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Pharma Waste and Green Manufacturing: Green Chemistry in Pharmaceutical Industry: Waste Minimization, E-Factor, and Sustainable API Manufacturing in India

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Abstract
The pharmacy industry, as vital as it is for public health, carries a high environmental price tag through multistep chemical syntheses, high solvent consumption, and the production of hazardous waste. The Environmental Factor (E-factor) measures this inefficiency, tending to uncover waste-to-product ratios of 25–100 kg per kilogram of active pharmaceutical ingredient (API).

Green chemistry and engineering concepts, such as catalysis, biocatalysis, intensification of processes, reduction in solvents, and lifecycle analysis, have come to reduce environmental impact without compromising product performance. Corporate social responsibility (CSR) campaigns, government policies, and research-government partnerships have helped the implementation of green practices in drug production in India. This overview consolidates recent literature on green pharmacy manufacturing, assesses waste minimisation strategies, examines technological advancements such as AI and IoT to enhance resource optimisation, and accentuates the pharmacists' role in minimising pharmaceutical waste. Inclusion of green chemistry across the supply chain, along with policy and technology interventions, offers a route to sustainable and eco-friendly pharmaceutical production.

Keywords: Green chemistry, Green engineering, Pharmaceutical industry, Sustainability, Drug development, Waste minimization, E Factor (Environmental Factor)

Introduction
Pharmaceutical green chemistry aims at increasing the drug discovery efficiency, safety, and environmental compatibility [1]. The world pharmaceutical market is expanding at around 5–6% annually, [2] but it produces enormous chemical waste because of intricate multi-step syntheses. The theory of the Environmental Factor (E-factor) by Sheldon in 1992 [3] is a common measure to determine waste, as the ratio of total waste generated to product mass produced. Fine chemicals and APIs have high E-factors, while bulk chemicals have low waste ratios [4].

The shift toward generics, biosimilars, and high-potency APIs has intensified the need for environmentally sustainable production methods [5, 6]. Catalysis, particularly biocatalysis using enzymes, has emerged as a critical tool for reducing energy consumption, hazardous solvent use, and waste generation [7]. Beyond production, waste prevention strategies, efficient supply chain management, and the incorporation of corporate social responsibility (CSR) frameworks are integral to minimising the environmental footprint of pharmaceutical operations [8].

Literature Review
1. In 2020, Vimarsa *et al*. highlighted the value of safe disposal of medications and the key role of pharmacists in educating patients to avoid contamination of water systems by medicines.
2. In 2018, Narayana *et al*. reported and examined reverse logistics in India's pharmaceutical market, where category-sensitive take-back schemes and controls at the supply side are essential to minimise stockpiling of expired inventory.
3. In 2018, Alinska *et al*. reported that the collaborative function of governments, financial

organisations, and private institutions towards sustainable development involved the sharing of resources and monetary incentives.

4. In 2017, Doshi *et al*. observed a strong interest in green chemistry among Indian generic pharmaceutical companies and API manufacturers, but also pointed out that a large majority of the firms preferred the treatment of wastewater to prevention, in which cost-saving and following regulations prompted implementation.
5. In 2017, Smith KR.et.al emphasised the high costs and environmental hazards of improper drug waste disposal, especially in Asian nations.
6. In 2016, Sheldon RA. *Et al*. Described E-factor, atom economy, and process mass intensity (PMI) as drivers towards sustainable drug manufacturing.
7. In 2006, Butter M. *et al*. discussed environmentally friendly synthetic methods in FDA-approved medicinal compounds, highlighting green chemistry's role in sustainable process design.
8. In 2004, Kautto. *et al*. analysed Finnish industry response to waste policy, highlighting the need for source-level waste reduction.
9. In 2001, Kidwai.et.al. reported on the shift toward low-cost APIs, emphasising greener technologies such as catalysis and biocatalysis supported by government and academic collaborations.

Pharmaceutical Waste: Types and Management

Waste Classification: Pharmaceutical waste is generally classified as:

Hazardous waste: Contains cytotoxic drugs, reactive chemicals, flammable or corrosive substances [9].

Non-hazardous waste: Expired or unused drugs that are not of high toxicity, e.g., certain over-the-counter tablets or vitamins [10]

Management Strategies: The best disposal practices are:

1. High-temperature incineration (>1200 °C) for cytotoxic and hazardous waste [11].
2. Encapsulation, inertization, and engineered landfills for low-to-moderate hazard materials [13].
3. Neutralisation of limited quantities by chemical agents like alkalis or acids [14].
4. Preventive measures include stopping medicinal drugs from entering water bodies and a prohibition on incineration at low temperatures to eliminate toxic emissions [15, 16].
5. Pharmacists must ensure rational prescribing, educate patients about drug disposal, and comply with environmental standards for safety [17].

Principles of Green Pharmaceutical Manufacturing

- Green manufacturing seeks to minimise the environmental footprint through:
- Energy and water savings: Preferential use of renewable energy and recycling of water [18].
- Green packaging: Use of recyclable or biodegradable packaging [19].
- Greener chemicals: Cleaner synthesis routes with minimal toxic by-products [20, 21].

Green Chemistry protocols

- Choice of safer solvents and reaction conditions [22].
- Practice of biocatalysis or enzymatic transformations [23, 24].
- Continuous flow chemistry and in-line process monitoring (Process Analytical Technology, PAT). Optimisation of atom economy and process intensification to minimise by-products [25, 26].
- Lifecycle analysis and eco-efficiency analysis to measure environmental impact [27].

Catalysis and API Manufacturing

Catalysis is at the heart of environmentally benign API manufacture [28]. Biocatalysis allows selective, efficient, and low-waste conversion relative to traditional chemical reactions [29]. Designing production pathways based on catalysis, continuous flow methods, and solvent recycle dramatically enhances sustainability indicators, minimises E-factors, and decreases the environmental impact of medicines [30].

Industrial Ecology and Waste Avoidance

Waste is not just material loss but also concealed costs, such as energy, labour, and liability [31]. Although industries traditionally concentrated on end-of-pipe treatment, current sustainable practices target waste prevention, recycling, and resource optimisation [32]. Industrial ecology principles bring together material and energy flows through production networks to reduce environmental footprint and enhance efficiency [33].

Green Chemistry in India

Green chemistry consciousness in India started in 1999 with academic symposia and later extended to industrial applications. Corporate social responsibility (CSR) activities of the Indian Companies Act, 2013, have made environmental and social contributions obligatory for pharmaceutical companies [34]. Such programs favour sustainable practices, community health, and environmental protection and improve corporate image and compliance [35].

Sustainable Pharmaceutical Supply Chains

- Pharmaceutical supply chains are a major source of environmental footprint due to energy-intensive API production, long-distance transportation, and non-biodegradable packaging [36]. Greening the supply chains can be achieved with the following strategies:
- Lean and just-in-time production with low resource usage [37]. Implementation of renewable power and water-effective processes [38]. Green packaging and logistics [39].
- Technology-driven monitoring based on AI, IoT, and data analysis for resource efficiency and waste minimisation [40].

Technological Innovations for Green Pharma:

Digital technologies such as AI, IoT, and digital analytics enable predictive waste management, process improvement, and resource optimisation [41]. Green-focused HRM, regulatory control, and data-enabled process design complement each other in their joint facilitation of green practice implementation [42, 43]. Their integration provides ongoing monitoring, eco-efficient process management, and better compliance with environmental standards [44].

Disposal Practices and Remedial Actions:

- Safe disposal is regulated by regulatory guidelines and best management practices (BMPs) [56,57,58]. Safe disposal options include:
- Drug take-back programs and community collection programs [45].
- High-temperature incineration of harmful substances [46].
- Immobilisation and engineered landfills for waste that cannot be incinerated [47].
- Mixing liquid and solid pharmaceuticals with inert substances before disposal [48].
- Pharmacists have an important role in informing patients and healthcare workers on safe disposal, reducing environmental pollution, and ensuring rational drug consumption [49]

Conclusion

Green chemistry has emerged as a reality in pharmaceutical production for sustainable development, environmental sustainability, and community health. With catalysis, biocatalysis, process optimisation, and CSR-based activities, the sector is shifting from wasteful processes to ecologically sound practices. Technological innovation, regulation, and inter-sectoral action between academia, industry, and government further increase sustainability. Green chemistry integration in pharmaceutical manufacture, supply chains, and clinic practice ensures that drugs cure diseases without harming the environment. Sustained efforts are needed for the balancing of innovation, profitability, and environmental stewardship in the pharma industry.

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