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A questionnaire-based study on industrial waste management in Indian biopharmaceutical industries

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ABSTRACT

This study investigates industrial waste management practices within the Indian biopharmaceutical sector through a questionnaire-based approach. The questionnaire was sent to ten Indian biopharmaceutical companies in Himachal Pradesh (30°57'26.3"N 76°47'27.4"E), Uttarakhand (30°19'03.8"N 78°01'55.4"E), East Sikkim (27°19'54.5"N 88°36'49.4"E), and Bangalore (12°58'19.4"N 77°36'53.3"E). It asked about different aspects of industrial waste management, such as how to get rid of waste, working with waste management groups, and promoting sustainable practices like treating and reusing wastewater. The results of this study revealed current industrial waste management practices adopted by Indian biopharmaceutical industries, highlighting trends, challenges, and opportunities for improvement. This study contributed to the knowledge of industrial waste management practices in the Indian biopharmaceutical sector, offering information for policymakers, industry officials, and environmental professionals seeking to enhance industrial waste management strategies and promote sustainable development in the Indian biopharmaceutical industry.

Introduction

In recent years, concerns have escalated regarding the improper disposal of biopharmaceutical waste, as it poses significant challenges to ecosystem integrity and human well-being. The disposal of industrial waste presents unique challenges due to the complex nature of these substances and their potential to cause harm if not mitigated appropriately (Rajbongshi *et al.*, 2016).

Effective waste management strategies, including proper segregation, storage, transportation, and disposal of biopharmaceutical waste, are essential to minimize environmental impact and protect public health (Jaseem *et al.*, 2017). One of the primary environmental risks posed by biopharmaceutical waste is the contamination of water bodies (Shukla *et al.*, 2017). Wastewater discharged from biopharmaceutical facilities may contain many chemical compounds, including active biopharmaceutical ingredients (APIs), solvents, and other process-related contaminants (Rajbongshi *et al.*, 2016). When released into water bodies without adequate treatment, these compounds can persist in the environment, posing risks to aquatic ecosystems and potentially entering the food chain (Dar *et al.*, 2019). Moreover, the presence of biopharmaceutical residues in water sources can also contribute to the development of antibiotic resistance in bacteria, further exacerbating public health concerns (Abhilash, 2012).

The production of biopharmaceuticals must adhere to regulatory requirements and Good Manufacturing Practices (GMP) to minimize environmental contamination and protect public health (Padilla-Zakour, 2009). Policies are crucial in shaping the framework for industrial waste management, providing guidelines and regulations that govern waste handling, storage, and disposal practices (Sreekanth *et al.*, 2014). Regulatory agencies, such as the United States Environmental Protection Agency (EPA) and the European Medicines Agency (EMA), establish standards and requirements to ensure compliance with environmental protection laws and public health standards (Rajbongshi *et al.*, 2016). In India, the regulatory body responsible for overseeing the biopharmaceutical industry, including waste management practices, is the Central Drugs Standard Control Organization (CDSCO) (Bakliwal, 2013). The CDSCO, operating under the Ministry of Health and Family Welfare, oversees biopharmaceutical

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products' safety, efficacy, and quality. The CDSCO issues guidelines and regulations about waste management practices for the biopharmaceutical industry in India (Chowdhury *et al*., 2015). Castensson (2008) designed these guidelines to ensure compliance with environmental protection laws, public health standards, and safety regulations. They cover various aspects of waste management, including handling, storage, transportation, treatment, and disposal (Vijaylakshmi *et al.*, 2023; Lalor *et al.*, 2019).
This research explores current industrial waste management practices, identifies key challenges, and proposes strategies for improving industrial waste management within the Indian biopharmaceutical industry. Through a literature review, case studies, and empirical analysis, this study seeks to contribute to developing sustainable industrial waste management practices that balance industry growth with environmental preservation, thereby advancing the broader goals of sustainable development and responsible corporate citizenship.

Material and Methods

The present study is a cross-sectional questionnaire-based approach to waste management (Bungau *et al.*, 2018) in 10 Indian biopharmaceutical industries conducted from August 2022 to March 2024. The questionnaire focused on critical aspects such as waste management procedures, protocols for proper handling and disposal of hazardous waste, checking the availability of on-premises sewage treatment systems, use of energy-saving technologies, regulated release of harmful substances, compliance challenges (if any), and proposed solutions.

Survey instrument

The study conducted a review of existing literature to understand how Indian biopharmaceutical companies adhered to waste management regulations, primarily focusing on GMP and other regulatory body guidelines. The authors then developed a structured questionnaire to address how Indian biopharmaceutical industries had followed manufacturing compliance regarding industrial waste management (Lipmann, 1999). This questionnaire discusses the techniques and systems involved in industrial waste management practices. It also included questions about their challenges in following these rules and what solutions industries would propose to regulatory bodies (Bungau *et al.*, 2018).

Data collection and analysis

We used a structured questionnaire as a study stool to gather data and responses from industry officials. In-person interviews were employed for data collection. Responses were gathered and analyzed from industry using descriptive statistics in Microsoft Excel (Behl *et al.*, 2022). Categorical data analysis was used to evaluate percentages (Salhia *et al.*, 2015).

Results and Discussion

The establishment of a protocol for the handling and disposal of hazardous materials is necessary

Waste management in biopharmaceutical industries is critical to ensuring environmental protection and public health (Handa and Rajmani, 2023). Establishing protocols for the handling and disposing of hazardous materials is essential to mitigate risks and comply with regulatory requirements (Rajbongshi *et al.*, 2016). The study of the data related to the set protocols for handling and getting rid of dangerous materials showed that businesses carefully followed the steps set by the Indian government for managing hazardous industrial waste under the Environmental Protection Act of 1986 and the rules made by regulatory bodies. These protocols ensured adherence and emphasized a dedication to safety and environmental responsibility. Trained personnel handled hazardous materials with utmost efficacy, subjecting their actions to frequent audits. This stringent oversight not only safeguarded the well-being of personnel but also minimized adverse environmental impact, thus reflecting a holistic approach towards risk management and sustainability. Effective protocols for handling and disposing of hazardous materials were vital to minimize environmental contamination and ensure personnel safety (Patneedi *et al.*, 2015). During their manufacturing processes, these biopharmaceutical industries dealt with a variety of hazardous substances, such as chemicals, biological agents, and biopharmaceutical waste (Vijayalakshmi et al., 2023). Establishing clear protocols helped with the proper containment, transportation, and disposal of these materials, reducing the risk of environmental pollution and human exposure. Implementing robust protocols for handling and disposal of hazardous materials allowed biopharmaceutical industries to effectively mitigate risks associated with industrial waste management (Shukla *et al.*, 2017). Proper personnel training, the use of appropriate containment measures, and regular monitoring of waste streams were all critical components of their risk mitigation strategies. Industries minimized environmental impact by identifying potential hazards and implementing preventive measures (Patneedi *et al.*, 2015). They also implemented waste segregation practices to properly identify and treat hazardous waste streams. Disposal methods for hazardous materials in biopharmaceutical industries varied depending on the type of waste and regulatory requirements (Letsitsi, 2012). Standard disposal methods included incineration, chemical treatment, landfilling, recycling, and on-site treatment. Each method was carefully selected based on effectiveness, environmental impact, and regulatory compliance (Kaushal *et al.*, 2022).

The optimization of manufacturing processes is crucial for ensuring environmental safety

During interviews, it was observed that 80% (Figure

1) of industries had implemented effective systems such as Air Pollution Control Systems, Effluent Treatment Plants (ETP) segregation, storage, treatment, and disposal of hazardous waste, often through methods like incineration or secure landfilling for managing the release of harmful substances into the environment during manufacturing processes. These systems typically included advanced filtration and treatment methods, stringent monitoring protocols, and compliance with regulatory standards. Such proactive measures mitigated environmental risks and demonstrated a commitment to sustainable manufacturing practices. However, it is worth noting that 20% (Figure 1) of the industries lacked this system. Nevertheless, they mentioned their intention to work on implementing such measures in the future, indicating a positive shift towards environmental responsibility within the industry. Among the industries surveyed, most biopharmaceutical industries had already instituted effective systems to manage the release of harmful substances during their manufacturing processes (Shukla *et al.*, 2017). These systems were comprehensive, incorporating advanced filtration, treatment methods, stringent monitoring protocols, and strict adherence to regulatory standards (Dar *et al.*, 2019). These proactive measures mitigated environmental risks and signified a deep-seated commitment to sustainable manufacturing practices (Mondal and Sinha, 2014). However, our findings also revealed that a few surveyed industries had yet to implement such systems. Despite this shortfall, it was encouraging to note that many of these industries expressed their intent to rectify this gap. This indicated a promising

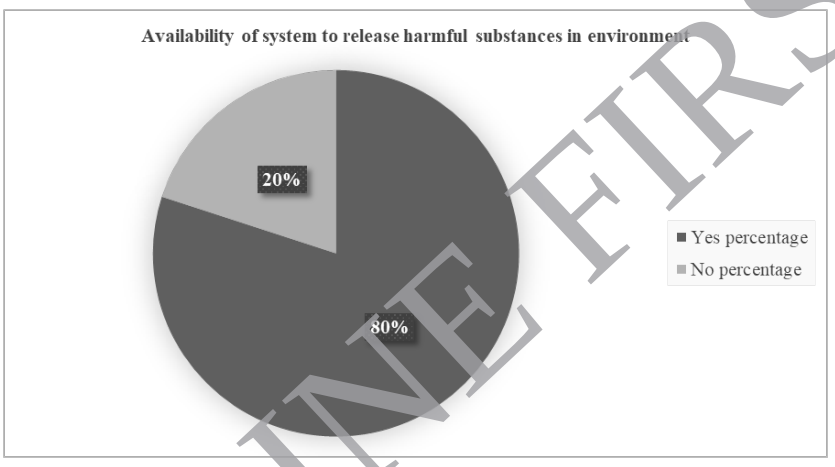

Figure 1: Displays the availability of environmental safety systems

trend toward increased environmental responsibility within the industry, as these industries recognized the importance of adopting measures to safeguard the environment while carrying out their biopharmaceutical manufacturing processes (Milanesi *et al.*, 2020). Overall, our findings underscored the critical importance of robust systems for preventing the release of hazardous substances into the environment during manufacturing processes (Patneedi *et al.*, 2015).

Adoption of energy-saving technologies is necessary to reduce the carbon footprint.

Data analysis revealed that only 50% (Figure 2) of industries were implementing energy-saving technologies to reduce their facility's carbon footprint. For instance, energy-efficient lighting using LED lights and the installation of solar panels helped to generate clean energy on site; energy-efficient heating, ventilation, and air conditioning systems enhanced building insulation to reduce heating and cooling needs and improved overall energy efficiency. This demonstrated a significant shift in the industry's adoption of these technologies. The companies that opted for these technologies recognized their numerous benefits, including reduced energy costs, enhanced sustainability, and minimal environmental impact. These companies demonstrated their commitment to responsible environmental responsibility by embracing energy-saving technologies, while also improving their operational efficiency and market competitiveness. Observations also revealed that some industries were actively implementing energy-saving technologies to lower their facilities' carbon footprint. This proactive approach aligned with broader sustainability initiatives aimed at minimizing environmental impact (Fernando and Hor, 2017). By adopting energy-saving technologies such as energy-efficient lighting and renewable energy sources, these companies reduced their greenhouse gas emissions, lowered operating costs, and enhanced operational sustainability (Lee, 2015). Additionally, integrating energy-saving measures underscored a commitment to environmental responsibility and positioned these companies as leaders in sustainable production business within the biopharmaceutical sector.

Waste disposal practices

According to the data, 70% of industries rely on non

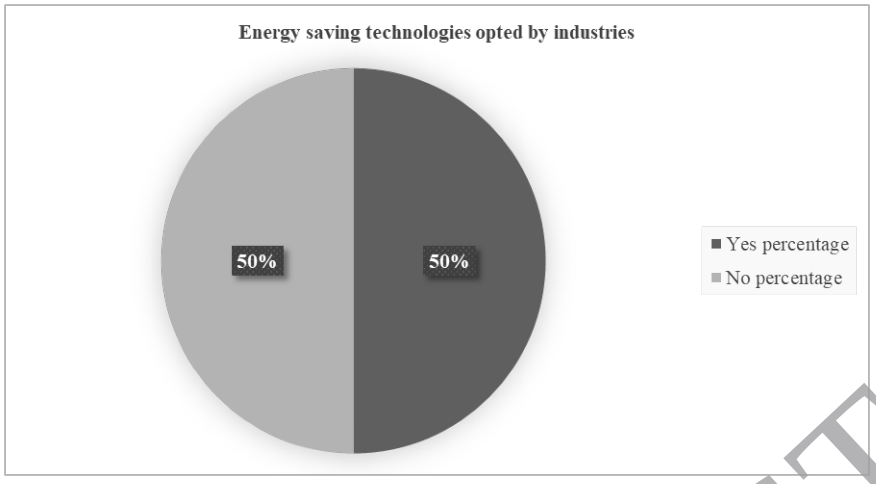

Figure 2: Illustrates the percentage of industries adopting technologies to reduce their carbon footprint

-government agencies for waste disposal. Meanwhile, the remaining 30% chose to dispose of their waste via government agencies (Figure 3). The study revealed that industries utilized government and non-government agencies for waste disposal. However, the data indicated a notable preference for non-governmental agencies (Damanhuri *et al.*, 2014). Several factors contributed to this observed preference. Industries perceived non-government agencies to offer more specialized services tailored to their unique needs, potentially leading to more efficient and cost-effective waste management solutions (Lipmann, 1999). Additionally, industries perceived non-government agencies as more responsive and adaptable to changing regulatory landscapes and environmental standards. In contrast, some industries chose to entrust their waste management responsibilities to government agencies.

An industrial wastewater treatment system is built in.

Figure 4 observed that 60% of industries had an in-built wastewater treatment system. The industrial premises designed these systems to treat wastewater. The physical treatment methods involved screening, sedimentation, filtration, and biological treatment. Furthermore, they employed advanced treatment technologies such as membrane filtration and electrocoagulation. They typically involved filtration, biological treatment, and disinfection to remove contaminants from the water before discharge or reusing. Such systems helped industries comply with environmental regulations, minimize pollution, and reduce their impact on local water resources. Biopharmaceutical industries prioritized pollution prevention strategies to minimize waste generation at the onset of the production process. This included implementing green chemistry principles, optimizing manufacturing processes to reduce raw material usage, and adopting innovative technologies that produced less industrial waste during production (Pratyusha *et al.*, 2012). Additionally, biopharmaceutical industries invested in advanced treatment technologies to effectively treat and manage the industrial waste generated during their processes

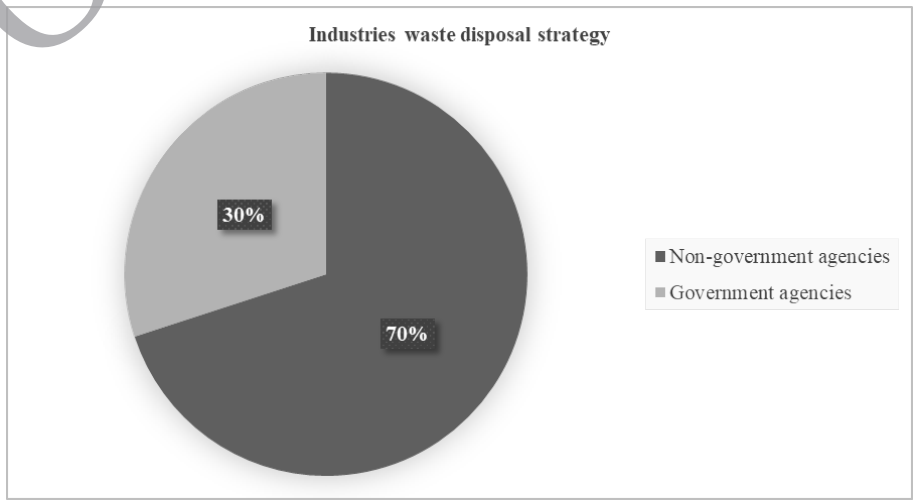

Figure 3: Demonstrating the approach to waste disposal by industries

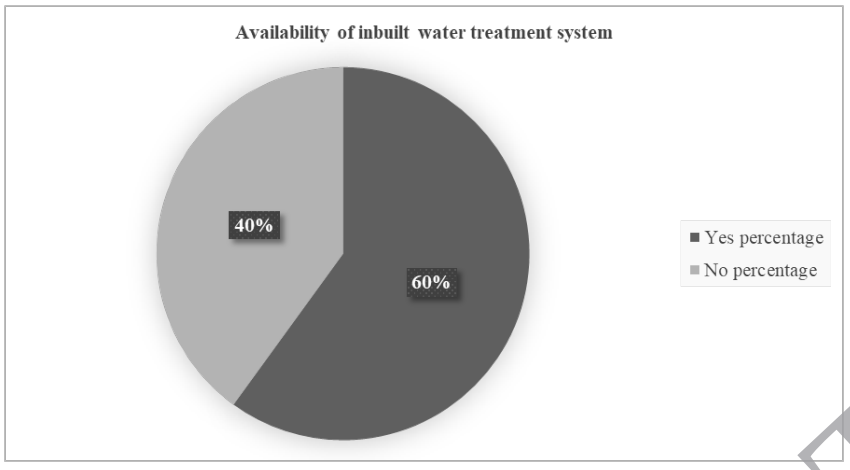

Figure 4: Shows whether industries had inbuilt wastewater treatment systems

(Kaushal *et al*., 2022). Many industries had inbuilt water treatment systems with state-of-the-art filtration, chemical treatment, and sterilization systems. Further, these industries explored emerging technologies such as bioremediation and electrochemical treatment for sustainable industrial waste treatment solutions (Acharya *et al.*, 2020). Also, they fostered a culture of environmental responsibility by promoting waste reduction initiatives and encouraging employee participation in sustainability efforts (Milanesi *et al.*, 2020). These industries regularly evaluated their waste management processes, identified areas for improvement, and implemented innovative solutions to enhance efficiency and sustainability. By embracing new technologies, best practices, and industry advancements, biopharmaceutical industries strived towards continuous improvement in environmental safety through industrial waste management.

Industries face challenges in managing industrial waste

The study results emphasized that industries did not encounter major challenges in industrial waste management by adhering to appropriate norms and guidelines set by regulatory bodies. Only 10% (Figure 5) of interviewed officials emphasized the importance of prompt responses from regulatory bodies to queries raised by the biopharmaceutical industries. They sought more explicit guidelines and assistance navigating complex regulatory frameworks to ensure effective waste management practices. This highlighted the need for proactive engagement and collaboration between industries and regulatory bodies to address challenges and promote sustainable waste management solutions.

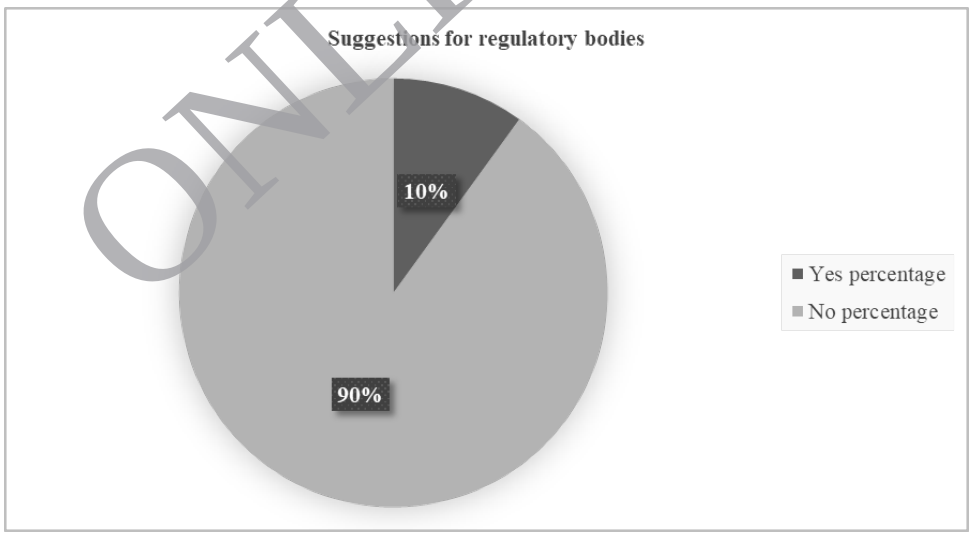

Figure 5: Representing percentage of queries raised by industry officials

Conclusion

Based on the data analyzed, this questionnaire-based study explored industrial waste management practices within Indian biopharmaceutical industries. The findings elucidated the necessity for optimizing

waste disposal methods to ensure environmental sustainability and regulatory adherence. By deploying state-of-the-art disposal methods, utilization of third-party vendors, collaboration with industrial waste management agencies, and initiatives towards sustainable practices, the study identified key trends, challenges, and scope for improvement. These findings served as a resource for policymakers, industry officials, and environmental professionals, facilitating the enhancement of industrial waste management strategies and promoting sustainable development in the Indian biopharmaceutical industry. Overall, this study contributed to the knowledge base on industrial waste management practices in the Indian biopharmaceutical sector, fostering informed decision-making and advancing environmental stewardship in the industry.

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Conflict of interest

The authors declare that they have no conflicts of interest.

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