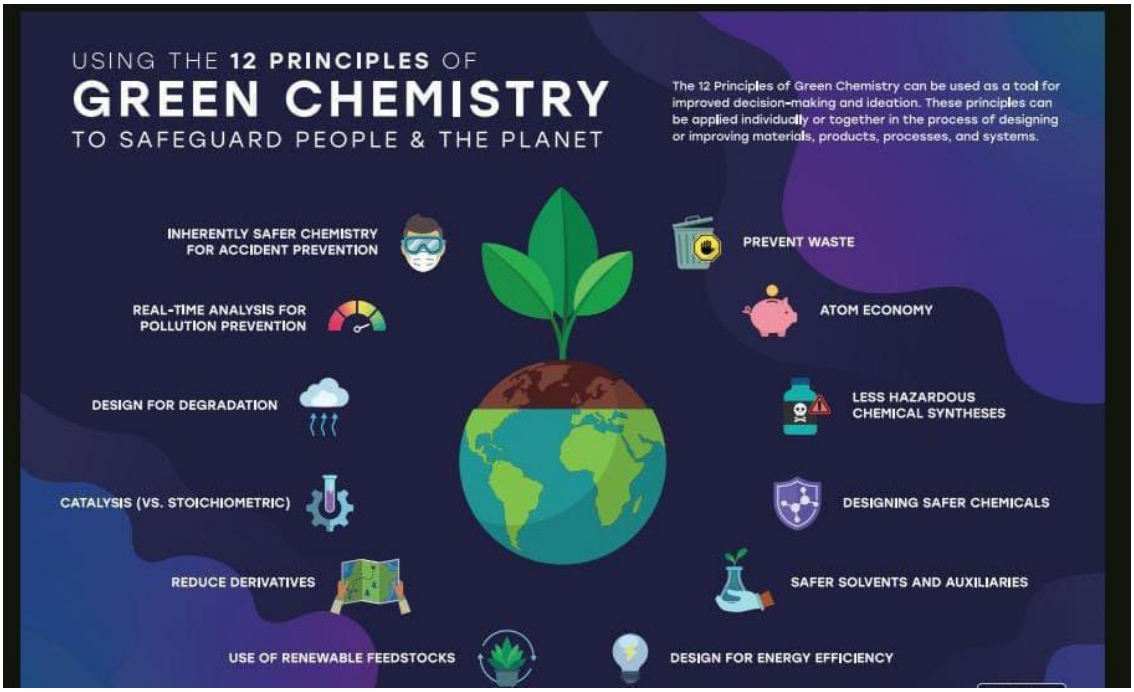


Fig 1.3: Twelve Principle of Green Chemistry. [12]

"The twelve Principle of green chemistry give a Guidelines for crating the chemical process that minimize waste, decreases the amount of dangerous by product, saves energy and raw material, and allows pharmaceutical companies to make drug in a more sustainable way"

1.5 Green chemistry metrics

Green chemistry metrics should be used to estimate the efficiency of any chemical process. The most common ones are E-factor, atom economy, process mass intensity, Reaction Productivity. All Those Ration are used to predict waste production levels and the amount material needed for the amount of used materials the better and greener the process.

<Environmental human health metrics

1.a collection of indicators organized in a hierarchical metrics has been suggested to assess the eco-friendly of both emerging and established chemical technologies, along with the evaluation of process flow diagram of new procedures. in this regard, two criteria were established

(a) it must allow for the evaluation of different technologies, and (b) ideally it ought to offer a unified structure, relevant trough out the chemical sectors with a suitable choice of indicators taking into account four levels of vertical hierarchy:1 product process ,2. organization .

2: infrastructure, and 4. community. it is essential to recognize that the choice of indicator varies by each industrial sector and which product they deem most significant element of green chemistry in vertical hierarchy levels (a)climate change (b) ongoing energy accessibility

(c) resource efficiency accessibility (d) harmfulness of product, (e)minimal solvent use, and (f) ability to be recycled [13]

3: in 2008 {63}a study aimed at producing nanomaterials was documented: this research combined both industrial engineering and sustainable chemistry, assessing the ecological effect on the production of silica nanoparticles involving: a sol-gel method, an easy flame- and an enhanced HMDSO-flame technique. Typically, the process Consist of two elements illustrated.

Mass metrics	**Expression**
E-factor (E)	total waste \ product
atom economy (AE)	(FW Product \ fW of all reactant used in reaction) x100
mass intensity index (MI)	total mass\ mass of product
mass productively	mass of product \ total mass in process or process step
effective mass yield (EMY)	(mass of product \ mass of non- being reagent)x1oo
generalized reaction mass efficiency (gRMI)	mass of product \ total mass in process in process step
reaction mass efficiency (RMI)	(mass of isolated product \\product \total mass of reactant used in reaction)x100
stoichiometric facto (sf)[1]	
carbon efficiency (CE)	(mass of carbon in product \ total mass of carbon in reactant)x100
process mass intensity (PMI)	total mass in a process or process step \ mass of product
Global material economy (GME)	mass of product \ total mass used in total synthesis
reaction mass intensity (RMI)	total of mass of reaction materials \ mass of product
Greener atomic level	100x (RMI\AE)
Greener atomic level[1]	
complete E-factor level[2]	Σm (raw material) +Σm (reagent) +Σm (solvent)+ Σ(water) -Σ(product) \m (product)
Transformation green aspiration level ™(GAL™)	xE\average complexity , where xE =cE $_0$E
green aspiration level^{tm} (tGAL)™	(tGAL™) x complexity
Relative process greenness (RPG)	GAL(xF)\xE
innovation green aspiration level (iGAL)	iGAL =(mGALxFMW)\1000
optimum efficiency (OE)	(RME\AE)x100
Renewable percentage (RP)	Renewable intensity \PMI)x100
Manufacture mass intensity (MMI)	(Renewable intensity \PMI)x100
Manufacturing mass intensity (MMI)	U(PMI)+U(MI of component under consideration)[3]
Scale risk index (SRI)	SRI=t($Hf_{R+}HF_p$+HF_D)

1.6: Ecology and Human Health That Impact on Pharmaceutical Product :

The presence of PPCPs in the environmental may have unclear implication for ecological or human health, especially given that their detected levels are extremely low, ranging from nanogram per liter (part per trillion) to micrograms per liter (Part per billion). Concern regarding possible ecological

effects cannot be addressed until to PPCPs that share similar mechanism of action. In fact, the therapeutic doses for target organism are often significantly higher than the concentration found in dissolved waste. It Become evident from the pattern observed in the published occurrence data that all municipal treated sewage, unless processed through advanced wastewater treatment method like reverse osmosis and granular activated carbon, will contain PPCPs is not confined to any specific municipal region. The variation between geographical areas lies solely in the particular types, amount, and relative concentration of distinct PPCPs, there are several primary Source that contribute to release of both legal and legal and illegal drug into the environment (Aughton/U.S. EPA 2002c). The three main Source are likely excretion, washing, and intentional disposal. There three Route are probably directed into municipal waste system and stormwater runoff (such as sanitary or combined sewers), and to a lesser yet meaningful extent are rehabilitation of existing sewerage and water supply us infrastructure development Require huge resource. American society civil Engineer Bulletin 2001 nominated for American infrastructure (ASCE2001) Both drinks are national grade "D" water supply and sanitation infrastructure. Learn more Estimated to be over $ 20 Billion annually the need to correct a declining nation Water PPCP is finished mental anxiety, unknown sewage treatment plants may even be profitable. Effectively modified to reduce emission Especially considering the huge costs involved. original restoration and maintenance productivity. Ultimately, version control system (pollution prevention) aimed at recycling practices. It can also be proven in actual therapeutic application. its's more efficient the rest of article. All of part 2 (Daughton 2003) is present wide range of activity ideas connection that can be affected by contamination. [14]

1.7: Pharmaceutical waste and: types of Management

Classification

Pharmaceutical Waste: Categories and Handling

Classification of Waste: Pharmaceutical waste is typically divided into two main types:

Hazardous waste: This includes materials containing cytotoxic drugs, reactive chemicals, or substances that are flammable or corrosive [9].

Non-hazardous waste: This category covers expired or unused medications that do not pose high toxicity risks, such as some over-the-counter pills.

Disposal Method for pharmaceutical waste:

Recommended disposal methods include

1. Incineration at high temperatures (above 1200 °C) for cytotoxic and hazardous pharmaceutical waste [11].
2. Encapsulation, Inertization, and disposal in specially designed landfills for materials posing low to moderate risks [13].

3. Chemical neutralization using agents such as acids or alkalis, suitable only for small amounts of certain substances [14].

4. Preventive strategies, such as preventing medications from entering water systems and avoiding lowtemperature incineration to reduce the release of harmful emissions [15, 16].

5. Pharmacists play a key role by supporting appropriate prescribing, informing patients on proper disposal practices, and adhering to environmental safety regulations [17].

Environmental Safer Chemical

Green manufacturing aims to reduce environmental impact by focusing on several key areas:

- Energy and water efficiency: Prioritizing renewable energy sources and implementing water recycling practices [18].
- Sustainable packaging: Utilizing materials that are either recyclable or biodegradable [19].
- Environmentally safer chemicals: Adopting cleaner production methods that generate fewer toxic by-products [20, 21].

Sustainable Manufacturing Approach:

- Utilization of biocatalysis or enzyme-driven chemical transformations [23, 24].
- Implementation of continuous flow reaction systems combined with real-time process monitoring (Process Analytical Technology, PAT), along with improvements in atom efficiency and process integration to reduce the formation of by-products [25, 26].
- Application of lifecycle assessment and eco-efficiency evaluation methods to quantify environmental impact.

Integration of Digital Technology and Green HRM

Digital technologies such as AI, IoT, and digital analytics Enabling predictable waste management, process improvement, and resource optimization [41]

. Green HRM, Regulatory management and data-driven process design

Complementing each other in joint promotion of green projects implementation of practices

. Benefits of integration Continuous monitoring, environmentally effective process management,

Improved compliance with environmental standards [15]

1.8 Green Solvents and Solvents Selection in pharmaceutical Manufacturing

Solvents are a major consideration when assessing pharmaceutical manufacturing processes because they significantly influence environmental impact, cost, and process safety. Process solvents can account for approximately 80–90% of the non-aqueous material used in the production of active pharmaceutical ingredients (APIs). Additionally, studies have indicated that solvents may contribute to nearly 50% of the greenhouse gas emissions associated with pharmaceutical manufacturing. Since a large proportion of substances used in API production involves organic solvents, the selection of safer

and more sustainable alternatives has become an important aspect of green pharmaceutical manufacturing. Consequently, organizations such as the Green Chemistry and Commerce Council have emphasized the development and adoption of environmentally preferable solvents, including solvent-free reactor cleaning methods and alternatives to hazardous dipolar aprotic solvents. Chlorinated hydrocarbons, which have traditionally been widely used in chemical processes, are increasingly being avoided because of their environmental and health hazards. [16]

Solvents guide

Addressing the overuse of hazardous dipolar aprotic solvents in active pharmaceutical ingredient (API) synthesis is an important aspect of green chemistry. Appropriate solvent selection can facilitate chemical synthesis and transformation while increasing awareness among chemistry professionals regarding the environmental, health, and safety impacts of solvents. To support daily solvent selection in the pharmaceutical industry, several solvent selection guides and rating systems have been developed by pharmaceutical companies and chemical agencies.

The GlaxoSmithKline (GSK) Solvent Guide provides a detailed assessment of commonly used solvents and serves as a useful tool for safer solvent selection. The guide includes approximately 154 solvents, including alcohols, aromatics, carbonates, chlorinated solvents, dipolar aprotic solvents, esters, ethers, hydrocarbons, ketones, organic acids, and water.

The GSK Solvent Guide evaluates solvents according to four major categories: (i) waste, including combustion, recycling, bioremediation, and volatile organic compound (VOC) emissions; (ii) environmental impact, particularly effects on air and water; (iii) human health, including health hazards and potential exposure; and (iv) safety, including flammability, explosiveness, and chemical reactivity. Therefore, the GSK Solvent Guide can be used for rapid evaluation and selection of safer and more environmentally sustainable solvents for pharmaceutical manufacturing processes.

The GSK Solvent Guide qualitatively evaluates solvent alternatives using four major categories—waste, environment, human health, and safety. Solvents are ranked from 1 (major issues) to 10 (few known issues), helping in the selection of safer and more sustainable solvents

The overall idea of generating rankings for solvent sustainability has evolved in various ways within the chemical industry. The pharmaceutical industry, specifically, has focused on developing its own institutional rankings of solvent sustainability after recognizing that solvents play a crucial role in a standard reaction when producing an active pharmaceutical ingredient.(7). prat,d et,.al(2016 [17]

1.9: Challenges of LCA Green Pharmaceutical Manufacturing

LCA remains a significant challenge in green pharmaceutical manufacturing because pharmaceutical processes involve multiple stages, raw materials, excipients, energy inputs, and environmental impact categories. Different production routes may show different environmental and economic advantages.

Therefore, LCA-based decision-making requires the integration of environmental, technical, and economic criteria to identify the most sustainable manufacturing pathway. [18]

Life Cycle Assessment (LCA) remains challenging in green pharmaceutical manufacturing because environmental impacts vary with energy consumption, dosage forms, excipients, raw materials, and manufacturing processes. Existing studies have mainly focused on selected APIs and formulations, while comprehensive LCA studies covering a wide range of pharmaceutical excipients remain limited. Future research should therefore evaluate the complete life cycle of commonly used excipients, including diluents, binders, lubricants, preservatives, wetting agents, emulsifying agents, stabilizers, and sustained-release agents. Such comprehensive assessments can support the selection of environmentally sustainable materials and help reduce the overall environmental footprint of pharmaceutical manufacturing.[19]

Future Perspective

The future of green pharmaceutical manufacturing focuses on the development and implementation of sustainable technologies that can reduce environmental impact while maintaining product quality and safety. Greater use of green solvents, renewable energy, biocatalysis, continuous manufacturing, and waste-minimization strategies is expected. Advanced technologies such as artificial intelligence, digital monitoring, and process analytical technology can improve resource utilization and process efficiency. Lifecycle assessment can also help industries identify environmental hotspots and select more sustainable processes. Future research should emphasize cost-effective, scalable, and industrially feasible green technologies, along with stronger regulatory support and collaboration between academia and pharmaceutical industries.[20]

Future researches in the pharmaceutical manufacturing should focus on the development of integrated sustainability strategies taking into account environmental, economic and social aspects at the same time. More attention should be paid to pharmaceutical waste disposal, water preservation, green manufacturing, sustainable supply chains and recyclable packaging. In addition, further work must evaluate the economic feasibility and scalability of sustainable technologies in the pharmaceutical industry. The development of standardized approaches to sustainability and better collaboration between the pharmaceutical industry, researchers and regulatory authorities can contribute to the transition toward sustainable pharmaceutical manufacturing [21]

CONCLUSION

The future of green pharmaceutical manufacturing is the development of safer and more sustainable synthetic processes. Green or solvent free reaction systems, biocatalysis, continuous processing and process intensification can all contribute to increased resource efficiency and reduced waste generation and environmental impact. Better atom economy and energy efficiency, and the incorporation of green chemistry principles throughout the life cycle of active pharmaceutical

ingredients (APIs), can offer further support to sustainable pharmaceutical production. Moreover, there is a need to develop advanced green technologies for industrial applications that are scalable and meet product quality, safety and regulatory requirements [22]

Green manufacturing is a promising approach for enhancing environmental and resource efficiency in pharmaceutical manufacturing. You can use sustainable production practices to cut waste and resource use and to improve the overall environmental performance of manufacturing processes. Successful implementation, however, requires the integration of green technologies with appropriate management strategies, and continuous improvement and cooperation between industry and other stakeholders. Therefore, the pharmaceutical industry needs to further develop and widely apply green manufacturing practices for long-term sustainability[23]

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