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SUSTAINABLE PHARMACEUTICAL TECHNOLOGIES IN MANUFACTURING AND PACKAGING

From Design to Disposal

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Prof. Vandana B. Patravale

The Chief Editor, APTI Women's Forum Newsletter

Dear Readers,

As the pharmaceutical industry continues to advance, sustainability is emerging as an essential part of how medicines are designed, manufactured, packaged, and ultimately disposed of. The **May–August 2026 edition** of the APTI Women's Forum Newsletter explores this evolving landscape under the theme **“Sustainable Pharmaceutical Technologies in Manufacturing and Packaging: From Design to Disposal.”**

The articles in this issue take us across the pharmaceutical lifecycle—from eco-by-design strategies and sustainable drug delivery systems to green formulation, circular manufacturing, solvent recovery, and single-use technologies for biologics. Particular attention is given to the transformation of pharmaceutical packaging, including recyclable, bio-based, mono-material, lightweight, and smart solutions, while balancing sustainability with product quality, sterility, and patient safety.

The journey extends beyond manufacturing and packaging to examine the environmental fate of pharmaceutical residues and the emerging role of eco-pharmacovigilance. Looking ahead, the issue also explores how artificial intelligence and digital twins could enable smarter and more resource-efficient pharmaceutical systems.

Together, these contributions highlight a fundamental shift: sustainability in pharmaceuticals is not a single intervention, but a lifecycle approach that begins with design and continues through manufacturing, packaging, use, and end-of-life.

The editorial board sincerely thanks all contributing authors for their valuable scholarly contributions. I extend my appreciation to the entire editorial team for their dedication in conceptualizing, reviewing, and curating this issue. Special thanks to Dr. Suneela Dhaneshwar, Dr. Shubhini Saraf, Dr. Vanaja Kenchappa, Dr. Preeti Suresh, Dr. Rakhi Khabiya, and Dr. Jubie Selvaraj for their valuable editorial inputs, and to Dr. Clara Fernandes for thoughtfully curating the puzzles featured in this issue.

Lastly, I express my heartfelt gratitude to the VBP research group, especially Ms. Alice John, Mr. Urmik Bhandari, Ms. Rama Yamkammardi and Mr. Shubham Karpe, for their constant support in bringing this newsletter to fruition.

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DESIGNING GREENER PHARMACEUTICALS

Programming the fate of medicines: An eco-by-design strategy for zero pharmaceutical residues



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Abstract:

Pharmaceutical residues are a serious threat to the environment, biodiversity, and human health. Traditional pharmaceutical research & development is inherently unsustainable, as it does not consider the environmental impact of drug design, synthesis, packaging, and disposal. The proposed solutions, Eco-by-Design Pharmaceuticals and Programming the Fate of Medicines, address the issue from multiple angles. At the molecular level, the design utilizes cleavable linkers that are stable in the shelf-life of the drug but are easily degraded in water, thus minimizing the environmental footprint. Green chemistry approaches, including catalysis, mechanochemistry, continuous flow, and solvent recycling, help reduce the ecological impact of drug synthesis. The use of chitosan, cellulose nanocrystal composites in packaging reduces plastic waste and ensures the stability of the drug during transportation. Finally, the use of biochar beds made from agricultural waste to trap and detoxify pharmaceutical residues is an excellent example of a sustainable end-of-life solution.

Keywords: Pharmaceutical residues, Sustainability, Eco-by-design, Bio-cleavable drugs, zero waste

1. Introduction

For a long time, people making new medicines focused on how well they work and how safe they are for patients. But they didn't think as much about how these medicines affect the environment. When medicines get into the soil and water, they can cause big problems like pollution and help create germs that are hard to kill with antibiotics. (1) The reason medicines work well in our bodies is because they are strong and don't break down easily. But this also means they don't break down easily in the environment, which can cause more problems (1)

Even trace amounts can upset aquatic ecosystems, with low-level residues shown in studies to contribute to ecological stress (2). This highlights the deficiencies of conventional

pharmaceutical development, where design, synthesis, manufacturing, packaging, and disposal are all done separately without regard for their combined environmental footprint (3). Medications that safeguard human health can simultaneously generate unintended ecological pressures (3).

In order to meet these challenges, sustainability must begin at the design stage rather than after contamination. This review describes the programming of the fate of medicines; a design-to-disposal framework that integrates bio-cleavable drug architecture, green synthesis, intelligent manufacturing, sustainable bio-packaging, and circular remediation (4).

2. Programming the fate of medicines through molecular design

The fate of medicines in the environment is determined at the design stage since Eco-by-Design Pharmaceuticals aims to develop medicines with reduced environmental impact while providing the desired therapeutic function (5). The principles of Green Medicinal Chemistry should be integrated into the design to ensure that pharmaceutical activity occurs with minimal negative effect on the environment (6).

The most promising strategy is based on the design of bio-cleavable drugs that can be easily degraded after use while providing the required therapeutic effect before entering the environment. It is possible due to the use of targeted linkers that can be cleaved using particular enzymes resulting in the formation of pharmacologically inactive molecules (7). Ester, hydrazone, carbonate, peptide, and disulfide linkages can be used to develop drugs degradable in different environments.

The key challenge associated with the design of degradable drugs is the need to ensure their stability during use while allowing their easy degradation after eliminating the pathology symptoms. The appropriate choice of linkers and enzymes responsible for drug degradation allows addressing this challenge and designing a medication degradable in specific environments, such as water, and not degradable in the human body (8). Table 1 depicts the various bio-cleavable linkers.

Table 1. The list of bio-cleavable targeted linkers

Linker	Cleavage mechanism	Stability	Environmental degradation	Pharmaceutical applications	Sustainability benefit
Ester	Hydrolysis (aqueous)	Moderate	Rapid	Prodrugs, biodegradable APIs	Fast breakdown in water
Carbonate	Enzymatic hydrolysis	Moderate	Efficient	Drug delivery carriers	Biocompatible by-products
Hydrazone	Acidic hydrolysis	Stable in neutral	Controlled	Targeted release systems	Reduced persistence

Peptide	Protease cleavage	High	Selective	Peptide drugs, carriers	Natural degradation
Disulfide	Oxidative cleavage	Stable in plasma	Rapid in oxidative media	Anticancer prodrugs	Environment-t triggered



Figure 1. Framework for programming fate of medicines

2.1. Translating Design into Practice

Sustainable molecular design requires translation into practice via green synthesis and intelligent manufacturing to make sure that the pharmaceutical industry remains eco-friendly. Although design programs the future of medicines, it is manufacturing that makes them sustainable. Green organic synthesis lies at the heart of the process, being focused on such a crucial concept as atom economy, thus minimizing waste (9). In addition, catalysis allows one to make processes more selective, cutting down on energy and undesirable byproducts (9).

Other innovative approaches to make the production of pharmaceuticals greener include mechanochemistry, which involves the mixing of compounds without a solvent, and flow chemistry that is used to make continuous manufacturing processes (9). Combined with continuous manufacturing, they make processes controlled and optimized, thus removing risks.

In addition to that, the use of Process Analytical Technology and Quality by Design makes it possible to monitor production and build sustainability into products (10). The development of new approaches to pharmaceutical manufacturing using artificial intelligence also contributes to the industry's sustainable development by being able to predict the most efficient processes

and conditions (10). Finally, the implementation of solvent recovery and zero-waste manufacturing is vital for pharmaceuticals' sustainability, as it allows one to recover expensive solvents and not impact the environment unnecessarily. Each step of the way, from design to manufacturing, pharmaceutical products are made to be sustainable and beneficial for health without compromising the environment.

2.2. Extending Sustainability beyond Manufacturing

Pharmaceutical sustainability should not be limited by the boundaries of manufacturing. The environmental impact of the drugs should be considered at later stages of consumption and even after disposal. Typically, traditional petroleum-based plastics used for packaging have significant environmental consequences after disposal. Materials such as chitosan provide an excellent alternative because they are biodegradable and possess antimicrobial properties, thus addressing two critical issues: the excessive plastic waste in the environment and multidrug resistance (11). Moreover, cellulose nanocrystals offer a sustainable option for wrapping and packing medications due to their mechanical properties, flexibility, and biodegradability (12). The combination of chitosan and cellulose nanocrystals in composite bio-films offers a platform for pharmaceutical packaging with improved properties.

Another significant advantage of pharmaceutical packaging is the potential to use smart wraps that can indicate the expiry date of the medicine. Besides, the use of such technology can also prevent the wastage of pharmaceutical products due to improper storage and ensure patient safety. However, even after use, pharmaceutical packaging can negatively impact the environment because some of the compounds can be hazardous in landfills. Indeed, most Active Pharmaceutical Ingredients (APIs) are poorly degraded in various environments and accumulate in it, severely impacting the waste treatment plants, wildlife, and even human health. For example, API residues disrupt essential microbial processes and threaten aquatic organisms with bioaccumulation. At the same time, antibiotics facilitate the development and dissemination of antibiotic resistance genes amongst bacteria (13).

Therefore, it is evident that the impact of pharmaceutical products should be considered even after their use. Thus, it is critical to ensure sustainable practices both in manufacturing and post-consumer use to minimize the impact on human health and the environment. Table 2 shows the comparison of traditional and sustainable packaging.

Table 2. Conventional vs Sustainable pharmaceutical packaging difference

Particulars	Conventional packaging	Sustainable packaging	Benefits to environment
Material	Petroleum based plastics	Chitosan, nanocellulose, biopolymers	Biodegradable, renewable resources
Barrier properties	High but non degradable	Comparable with eco-friendly composites	Maintains drug stability, reduces waste
End of life fate	Landfill accumulation	Compostable or recyclable	Lower ecological footprint

Functionality added	Passive containment	Smart indicators, antimicrobial films	Reduced drug wastage, improved safety
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2.3. Closing the loop

Pharmaceutical sustainability requires a cradle-to-grave approach; thus, the industry should create ways to reuse or remove drug residues. Medicine take-back programs can ensure that the compounds are disposed of correctly instead of being flushed down the drain (14). The pharmaceutical residues can then be treated using agricultural biochar to remove pollutants before they reach the environment (15). More sophisticated technology, such as advanced oxidation processes, photocatalysis, and enzymatic treatments, can break down the contaminants into simpler, harmless molecules as shown in Table 3.(16,17). This way, the loop of pharmaceutical waste is closed, and the medicines are taken away from the environment after use.

Table 3. The end-of-life circular technologies

Technology	Principle	Advantages	Limitations	Best Application
Medicine Take-back	Safe collection of unused drugs	Prevents improper disposal	Requires public participation	Community pharmacies, hospitals
Agricultural biochar	Adsorption of pollutants	Low-cost, scalable	Limited for highly soluble APIs	Soil and water remediation
Advanced oxidation	Hydroxyl radical degradation	Rapid breakdown	Energy intensive	Wastewater treatment plants
Photocatalysis	Light-activated mineralization	Complete degradation	Catalyst stability issues	Aquatic effluent treatment
Enzymatic degradation	Biological cleavage of molecules	Selective, eco-friendly	Slow kinetics	Targeted pharmaceutical residues



Figure 2. The design-to-disposal circular framework

3. Future Prospects

With the future prospects, pharmaceutical sustainability will be achieved through the development of AI-designed biodegradable drugs and the use of carbon-neutral production technologies to ensure therapeutic stability while promoting environmental sustainability (18,19). Smart biodegradable packaging will also contribute to sustainability by minimizing waste and enhancing shelf-life (20). Also, advanced regulations and continued research on biodegradable designs are critical factors that will promote pharmaceutical sustainability.

4. Conclusion

Drugs should be designed to be effective and safe for the environment by incorporating the principles of eco-by-design, using green synthesis, and implementing strategies to mitigate the threat of drug resistance, as well as designing sustainable approaches to packaging and disposal to minimize the impact on the environment. Design to-disposal concept makes sure that drugs are developed and used in a way that helps both patients and environment.

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Sustainable drug delivery systems: Building a greener future from design to disposal

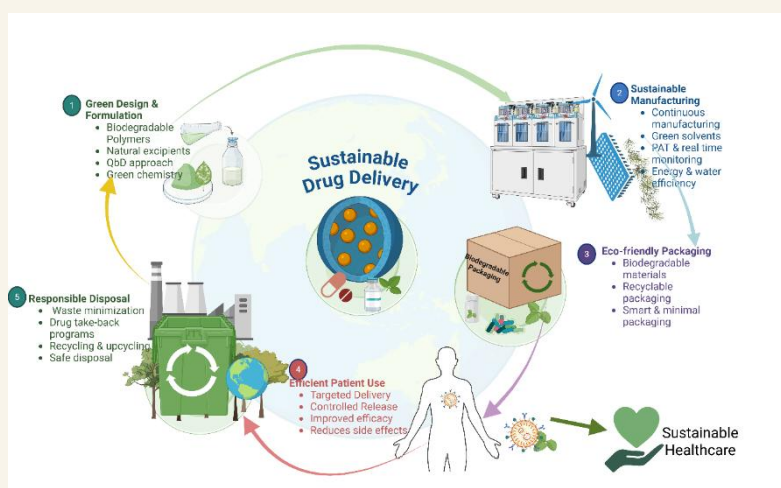


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Graphical Abstract



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Abstract

The increasing demand for pharmaceuticals has raised concerns regarding resource use, waste generation, environmental pollution, and sustainability of healthcare systems in the long run. To overcome these challenges and ensure the therapeutic efficacy and safety of patients, sustainable drug delivery systems (SDDS) have been proposed as a promising strategy. The present review deals with the use of biodegradable and renewable biomaterials such as chitosan, alginate, starch-based polymers, polylactic acid (PLA), cellulose nanofibers, silk fibroin, lignin nanoparticles, and bacterial cellulose for the preparation of green drug delivery systems. The article also discusses sustainable manufacturing techniques such as continuous

manufacturing, green solvents, Process Analytical Technology (PAT), and Quality by Design (QbD) that enhance resource efficiency and minimize waste. It also addresses the role of eco-friendly packaging, life-cycle assessment, waste management, and circular economy principles. Future drivers of sustainable pharmaceutical innovation were discussed including nanomedicine, artificial intelligence, digital twins and personalised medicine. In conclusion, SDDS is a revolutionary approach towards greener, smarter, and patient-centric healthcare.

Keywords: Sustainable Drug Delivery Systems, Green Pharmaceutical Manufacturing, Biodegradable Biomaterials, Nanomedicine, Life-Cycle Assessment (LCA)

1. Introduction

The pharmaceutical industry has been an important part of improving global health through the development of new drugs and advanced drug delivery systems. However, the rising consumption of pharmaceutical products has been accompanied by concerns related to resource consumption, waste generation, environmental contamination, and disposal of pharmaceutical residues. The growing emphasis on sustainable healthcare systems has made environmental considerations increasingly important throughout the pharmaceutical product lifecycle. The modernized therapeutics with improved efficacy, safety, and compliance of patients are achieved by the introduction of advanced drug delivery systems such as nanoparticles, liposomes, microspheres, and targeted delivery systems. Therefore, the development of sustainable pharmaceutical technologies, with a focus on innovation and environmental responsibility, is more relevant than ever (1). The present review discusses sustainable approaches to advanced drug delivery systems across the pharmaceutical product lifecycle, from formulation design and manufacturing to product use, waste management, and disposal.

2. Design of Sustainable Drug Delivery Systems

2.1 Sustainable Biomaterials

The choice of raw materials, excipients, drug carriers and manufacturing processes has a strong impact on the environmental footprint of a drug delivery system for its entire life cycle; therefore, sustainability considerations should be embedded at the earliest stages of pharmaceutical product design. However, contemporary formulation scientists are beginning to explore biodegradable and biocompatible polymers such as chitosan, alginate, gelatin, and polylactic acid (PLA) as alternatives to synthetic materials. These materials can support

effective drug delivery while reducing environmental persistence after disposal because of their biodegradable and, in many cases, renewable nature (2).

2.2 Green Manufacturing Technologies

The integration of sustainability principles into pharmaceutical product design, often referred to as ‘Green by Design,’ aims to minimize material consumption, streamline manufacturing processes, and enhance product stability, thereby reducing waste generation throughout the production cycle. Furthermore, Quality by Design (QbD) approaches aid in sustainability through the optimization of formulation variables and manufacturing parameters in the initial phases. By reducing trial-and-error experimentation, QbD can decrease the consumption of chemicals, solvents, energy, and laboratory resources (3). The most studied sustainable biomaterials for advanced drug delivery systems, their pharmaceutical applications, and environmental benefits are presented in **Table 1**.

Table 1. Sustainable Materials Utilized in Advanced Drug Delivery Systems

Material	Role in Drug Delivery Systems	Sustainability Benefit
Chitosan	Used in nanoparticles, hydrogels, and mucoadhesive formulations	Biodegradable, biocompatible, and derived from natural sources (4)
Alginate	Supports controlled and sustained drug release	Renewable, non-toxic, and environmentally friendly (5)
Gelatin	Used in microspheres, capsules, and drug carriers	Naturally degradable and safe for biomedical applications (6)
Polylactic Acid (PLA)	Applied in implants and nanoparticle formulations	Produced from renewable resources and is readily biodegradable (7)

Sustainable pharmaceutical manufacturing aims to improve process efficiency while reducing energy consumption, material use, waste generation, and environmental impact. Important advances include the use of green solvents and aqueous processing systems as safer alternatives to hazardous organic solvents. Real-time monitoring and process control maintains product quality uniformity and minimises material losses (8).

Techniques such as spray drying, supercritical fluid technology and solvent-free processing are being investigated for nanoparticle production to reduce the environmental impact. These

technologies support the production of quality pharmaceutical products while contributing to the goals of sustainable manufacturing. Additionally, the use of PAT (Process Analytical Technology) allows real-time monitoring of critical process parameters, leading to fewer batch failures and less waste of resources (9). **Figure 1** summarizes the key sustainable materials and technologies used to reduce resource consumption, minimize waste generation, and improve process efficiency. **Table 2** provides a comparative overview of these technologies.

Representative applications demonstrate how sustainable approaches can be incorporated into drug delivery systems. Chitosan has been used in biodegradable nanoparticles and mucoadhesive formulations for mucosal drug delivery, while alginate-based carriers have been investigated for controlled and sustained drug release. Gelatin-based nanoparticles and microspheres provide biodegradable platforms for controlled drug delivery, whereas PLA-based nanoparticles and implants enable sustained drug release followed by degradation of the polymeric matrix (4–6). Microfluidic technologies further support the resource-efficient preparation of nano formulations by reducing material and reagent requirements while enabling precise process control (10).

Table 2. Green manufacturing technologies for sustainable pharmaceutical production Technologies

Technology	Application in Pharmaceutical Manufacturing	Key Advantage
Continuous Manufacturing	Enables uninterrupted production of pharmaceutical products	Reduces waste, energy consumption, and production time (11)
Spray Drying	Produces dry powders and nanoparticulate formulations	Improves process efficiency and minimizes material loss (12)
Supercritical Fluid Technology	Used for particle engineering and drug encapsulation	Reduces dependence on organic solvents (13)
Microfluidics	Facilitates precise preparation of nano formulations	Requires smaller quantities of materials and reagents (10)

Process Analytical Technology (PAT)	Supports real-time monitoring and process control	Prevents batch failures and improves resource efficiency (14)
Solvent Recovery Systems	Reclaims and reuses process solvents	Reduces waste generation and operational costs (15)

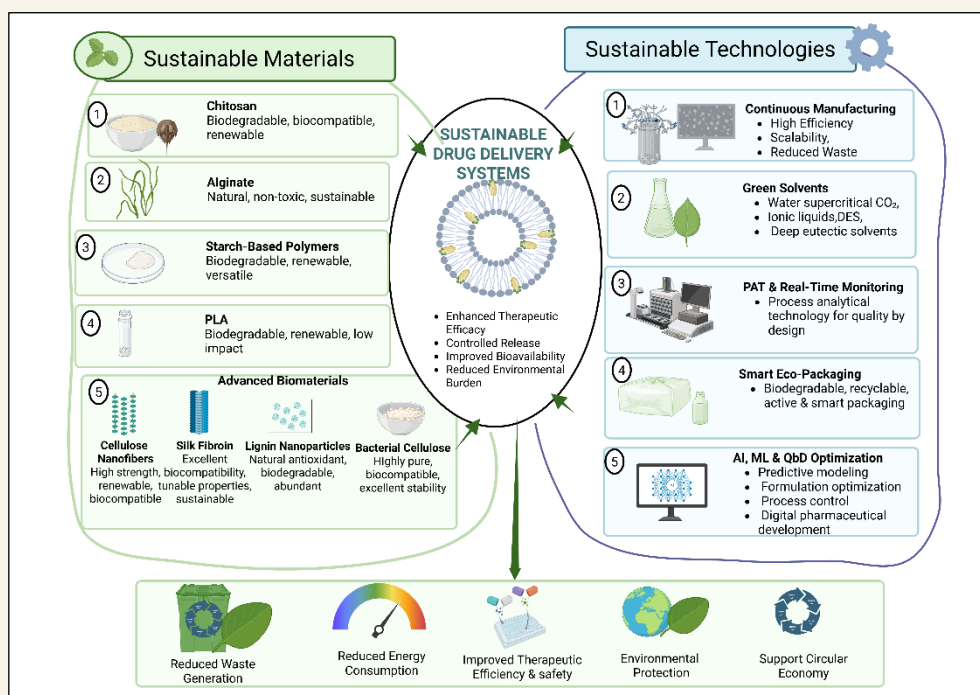


Figure 1. Key enablers of sustainable drug delivery systems: synergistic integration of sustainable biomaterials and innovative technologies.

(**Abbreviations:** PLA, Poly(lactic acid); PAT, Process Analytical Technology; QbD, Quality by Design; AI, Artificial Intelligence; ML, Machine Learning; DES, Deep Eutectic Solvents.)

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2.3 Sustainable Packaging

Packaging is an integral part of pharmaceutical products, providing stability, protection, and patient safety; however, conventional pharmaceutical packaging contributes substantially to plastic waste generation. The latest developments are based on packaging materials which are biodegradable and made from renewable resources. Scientists are searching for green alternatives to conventional plastics. These include plant-based polymers, paper-based composites and recyclable materials. There is also the attention to smart packaging technology.

Features such as temperature indicators, tamper-evident systems and digital tracking improve product management and reduce wastage due to improper storage or expired medicines. Designing sustainable packaging that is recyclable, responsibly sourced and reduces the amount of material can help support the circular economy principles in the pharmaceutical industry (16).

3. Environmental Aspects During the Use Phase

Sustainability of pharmaceutical products is not just the manufacturing process and packaging. Some of the drugs given to patients can enter the environment from excretion and improper disposal practices when patients take the drugs. Pharmaceuticals have been detected in surface waters, groundwaters, and in wastewater treatment systems. Some of these concerns could be solved by advanced drug delivery systems that could improve the drug targeting and reduce the needed doses. Targeted delivery methods improve therapeutic efficiency, minimise off target exposure and reduce environmental release. Research is also being conducted on biodegradable nanocarriers that degrade to non-toxic components after delivering their therapeutic payload (17).

4. Closing the Loop: Disposal and Waste Management

Public awareness programs and drug take-back initiatives can promote safer disposal practices and reduce the environmental release of unused medicines. Nanomaterials and polymeric carriers used in advanced drug delivery systems should be disposed of carefully. To minimise their environmental footprint, pharmaceutical manufacturers are adopting waste-minimization techniques, solvent-recovery systems, recycling procedures, and environmentally responsible disposal practices (18). **Table 3**, Comparison between conventional and sustainable approaches at different lifecycle stages.

Table 3. Moving to Sustainability Across the Pharmaceutical Product Lifecycle

Stage

Stage	Conventional Approach	Sustainable Approach
Product Design	Repeated trial-and-error formulation development	Systematic design using Quality by Design (QbD) principles (19)
Solvent Use	Dependence on organic solvents	Preference for safer and environmentally friendly solvents (20)

Manufacturing	Batch-wise production processes	Continuous and resource-efficient manufacturing (21)
Packaging	Conventional plastic-based materials	Biodegradable and recyclable packaging options (22)
Product Use	Limited focus on environmental impact	Improved targeting and optimized dosing to reduce waste (23)
Disposal	Medicines often discarded with general waste	Safe collection and responsible disposal practices (24)
Waste Management	Linear use-and-discard model	Recycling and circular economy approaches

5. Nanotechnology and the Future of Sustainable Drug Delivery

Nanotechnology is an emerging role of drug delivery towards sustainability. Nanotechnology plays an important role in modern drug delivery in the areas of targeted therapy, improved bioavailability and controlled release of drugs (25). Another emerging field of interest is the use of natural materials such as chitosan, alginate and gelatin in the development of nanocarriers. These methods reduce the need for hazardous solvents and enable cleaner manufacturing processes without sacrificing performance of the formulation. One less obvious way that nanotechnology may contribute to sustainability is in improving the efficiency of the treatment process itself. Targeted and controlled release systems usually lead to better therapeutic effects at lower drug doses and less frequent administrations (26). This can help reduce the total amount of pharmaceutical ingredients used, minimise waste in treatment and potentially reduce the amount of drug residues entering the environment. Another interesting development is the implementation of the Quality by Design (QbD) principles in nanomedicine development. QbD identifies the critical formulation and process variables systematically, thus reducing the unnecessary experimentation and making better use of laboratory resources (27). Meanwhile, breakthroughs in artificial intelligence and computational modelling are aiding researchers in predicting the behaviour of formulations and speeding up development to save time, materials and energy.

6. Limitations and Challenges

Despite their promising advantages, sustainable drug delivery systems face challenges related to the variability of biodegradable materials, the scalability of green manufacturing processes, and high upfront implementation costs. Limited knowledge of the environmental fate and ecotoxicity of nanocarriers, together with the lack of standardized methods for sustainability assessment and regulatory guidance, further limits their widespread adoption. Overcoming these challenges is essential for the successful translation of sustainable drug delivery systems from the laboratory to industrial and clinical applications.

7. Future Outlook: Circular Innovation in the Pharmaceutical Sector

Biodegradable nanocarriers and green manufacturing highlight the industry's commitment to innovation in sustainability.

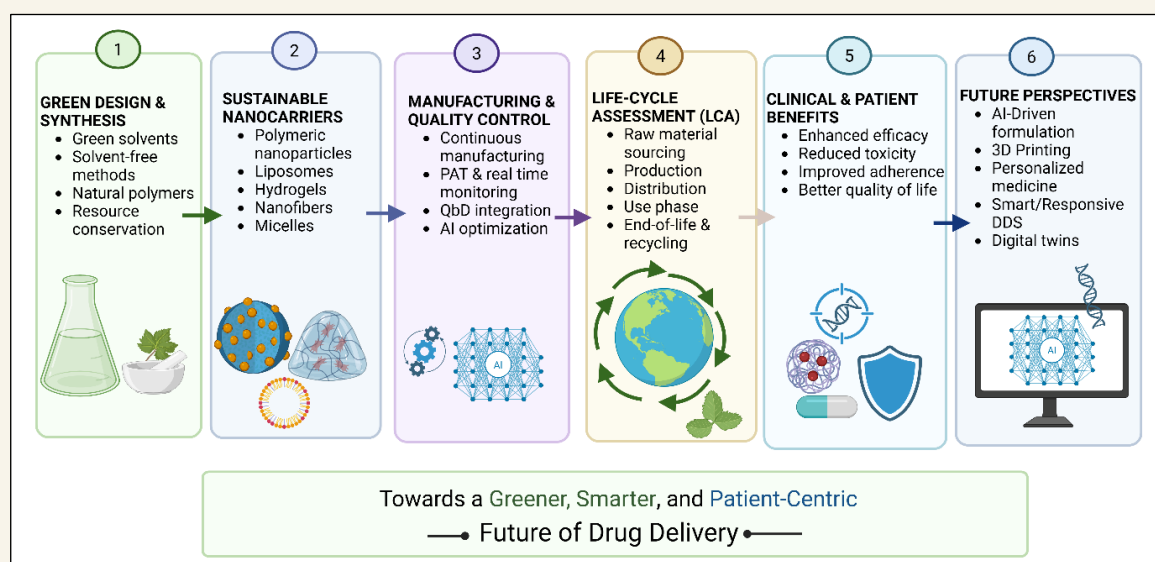


Figure 2. Sustainable drug delivery development pathway: from green design to clinical translation.

(Abbreviations: DDS, Drug Delivery Systems; LCA, Life-Cycle Assessment; PAT, Process Analytical Technology; QbD, Quality by Design; AI, Artificial Intelligence)

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8. Conclusion

In conclusion, sustainable pharmaceutical technologies are revolutionising the future of drug delivery systems. Opportunities exist at every stage of the product lifecycle, from formulation design and manufacturing to packaging and disposal, to reduce the environmental impact while

maintaining therapeutic usefulness. Advanced drug delivery systems, particularly using biodegradable materials and green manufacturing processes, could benefit patients' health and the sustainability of the environment. Lifecycle thinking and sustainable innovation can allow the pharmaceutical community to make a major contribution to global health goals and to protect the environment for future generations.

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Eco-friendly pharmaceutical formulation and production strategies and future perspectives



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Abstract

The pharmaceutical industry plays a vital role in global health; however, its traditional manufacturing workflows carry a massive environmental footprint, characterized by high carbon emissions, volatile solvent waste, and non-biodegradable packaging. This paper reviews the current transition toward "green pharmaceuticals," exploring sustainable advancements across formulation design, manufacturing processes, and future life-cycle perspectives.

In drug formulation, the substitution of petroleum-derived synthetic polymers with bio-based, biodegradable excipients (such as chitosan, alginate, and polylactic acid) significantly mitigates post-consumption environmental toxicity. Furthermore, the adoption of green solvents such as supercritical CO₂ and water, alongside solvent-free technologies like hot-melt extrusion radically reduces the hazardous volatile organic compound (VOC) waste streams typical of traditional processing. Green chemistry principles like biocatalysis and advanced atom economy are streamlining active pharmaceutical ingredient (API) synthesis to reduce the industry's high environmental factor (E-factor). Downstream, the integration of recyclable mono-materials and bio-based blister packaging addresses the challenge of municipal medical waste.

Keywords: Green Pharmaceuticals, Continuous Manufacturing, Biodegradable Excipients, Green Chemistry, Sustainable Packaging, Life-Cycle Assessment (LCA).

1. Introduction

Eco-Friendly Pharmaceutical Formulation: Green Medicine

Traditional pharmaceutical development focuses heavily on safety and efficacy, but often at the cost of high environmental waste. Eco-friendly pharmaceutical formulation (or "green pharmaceuticals") redesigns the actual makeup of a drug to minimize its ecological footprint from production to disposal (1).

1.1 Key Strategies in Green Formulation

Sustainable and Biodegradable Excipients

Excipients are the inactive ingredients (binders, fillers, and coatings) that make up the bulk of a pill or liquid medication.

- The Problem: Many conventional polymers used for controlled drug release are petroleum-based and persist in the environment for decades.
- The Green Solution: Replacing synthetics with natural, renewable biopolymers like chitosan (from crustacean shells), alginate (from seaweed), and cellulose/starch derivatives. These break down naturally without leaving toxic residues in water systems (1).

2. Switching to Green Solvents

Solvents are required to dissolve active ingredients during mixing and coating.

- The Problem: Volatile Organic Compounds (VOCs) like acetone or dichloromethane are highly toxic to handle and pollute the air and soil.
- The Green Solution: Formulators are shifting to benign solvents like water, ethanol, or supercritical carbon dioxide (CO₂), which can be safely recycled within the manufacturing facility (1).

2.1 Solvent-Free Advanced Technologies

The cleanest solvent is no solvent at all. Modern techniques eliminate liquids entirely from the formulation stage:

- Hot-Melt Extrusion (HME): Molecularly blends the active drug with a polymer using heat and mechanical pressure instead of chemical solvents (1).
- Direct Compression: Engineering excipients so they can be pressed directly into tablets without needing wet granulation steps.

3. "Design for Degradation" (DfD)

A significant amount of consumed medicine is excreted by patients and ends up in wastewater, where it can harm aquatic life. Future eco-friendly formulations are designed so that the Active Pharmaceutical Ingredient (API) remains perfectly stable inside the human body but rapidly breaks down into harmless molecules once exposed to natural sunlight or wastewater microbes². The pharmaceutical industry plays a massive role in global health, but it has traditionally carried a heavy ecological footprint. Research indicates that the sector's complex chemical syntheses, intensive energy use, and packaging waste cause its carbon emissions to rival and sometimes surpass those of the automotive sector (2).

Transitioning toward eco-friendly formulation and production is no longer just a regulatory compliance check; it is a critical evolution (2).

4. Eco-Friendly Formulation Strategies

Green formulation shifts the focus from purely synthetic, petroleum-derived components to renewable and naturally degradable materials.

- **Biodegradable Excipients:** Traditional synthetic polymers used to control drug release are increasingly replaced with natural biopolymers like chitosan (derived from crustacean shells), alginate (from brown seaweed), and starch-derived polymers. These offer excellent biocompatibility and break down harmlessly in the environment.
- **Green Solvents:** Volatile Organic Compounds (VOCs) like chloroform or benzene are major pollutants. Modern formulations substitute these with water, ethanol, or supercritical (2).
- **Solvent-Free Technologies:** Techniques like Hot-Melt Extrusion (HME) allow manufacturers to blend active pharmaceutical ingredients (APIs) with excipients physically without using any liquid solvent at all (2).
- **Design for Degradation:** Medications are designed so that any excreted trace elements break down quickly into non-toxic compounds when they enter wastewater systems, mitigating the issue of "pharma pollution" in aquatic ecosystems (2).

5. Sustainable Production Strategies

Greening the manufacturing plant requires a transition from old-school batch processing to lean, high-efficiency systems (3-5).

A. Continuous Manufacturing vs. Traditional Batch Processing

Instead of producing drugs in massive, energy-intensive standalone batches, Continuous Manufacturing integrates production into a seamless, automated flow (3-5).

Table 1. Continuous Manufacturing vs. Traditional Batch Processing

Feature	Traditional Batch Processing	Green Continuous Manufacturing
Footprint & Waste	High raw material waste; massive storage footprint.	Minimal material waste; compact facility size.
Energy Consumption	High (frequent heating, cooling, and equipment cleaning cycles).	Low (steady-state operation maximizes thermal efficiency).
Quality Control	Tested after the batch is finished; failure means discarding tons of product.	Real-time monitoring (Process Analytical Technology - PAT) catches errors instantly.

B. Green Chemistry Principles in API Synthesis

- **Atom Economy:** Syntheses are designed to ensure that the maximum number of starting atoms end up in the final product, leaving minimal hazardous by-products (3-5).

Biocatalysis: Utilizing enzymes as natural catalysts allows complex chemical reactions to occur at lower temperatures and pressures without relying on toxic heavy metal catalysts.

- **Microwave-Assisted Synthesis:** Utilizing localized microwave energy heats the reaction medium uniformly and rapidly, cutting chemical reaction times down from hours to minutes (3-5).

6. Green Packaging Initiatives

Pharmaceutical packaging requires strict barriers to protect drug stability, which historically meant relying heavily on multi-layered plastics and foils that cannot be recycled (6-9).

- **Bio-Based Materials:** Integrating **Polylactic Acid (PLA)** and **Polyhydroxyalkanoates (PHA)** derived from renewable biomass to replace petroleum-based blister packs (6-9).
- **Circular Economy:** Major firms are designing monomaterial packaging (using a single type of plastic or material) to drastically improve the ease of recycling medicine containers (6-9).

7. Future Perspectives

The horizon of sustainable pharmacy relies on a "cradle-to-grave" approach evaluated by strict **Life-Cycle Assessments (LCA)**. Moving forward, the widespread integration of Artificial Intelligence (AI) will likely predict the greenest synthetic pathways before a chemical is even mixed in a lab. Additionally, as global regulatory bodies introduce stricter incentives for carbon-neutral manufacturing, eco-friendly formulation will pivot from an innovative niche into the baseline standard for global medicine production (6-9).

Building out a robust **Future Perspectives** section for an academic paper, presentation, or review requires looking at the convergence of technology, stricter global regulations, and holistic environmental metrics (10-13).

7.1 The Next Frontier of Green Pharmaceuticals

The transition toward eco-friendly pharmaceutical formulation and production is evolving from a voluntary corporate social responsibility (CSR) initiative into a strictly regulated operational mandate. As the industry looks toward the next decade, several paradigm shifts will define the future of sustainable medicine (10-13).

8. Integration of Artificial Intelligence (AI) and Machine Learning

AI is poised to revolutionize green chemistry by eliminating the resource-heavy "trial and error" phase of drug development.

- **Predictive Yield and E-Factor Modelling:** AI algorithms will evaluate thousands of potential synthetic pathways for a new drug molecule, pre-selecting the routes that maximize atom economy and minimize the environmental factor (E-factor) before a single chemical is mixed in a lab (10-13).
- **Smart Formulation Design:** Machine learning models will predict the stability and bio-accessibility of novel, biodegradable excipients (like tailored starch or algae derivatives), accelerating the replacement of petroleum-based synthetic polymers (10-13).

9. Digital Twins and Cyber-Physical Systems

The future of sustainable production lies in the digitalization of the factory floor.

- **Process Optimization:** By creating a "Digital Twin" (a virtual replica) of a continuous manufacturing line, engineers can simulate and optimize energy consumption, solvent recycling loops, and heat recovery systems in real-time (10-13).

- **Zero-Waste Quality Control:** Advanced Process Analytical Technology (PAT) combined with AI will enable predictive maintenance and instant flaw detection, reducing waste from rejected batches to virtually zero (14-16).

10. Cradle-to-Grave Life-Cycle Assessments (LCA)

Historically, pharmaceutical footprints were measured purely by production emissions. The future will mandate holistic, standardized **Life-Cycle Assessments (LCAs)**.

- **Eco-Labeling for Medicines:** Similar to energy ratings on appliances, future pharmaceuticals may carry eco-scores reflecting their total carbon footprint, ecotoxicity, and biodegradability (14-16).
- **Design for Degradation (DfD):** Future drug design will intentionally program the metabolic path of a drug. Active Pharmaceutical Ingredients (APIs) will be engineered to remain stable and potent inside the human body, but rapidly degrade into benign compounds once excreted and exposed to wastewater treatment conditions, solving the growing global crisis of aquatic pharma-pollution (14-16).

11. Regulatory Frameworks and "Green Incentives"

Regulatory bodies like the FDA (United States) and EMA (Europe) are shifting from passive encouragement to active enforcement (14-16).

- **Fast-Track Approvals:** Regulatory agencies are expected to introduce "green lanes," offering expedited review times for drugs manufactured using certified sustainable processes or continuous manufacturing setups (14-16).
- **Strict Effluent Limits:** Stricter global thresholds on antimicrobial and hormonal residues in factory wastewater will force manufacturing plants to adopt advanced oxidation processes and decentralized, on-site water purification technologies (14-16).

12. Decentralized and On-Demand Manufacturing

The standard model of massive, centralized manufacturing plants shipping products across global supply chains is inherently carbon-intensive.

- **3D-Printed Pharmaceuticals:** Point-of-care 3D printing of personalized medications at local hospitals or pharmacies will significantly reduce overproduction, lower inventory waste, eliminate complex cold-chain logistics, and reduce localized packaging demands (17-20).

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WORD SCRAMBLE

Unscramble these Sustainable packaging trends:

1. LNOO-MAETRIAL
2. GTDIIL KPCAGNAGI
3. DIOEBGARDABELE
4. DLOSE-COLPO YICRCLNEG
5. TANICOUNOUS MNAUFACTURING
6. SLVNOTE RECOVERY
7. OCOTAPMSBLE
8. LEFLLIBARE
9. ERZO EATWS
10. LEDCYCRE CNTTONE
11. BRNOAC OOFPRTTNI



REINVENTING PHARMACEUTICAL MANUFACTURING

Sustainability of single use technology in the manufacturing of biologics



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Abstract

The biopharmaceutical industries are dominated by stainless steel systems for the commercial manufacturing of biologics and biosimilars due to its proven reliability and scalability. The integration of Single use systems was retarded due to concerns over extractability, leachability, scale up and operational equivalence. However, the Single use systems have gathered momentum in biopharma industries by offering pre-sterilized, disposable, and aseptic components which can further reduce cost, cross contamination risk, increased production, and shorter turnover times. These benefits have gained widespread adoption of these technologies in upstream and downstream bioprocessing, from vaccine research to monoclonal antibody development.

Keywords: Single Use Technology, sustainability, biologics, biosimilars, biopharmaceuticals, , stainless steel, flexibility.

1. Introduction

Single Use Technologies (SUT) also known as Single Use System (SUS) are disposable bioprocessing components such as filter, tubing, connectors, clamps, bags, buffer containers, and bioreactors. (1)

Biologics are medicines whose active drug substance is produced by a living organism using techniques like recombinant DNA technology with regulated gene expression. (2) Over past two decades, SUS have revolutionized manufacturing of biologics and gained momentum in biopharmaceutical industries. Particularly in the manufacturing of modern modalities such as monoclonal antibodies, viral vectors, vaccines, gene therapies and mRNA therapeutics. Compared to the traditional approach which rely on stainless steel equipment and bioreactors, is expensive and demands high maintenance for re-use. The primary disadvantages of traditional manufacturing are the limited level of flexibility, which requires separate facilities for each manufacturing step or drug product, as well as the high time and man power in preparing equipment for readiness. Requalification of the reused bioprocessing equipment comes after resource-intensive clean-in-place (CIP) and sterilize-in-place (SIP) operations, which take a lot of time and tie up important operational resources. (1,3)

2. Advantages:

Modern SUT promises reduced cost, lowers risk of cross contamination and increased productivity and improves quality products. Therefore, these benefits have led them widespread adoption in biopharmaceutical industries. (4)

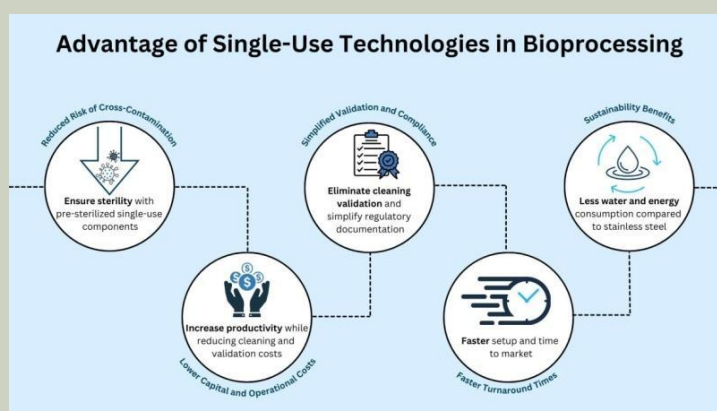


Figure 1. Advantage of Single Use Technology (6)

- (i) **Cross-contamination risk minimized:** One of the major issues in the manufacturing of biologics is cross contamination between batches and products. (5) The conventional system involves rigorous cleaning and sterilization between batches, creating possibilities of contamination. Single use systems eliminate this concern by offering pre-sterilized and disposable components preventing product carry over and microbial contamination. (6)
- (ii) **Cost reduction:** Traditional bioprocessing facilities require expensive stainless-steel infrastructure along with extensive cleaning and maintenance. Implementing SUS significantly reduce costs and resources for complex production stages like cleaning (CIP) and sterilization (SIP). (5) Capital and operational expenditure like direct labor costs for installation as well as costs for water and cleaning chemicals can be minimized. Furthermore, the facilities do not require cleaning and sterilization, which in turn accelerates batches turnovers resulting in overall productivity and lowering operational cost. (7)
- (iii) **Simplified Validation and Compliance:** Regulatory compliance is an essential requirement in biopharmaceutical manufacturing. (7) In order to meet current Good Manufacturing Practices (cGMP) conventional stainless-steel system need extensive cleaning validation, detailed documentation, and repeated testing. In contrast, a single-use system reduces validation requirements and simplifies regulatory compliance. Furthermore, materials used in single-use equipment follows very high regulation standards with different kinds of certificates and studies, for example, extractables and leachable studies, certificates, including BSE, TSE, Bis-Phenol-A, phthalates and melamine etc. These systems support consistent product quality while meeting the requirements of regulatory authorities and standards such as the FDA, USP, and ISO. (6)
- (iv) **Faster turnover times:** The requirement for thorough cleaning and sterilization of stainless-steel systems is essential for producing contamination-free products, leading to increased expenses for manufacturers. (6) Conversely, single-use systems, which are pre-sterilized and disposable, remove the need for lengthy turnaround processes and help to

reduce production delays. As a result, the adoption of single-use technology boosts productivity and decreases both costs and process complexity. (5)

- (v) **Sustainability benefits:** SUS significantly reduce the consumption of energy, water, and media. (7) Traditional stainless-steel systems requires large amount of energy to heat and sterilize equipment during manufacturing and rely heavily on utilities like purified water, water for injection (WFI), compressed air and steam etc. (3)

On the other hand, single-use assemblies have been demonstrated to significantly decrease media consumption and reduction in water usage when compared to plants utilizing steel equipment. (8) Overall, the average decrease in the carbon footprint which encompasses reductions in water, energy, chemicals, and more was found in comparison to stainless steel. (5,7)

In terms of sustainability, SUS offers more advantages at the end of their lifecycle. Most SUS are manufactured from high grade polymers that can be recycled into other plastics or alternatively be incinerated to release their stored chemical energy for electricity or heat generation. These features enhance resource efficiency and support more sustainable manufacturing practices while maintaining operational flexibility. (8)

3. Challenges and solution

Despite their benefits, SUS also pose environmental challenges, especially concerning plastic waste management. Large amounts of plastic waste are produced by laboratories and bioprocessing facilities, primarily from single-use products like tubes, petri dishes, and disposable culture vessels, which are usually made of petroleum-based polymers like polystyrene. (8)

Another method of waste management is incineration, which results in the release of carbon dioxide that had been sequestered underground in fossil fuels, thus contributing to climate change. To mitigate this problem, the industry is increasingly pursuing sustainable alternatives. One viable solution is the adoption of biodegradable materials, including polylactic acid (PLA), a renewable polymer obtained from plant sources such as corn starch. Although its use in bioprocessing is still in its infancy, PLA significantly reduces environmental impact relative to petroleum-derived plastics. (9)

The adoption of circular economy principles, including the recycling and repurposing of single-use components, has the potential to greatly mitigate the adverse environmental effects linked to SUT.(10) Studies suggest that single use bioreactors lead to a significant reduction in water and energy consumption in facilities when compared to stainless steel bioreactors.(11)Nonetheless, the disposal of SUS raises critical concerns regarding waste generation and potential environmental impacts.(12) Life cycle assessments evaluating single use bioreactors and stainless steel bioreactors have revealed that the environmental impacts of both systems are largely dependent on manufacturing conditions and disposal practices.(13,14)Furthermore, substantial progress is being achieved in enhancing the sustainability of SUT, addressing factors from materials to packaging, as well as regional manufacturing and distribution.(15)

4. Conclusion

Despite the ongoing concerns regarding plastic waste and the disposal of products at the end of their lifecycle, single-use systems provide a persuasive argument for adopting more flexible and sustainable manufacturing methods when considered in a holistic context, which includes energy requirements, carbon footprints, and water consumption. This review suggests that the sustainability profile of contemporary biopharmaceutical production could be significantly enhanced without compromising quality or scalability by effectively integrating single-use technologies with advancements in recyclable materials and waste management.

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Beyond waste reduction: Solvent recovery and circular manufacturing in the pharmaceutical industry



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Abstract

Organic solvents are commonly used in pharmaceutical manufacturing. The extensive use of organic solvents generates hazardous waste, volatile organic compound emissions, increased energy consumption, and an environmental burden. Solvent recovery and recycling are increasingly adopted key strategies to transition from linear to circular solvent use. The purpose of this article is to emphasize the importance of solvent recovery, purification and reuse in the sustainability of pharmaceutical processes. It addresses the working principles and industrial relevance of distillation, membrane-based separation, adsorption, and hybrid recovery systems, as well as green design approaches such as solvent selection, digital process monitoring, Industry 4.0 integration, and artificial intelligence. Solvent recycling reduces raw material consumption, waste-treatment costs, and greenhouse gas emissions, supporting ESG objectives and the circular economy. Despite these benefits, capital expenses, regulatory compliance, and solvent validation remain issues. Pharmaceutical solvent recovery promotes resource conservation, environmental responsibility, and industrial sustainability.

Keywords: Solvent recovery; Green chemistry; Sustainable technology; Solvent recycling

1. Introduction

While the industry has an important role in improving global health, its manufacturing processes can have significant environmental implications. Organic solvents are a major source of waste generation in the industry representing a significant amount of material consumption and waste generation (1). Solvents are extensively used in processes such as synthesis, purification, extraction, crystallisation and formulation. They have to manufacture good quality medicines.

However, the overuse of them increases the production cost, waste generation, resource depletion, and greenhouse gas emission (2). Historically, traditional approaches to solvent management have focused on the safe and compliant disposal of solvents. However, with the growing concern for environmental issues, strict sustainability targets and the emergence of environmentally friendly manufacturing processes, the focus has shifted to the recovery and recycling of solvents (3).

Today, the industry is moving from waste reduction to a circular manufacturing model where solvents are recovered, refined, reused and cycled through production processes in perpetuity. This transition is intimately linked to the discipline's consideration of sustainable technology, from design to disposal. (4)

2. The challenges of Solvents in Pharmaceutical Manufacturing

In the manufacture of medicines, solvents can constitute a large proportion of the overall mass – around 80-90%. Methanol, ethanol, acetone, acetonitrile, Isopropanol, dichloromethane, and ethyl acetate are common solvents. Large-scale production of active substances often includes a great number of steps that require substantial amounts of solvent (4).

Environmental hazards related to solvent use include:

- High energy consumption in production and disposal
- Volatile Organic Compound (VOC) Emissions
- Generation of hazardous waste streams
- Increase of carbon footprint of pharmaceuticals
- Occupational and environmental health risks



Figure 1. Circular approach to solvent recovery and reuse in the pharma industry

Efficient solvent management is a major sustainability focus as pharma companies strive to achieve their Environmental, Social and Governance (ESG) goals (1).

2.1 Linear to Circular production

The traditional pharmaceutical manufacturing process is linear, following the pattern of acquisition, use, and disposal. This linear pattern leads to the continuous depletion of resources and the generation of waste (5). On the contrary, the circular manufacturing follows a closed-loop approach of selection, use, recovery, purification, reuse, and ultimate disposal. This framework encourages the recycle and reuse of solvents and other materials in the process before they are disposed of. This minimises the waste and maximises the use of resources in the product life cycle. That's why circular manufacturing is more sustainable, because it reduces the use of raw materials, emissions and total production costs (4).

3. Solvent Recovery Technologies

Distillation

Distillation remains one of the most widely employed technique for solvent recovery in the industry. It distinguishes solvents according to differences in their boiling points. It facilitates the retrieval of solvents with exceptional purity for subsequent utilization.(5)

Advantages

- High recuperation rate.
- Industrial scalability proven.
- Cost effectiveness in big scale activities.

Modern energy-efficient distillation systems have significantly reduced energy requirements compared with traditional designs (6).

3.1 Membrane separation

Membrane technologies are emerging as green alternatives for solvent purification. These systems have many important features such as low energy consumption, low operational cost, high chemical efficiency and continuous operation. They are particularly appealing to production facilities seeking more sustainable manufacturing methods (7).

3.2 Adsorption Technology

Activated charcoal and special adsorbent materials can trap solvent vapours from exhaust streams for recovery and reuse. This technique has many advantages such as reduced VOC emissions, safer work environment and better compliance to environmental regulations. (1)

3.3 Hybrid Recovery Systems

Often combining different restorative approaches leads to greater effectiveness. For example, the combination of distillation with membrane separation can improve the purity of solvents, as well as lower energy consumption (5).

3.4 Green-by-Design Solvent Choice

Our sustainability promise begins before we make something. The solvent choice has a major role in determining the environmental impacts of the development process. Techniques oriented towards sustainability emphasize the use of solvents that are less toxic, readily decomposable, renewable, when possible, easy to recover, and energy-efficient for recycling. Ethanol, ethyl acetate and aqueous solutions are the preferred solvents where feasible. Focusing on process design and the possibility for recovery to realize intrinsically sustainable production systems (1).

4. Economic Advantages of Recycling Solvents

Although sustainability efforts primarily focus on environmental protection, the recovery of solvents also provides considerable economic advantages. (7) Substantial cost savings can be realised by using reclaimed solvents due to reduced raw material purchase costs, reduced waste treatment costs, reduced hazardous waste disposal costs and reduced regulatory compliance costs. Many facilities in the industry achieve a quick return on their investment in implementing solvent recovery systems. In a world that is becoming increasingly competitive, the pursuit of sustainability and profitability is becoming a symbiotic, rather than a conflicting, relationship. (8)

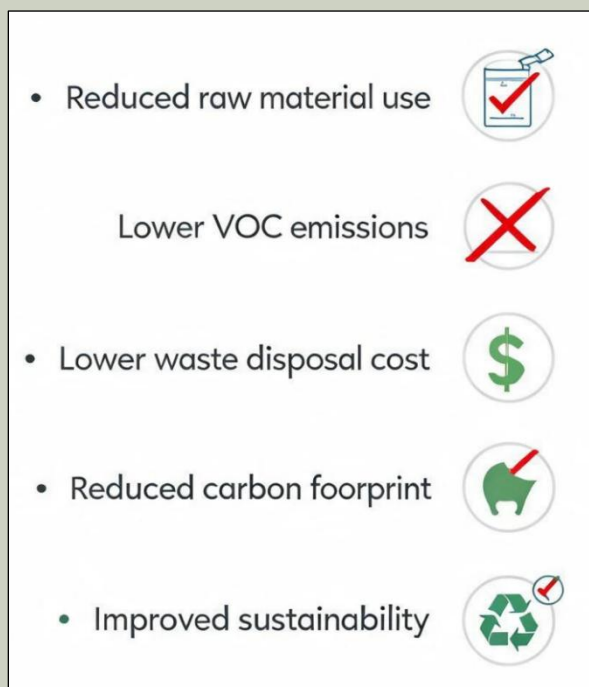


Figure 3. Environmental and economic benefits of solvent recycling

4.1 Solvent Recovery & Carbon Footprint Reduction

The pharmaceutical industry is under increasing pressure to decrease greenhouse gas emissions. Solvent recovery helps to reduce carbon through reduction of the need to produce virgin solvent, decrease in the need for transportation, reduction in volume of trash incinerated and reduction in the need for energy intensive disposal operations (9). Life cycle assessments indicate that recycled solvents typically have far fewer environmental implications than those created from scratch. Consequently, solvent recovery has become a key method in pharmaceutical decarbonisation (2).

4.2 Digitalization and intelligent manufacturing

The future of sustainable solvent management is in Industry 4.0 technologies. Sophisticated systems today can monitor processes in real time, optimize with artificial intelligence, predict maintenance needs, use digital twins, and automatically control recovery. These solutions are more efficient in recovery, use less energy and help to make decisions on sustainability based on data. Solvent recovery is integrated into pharmaceutical manufacturing within smart manufacturing, rather than as a standalone waste management process (10).

5. Challenges and Future Directions

These comprise the large upfront capital cost, the reduced recovery of complex solvent mixtures, the requirement to validate the recycled solvents and the regulatory aspects of reuse in GMP environments (6). Trends expected in the future will be energy-efficient recovery technologies, renewable bio-based solvents, integration with continuous manufacturing, AI-assisted solvent optimization, and the circular economy frameworks in pharmaceutical supply chains. These developments will further increase the importance of solvent recovery in sustainable pharmaceutical manufacturing (11).

6. Summary & Conclusion

Pharmaceutical sustainability is far more than the usual waste reduction efforts. Recycling and recovery of solvents are becoming important aspects of circular pharmaceutical manufacturing, since solvents are increasingly seen not as consumable materials, but as valuable resources that should be efficiently recovered and reused. Pharmaceutical producers may mitigate the environmental impact, reduce resource consumption, and improve operational efficiency by implementing modern recovery technologies, cleaner solvent alternatives, digital process monitoring, and circular economy principles. As the industry moves towards sustainable manufacturing processes, solvent recovery should be seen not just as a waste management technique but as a fundamental pillar of green pharmaceutical technology.(12)

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Eco-architecting the drug lifecycle: Green engineering and circular design in modern pharmaceuticals



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Abstract

The pharmaceutical business is under unprecedented pressure to reduce its environmental impact while upholding strict requirements for product efficacy, safety, and quality. This article traces the lifecycle of a drug product from green molecule design through eco-friendly manufacturing and packaging to responsible disposal, examining the paradigm change toward sustainable pharmaceutical technologies. The industry may move toward a net-zero future by incorporating Green Chemistry concepts, cutting-edge engineering like continuous manufacturing, biodegradable packaging materials, and circular economy waste management techniques.

Keywords: Sustainable Pharmaceutical Technology, Green Chemistry, Continuous Manufacturing

1. Introduction

Although the global pharmaceutical industry is vital to human healthcare, its waste streams and manufacturing supply chains greatly worsen environmental conditions. Conventional batch manufacturing methods use a lot of resources and frequently produce large amounts of toxic organic waste, high carbon emissions, and packaging materials that are not biodegradable. Additionally, an increasing ecotoxicological hazard is posed by the ongoing introduction of Active Pharmaceutical Ingredients (APIs) into aquatic ecosystems through production effluents and inappropriate disposal, which is accelerated by the increase of Antimicrobial Resistance (AMR) (1).

The idea of "Sustainability by Design" (SbD) (Figure 1) has arisen as a guiding framework to solve these issues. From the very beginning of medication development to the final phases of patient use and disposal, this method requires that the effects on the environment, human health, and safety be assessed alongside therapeutic efficacy. Three main pillars must be

completely transformed in order to achieve sustainable pharmacy: green synthesis, eco-efficient manufacturing technologies, and circular packaging solutions.

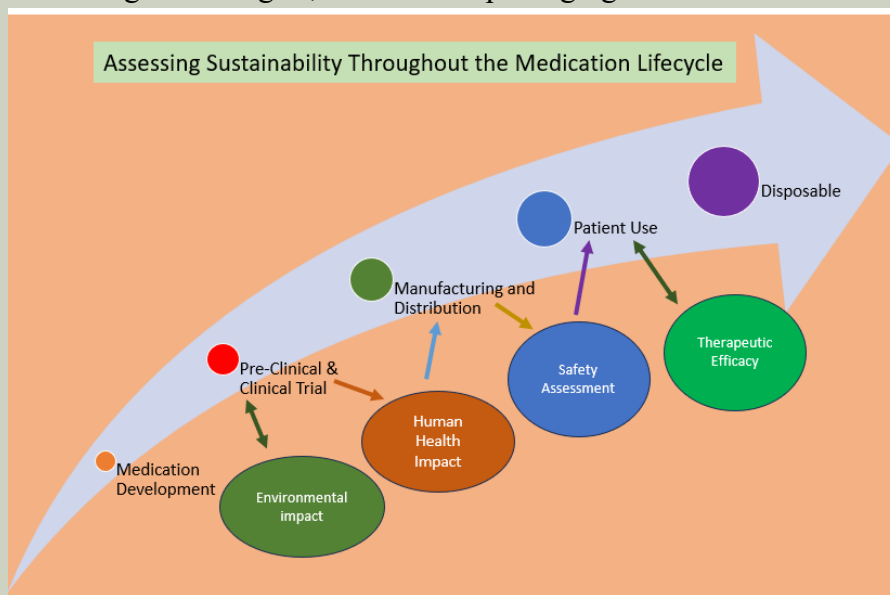


Figure 1. Sustainability by Design approach in drug lifecycle

2. Green Chemistry and Sustainable Process Design

The pursuit of sustainable pharmaceutical technology commences at the molecular level. Historically, the synthesis of intricate active pharmaceutical ingredients has depended on multi-step organic processes employing toxic solvents, heavy metal catalysts, and energy-intensive heat conditions. The concept of Green Chemistry formulated by Anastas and Warner, has been introduced in order to minimize the environmental impact (2, 3).

The Environmental Factor (E-factor), which quantify the waste produced per kilogram of intended output, is very important indicator employed to assess efficiency (4). A value closer to zero (E-Factor ~ 0) indicates less waste generation and a more sustainable and greener process (5). Traditional pharmaceutical manufacturing often has E-factors ranging from 25 to 100, indicating a significant waste imbalance, whereas oil refining has an E-factor near zero (6). Modern technologies based on sustainability focuses to lower this ratio through several approaches:

- **Biocatalysis and Enzyme Engineering**

Substituting highly precise, designed enzymes for dangerous heavy metal catalysts like palladium or platinum is preferred so that reactions could occur at mild, ambient settings in aqueous environments. Energy use and hazardous secondary waste production are significantly reduced as a result (7).

- **Solvent Selection and Recovery**

Economical recycling strategies can be improved by effective solvent selection and recovery. Volatile Organic Compounds (VOCs) used in typical batch processes generally comprise 80% of the non-API mass. Sustainable manufacturing is possible by prioritizing bio-derived or "green" solvents (e.g., ethyl lactate, 2-methyltetrahydrofuran) and implementing closed-loop solvent recovery systems to recycle media directly back into the production cycle (8).

3. Advanced Manufacturing Technologies

Transformation from conventional batch processing to advanced engineering paradigms is a cornerstone of industrial sustainability.

3.1 Continuous Manufacturing (CM)

Continuous Manufacturing (CM) signifies a significant shift away from conventional batch processing methods. Within a CM configuration, raw materials are consistently introduced into a cohesive system that carries out synthesis, purification, blending, and tableting in one seamless, ongoing process (9).

The sustainability advantages of CM over batch processing are extensive, as detailed in Table 1.

Table 1. Comparative Sustainability Matrix of Batch vs. Continuous Manufacturing.

Parameter	Traditional Batch Manufacturing	Continuous Manufacturing (CM)	Sustainability Impact
Equipment Footprint	Large facilities, massive holding tanks	Compact, integrated modular units	Up to 70% reduction in facility footprint, lowering HVAC energy loads.
Material Waste	High; entire batches discarded if deviations occur	Minimal; out-of-specification material rejected instantly	Significant reduction in raw material consumption and scrap waste.
Solvent/Water Use	Extensive cleaning validation between batches	Long production runs minimize cleaning frequency	Lower water-for-injection (WFI) usage and reduced chemical detergent waste.

3.2 Process Analytical Technology (PAT)

Utilizing Process Analytical Technology (PAT) tools, like Near-Infrared (NIR) and Raman spectroscopy, enables ongoing, non-intrusive monitoring of critical quality attributes during manufacturing. The capability of PAT to identify process deviations aids in preventing the creation of defective sub-batches, thereby minimizing the considerable energy and material waste associated with reprocessing or discarding unsuccessful batches (10). Below are given some of the examples:

- **Moisture and Particle Growth (NIR):** Simultaneous determination of some characteristics like moisture content, bulk density, and particle size distribution in fluidized bed granulators using multi-wavelength/diffuse reflectance sensors through glass sight windows.
- **Polymer-Drug Interactions (Raman):** Using die-mounted contact probes, in-line monitoring of continuous hot-melt extrusion (HME) is used to measure API concentration and distinguish between solid solutions and solid dispersions using Raman peak shifts and band broadening.
- **Active Coating Quantitation (Raman):** Using non-contact optics shielded by pressured air purges, in-line tracking of API deposition and process endpoint determination during active pan coating is done.

4. Eco-Friendly Packaging Technologies

Every product has its shelf life. To ensure the safety of a product during its shelf-life period is possible only if we protect it appropriately with proper packaging. The pharmaceutical product might degrade under a number of unfavourable conditions like oxygen, light, moisture etc. To address this, multi-layer plastic blister packs laminated with polyvinyl chloride (PVC) and aluminium foil remain common in practice. These composite materials are hard to recycle, so they are mainly disposed of in landfills or incinerated.

4.1 Bio-Based and Biodegradable Polymers

Innovations in material science have recently introduced sustainable options that align with strict regulatory standards.:

- **Polylactic Acid (PLA):** PLA is a plant-based polyester obtained from renewable agricultural resources like sugarcane and corn starch. It is produced by fermenting plant starches into lactic acid and then polymerised into raw plastic resin. It is often used for non-sterile device components and secondary packaging to rely minimally on polymers originating from fossil fuels (11).
- **Polyhydroxyalkanoates (PHAs):** These biodegradable polymers are fermented microbially and have proven to be superior moisture barriers which are completely biodegradable in soil and marine settings. At the industrial level these polymers have been widely used for making water resistance surface over paper and cardboard, food packaging, and plastic beverage bottles (12).

4.2 Mono-Material Blister Packs

To overcome the recycling limitations of composite blisters, the industry is shifting towards designs that use a single material. There are more sustainable alternatives to conventional pharmaceutical packaging, like the utilization of waterproof paper enhanced with nanoclay and starch and a modified PVC alternative to costly PVDC. With sustainability as a key factor, the entire blister pack is structured to be recyclable within standard household recycling systems. This has been made possible by using mono-materials such as high-density polyethylene (HDPE) or polypropylene (PP), which have been enhanced with particular barrier coatings, thus removing the necessity to mechanically separate the foil from the plastic (13).

5. End-of-Life Management: From Facility to Disposal

A truly sustainable pharmaceutical lifecycle must address the fate of chemical compounds and packaging materials after they leave the manufacturing floor.

5.1 Mitigation of Active Pharmaceutical Ingredients in the Environment (PIE)

The contamination of waterways by APIs via discharge from pharmaceutical manufacturing and patient excretion is an evolving global crisis. Actions have been taken like destruction of active metabolites at the manufacturing site before discharge, to lower the risk caused by discharge:

- **Advanced Oxidation Processes (AOPs):** AOPs serve as an efficient treatment strategy where other standard biological and physical treatments fail because of low pollutant biodegradability. Chemical and irradiation-driven techniques—such as ozonation, photo-Fenton reactions, radical-based UV systems, electrochemical oxidation, and

sonolysis produce reactive oxidative radicals through decomposition of ozone, iron-peroxide reactions, oxidant activation, and sonic cavitation (14).

- **Membrane Bioreactors (MBRs):** Biological degradation of organic matter is integrated with membrane filtration (microfiltration/ultrafiltration) more efficiently than traditional wastewater treatment facilities. MBR systems reinforce the growth of specialized, slow-growing, and dispersed bacteria along with standard floc-forming microorganisms. This process plays a significant role in Enhanced Contaminant Elimination (Pravastatin, mefenamic acid, indomethacin, diclofenac, achieving higher biodegradation rates in the aqueous phase), Superior Effluent Quality (lower chemical oxygen demand, lower biological oxygen demand, and effective ammonia removal), and Reduced Sludge Contamination & Cost (15).

5.2 Extended Producer Responsibility (EPR) and Circular Economy

Pharmaceutical businesses are embracing Extended Producer Responsibility (EPR) with a target to minimize waste at the patient level. Instead of being drained down the toilet or dumped in municipal landfills, these architectures create institutional take-back programs that assures that untapped or expired medications are assembled and burned in high-temperature, clean-emissions facilities with high energy recovery systems (16, 17).

6. Conclusion

From molecular design to end-of-life disposal, the shift to sustainable pharmaceutical technologies necessitates an integrated commitment. The pharmaceutical sector can attain ecological neutrality without sacrificing patient safety by implementing Green Chemistry, switching to continuous manufacturing paradigms, developing mono-material packaging, and protecting waste streams from environmental leakage. Adopting this cutting-edge technology is now an ethical requirement to safeguard the environment and public health worldwide, rather than just a way to comply with regulations.

Transitioning from molecular design to end of life, environmental sustainability requires a systemic lifecycle shift guided by the "Sustainability by Design" (SbD) structure, aligning product efficacy and safety with ecological responsibility. Accomplishing this balance depends on integrating green chemistry—like biocatalysis and renewable solvents to lower high E-factors—with continuous manufacturing and Process Analytical Technology (PAT) to reduce energy, water, and material waste. Concurrently, switching to recyclable mono-materials and bio-based polymers eradicates downstream packaging burdens, while advanced effluent treatments (AOPs and MBRs) alongside Extended Producer Responsibility (EPR) approaches prevent aquatic contamination. Ultimately, realizing a net-zero pharmaceutical sector necessitates multi-stakeholder collaboration across chemistry, regulation and engineering, ensuring that safeguarding human health does not challenge environmental integrity.

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Closing-the-loop in pharma: How green chemistry, continuous manufacturing, and mono-materials are shaping tomorrow



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Abstract

The pharmaceutical industry heals millions, yet before single tablet reaches patient, its production and packaging operations silently consume vast reserves of energy, water, and raw materials, leaving behind carbon and plastic footprints that demand urgent, systemic reform. This article summarizes journey towards sustainable pharmaceutical technologies, from green chemistry in synthesis of APIs to lifecycle assessment (LCA)-guided manufacturing & packaging design to circular end-of-life management. It covers continuous-manufacturing, process analytical technology (PAT) & green solvents as waste-reducing manufacturing methods, mono-material, biodegradable & smart packaging innovations that are changing primary & secondary packaging. 3R framework, extended producer responsibility (EPR), & zero liquid discharge (ZLD) are discussed, focusing on regulatory developments in India. New digital technologies, like Artificial intelligence (AI) & digital twins, are identified as enablers to achieve greener operations. The article concludes that sustainability isn't an option but a scientific & professional necessity when designing products & systems from outset to their end-of-life.

Keywords: Green Chemistry; Sustainable Manufacturing; Pharmaceutical Packaging; Lifecycle Assessment; Circular Economy; Pharmaceutical Waste Management

1. Introduction

The processes used to make & package medicines are resource-intensive, & modern health care relies on uninterrupted access to safe, effective medicines. Carbon footprint of healthcare systems is estimated around 3-8% of total, while medicine alone can make up between 20-25% of healthcare carbon footprint, depending on prescribing patterns & packaging choices (1). In this footprint, energy, water & organic solvents are significant inputs to pharmaceutical manufacturing, & packaging, which is used to ensure product safety & integrity, has traditionally been made from multilayer plastics & laminates that are difficult to recycle.

Change is being driven by regulation. EU's Packaging & Packaging Waste Regulation, among others, stipulates all packaging for medicinal products must be fully recyclable within 10 years, & several multinational manufacturers have made commitments to recyclable packaging that are also time-bound (2,3). Sustainability is no longer a downstream “green” add-on for pharmaceutical profession but must be designed in from the molecule up, with environmental performance being considered alongside efficacy, safety & cost at every development milestone. This article follows that journey, from API synthesis & manufacturing to packaging & finally to disposal, focusing on technologies & the regulatory environment that influences practice in India.

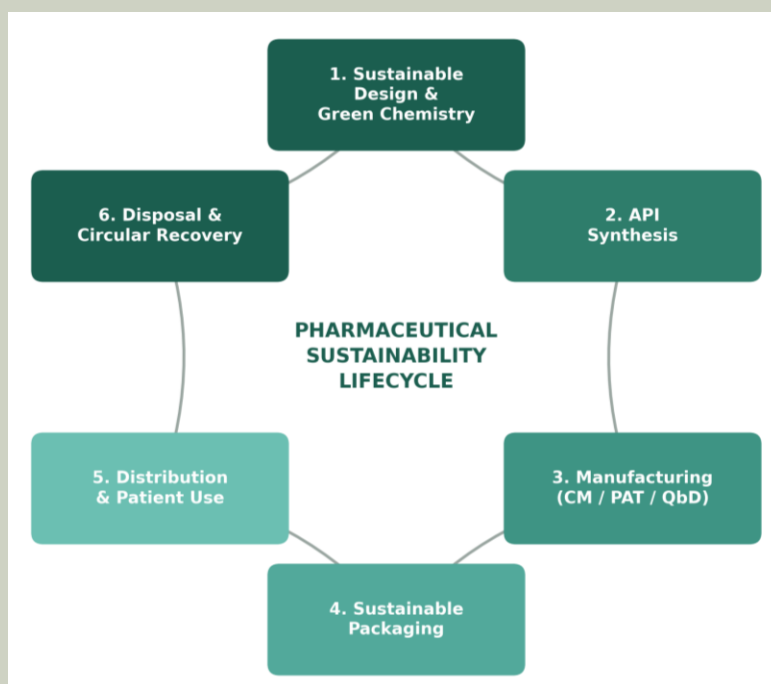


Figure 1: Pharmaceutical sustainability lifecycle

2. Green Chemistry & Sustainable API Synthesis

Multistep synthesis routes are frequently the most resource & waste-consuming step in manufacture of drugs, as significant number of hazardous by-products are formed (4). 12 principles of green chemistry are all about modifying synthetic routes, such as **Boots' 1960s** ibuprofen synthesis used stoichiometric aluminum chloride and zinc, producing 6 pounds of toxic waste per pound of drug; while **BASF's 1990s** catalytic route used recyclable palladium and solid acid catalysts, eliminating millions of pounds of waste annually. Common strategies include the use of renewable biomass feedstocks to decrease dependency on fossil carbon, replacement of toxic solvents with less hazardous solvents such as water & supercritical CO₂, & biocatalysis(5). Compared to batch synthesis, continuous flow chemistry enables more precise control of temperature, pressure & residence time, which leads to higher yields, selectivity, lower solvent & energy use & is already used at scale in APIs such as celecoxib, valsartan & mesalamine (6). These routes are increasingly gaining acceptance by regulatory agencies such as US FDA & EMA for

their contribution to process robustness & product consistency, & this is slowly paving the way for their commercialization, in addition to their environmental advantages (6).

3. Lifecycle Assessment: The Quantitative Backbone

To bring evidence and data into these design decisions, rather than relying on guesswork, industries are increasingly turning to Lifecycle Assessment (LCA), which is standardized under ISO 14040/14044 & quantifies environmental impacts over 4 stages: goal & scope definition, inventory analysis, impact assessment & interpretation, and raw material extraction to manufacture, distribution, use & disposal. The mean packaging-inclusive carbon footprint of over 12,000 oral medicines was 8.47 kg of CO₂ equivalent/medicine box, with significant variations in impact per medicine, depending on formulation & packaging type (1). Pharmaceutical packaging LCA studies usually consider over a dozen categories such as global warming, eutrophication, water & land use, etc.(7)

4. Sustainable Manufacturing Technologies

4.1 Continuous Manufacturing & Process Analytical Technology

Continuous manufacturing (CM) replaces stop-start batch production with an uninterrupted material flow under a Quality-by-Design (QbD) framework, building product understanding throughout the process rather than only at the end. Compared to batch processes, CM delivers fewer synthetic steps, lower solvent and reagent use, reduced power consumption, and faster scale-up. **Eli Lilly**, an early adopter, demonstrated CM's sustainability case in practice: its continuous tablet manufacturing lines enabled measurable reductions in material waste and facility footprint while meeting FDA quality standards. Process Analytical Technology (PAT), using in-line near-infrared and Raman spectroscopy, complements CM by enabling real-time quality monitoring, immediate process corrections, and elimination of waste from batch rejections.(8)

4.2 Green Solvents & Energy Management

Solvent selection significantly influences manufacturing's environmental burden, driving a shift from toxic options like dichloromethane toward water, ethanol, and ionic liquids. Downstream purification and cooling water systems are being redesigned across the industry to cut both solvent and freshwater use per unit of product. A landmark example comes from **GSK**, whose second-generation manufacturing route for the cancer drug mCMAF reduced solvent consumption by 16,160 kg per kilogram of product, cut greenhouse gas emissions by 71%, and slashed energy consumption by 76%. (9)

5. Sustainable Packaging Innovations

5.1 Mono-Material & Recyclable Design

Traditional blister packs are laminates of PVC, aluminum foil, & other polymers that provide good protection for the drug but are difficult to mechanically recycle. Industry's answer is mono-material packaging, in which packaging is constructed from a single polymer family, e.g. polypropylene, polyethylene terephthalate, or high-density polyethylene, which maintains barrier properties &

enables it to be recycled in conventional polymer streams. (fig. 2) This transition is supported by regulation: the EU's Packaging & Packaging Waste Regulation 2025/40 will mandate medicinal primary packaging be fully recyclable by 2034; manufacturers such as **Novartis & Merck KGaA** have established their own time-bound targets for packaging to be recyclable. (2,3)

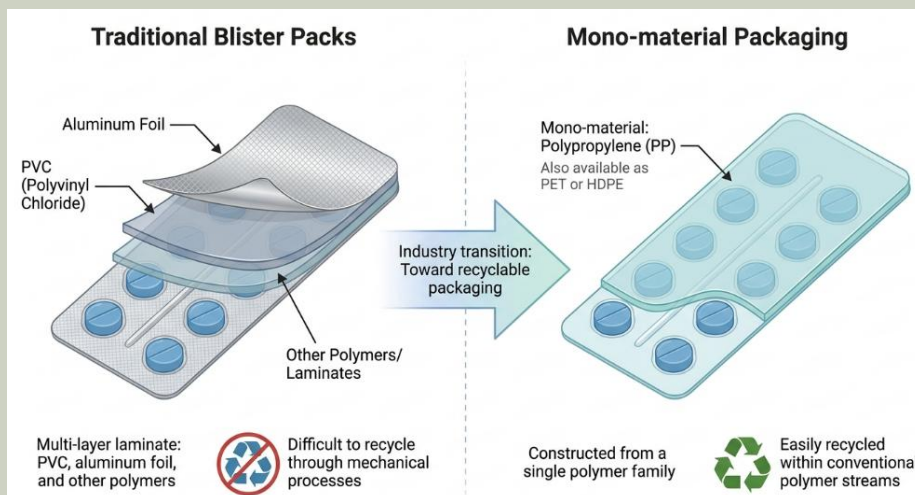


Figure 1: Shift from traditional to monomaterial packaging

5.2 Bio-Based, Biodegradable, & Smart Packaging

Research into bio-based polymers such as polylactic acid and polyhydroxyalkanoates for secondary and tertiary pharmaceutical packaging is advancing, alongside exploration of cornstarch-, sugarcane-, and cellulose-derived films where barrier requirements are less stringent. A milestone case study arrived in late 2024, when UPM Biochemicals, Selenis, and Bormioli Pharma jointly launched the world's first pharmaceutical bottle made from partially wood-based PET, using UPM's carbon-negative BioMEG and receiving European Pharmacopeia approval for global availability from Q1 2025. (10) Alongside materials innovation, smart packaging incorporating QR codes, RFID tags, and temperature indicators is strengthening anti-counterfeiting, supply-chain transparency, and patient safety, while also offering digital alternatives to printed package inserts.

6. Circular Economy & End-of-Life Waste Management

Closing the loop means something after the medicine leaves the pharmacy. Circular economy approaches in pharma are based on 3R principle (Reduce, Reuse, Recycle) Fig. 3

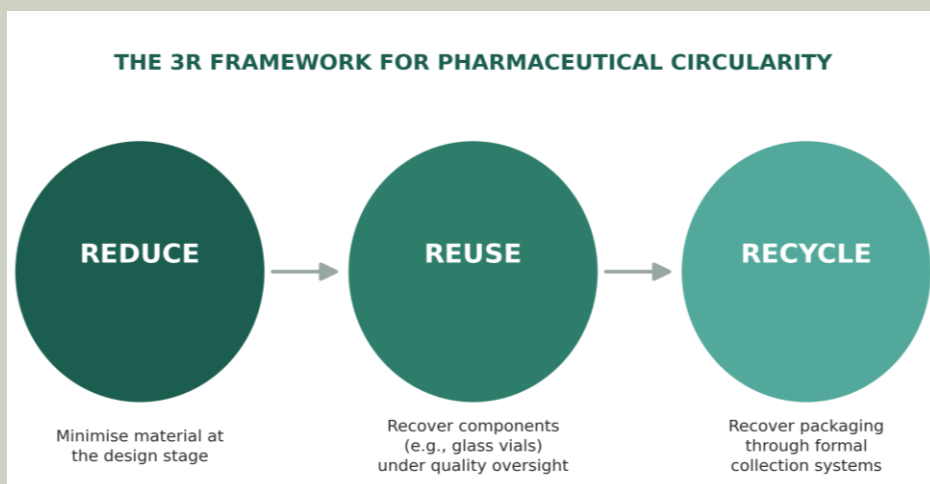


Figure 2: The 3R framework for sustainable pharmaceutical waste management.

Unused & expired medicines pose a significant but often overlooked environmental & public health issue. Improper disposal methods, such as flushing or throwing them in the trash, contribute to water & soil contamination & are linked to the global rise of antimicrobial resistance (AMR), a major public health threat (11). International agencies advocate enhanced national systems for safe medicine disposal, promoting pharmacy or drug take-back programs for appropriate incineration as a preferred solution. Advanced oxidation processes, activated-carbon adsorption, & zero liquid discharge systems are mandated in some areas for highly polluting industries like pharmaceuticals (12).

7. Emerging Technologies & Outlook

Artificial Intelligence and digital twins are transforming sustainable pharmaceutical manufacturing by predicting process deviations, optimizing energy use, and enabling real-time quality decisions without resource-intensive physical experimentation. AstraZeneca, operating across 26 global manufacturing sites, is a frontrunner: in 2026 it detailed how AI-agent-driven digital twins now arrange the full development pipeline from API to coated tablet, directly reducing waste by eliminating redundant physical trials. Roche is similarly deploying NVIDIA Omniverse-based digital twins to simulate and optimize biomanufacturing facilities before they go live, applying a "simulation first, construction second" principle. Looking ahead, on-demand 3D-printed dosage forms and AI-guided selection of greener synthetic routes in early R&D are set to extend these gains further.(13,14)

8. Challenges to Implementation

Despite this, adoption is still not widespread. The high capital costs of retrofitting & filing challenges uptake of sealing equipment & regulatory uncertainty about new materials. Even though the mono-material substrates have proven to be oxygen & moisture resistant, in moisture-sensitive applications, they offer a 27% shorter shelf life even when used in properties. Compared to multi-layer laminates, applications are used in greater numbers. Insufficient recycling facilities, local variations in regulations, & a lack of trained personnel impede scale-up, particularly smaller manufacturers who have low margins.(15)

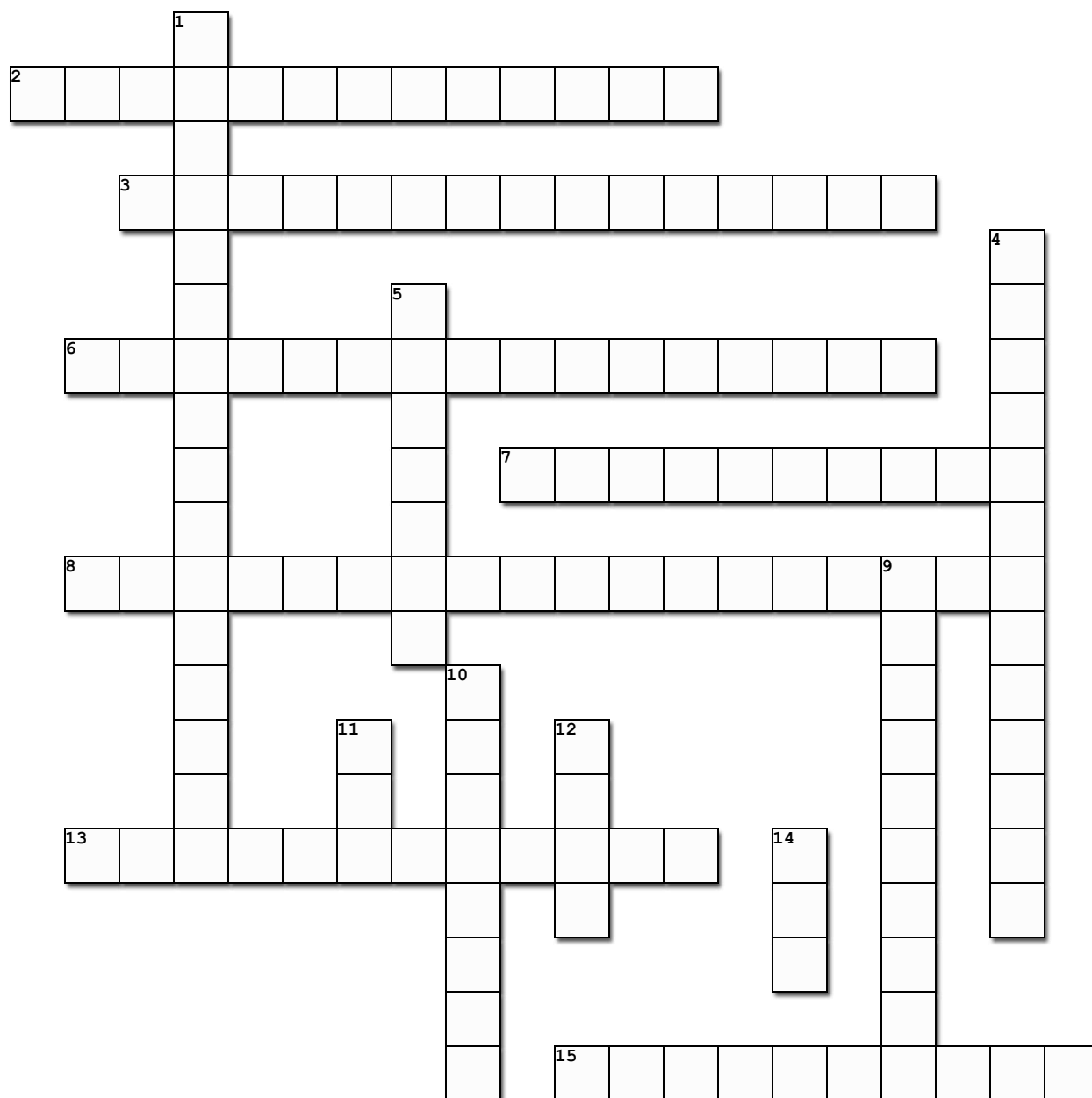
9. Conclusion

Sustainability in pharmaceutical industry is not a one-off initiative in a department but a part of the product life cycle. Design decisions ensure that entire process is both efficient & transparent. From API synthesis bench to use of LCA to inform design decisions, every step is efficient & transparent. From manufacturing & packaging design to collection & disposal at the end of their useful lives, medicines are essential for living. Medicines are vital to life from their manufacturing & packaging design to their collection & disposal at the end of their useful lives. A tangible opportunity to reduce environmental impacts without compromising the maintenance of life in the process is provided by life. Pharmaceutical industry is in the process of changing. In this context, towards a unified approach to sustainability, continuous manufacturing, mono-material & biodegradable plastics are gaining increased traction. The three solutions are all linked to bio-based packaging. The three solutions mentioned above are all related to bio-based packaging, coming together.

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Complete the crossword puzzle below

**Across**

- 2. Concept of biodegradable pharmaceuticals
- 3. Economy focusing on minimizing waste
- 6. sustainable alternative to reduce power consumption and waste
- 7. Plastic derived from renewable biological sources
- 8. Method to split complex aluminum-plastic blister foils
- 13. Packaging made primarily from a single material to facilitate recycling
- 15. Green pharma packaging

Down

- 1. creating medicines that safely break down in nature after use
- 4. Plant based packaging material
- 5. Digital Packaging
- 9. Recycling system that returns recovered materials to production
- 10. Structured medicine and device recovery scheme
- 11. Tool for Eco Design abbr
- 12. Eco-packaging innovation
- 14. Recyclable plastic abbr.



FROM PACKAGING TO ENVIRONMENTAL FATE

From protection to sustainability: Transforming packaging for oral solid dosage forms



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Abstract

Sustainability has become a key emphasis in the pharmaceutical industry, with packaging playing a vital role in product protection, patient safety, and environmental impact. This review examines sustainable packaging technologies for oral solid dosage forms (OSDs), including tablets, capsules, powders, and granules, by comparing conventional materials such as PVC/PVDC blisters, aluminium foils, glass bottles, HDPE containers, and paperboard cartons with eco-friendly alternatives like paper-based blisters, cellulose materials, starch-derived polymers, polylactic acid (PLA), and polyhydroxyalkanoates (PHAs). Sustainable design strategies, including lightweight packaging, material reduction, recyclable mono-material systems, and life-cycle assessment, are discussed for minimizing environmental burden while maintaining product quality. The review also highlights pharmaceutical waste management approaches, including recycling, solvent recovery, wastewater treatment, and medicine take-back programs. Review addresses challenges including regulatory requirements, high costs, limited recycling infrastructure, and biodegradable material limitations, while exploring future opportunities through artificial intelligence, continuous manufacturing, renewable energy, circular economy principles, and evolving environmental regulations.

Keywords: Sustainability, Biodegradable packaging, pharmaceutical disposal

1 Introduction

The pharmaceutical industry is essential to global healthcare, contributing to the prevention, diagnosis, and treatment of various diseases through the development of safe and effective medicinal products. Growing environmental concerns, pollution and resource limits are encouraging industries to adopt eco-friendly packaging while maintaining safety and quality standards (1-3).

Sustainability in the pharmaceutical industry mainly focuses to reduce environmental impact at every stage of a medicine's life cycle, from development and manufacturing to packaging, transport, use and disposal. It supports circular economy practices through resource reuse and responsible handling, while reducing waste and costs, improving efficiency, and protecting the environment (4).

Global initiatives such as the United Nations Sustainable Development Goals (SDGs), encourage pharmaceutical companies to reduce environmental impact (3). Green manufacturing, renewable energy, modern technologies, and sustainable packaging help reduce waste and pollution while maintaining medicine quality and safety.

The objective of this review is to discuss primary and secondary packaging material used for oral solid dosage forms in pharmacy, its design specification with appropriate features and disposal procedure for sustainable technology.

2 Sustainable Packaging Solutions in the Pharmaceutical Industry

Pharmaceutical packaging plays an important role in protecting medicine quality, ensuring patient safety, and meeting regulatory requirements. Conventional packaging materials, including petroleum-based plastics, aluminum foils, laminates, and multilayer materials, provide effective protection against moisture, light, and contamination(5). However, many of these materials are difficult to recycle and degrade slowly, which contributes to environmental concerns. As a result, the pharmaceutical industries are focusing on sustainable packaging approaches to reduce its environmental impact.

The main goal of sustainable pharmaceutical packaging is to protect medicines while reducing environmental burden. This involves choosing safer materials, improving packaging design, and considering the entire life cycle of packaging, from production to disposal.

2.1 Overview of Pharmaceutical Packaging Materials for Oral Solid Dosage Forms

Table 1 summarizes the packaging materials mainly used for oral solid dosage forms (OSD) including tablets, capsules, powders and granules. These materials are important for maintaining product quality, stability, safety and therapeutic efficacy. Primary packaging materials, including strip and blister packs, HDPE container, glass bottles and sachets come into direct contact with the product and protect it from moisture, oxygen, light, and contamination. Secondary packaging, including paperboard cartons and cardboard boxes(6), provides mechanical protection during handling, transportation and storage and may also offer opportunities for recycling and biodegradation.

Table 1: Key Features, Disposal Strategies and Challenges of Different Pharmaceutical Packaging Materials for Oral Solid Dosage Forms

Source of packaging	Name of packaing material	Name of formulation to be packed	Recommended Storage condition	Protection/features	Primary/secondary	Disposal	Challenges
Cartonbox	Paper-board/card board	ORS/Glucose powder pack-ets Blister pack cartons	Room temperature	Mechanical protection	Secondary	Recyclable through paper pulping; biodegradable	Residue after burning, reduced strength with moisture
Blister pack	PVC/PVDC-Aluminium foil	Tablet/Capsules	Room temperature	Excellent moisture, oxygen, and light barrier; tamper evidence	Primary	Difficult to recycle due to plastic-aluminium layers	Layers seperation is challanging
Plastic bottle	HDPE	Tablets Capsules	Room temperature	Temper-proof Moisture protection, lightweight, easy dispensing	Primary	Mechanical recycling	Plastic waste can cause pollution
Glass bottles	Amber/Transparent glass	Effervescent Tablets, Capsules	Room temperature	Excellent moisture, chemical and light protection, inert	Primary	100% recyclable and reusable	Heavy weight
Plastic sachets	Plastic laminate (Multilayer)	Powders, Granules, ORS	Cool and dry place	Moisture barrier, single-dose convenience, lightweight and portable	Primary	Multilayer structure	Difficult recycling
Strip pack	Aluminium	Tablets, Capsules	Room temperature	Moisture proof	Primary	Recyclable when properly collected	Aluminium production requires higher energy
Paper based blister	Cellulose/Fiber based materials	Tablets	Room temperature	Reduced plastic content	Primary	Recyclable and biodegradable (depending on coating)	Modification is required to due to barrier
Bio based packing	Starch based/Cellulose	Tablets, Capsules	Controlled temperature	biodegradable, reduced carbon footprint	Primary	Compostable or biodegradable under suitable conditions	High Cost

Sustainable alternatives, including paper-based blister packs and bio-based materials derived from cellulose or starch, are gaining attention due to their reduced environmental impact and improved biodegradability. However, high production costs, reduced barrier performance, and limited large-scale recycling remain significant challenges. Conventional materials like glass and aluminum offer excellent recyclability and product protection but may involve higher energy during manufacturing and transportation. Therefore, pharmaceutical packaging selection must balance product stability, protection, cost-effectiveness and end-of-life disposal considerations(5).

2.2 Eco-Friendly Packaging Materials

Advances in material science have enabled the use of more environmentally friendly pharmaceutical packaging. Materials like polylactic acid (PLA), cellulose, starch-based materials and polyhydroxyalkanoates (PHAs) use fewer fossil resources and may create less pollution after disposal. Recycled paper and responsibly sourced paper help conserve natural resources and reduce waste(7). Glass and aluminium remain sustainable options due to their strong protection and high recyclability. Single-material recyclable packaging, lightweight containers, thinner films, and intelligent design can further reduce material use and transportation-related carbon emissions(8).

Sustainable packaging depends not only on using sustainable materials but also on how the package is designed. Important strategies include reducing packaging components, minimizing package weight, improving recyclability, and making packaging more efficient for transport and storage (Figure 1). Life-cycle assessment helps manufacturers evaluate environmental impacts from raw material selection, production, transportation, use, and disposal(9). This supports sustainable packaging choices while maintaining medicine safety, product quality, patient convenience, and regulatory requirements.

2.3 Pharmaceutical Waste Management and Safe Disposal

Despite progress in pharmaceutical sustainability, pharmaceutical waste remains an environmental issue. Waste is generated throughout the medicine life cycle, including research labs, manufacturing plants, hospitals, pharmacies, and homes. Proper disposal is essential to prevent hazardous substances from entering soil, groundwater, rivers, and wastewater(10). They can be detrimental to aquatic life and contribute to antibiotic resistance.

Pharmaceutical industries generate solid and chemical waste, leftover solvents, wastewater, and damaged/rejected product. Effective waste management begins by minimizing waste during production through optimized processes. Waste sorting enables safe treatment of harmful waste and reuse of recyclable materials, reducing environmental harm and simplifying disposal.

One of the significant methods used in the manufacture of pharmaceuticals is solvent recovery. Solvents can be recovered and reused with technologies such as distillation and purification to decrease pollution, conserve resources, and decrease production costs. Wastewater treatments, such as filtration, activated carbon, oxidation, and biological processes, remove harmful pharmaceutical chemicals before discharge.

2.4 Safe Disposal of Unused Medicines by Consumers

Unused or expired medicines should not be thrown in household waste or flushed. Medicine residue may be released to water and impact microbial flora. Public awareness is crucial, as

many people are unaware of proper medicine disposal. Encouraging them to return unused medicines can help protect the environment(11).



Figure 1: Overview of Sustainable Pharmaceutical technologies for packaging of OSD (19)

2.5 Challenges to Sustainable Pharmaceutical Technologies

Sustainable technologies offer environmental and economic benefits, but high investment costs and strict regulations can limit its adoption. Some eco-friendly packaging materials also have lower strength, protection, and shelf life(12). Further R&D is needed to improve their performance. Collaboration among industry, researchers, regulators, healthcare professionals, and consumers is essential for lasting environmental benefits(13).

2.6 Carbon Border Adjustment Mechanism (CBAM) Risk in Pharmaceutical Packaging for Export: An Emerging Challenge for Sustainable Packaging

Pharmaceutical companies are moving toward greener packaging as environmental concerns and global regulations increase. Materials such as aluminium foil, plastics, blister packs, glass, and paper cartons protect and stabilize tablets and capsules(14). However, their production and disposal can be carbon intensive, creating challenges for global trade. The CBAM is a carbon-based policy that the European Union has enacted to lower carbon emissions and promote the use of low-carbon products. Although, the CBAM does not currently target pharmaceuticals, packaging may face future attention due to its carbon footprint. Therefore, future packaging should balance emissions, sustainability and safety performance(15).

2.7 Future Perspectives of Sustainable Pharmaceutical Industry

New technologies and environmental goals are shaping a greener pharmaceutical industry. AI, digital tools, and smart systems can improve production, reduce waste, and save energy(16). Continuous manufacturing may grow due to lower material loss. Future packaging will focus on biodegradable and recyclable materials, renewable energy and better water management(17). Life-cycle assessment, circular economy practices, and reuse and recovery of solvents and medicines will further reduce waste. Strong coordination among industry, researchers, government, and healthcare professionals will support sustainable development(18).

3 Conclusion

Sustainability has become an integral component of the pharmaceutical manufacturing and packaging, with greater focus on reducing their impact on the environment. Greener production methods, sustainable packaging, renewable energy, and proper waste management can help reduce waste, energy use, and harmful emissions while protecting water, wildlife, and human health. Although some challenges remain, continued research, innovation, and collaboration can help the pharmaceutical industry move towards a safer and more sustainable future.

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Balancing sterility and sustainability: Novel strategies in ophthalmic packaging



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Abstract

The sterile ophthalmic products require a specialized packaging to maintain the sterility, ensure product stability and protect patient safety. Growing environmental concerns associated with conventional plastic packaging have accelerated the development of sustainable alternatives. This review highlights recent advances in sustainable packaging technologies for sterile ophthalmic products, including mono-material packaging, bio-based polymers, smart packaging, lightweight designs and preservative-free multidose systems. It also discusses key challenges related to the material compatibility, sterility assurance, regulatory compliance and large-scale implementation.

Keywords: Sterile ophthalmic products, Sustainable packaging, pharmaceutical packaging, Bio-based polymers, Smart packaging

1.Introduction

Maintaining the sterility, physicochemical stability, and guarantee patient safety throughout storage and usage, sterile ophthalmic products for example - eye drops, ophthalmic solutions, emulsions, suspensions, gels and ointments need extremely effective packaging techniques. These formulations are more susceptible to the environmental exposure and microbiological contamination since they are applied directly to the eye surface. Furthermore, packaging design affects patient compliance, dose accuracy, and convenience of administration, making it more than just a container and an integral part of ophthalmic drug delivery systems (1).

Development of sustainable pharmaceutical packaging has increased due to growing environmental impact of the petroleum-based polymers. Although they offer a superior barrier quality, conventional materials like LDPE, HDPE significantly increase plastic waste (2). The recyclable mono-material packaging, bio-based polymers, lightweight packaging designs and recyclable secondary packaging are examples of recent developments in sustainable packaging

(3) . Innovations in sustainable packaging offer opportunities to enhance eco-friendliness of sterile ophthalmic products while maintaining their quality, safety and functionality (4).



Figure 1. Sustainable Packaging Framework for Sterile Ophthalmic Products

2. Packaging Requirements for Sterile Ophthalmic Products

Sterile ophthalmic products demand strict packaging standards to guarantee the quality, safety and therapeutic efficacy. Applied directly to the delicate ocular surface, these formulations require container-closure systems that prevent physical damage, environmental exposure and subsequent degradation (5, 6). Maintaining a container closure integrity is crucial for the ophthalmic packaging because it stops product leakage and microbiological infiltration during production, shipping, storage, and recurrent use. Therefore, maintaining product quality over the course of its stated shelf life requires appropriate sealing technology and validated integrity testing (7, 8).

Ophthalmic packaging should enable the safe handling, precise dose delivery and convenience of administration without sacrificing formulation quality, in addition to preserving sterility and product integrity. Because it directly affects product stability, compatibility and patient safety throughout the product lifecycle choosing the right packaging materials and container-closure methods is crucial to the development of pharmaceutical products (9).



Figure 2. Schematic representation of packaging requirements for sterile ophthalmic products

2.1 Recent Advances in Sustainable Packaging Technologies

In order to reduce its environmental effect while upholding its quality, sterility and safety standards of sterile ophthalmic goods, the pharmaceutical sector is progressively implementing sustainable packaging methods. The development of ecologically friendly packaging methods that satisfy the pharmaceutical regulatory requirements and promote sustainable healthcare practices for developments in material science, eco-design principles, life-cycle assessment (10, 11).

The shift to recyclable and mono-material packaging methods is one of biggest advancements in environmentally friendly pharmaceutical packaging. By increasing material recovery and lowering the environmental impact of pharmaceutical packaging (12).

The creations of bio-based and biodegradable polymers as substitutes for traditional plastics made from the petroleum is another significant achievement due to its renewable source and reduced environmental effect materials such as polylactic acid , polyhydroxyalkanoates, cellulose derivatives (13)(14).

Additionally, integrating intelligent packaging solutions optimizes patient compliance, inventory management and lifecycle tracking that facilitates the shift to more sustainable pharmaceutical packaging (15)16). A major step towards sustainable pharmaceutical packaging is adopting lightweight packaging designs and paper-based secondary packaging (17). Preservative-free solutions improve patient comfort and encourage long-term treatment adherence while lowering preservative-induced ocular toxicity as compared to traditional multidose eye drop bottles (18). Additionally, recent research has shown sophisticated multidose packaging solutions successfully preserve microbiological integrity during the

duration of usage (3). The various eco-friendly packaging option for sterile ophthalmic products are summarised in Table 1.

Table 1. Current eco-friendly packaging innovations for sterile ophthalmic products

Sustainable Technology	Packaging Material/Approach	Major Advantages	Current Challenges
Mono-material packaging	HDPE, PP	Better recyclability	Limited high-barrier performance
Bio-based polymers	PLA, cellulose derivatives	Renewable source	Sterilization compatibility
Smart packaging	RFID, NFC, QR codes	Traceability, anti-counterfeiting	Higher implementation cost
Lightweight packaging	Thin-wall HDPE	Lower material consumption	Mechanical strength optimization
Preservative-free multidose systems	One-way valve	Maintains sterility without preservatives	Complex manufacturing and validation

While each technology has unique benefits and implementation obstacles, their combined use can greatly advance sustainable pharmaceutical manufacture, resource efficiency, and the circular economy. Table 2 lists the salient features of various environmentally friendly packaging systems.

Table 2. Comparative overview of sustainable packaging technologies for sterile ophthalmic products

Technology	Primary Objective	Sustainability Benefit	Major Limitation	References
Mono-material packaging	Improve recyclability	Simplified recycling, reduced plastic waste	Barrier performance optimization	(11)
Bio-based polymers	Replace fossil-derived plastics	Renewable feedstocks	Sterilization compatibility	(14)
Smart packaging	Product authentication and monitoring	Better traceability	High implementation cost	(15)

Lightweight packaging	Material reduction	Lower transportation emissions and resource consumption	Mechanical strength	(11)
Preservative-free multidose systems	Maintain sterility without preservatives	Reduced packaging waste	Manufacturing complexity	(19)

2.2 Challenges and Regulatory Considerations

While sustainable packaging technologies have witnessed considerable innovations, their application to sterile ophthalmic products poses unique challenges. Packaging materials must meet stringent pharmaceutical quality standards while reducing environmental impact. In order to ensure that sustainable substitutes preserve sterility, maintain container-closure (20, 21).

As manufacturers offer new polymers, recycled materials and the cutting-edge packaging technologies, the regulatory evaluation of sustainable pharmaceutical packaging has also grown more complicated. To verify that new packaging solutions and patient safety criteria thorough risk assessment, migration studies and long-term stability testing are required (22) (21).

Ophthalmic container closure systems are advised by the U.S. Food and Drug Administration (FDA) to preserve the drug product's sterility, stability, safety and quality for the duration of its intended usage and its shelf life. Components of the packaging should be compatible with formulation and thus offer sufficient defence against environmental influences and contamination. Particulate matter, extractables and leachable, dispensing performance and container-closure integrity should all receive special consideration. The packaging and dispensing mechanism for multidose ophthalmic medications should reduce the possibility of microbial contamination over time. Additionally, during stability tests, the FDA advises that the container-closure mechanism be appropriately evaluated. The FDA Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics and the Quality Considerations for Topical Ophthalmic Drug Products outlines these factors (24).

Table 3. Obstacles and potential solutions for eco-friendly ophthalmic packaging

Challenge	Impact	Regulatory Consideration	Potential Solution	References
Sterility maintenance	Risk of microbial contamination	Container–closure integrity	Advanced multidose dispensing systems	(7)
Extractables & Leachable	Chemical migration into formulation	Toxicological risk assessment	Pharmaceutical-grade polymers	(20)

Bio-based polymer limitations	Lower moisture	Stability	Polymer blending	(23)
Recycling limitations	Increased pharmaceutical plastic waste	Environmental sustainability compliance	Mono-material packaging and circular economy	(11)
Smart packaging implementation	High manufacturing cost	Validation of electronic packaging systems	QR-code technologies	(10)
Commercial scale-up	Slow industrial adoption	GMP compliance and process validation	Sustainable manufacturing	(14)

2.3 Future Prospectives

It is anticipated that the advancements in sophisticated biomaterials, smart packaging technologies and the circular economy concepts will propel the development of sustainable packaging for sterile ophthalmic items in the future (19, 15).

In order to expedite the adoption of environmentally friendly pharmaceutical packaging the future initiatives should also prioritize the integration of life-cycle assessment, eco-design methods and the harmonized regulatory frameworks to create affordable packaging technologies that preserve sterility, product quality and regulatory compliance while reducing environmental impact (11, 14).

3. Conclusion

In order to minimize the environmental impact of sterile ophthalmic goods while upholding the strict standards for sterility, product stability and the patient safety, sustainable packaging has become an essential part of contemporary pharmaceutical manufacture. Mono-material packaging, bio-based polymers, smart packaging technologies and preservative-free multidose delivery systems are examples of the recent innovations that have shown a great deal of promise to increase resource efficiency and decrease plastic waste without sacrificing packaging performance.

Even with these developments there are still a number of obstacles to overcome like material compatibility, sterilizing needs, cost-effectiveness, regulatory compliance and the widespread adoption of sustainable packaging technologies. It is anticipated that future advancements in sophisticated biomaterials, intelligent packaging systems, ultimately promoting better patient care as well as global environmental sustainability.

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From excretion to ecology: The strategic imperative of eco-pharmacovigilance



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Abstract

As the widespread presence of active pharmaceutical compounds in the environment poses a growing threat to ecosystems worldwide, understanding & mitigating medicinal pollution has become crucial. Drugs in active form pose a serious threat to the environment as they enter the ecosystem through different channels. Some high-profile examples are the toxicity of Diclofenac that results in death of vultures from feeding on dead livestock due to consumption of Diclofenac, Ethinyl estradiol that causes feminization of males in fish species, progesterone that leads to amphibian infertility, Ivermectin that affects dung beetles' development process, and fluoxetine that affects shrimp behavior in addition to promoting microorganisms' resistance. In order to minimize this threat, the adoption of some measures such as reduction in pharmaceutical waste production, updating of wastewater management systems, green pharmacy initiatives, and proper pharmaceuticals disposal is imperative. Moreover, some regulations, including ERA, RCRA, and risk mitigation measures, are important.

Keywords: Eco-Pharmacovigilance, Medicinal Pollution, Eco-toxicology, green drug, Risk Assessment.

1. Introduction

Environment is not only polluted by smog, heavy metals or gaseous emissions but it is also harmed by the pharmaceutical drugs. Active ingredients of drugs are getting into the environment through various processes and causing significant harm to wildlife. (1)

The harmful effects of pharmaceutical ingredients in the environment were highlighted by the mysterious mass poisoning of vultures that occurred in South Asia several years ago. This incident, in which the use of Diclofenac by veterinarians led to the suppression of kidney function in the vultures, drew attention to the problem of the impact of drugs on the environment. As a result, eco-pharmacovigilance was created, a discipline that studies the

effects of drugs on the environment and develops measures to prevent them (for example, the hormone Ethinyl Estradiol, which turns male fish into females) (2).

Eco-pharmacovigilance includes four areas of study:

1. Pharmaceutical residues in the environment and their impact on it.
2. Approaches to reduce the number of pharmaceuticals released in the environment.
3. The development of green pharmacy.
4. Ecological and environmental aspects of drug use and regulation.

2. Pathways of pharmaceutical release into the environment

2.1 Patient Excretion (Human & Veterinary)

After therapeutic administration, drugs are excreted from the body as inactive molecules, broken-down metabolites, or a combination of both. Drugs that are administered via oral route but poorly absorbed are directly excreted with feces. Drugs that are either partially or totally absorbed are excreted as metabolites with urine, feces, or air. After their release with bodily fluids, pharmaceuticals enter the food chain, accumulating in higher-trophic-level organisms. Excretion of drug residues with the patient's fluid is the major source of pharmaceuticals in the environment since it occurs at both human and veterinary levels (4).

2.2 Wash-off and Sweat

Pharmaceuticals in topical formulations (creams, gels, patches) are washed off with water during bathing and enter the water system. Also, a small amount of therapeutics is released to the environment by the means of sweat.

2.3 Unused/Left-over Medicines

Leftover medicines include the medication no longer being used for the prescribed condition, constitute another cause of environmental pollution. The dispensing of larger quantities (e.g., 90-day supplies) and inappropriate management of the left-over medicines are some of the factors that contribute to this problem.

2.4 Industrial and Institutional Effluents

Large amounts of pharmaceuticals are released to the environment through industrial and institutional wastes. This pathway is serious as it provides a direct and concentrated source of chemicals to the local environment (5).

2.5 Animal Carcasses

The dead animals that have been treated with pharmaceuticals pose a significant hazard to the environment and also to the animal scavengers as their bodies carry high level of therapeutic drugs (6).

3. Biological diversity impact of pharmaceuticals

Pharmaceutical products play a crucial role in the treatment of both human beings and animals. But due to high biological activity of APIs released into the environment always lead to unpredicted toxic effects on flora and fauna. Though standard clinical tests provide all the necessary information about potential side effects and drug safety on target organisms, the effects of drugs on the environment after consumption are not well studied yet. Following are some examples of the toxic effects of pharmaceuticals on different animal species (8).

Table 1. Impact of Pharmaceuticals Across Species (8).

S.No.	Affected species	Pharmaceutical contaminant	Primary and biological impact & mechanism	Specific consequences observed
1.	Vultures (Gyps species)	Diclofenac	Causing acute renal failure & visceral gout when consumed from treated animal's carcass	Leads to the population's decline of >97-99.9% in South Asia, creating an ecological catastrophe.
2.	Amphibians (Frogs/Tadpoles)	Levonorgestrel	Damaging reproductive tract development causing females to have short oviducts and arrested follicles	Sterility in female frogs when exposed to this pharmaceutical at trace levels similar to environment concentrations.
3	Aquatic life (Fish)	Fluoxetine (SSRI antidepressant)	Accumulates in the brain, and exposure is linked to altered behavioral responses to environmental cues.	Interfere with the growth and reproduction in fishes
4	Microorganisms	Various antibiotics (Ampicillin, Oxytetracycline, Vancomycin)	By promoting antibiotic resistance in environmental bacteria, it creates conditions for generating drug-resistant microbes. For example, Acinetobacter – a multi-resistant bacterium now	This resistance can in turn be passed on to bacteria that cause diseases in humans and animals, making it more difficult to control bacterial infections.

			present in water bodies.	
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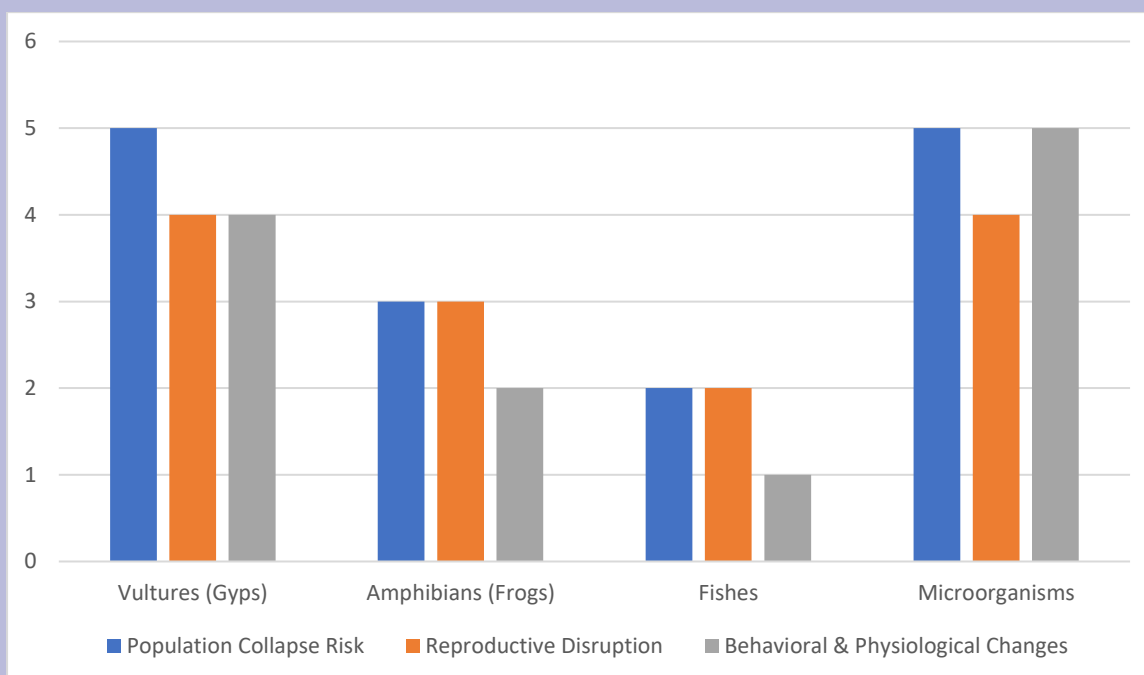


Figure 1. Ecotoxicity of Active Pharmaceuticals Across Species

4. Eco-pharmacovigilance

Eco-pharmacovigilance (EPV) is the science and practice of detecting, assessing, understanding and preventing the harmful effects of pharmaceuticals and chemical residues on ecosystems, animals and human health. Whereas pharmacovigilance deals mainly with the drug's impact on patients and human health, eco-pharmacovigilance goes further in terms of responsibility by also considering the effects of drugs and their ingredients on the environment after use. In other words, Eco-pharmacovigilance (EPV) refers to the entire post-consumer use of an active pharmaceutical ingredient that may endanger ecosystems and domestic animals as well as humans (9).

4.1 Objectives of Eco-pharmacovigilance

4.1.1 Ecosystem ecotoxicity profiling

This objective primarily focuses on the scientific and statistical analysis of the impact that the drug's ingredients have on the environment both before and after being launched. It requires:

- Calculation of concentration of drugs in the environment to establish exposure – predicted environmental concentration (PEC) which is done by comparing the PEC to the predicted no-effect concentration (PNEC) of water, soil, and biota.
- Identification of ecotoxicological hazards which aims to determine the most severe consequences on plants, fish, and other organisms when they are exposed to pharmaceuticals through the examination of acute and chronic toxicity of the ingredient, its bioaccumulation as

well as persistence in water, hormonal activity in fish and other species and ability to disrupt the water's endocrine functions in animals.

c) Regulatory gatekeeping falls under the competence of the European Medicines Agency (EMA), as well as the FDA and other drug regulatory agencies worldwide. The main task is to review and assess submissions on the potential risks posed by the drug to the environment. It ensures that the potential negative changes to the environment are taken into account during the approval process (10).

4.1.2 Targeted ecological hazard control

This objective involves various post-market control measures needed to prevent drug pollution. The measures include:

a) Eco-friendly design and prescribing initiatives which mainly move towards the promotion of chemical design, manufacturing, and prescribing policies that would reduce the quantity and toxicity of pharmaceutical waste. They include “Benign-by-design” philosophies, Eco-prescribing initiatives, pharmaceutical waste minimization strategies such as dose optimization, packaging optimization initiatives, take-back programs that facilitate the return and proper disposal of pharmaceutical waste.

b) Industrial, institutional, and municipal waste control which is primarily achieved through the implementation of more stringent effluent regulations for pharmaceutical manufacturers, hospitals, and other industrial institutions that play a role in introducing pharmaceutical compounds into the environment. Some of the measures include imposing strict control and regulations on the industries, developing more efficient waste treatment systems such as ozonation and activated carbon monitoring and controlling pharmaceutical pollution at the community level.

c) Implementation of policies and surveillance measures which focuses on periodic assessments of environmental hotspots and establishing monitoring plans that will ensure the continuous evaluation of the impact pharmaceuticals have on the environment. It also requires the introduction of regulations, restrictions, or warnings to cut down on environmental drug pollution when the surveillance results indicate that it is necessary (10).

5. Twin pillars of green drug design

5.1 Complete Absorption and Internal Metabolism

The first strategy focuses on designing the pharmaceutical products that can be completely metabolized in the body. Such drugs are integrated into the targeted nanoparticles to ensure that the drug is delivered directly to the target tissues and cells. This will help to reduce the initial dose as the nanoparticle system will actively participate in the delivery process. Ideally, 100 percent of the administered dose must be absorbed and metabolized inside the patient's body, resulting in harmless byproducts such as water and carbon dioxide. Not a single molecule of the drug remains unmetabolized and has to be excreted through the patient's urine, feces, or sweat, thus contaminating the environment.

5.2 Environmental Biodegradation (“Benign by Design”)

The second strategy is also based on the latest achievements in medicinal chemistry, that allows to modify the molecular structure of the drug in such a way that it can withstand the destructive action of patient’s body. However, once the drug is excreted with the urine, it is introduced to the environmental conditions and can be degraded by bacteria, sun light, or water. To do so, the researchers replace the strongest and most stable chemical bonds with weaker ones so that the drug will not last for long after being excreted. In this way, the pharmaceutical substance remains stable inside the patient’s body for a necessary timeframe, but once it enters the sewage system, it will degrade quickly and will not harm the environment (11,12).

6. Guardians of green healthcare: The strategic role of pharmacy in Eco-pharmacovigilance

Due to the leading role of pharmacists in health care delivery and social services, pharmacists play an important role in addressing pharmaceutical pollution from major five areas, including:

6.1 Educating the community: The first area is educating the community about the toxic hazards of pharmaceutical wastes on environment and motivating them to bring their expired and unwanted medicines to the pharmacies for proper disposal.

6.2 Take-back programs: Introducing take-back programs to help collect pharmaceutical wastes for safe and responsible disposal, thus preventing the expired or unused drugs from entering the environment through water resources and soil.

6.3 Eco-prescribing and waste reduction : Collaborating with other healthcare professionals, particularly doctors, to promote eco-friendly drug and appropriate prescription to reduce pharmaceutical pollutants, particularly antibiotics and ensure environmental sustainability.

6.4 Policies formulation and environmental management: The pharmacies may collaborate with other organizations to develop policies and regulations regarding industrial waste and water management and manage medical waste.

6.5 Advancement of sustainable healthcare initiatives: Advancing sustainable health care initiatives may involve the development of environmentally friendly pharmaceutical products and the reduction of plastic usage in the pharmacy (13,14).

7. Conclusion

For decades, the primary aim of drug development has been the maximization of therapeutic efficacy. Yet, the active principle of a pharmaceutical substance is increasingly found in water systems, in the food chain, and in wild animals. It turns out that the useful effects of a drug should not be exclusively aimed at patients – the health of the planet must also be maintained. Eco-pharmacovigilance helps to transform the pharmaceutical industry into a truly sustainable business by changing the definition of an ideal drug to one that is “good for patients as well as ecosystem”.

The concept of eco-pharmacovigilance allows for turning the pharmaceutical industry towards a more extensive and lasting commitment to environmental protection. Green drug design

principles help the pharmaceutical companies to change the nature of business by making medicines fit for purpose while being harmless to the environment: this is the goal of pharmacovigilance and pharmacy in everyday practice. The task of pharmacists and physicians is to ensure that drugs are used in terms of ecological safety: this includes dispensing medical advice, proper disposal of medicines, and raising awareness. The essence of green healthcare is to create the most favorable conditions for the patient, for whom the “medication is intended to be disposed of in a way that is safe for the environment, which will be rid of it.”

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Large language models as the cognitive layer of next generation digital twins in pharmaceutical manufacturing and packaging



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Abstract

Digital Twins (DTs) are a virtual representation of physical processes, equipment, and products that can transform pharmaceutical manufacturing and packaging by enabling sustainable manufacturing (*in-silico* experimentation reducing material waste), real-time monitoring, predictive maintenance, and Quality by Design (QbD) optimization under the Pharma 4.0™ operating model. However, conventional DTs remain largely inaccessible to plant personnel, demanding specialist expertise to interpret outputs from numerical dashboards and physics-based models. Large language models (LLMs), built in the transformer architecture, offer a promising cognitive layer that enables operators to interact with DTs through natural language, supporting root-cause analysis, standard operating procedures (SOP) retrieval, and automated documentation. This perspective synthesizes established DT practice with emerging LLM-DT integration concepts from Industry 4.0 literature, while explicitly distinguishing validated evidence from proposed future directions. Key challenges include hallucination risk, Good Manufacturing Practice (GMP) validation, and regulatory acceptance which are critically examined alongside a roadmap for responsible adoption.

Keywords: Digital Twin; Large Language Model; Pharma 4.0™; Pharmaceutical Manufacturing; Pharmaceutical Packaging; Sustainable Manufacturing; Good Manufacturing Practice; Artificial Intelligence; Process Analytical Technology

1. Introduction

The progressive adoption of the Pharma 4.0™ operational model in the pharmaceutical industry, which connects the principles of Industry 4.0 digitalization with the quality system defined by ICH Q10, has brought about the need for advanced information and decision support systems(1,2). Within the framework of this model, digital twins, which are defined as virtual replicas of real-life processes continuously updated with the help of sensors and information from production processes, have proven to be enabling technologies for continuous process monitoring, in-silico experiments, and predictive quality assurance in the pharmaceutical industry.

The formal introduction of the digital twin concept within the systems engineering framework can be attributed to Grieves and Vickers (2017)(3), while the application of digital twins in the pharmaceutical sector has its roots in the FDA Process Analytical Technology (PAT) regulatory framework established in 2004(4). This framework proposes using real-time information about production processes, which is supported by ICH Q8(R2), Q9, and Q10 guidelines that define the Quality by Design (QbD) concept used specifically by digital twins to improve pharmaceutical development and production processes.

Traditional pharmaceutical DT implementations depend mainly on physically based models or classical ML techniques, where operators interact using numerical dashboards and graphical interfaces, instead of using natural language communication(5). LLMs, which are based on the transformer model introduced by Vaswani et al., have shown some good ideas for reasoning, retrieving information, and creating meaningful texts(6). Using LLMs as a cognitive interface in conjunction with DTs in the pharmaceutical sector provides a valid opportunity to bring DT information to shop personnel, thus speeding up corrective actions, decreasing the frequency of deviations, and fulfilling the requirements for resource-effective Pharma 4.0 production.

2. Digital Twins in Pharmaceutical Manufacturing: A Sustainable Technology enabler

According to manufacturers, pharmaceutical digital twins (DTs) are virtual models of processes that combine sensor and analytical instrument data with real-time data streams to model, predict, and improve operations before taking any action. Using this approach supports sustainable manufacturing because in-silico methods are applied, which helps avoid wasted raw materials and solvents that are associated with standard R&D processes. Examples include real-time monitoring of critical quality attributes (CQAs) by PAT devices and various applications of QbD methods in manufacturing(5,7).

Moreno-Benito et al. (Pfizer, 2022)(7) have presented the largest collection of information about how to utilize the pharmaceutical DT approach. The authors developed digital twins of the continuous direct compression (CDC) line that included a combination of multiple mechanistic and data-driven models. Such digital twins were successfully used for the modeling of CQAs such as tablet hardness, dissolution, and blend uniformity allowing for exploratory design of the process leading to significant reduction in the quantity of necessary raw materials when conducting real experiments. Copot et al. (2026)(8) also presented an additional CDC simulations system.

In the manufacturing of biopharmaceuticals, digital twins enabled by the application of process analytical technology (PAT) in the production of drugs are used to manage various critical process parameters (CPP). Furthermore, this enables the production of reliable data that can be utilized by machine learning algorithms in the future. Among the implementations of digital twins in industry are examples such as the one of Johnson & Johnson that collaborated with Siemens in coming up with the system. This led it to reduce its production time and use of solvents by around 30% along with overall costs by about 35%. Eli Lilly has been known to also use digital twins to assess scale-up for glucagon-like peptide-1 (GLP-1) receptor agonists Zepbound® and Mounjaro® before embarking on actual manufacturing. The effects of the case studies have not been confirmed.

3. Digital Twins in Pharmaceutical Packaging

The domain of packaging-specific digital twins (DTs) is relatively newly established and lacks the extensive peer-reviewed literature seen in process manufacturing. Secondary packaging DTs make use of data from machine vision cameras, heat-seal monitors, serialization printers, and cartoning systems to create a live virtual model of the packaging line. The only established case is in predictive maintenance, wherein DTs use vibration effects of filling and cartoning machinery along with the seal-bar temperature to detect the build-up of mechanical failures before any significant rejection issues or unforeseen interruptions arise(9). This ability does not only allow DTs to perform maintenance but directly contributes towards lowering materials and packaging waste.

Remote access to optical systems by means of DTs enables virtual commissioning and process optimization when developing new defect detection solutions. Moreover, the issue of serialization, which is now required under the EU Falsified Medicines Directive (FMD 2011/62/EU)(10) and the US Drug Supply Chain Security Act (DSCSA)(11), becomes an

increasingly important application: packaging DTs can recreate the flow of serialization data, check aggregation logic, and detect integration issues before implementation on actual lines.

Cold-chain packaging DTs use temperature-excursion sensor data with existing stability modelling concepts to make instant predictions about shelf-life effects which is the necessary data infrastructure for continuous real-time release testing (RTRt) programmes. This field offers a significant opportunity for using LLM for providing data in situations where errors in packaging, mismatches with serialization or cold-chain accidents require fast inquiries based on the context of the non-expert operators acting in the absence of highly-skilled professionals.

4. Large Language Models as the Cognitive Layer

LLMs based on the transformer architecture(6) are trained using large and diverse sources of information including scientific information, regulatory guidelines, and operational documentation. LLMs possess a good capacity for carrying out multi-step reasoning, retrieving domain-specific knowledge, answering questions, and creating structured documents(12). In the context of its application to pharmaceutical digital twins, the cognitive layer can perform the following four functions: (i) provide a language- based interface for communicating the DT data in real time, (ii) prepare hypotheses of the root cause by checking the sensor data against the batch records and corrective and preventive action databases, (iii) prepare primary version of GMP deviation reports and SOPs, and (iv) provide real-time decision-making support taking into account the applicable regulations (Figure 1).

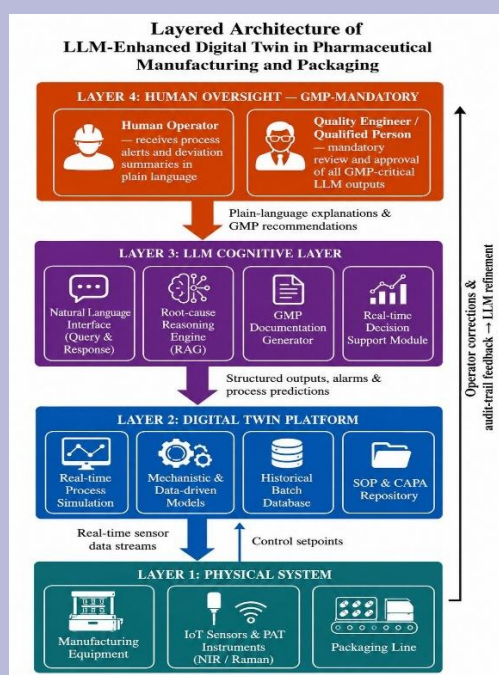


Figure 1. Layered architecture of an LLM-enhanced pharmaceutical Digital Twin (DT).

[The physical system layer (manufacturing equipment, IoT sensors, Process Analytical Technology (PAT) instruments, and packaging line) feeds real-time data streams into the Digital Twin Platform, which executes process simulations and maintains historical batch records, standard operating procedure (SOP) repositories, and corrective and preventive action (CAPA) databases. The LLM Cognitive Layer provides a natural-language interface, root-cause reasoning via Retrieval-Augmented Generation (RAG), GMP documentation generation, and real-time decision support. The Human Oversight layer (human operator and qualified person) receives plain-language outputs from the LLM and retains mandatory approval authority for all GMP-critical decisions. A feedback loop enables continuous LLM refinement from operator corrections and audit-trail data. NIR, near-infrared spectroscopy; RAG, Retrieval-Augmented Generation; GMP, Good Manufacturing Practices.]

In 2025, Yang et al. published a study presenting the DPP framework for LLMs in DT modeling (13). The framework consists of three stages of contributions from LLMs to DT workflows — descriptive, predictive, and prescriptive — where descriptive entails the processing of inputs from sensors describing both the state of the plant and the data provided by DT; predictive stage is based on LLM reasoning that assists in providing information on future trajectory of processes; and prescriptive stage involves issuing recommendations on corrective actions relative to the current state of the manufacturing process. Later studies in the pharmaceutical area focused on the research conducted by Salami et al. allowing comparison of the performance of three LLMs including GPT-3.5, GPT-4, and LLaMA offering a well-balanced dataset consisting of data on actual deviations during manufacturing (14). The outcome of the study revealed that LLMs may offer insights regarding the underlying issues prompting companies to use that information indicating at the importance of fine-tuning of such models according to particular area of application as well as employing the expertise of professionals during the implementation process.

The engineering evidence discussed by Gill et al. (2025)(15), presented at IEEE ETFA, gives proof for LLM agents working in a DT environment and launching autonomous fault-management actions with the DT giving the true state of the system which can be used for confirming LLM decisions in real time. Papacharalampopoulos et al. (2026)(16) improved the presented architecture by creating a fault-resistant process and installing a cognitive supervisory control level where an LLM reasoning agent processes DT telemetry data and suggests corrective actions. Thus, the combined results of the described works show the technical approaches to the practical implementation of LLM-DT connectivity. Han and Tao

(2024)(17) describe the manufacturing DT application in a broad context of the application of AI and LLM technologies in the pharmaceutical business.

Table 1. Comparison of conventional AI-driven DT platforms and LLM-enhanced DTs across key operational dimensions.

Feature	Conventional AI-driven DT	LLM-enhanced DT
Operator Interface	Numerical dashboards; graphical process charts	Natural-language Q&A conversational interface
Root-cause Analysis	Engineers manually interpret alarms and multivariate data	LLM synthesizes sensor logs, batch history, SOPs, and CAPA records automatically
SOP Access	Manual document search by operator	LLM retrieves and contextualizes relevant SOP to current DT status
Deviation Report Drafting	Manual GMP writing by qualified person	LLM generates first draft; qualified person reviews and approves
Operator Training Demand	High — requires dashboard and process model expertise	Reduced — conversational interface lowers the specialist skill barrier
Primary Limitation	Cognitive burden on operator; siloed data views	Hallucination risk; probabilistic outputs require rigorous GMP validation

5. Potential Applications across the Pharmaceutical Value Chain

Extrapolating the demonstrated capabilities to the full pharmaceutical value chain yields several technically plausible, though not yet fully validated, applications:

Manufacturing decision support: LLM-generated root-cause hypotheses for process deviations, synthesizing real-time sensor trends with historical batch records and CAPA

databases, could reduce deviation investigation cycle times from days to hours while maintaining full audit-trail traceability.

Packaging troubleshooting: Natural-language queries to diagnose line stoppages, serialization mismatches, or seal integrity failures using DT-linked packaging line data, enabling rapid operator-level triage without specialist engineering intervention.

Quality and deviation investigation: Automated generation of first-draft CAPA documentation and deviation reports from DT data records, subject to mandatory qualified-person review and approval prior to GMP-release.

Regulatory support: LLM-assisted compilation of process validation summaries aligned with ICH Q10 change-control expectations, accelerating the documentation burden associated with post-approval changes (Table 2).

Table 2. Proposed LLM-enhanced DT applications across the pharmaceutical value chain and their current maturity status.

Domain	Proposed LLM-DT Application	Maturity Status
Manufacturing	Root-cause analysis via natural language query; batch deviation hypothesis generation with cross-referencing of real-time sensor trends and CAPA databases	Conceptual / early preprint stage
Packaging	Line-stoppage and serialization troubleshooting; seal-integrity failure diagnosis; cold-chain excursion alerts with shelf-life impact assessment	Conceptual — not yet validated in pharmaceutical packaging
Quality (GMP)	Automated first-draft CAPA documentation and deviation reports, subject to mandatory qualified-person review and approval	Early research — Merck & Co. empirical demonstration (Salami et al., 2025)(14)
Regulatory Affairs	LLM-assisted process validation summaries and ICH Q10 change-control documentation; gap analysis against FDA	No formal FDA/EMA guidance for LLM-

	2025 Draft Guidance (FDA-2024-D-4689)	specific use; emerging regulatory attention
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6. Challenges and Regulatory Considerations

LLM-DT integration faces substantive technical, regulatory, and ethical barriers that necessitate systematic resolution before deployment in GMP-regulated pharmaceutical environments.

Hallucination and Factual Accuracy: LLMs are susceptible to generating syntactically plausible but factually incorrect outputs — a critical liability in GMP-regulated environments where decisions must be defensible and auditable. Retrieval-Augmented Generation (RAG) architectures, which ground LLM outputs in verified document retrieval rather than parametric memory, attenuate hallucination risk but do not eliminate it. All LLM-generated outputs must therefore be subject to qualified-person verification before any operational action is taken.

GMP Validation and Electronic Records Compliance: All software components within pharmaceutical manufacturing environments must satisfy applicable validation requirements. FDA 21 CFR Part 11(18) mandates controls for electronic records and signatures; EU GMP Annex 11(19) specifies equivalent requirements for computerized systems under EudraLex. LLM systems, as probabilistic and non-deterministic computational components, present unprecedented challenges for traditional Computer System Validation (CSV) frameworks, which were designed for deterministic, rule-based software.

Data Privacy and Cybersecurity: LLM-DT platforms process proprietary batch records, formulation parameters, and equipment-specific operational data. Deploying external API-based LLM services introduces data confidentiality risks incompatible with standard pharmaceutical data governance protocols. Private on-premises or air-gapped LLM deployments represent likely prerequisites for GMP-compliant operation.

Sustainability Trade-Offs: Quantified lifecycle analyses comparing the compute energy cost of LLM deployment against measurable reductions in solvent consumption, batch failures, and packaging scrap are currently absent from the peer-reviewed literature. This represents a substantive evidence gap that must be addressed before net-sustainability claims for LLM-DT integration can be rigorously validated.

Regulatory Acceptance and Human Oversight: Both the FDA and EMA are actively developing governance frameworks for AI and ML in pharmaceutical manufacturing. The FDA's 2023 Discussion Paper on Artificial Intelligence in Drug Manufacturing (Docket No. FDA-2023-N-0487)(20) and its 2025 Draft Guidance on the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products (Docket No. FDA-2024-D-4689)(21) signal accelerating regulatory attention to AI in pharmaceutical operations. LLM outputs must function exclusively as decision-support tools, with qualified personnel retaining unambiguous approval authority for all GMP-critical actions. A phased implementation and validation pathway structured around these regulatory anchors is illustrated in Figure 2.

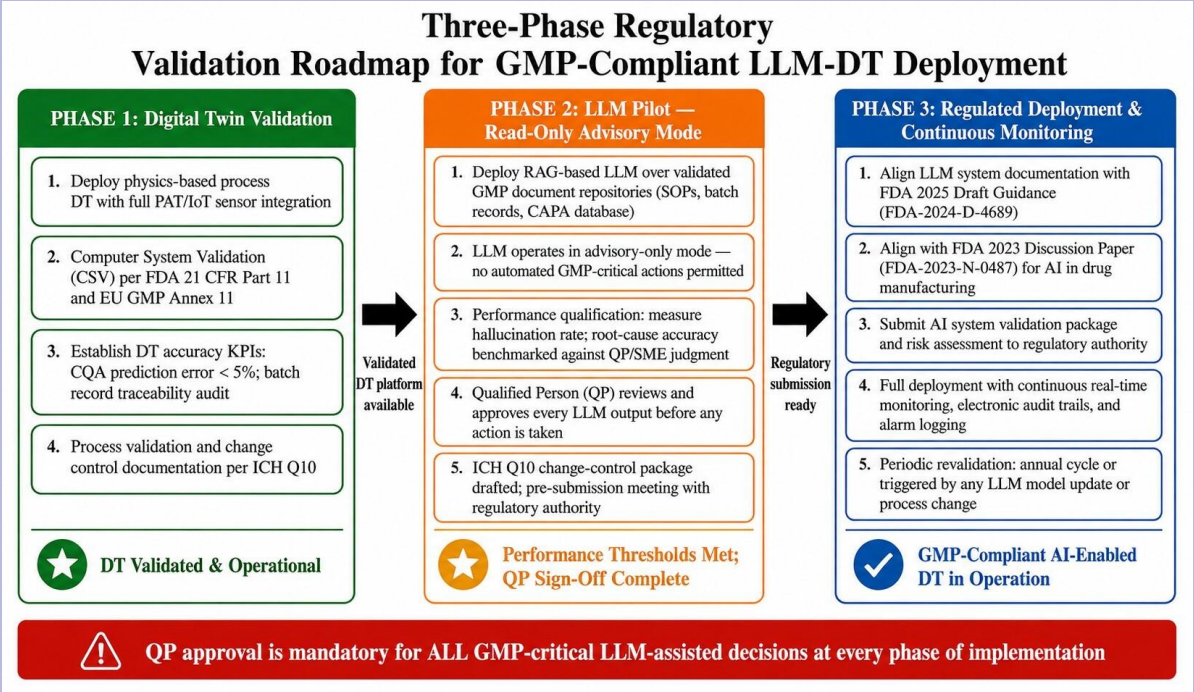


Figure 2. Three-phase regulatory validation roadmap for GMP-compliant LLM-enhanced Digital Twin (DT) deployment in pharmaceutical manufacturing.

[Phase 1 establishes the validated DT foundation through Computer System Validation (CSV) aligned with FDA 21 CFR Part 11 and EU GMP Annex 11. Phase 2 integrates the LLM in read-only advisory mode over a Retrieval-Augmented Generation (RAG) architecture, with performance qualification benchmarked against qualified person (QP) judgment and ICH Q10 change-control documentation submitted to the regulatory authority. Phase 3 delivers GMP-compliant full deployment with continuous real-time monitoring, electronic audit trails, and periodic revalidation, aligned with the FDA 2023 Discussion Paper on AI in Drug Manufacturing (Docket No. FDA-2023-N-0487) and FDA 2025 Draft Guidance (Docket No.

FDA-2024-D-4689). QP approval for all GMP-critical LLM-assisted decisions is mandatory at every phase. CSV, Computer System Validation; RAG, Retrieval-Augmented Generation; QP, qualified person; ICH, International Council for Harmonization; GMP, Good Manufacturing Practices.]

7. Future Outlook

The establishment of validated LLM models for the pharmaceutical industry, which includes the use of RAG across GMP doc archives, regulatory documents, and manufacturing history records, is the next step in the advancement of LLM-DT. In terms of sustainability, LLM-DT allows for recognizing quality issues and recommending corrective measures to assure resource-efficient Pharma 4.0 processes. However, implementation of this idea requires simultaneous developments in the fields of explainability frameworks, regulatory science, and energy-efficient LLM architectures, which are still under study now.

8. Conclusion

The use of digital twins shows visible results in pharmaceutical production and packaging through continual, live tracking of production processes, prediction of machinery failures and detecting problems at every level of CQA, while simultaneously bringing evident benefits in terms of sustainability including reduced material and solvent consumption as well as packaging waste. The introduction of LLMs as a basis for natural-language reasoning in DT platforms is a new trend which is based on certain scientific evidence and the outcomes of the preliminary study of pharmaceutical failures and successes in error rectifying methods in various industries. There are several issues that need to be addressed, particularly in respect of hallucination control, validation of GMP compliance in results of probabilistic software and evaluation of overall sustainability impact.

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N W S K W F E N D O F L I F E S P T T T
 R Y B O F E E L B A N I A T S U S H F H
 W M D L G H O L O G R A M P Z X F D V F
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SUSTAINABLE
 INTERNETOFTHINGS
 GREENRATING
 RENEWABLE
 RECYCLABLE
 HYBRID

REDISTRIBUTION
 BIOBASED
 BIOECONOMY
 THERMOPLASTIC
 ENDOFLIFE
 ANTICOUNTERFEIT

BLOCKCHAIN
 CARBONFOOTPRINT
 EFACTOR
 REVERSELOGISTICS
 HOLOGRAM

PHARMA NEWS ROUND-UP

14th May, 2026:

Roche Pharma has launched Tecentriq (atezolizumab) in India as the country's first subcutaneous immunotherapy for lung cancer. Administered as an under-the-skin injection, the treatment takes approximately seven minutes, significantly reducing administration time compared with conventional intravenous infusion, which can take several hours. The launch marks an advancement in patient-centric cancer care, offering a more convenient route of administration while potentially improving the overall treatment experience and quality of life for patients.

30th May, 2026:

Revolution Medicines has reported promising results from one of its cancer therapies based on the emerging concept of “molecular glue” drugs. This novel class of targeted therapies can promote interactions between proteins that would otherwise not interact, resulting in the selective degradation or functional disruption of disease-driving proteins. The therapy nearly doubled median survival in patients with aggressive forms of cancer, increasing it from 6.7 months to 13.2 months. Following these encouraging results, several pharmaceutical and biotechnology companies are investing in the development of similar therapies, highlighting the growing potential of molecular glue technology as an innovative strategy for targeted cancer drug discovery and treatment.

17th June, 2026:

The government has imposed restriction the over-the-counter sale of cough syrups across India. Henceforth, these medicines to be dispensed only against a doctor's prescription through licensed pharmacies. The move follows safety concerns associated with the unsupervised use of cough syrup formulations. To implement the restriction, the government has amended the Drugs Rules, 1945, removing syrup-based medicines from the list of drugs exempted under Schedule K from certain provisions governing their manufacture, sale, and distribution.

01st July, 2026:

Mankind Pharma Ltd. has partnered with Denovo Sciences to launch an AI-driven drug discovery programme. The collaboration aims to leverage artificial intelligence and advanced computational approaches to accelerate the identification and development of potential drug candidates. The initiative reflects the growing adoption of AI-enabled technologies in pharmaceutical research and drug discovery.

9th July, 2026:

Denmark-based Novo Nordisk has launched Awikli, the world's first once-weekly basal insulin injection, in India, for adults with both type 1 and type 2 diabetes. The launch represents a significant advancement in insulin delivery by reducing the frequency of administration compared with conventional daily basal insulin regimens. The once-weekly formulation could offer greater convenience and potentially improve treatment adherence, while competing with established daily insulin therapies in the Indian market.

10th July, 2026:

The government has tightened regulations on oral medicines containing more than 12% v/v ethyl alcohol when sold in packs or bottles exceeding 30 mL. These formulations will no longer be covered under the Schedule K exemption and will require the necessary drug licences. They have also been included under Schedule H1, meaning they can be dispensed only against a prescription from a registered medical practitioner, with stricter record-keeping requirements. The move aims to prevent the misuse and diversion of high-alcohol medicinal formulations while ensuring their availability for legitimate therapeutic use.

14th July, 2026:

The U.S. FDA has approved an at-home subcutaneous starting dose of lecanemab (Leqembi), developed by Eisai and Biogen, allowing eligible patients to initiate treatment through self-administration or with the help of a caregiver. Lecanemab is a monoclonal antibody that selectively targets soluble amyloid-beta aggregates (protofibrils), facilitating their clearance and slowing the progression of early Alzheimer's disease. The subcutaneous option provides an alternative to conventional intravenous infusion, offering greater convenience and reducing the burden of hospital-based administration.

22nd July, 2026:

The Indian Council of Medical Research (ICMR) has licensed three biomedical technologies aimed at addressing cancer and infectious diseases to Emcure Pharmaceuticals and Biological E. One of the technologies SHetA2, a drug candidate designed to target Cervical Intraepithelial Neoplasia, precancerous cervical lesions caused by HPV, has been licensed to Emcure Pharmaceuticals. The other two technologies; Typhoid Vaccine Candidate and Combination Vaccine (designed to combined immunity against *Salmonella typhi*, *Salmonella paratyphi*, and *Shigella* simultaneously) are vaccine candidates licensed to Biological E. The initiative represents an important step in translating publicly funded biomedical research into practical healthcare solutions.

11th August, 2026:

The medical device industry, patient safety organisations, and healthcare providers have raised concerns over the draft Drugs, Medical Devices and Cosmetics Bill, 2026. Stakeholders are particularly concerned that the proposed legislation may subject medical devices to a regulatory framework similar to that governing medicines. The Bill reportedly proposes imprisonment of one to seven years for certain labelling errors, documentation lapses, or engineering defects, even when no patient harm has occurred. It also proposes similar penalties for low-risk surgical instruments and high-risk medical implants. Industry stakeholders argue that this approach does not adequately account for the distinct technological, clinical, and risk profiles of medical devices. They caution that disproportionate regulatory requirements could hamper domestic manufacturing, discourage foreign investment, and slow the development and adoption of innovative medical technologies.

11th August, 2026:

Amgen, a leading US-based biopharmaceutical company, plans to establish a new Science and Innovation Center at Genome Valley in Hyderabad, with the facility expected to become operational by 2027. The center will bring together experimental science, advanced data analytics, and digital technologies to support innovative drug discovery and development.

25th August, 2026:

CDSCO has approved the local manufacturing pathway for lenacapavir, with Dr. Reddy's Laboratories and Emcure Pharmaceuticals receiving waivers from the requirement to conduct Phase 3 clinical trials and bioequivalence studies. This decision marks an important step toward accelerating domestic production and facilitating access to twice-yearly long-acting injectable lenacapavir for HIV prevention. However, both companies are expected to conduct a Phase 4 post-marketing efficacy study in India. As part of this requirement, they must submit the study protocol to CDSCO within three months of receiving authorization.

29th August, 2026:

The National Pharmaceutical Pricing Authority (NPPA) has proposed a draft amendment of Drugs (Prices Control) Order (DPCO) 2013 wherein the drug manufacturers will be solely prosecuted for the overpricing of essential medicines while exempting retail chemists, stockists, distributors and hospitals. With this proposed amendment, the drug manufacturers will have to face the legal and financial liability arising from violations of prescribed price limits. This significant shift in accountability is expected to face strong opposition from pharmaceutical companies, which may argue that the proposal places an excessive and disproportionate burden on manufacturers.

<https://economictimes.indiatimes.com/>

APTI Forum News

1. Bela Pharmacy College Organize ‘Drink Buttermilk, Live Healthy’ Seminar

Rotary Club Ropar Central, in collaboration with the Rotaract Club of the College of Pharmacy, Bela Ropar, organized an awareness seminar titled **“Drink Buttermilk, Live Healthy”** to promote the health benefits of traditional probiotic beverages. The event featured Prof. Dr. Swaranjit Singh as the chief speaker. Dr. Singh, who serves as the National Chairman of the Drink Buttermilk initiative, Director of SAS Polyclinic, and former Professor and Head of Environmental Biotechnology at AcSIR-IMTECH Chandigarh, delivered an informative address on the nutritional and medicinal value of buttermilk. Speaking on the occasion, Dr. Singh described buttermilk as an excellent natural probiotic that supports digestive health by restoring beneficial gut bacteria. He emphasized that regular consumption of buttermilk strengthens immunity, improves digestion, maintains hydration, and provides essential nutrients while containing significantly fewer calories and sugars than aerated beverages. He encouraged people to adopt buttermilk as a healthy daily drink, especially during the summer season. To complement the awareness campaign, the College of Pharmacy organized a community langar during which buttermilk was served to more than 2,000 people. Volunteers distributed approximately 750 litres of buttermilk among attendees, receiving an enthusiastic response from the public. Dr. Shailesh Sharma, Director of the College of Pharmacy, Bela, highlighted the importance of promoting healthy dietary habits and noted that buttermilk is a far superior cooling beverage compared to carbonated soft drinks. Dr. Neelam Sharma and her team efficiently coordinated the langar service, ensuring smooth distribution throughout the event. The seminar successfully combined expert guidance with community outreach, encouraging people to embrace traditional, nutritious, and probiotic-rich beverages for better health.



2. **Dr. Poonam Nikam**, Assistant Professor at Amity Institute of Pharmacy, Amity University Maharashtra, Mumbai Campus, and APTI Life Member (Ref. No. MA/LM 2844), has been granted an Indian patent titled **“Transdermal Composition and Method for Sustained Delivery of Antihypertensive Agents”** (Application No. 202521097471), filed on October 9, 2025, and granted on May 26, 2026. The innovation focuses on developing a transdermal drug delivery

system for the sustained release of antihypertensive agents, aiming to improve therapeutic efficacy and patient compliance.



3. International Yoga Day Celebrated at COP-BELA

Amar Shaheed Baba Ajit Singh Jujhar Singh Memorial College of Pharmacy, Bela, (An Autonomous College) celebrated International Yoga Day with great enthusiasm. Students, faculty members, and staff actively participated in the yoga session and performed various asanas, breathing exercises, and meditation techniques. The participants were encouraged to adopt yoga as a regular practice for maintaining a healthy lifestyle and managing stress effectively. On this occasion, Director Dr. Shailesh Sharma highlighted the benefits of yoga, stating that regular practice improves physical fitness, mental peace, concentration, and overall health. He emphasized that yoga helps individuals achieve balance in life and contributes to building a healthier society. The programme was organized by Dr. Sandeep Kumar and Dr. Suman Lata to promote awareness about the importance of yoga for physical, mental, and emotional well-being. The programme concluded with a message encouraging everyone to make yoga a part of their daily routine for holistic well-being and a healthier future.



4. **Dr. Jubie Selvaraj** has been nominated to serve on the Academic Activity Cell of the APTI Women's Forum, with the approval of the National President, APTI, and on the recommendation of the National Convenor and Co-Convenor. The Cell aims to promote academic excellence, faculty development, continuous learning, and professional growth through academic activities and faculty development programmes in pharmacy education.



5. **Dr. Shailaja S. Shirsath**, Associate Professor at Shree Ambabai Talim Sanstha's Diploma in Pharmacy College, Miraj, and APTI Life Member (Ref. No. MA/LM-3136), has been awarded the Doctor of Philosophy (Ph.D.) in Pharmacy by Dr. Babasaheb Ambedkar Technological University. She completed her doctoral research under the guidance of Dr. K. V. Otari, contributing to the field of cardiovascular pharmacology and experimental therapeutics.



6. **Periyar College of Pharmaceutical Sciences, Tiruchirappalli Strengthens Academic, Industrial and Healthcare Collaborations through a Series of MoUs**

Tiruchirappalli, 27 August 2026:

Periyar College of Pharmaceutical Sciences (PCPS), Tiruchirappalli, strengthened its academic, industrial and healthcare collaborations through a series of Memoranda of Understanding (MoUs) with reputed institutions and organisations during August 2026.

Prof.Dr. R. Senthamarai, Principal, Periyar College of Pharmaceutical Sciences, Tiruchirappalli, signed the MoUs with the respective Heads/Authorised Representatives of the partner institutions and organisations, in the presence of the Vice Principal, faculty members and other officials of the college and partner organisations. The college signed MoUs with Emmchak Formulations Pvt. Ltd. on 18 August; K. S. Varier's Ashtanga Ayurvedics Pvt. Ltd. on 19 August; Aruna Clinical Laboratory & X-Rays, Puducherry on 20 August; Siddha Forest on 21 August; Jamal Mohamed

College (Autonomous) on 22 August; HarshaMitra Oncology Pvt. Ltd.; on 24 August, and GRT Institute of Pharmaceutical Education and Research, Tiruttani on 25 August 2026. The collaborations aim to create enhanced opportunities for industrial and healthcare exposure, internships, practical training, research, skill development, knowledge exchange and professional development for students and faculty.

The series of MoU signings marks a significant milestone in PCPS's continued efforts to build strong institutional partnership and provide students with practical, experiential and career-oriented learning opportunities.

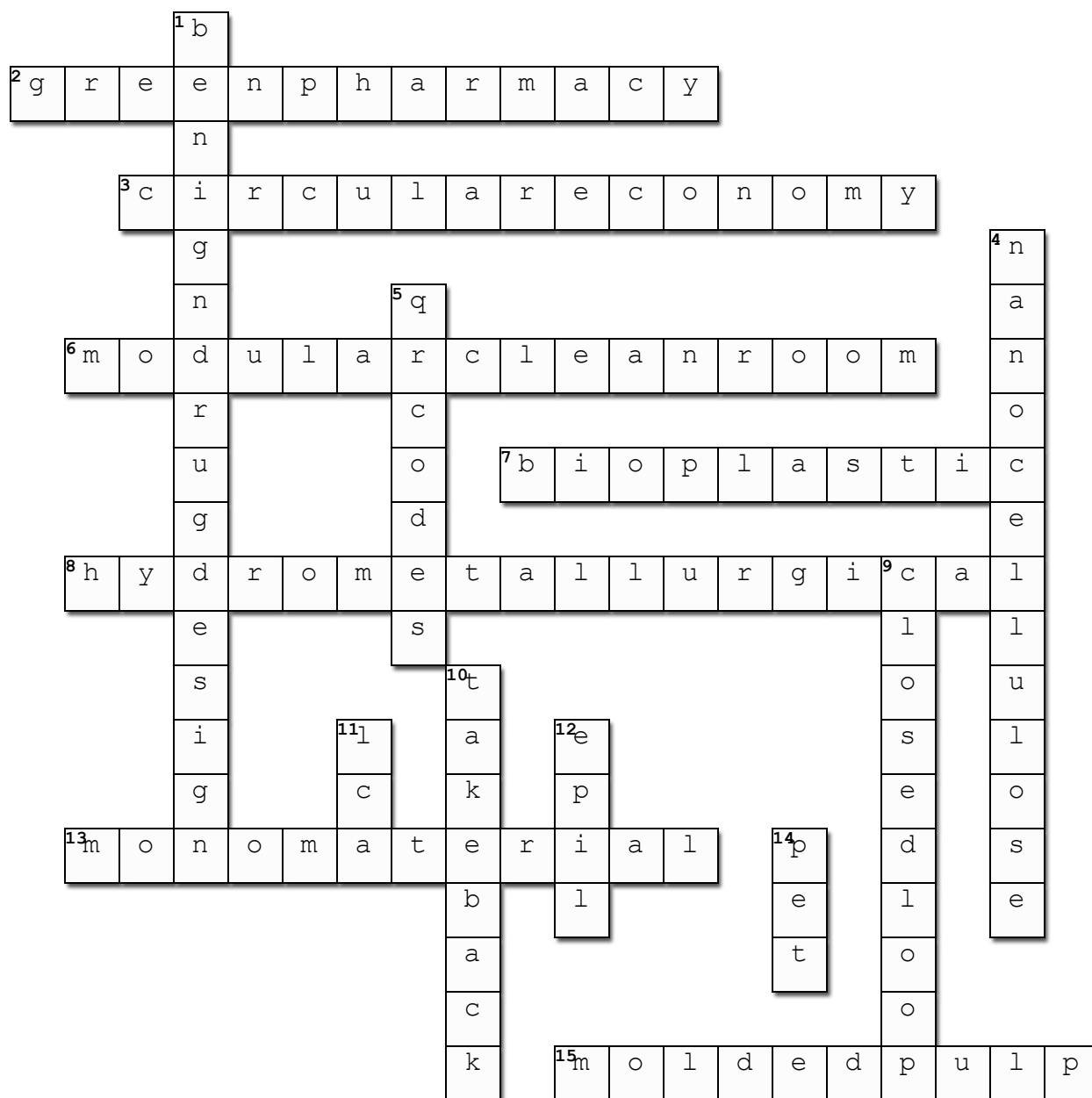


WORD SCRAMBLE

Answers:

1. MONO-MATERIAL
2. DIGITAL PACKAGING
3. BIODEGRADABLE
4. CLOSED-LOOP RECYCLING
5. CONTINUOUS MANUFACTURING
6. SOLVENT RECOVERY
7. COMPOSTABLE
8. REFILLABLE
9. ZERO WASTE
10. RECYCLED CONTENT
11. CARBON FOOTPRINT

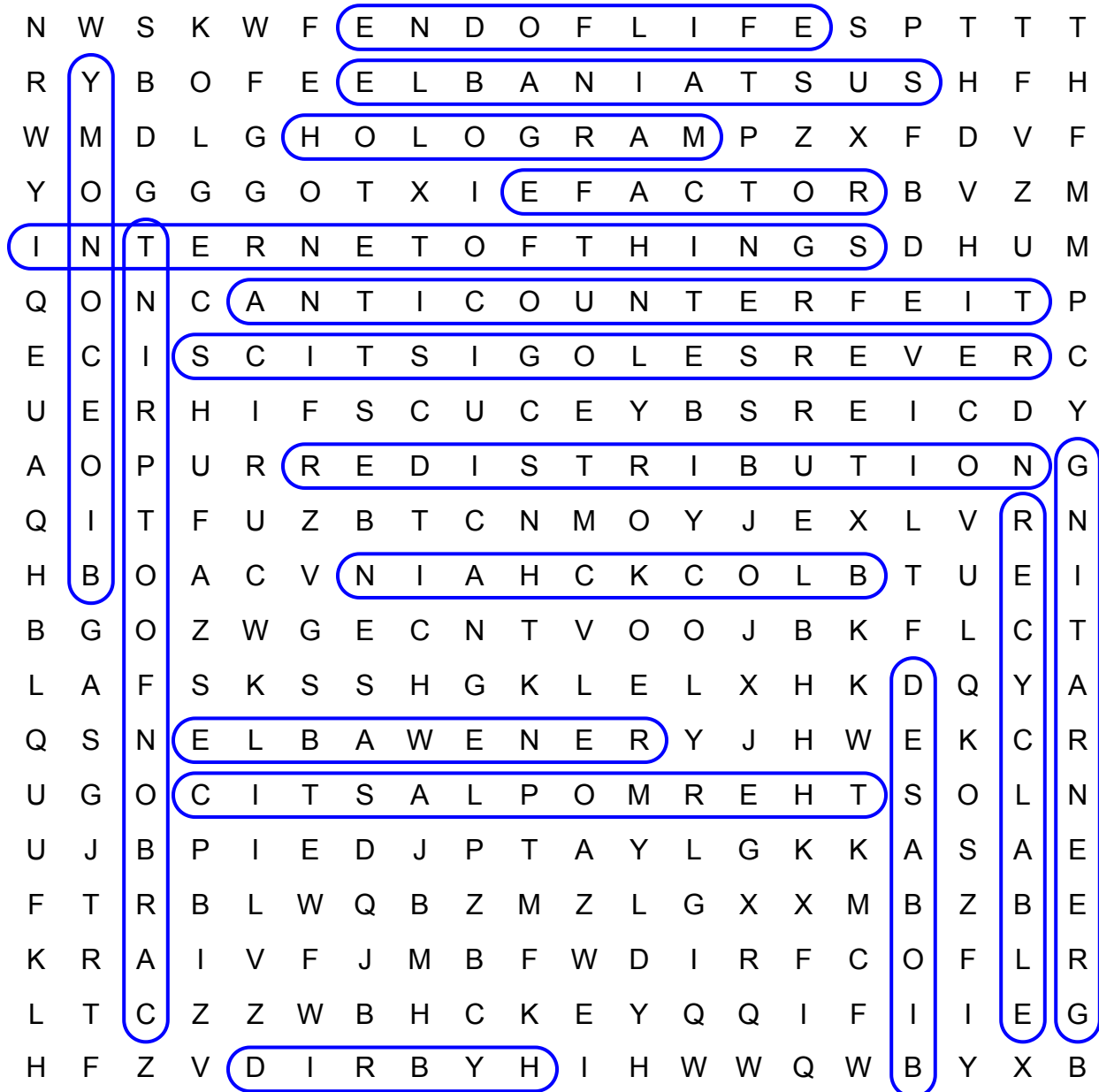
Complete the crossword puzzle below

**Across**

2. Concept of biodegradable pharmaceuticals (**greenpharmacy**)
3. Economy focusing on minimizing waste (**circulareconomy**)
6. sustainable alternative to reduce power consumption and waste (**modularcleanroom**)
7. Plastic derived from renewable biological sources (**bioplastic**)
8. Method to split complex aluminum-plastic blister foils (**hydrometallurgical**)
13. Packaging made primarily from a single material to facilitate recycling (**monomaterial**)
15. Green pharma packaging (**moldedpulp**)

Down

1. creating medicines that safely break down in nature after use (**benigndrugdesign**)
4. Plant based packaging material (**nanocellulose**)
5. Digital Packaging (**qr codes**)
9. Recycling system that returns recovered materials to production (**closedloop**)
10. Structured medicine and device recovery scheme (**takeback**)
11. Tool for Eco Design abbr (**lca**)
12. Eco-packaging innovation (**epil**)
14. Recyclable plastic abbr. (**pet**)



SUSTAINABLE
 INTERNET OF THINGS
 GREEN RATING
 RENEWABLE
 RECYCLABLE
 HYBRID

REDISTRIBUTION
 BIOBASED
 BIOECONOMY
 THERMOPLASTIC
 ENDOFLIFE
 ANTICOUNTERFEIT

BLOCKCHAIN
 CARBON FOOTPRINT
 EFACOR
 REVERSE LOGISTICS
 HOLOGRAM

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LOTUS LOGO STORY

As a lotus is able to emerge from muddy waters un-spoilt and pure it is considered to represent a wise and spiritually enlightened quality in a person; it is representative of a woman who carries out her tasks with little concern for any reward and with a full liberation from attachment. Lotus-woman in the modern sense of women's qualities: she is superbly intelligent, highly educated, and totally committed to individualism. She is exquisite in her taste for music, art and culture, abounds in social graces and performs brilliantly in communication.



*Empowering
Women
in Pharmaceutical
Sciences*



*Connect, Collaborate,
Contribute
for a Sustainable
Tomorrow*

