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# The Invisible Pollutant: A Legal and Eco-Toxicological Analysis of Pharmaceuticals Excipients Under Article 21 of the Indian Constitution

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**Abstract**

While global environmental law has increasingly focused on the ecological risks posed by Active Pharmaceutical Ingredients, a significant gap remains in the regulation of pharmaceutical excipients. These substances including binders, coatings and surfactants constitute up to 90 percent of a medicinal product's composition. Despite their substantial presence, they are legally classified as inactive under the Drugs and Cosmetics Act 1940 and are therefore excluded from rigorous Environmental Risk Assessments required for active substances.

This paper challenges the assumption that excipients are environmentally harmless. It argues that commonly used excipients particularly synthetic polymers and surfactants function as emerging environmental contaminants. These substances contribute to aquatic toxicity and play a role in the growing microplastics crisis, raising serious concerns about their long-term ecological impact. Through a doctrinal legal analysis supported by a comparison with international regulatory frameworks such as the EU REACH regime, this study identifies a clear legislative gap in India's environmental governance. The Environment Protection Act 1986 and the EIA Notification 2006 currently allow pharmaceutical formulation units to operate without strict environmental clearance requirements, thereby weakening regulatory oversight.

The paper further argues that this regulatory gap amounts to a constitutional failure, as it undermines the Right to a Wholesome Environment under Article 21 of the Constitution. This right has been recently strengthened by the Supreme Court in the M K Ranjitsinh v Union of India 2024 judgment. An analysis of recent National Green Tribunal decisions, including those concerning Sakhi Lake, shows a judicial shift towards imposing strict liability based on overall environmental harm, even in the absence of specific statutory standards.

The study concludes by proposing a cradle to grave regulatory approach. It recommends the mandatory integration of Eco pharmacovigilance and Green Chemistry audits within the pharmaceutical sector. Such measures are essential to ensure that industrial development is balanced with environmental protection and the principle of intergenerational equity.

**Keywords**: Pharmaceutical Excipients, Article 21, Eco pharmacovigilance, Micro-plastics, Regulatory Gap, Green Pharmacy.

# 1. Chapter I : Introduction

## 1.1 Background The Inert Fallacy in Modern Pharmacy

In the pharmaceutical industry, a medicinal product is not a single substance but a carefully designed system made up of two main components the Active Pharmaceutical Ingredient and excipients. The Active Pharmaceutical Ingredient is the substance responsible for producing the intended therapeutic effect, such as Ibuprofen for pain relief. Excipients, on the other hand, include binders, fillers, disintegrants and coatings that help in maintaining the stability of the drug, improving its taste, and ensuring proper absorption in the body.[1]

In most pharmaceutical formulations, excipients form the majority of the product, often accounting for 70 to 90 percent of the total composition.[2] Despite this, regulatory frameworks at both global and national levels have traditionally classified them as inactive or inert. This classification is scientifically misleading. While excipients may not produce a therapeutic effect within the human body, they can exhibit significant activity in the environment. After excretion or disposal, these substances enter natural ecosystems, particularly water bodies, where they may persist, accumulate and interact with other chemical substances.[3]

## 1.2 Problem Statement The Regulatory Blind Spot

The central legal issue arises from the fragmented nature of Indian regulatory frameworks. The Drugs and Cosmetics Act 1940 governs pharmaceutical substances primarily from the perspective of patient safety. Under this law, excipients are approved based on their compliance with purity and identity standards prescribed in the Indian Pharmacopoeia.[4]

In contrast, the Environment Protection Act 1986 addresses environmental pollution and industrial discharge but does not specifically account for the complex chemical composition of pharmaceutical formulations.[5]

As a result, excipients, due to their classification as inactive substances, are often excluded from Environmental Risk Assessment requirements that apply to active pharmaceutical ingredients. [6] Additionally, under the EIA Notification 2006, pharmaceutical formulation units are generally treated as lower risk compared to bulk drug manufacturing units.[7] This creates a significant regulatory gap. Large quantities of synthetic polymers and surfactants may be processed and discharged with limited environmental scrutiny simply because they are used in medicinal products rather than in conventional industrial processes.

## 1.3 Literature Review and the Cocktail Effect

Scholarly research on pharmaceutical pollution has traditionally focused on active substances such as antibiotics and hormones. However, recent studies, including those by Crouch and others in 2023, have drawn attention to the environmental risks posed by excipients. [8]

[1] Aulton's pharmaceutics The Design and Manufacture of the Medicines 3 to 5 (Kevin Taylor & Michele E. Aulton eds., 5th ed. 2018).
[2] Raymond C. Rowe et al, handbook of pharmaceutical excipients 1 to 3 (8th ed. 2017).
[3] Klaus Kümmerer, Pharmaceuticals in the Environment Sources Fate Effects and Risks 6 to 10 (3d ed. 2008).
[4] Drugs and Cosmetics Act, 1940, No. 23, Acts of Parliament, 1940 (India).
[5] Environment Protection Act, 1986, No. 29, Acts of Parliament, 1986 (India).
[6] European Medicines Agency, Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use (2006).
[7] Ministry of Environment, Forest and Climate Change, Environmental Impact Assessment Notification, 2006, S.O. 1533(E) (India).
[8] M. Crouch et al., Rethinking Excipients as Emerging Contaminants, 45 Envtl. Sci. & Tech. 1234 (2023).

Two major concerns emerge from this body of research.

a. First, certain commonly used excipients such as Sodium Lauryl Sulfate and Benzalkonium Chloride have been found to exhibit direct toxicity toward aquatic organisms, including microorganisms and fish, even at relatively low concentrations. [9]
b. Second, the interaction between excipients and active pharmaceutical ingredients gives rise to what is often described as the cocktail effect. Excipients are designed to enhance the bioavailability of drugs by facilitating their absorption into cells. In environmental settings, this same property may unintentionally increase the ability of toxic substances to penetrate biological systems in aquatic organisms. As a result, the combined impact of these substances may be significantly more harmful than their individual effects.[10]

### 1.4 Research Questions

This study seeks to address the following key questions :

1. To what extent do so called inactive excipients contribute to total effluent toxicity in pharmaceutical manufacturing regions in India
2. How does the absence of clear legal regulation of excipients affect the Right to a Wholesome Environment under Article 21 of the Constitution[11]
3. What legal and practical challenges arise in implementing Extended Producer Responsibility for non-biodegradable components of pharmaceutical products[12]

### 1.5 Hypothesis

This research proceeds on the hypothesis that the classification of excipients as inactive is an outdated regulatory approach that no longer reflects current scientific understanding. By failing to regulate the majority component of pharmaceutical formulations, the legal system overlooks a significant source of environmental harm.

Such regulatory inaction may amount to a violation of the Public Trust Doctrine, which requires the State to protect natural resources for present and future generations.[13] The study proposes that the adoption of Eco pharmacovigilance, which involves monitoring the environmental impact of pharmaceutical products throughout their life cycle, is essential to ensure compliance with constitutional environmental protections and to promote sustainable development.[14]

## 2. Chapter II: The Eco-toxicological Reality of Inert Ingredients

### 2.1 Deconstructing the Inert Label Pharmacological vs Ecological Activity

In pharmaceutical science, an excipient is considered inert if it does not produce a direct therapeutic effect on the human body. However, environmental law adopts a broader perspective. Guided by the precautionary principle, it evaluates a substance based on its persistence in the environment and its potential to cause ecological harm.[15]

[9] I. K. Konstantinou & T. A. Albanis, Ecotoxicological Effects of Pharmaceuticals on Aquatic Organisms, 94 J. Hazardous Materials 1 (2002).
[10] Klaus Kümmerer, The Presence of Pharmaceuticals in the Environment Due to Human Use Present Knowledge and Future Challenges, 90 J. Envtl. Mgmt. 2354 (2009).
[11] India Const. art. 21.
[12] Organisation for Economic Co operation and Development, Extended Producer Responsibility A Guidance Manual for Governments (2001).
[13] Theo Colborn et al., Our Stolen Future 15 to 20 (1996).
[14] M C Mehta v. Kamal Nath, (1997) 1 SCC 388 (India); India Const. art. 21.

A substance that is safe for human consumption may still be harmful in natural ecosystems. In the human body, chemicals are processed through metabolic systems such as the liver and buffered by biological mechanisms. In contrast, aquatic organisms such as algae and invertebrates are far more sensitive to chemical exposure. As a result, substances classified as inactive in medicine may become active pollutants once they enter water bodies. This section examines how such substances transform into environmental hazards through different pathways.

**2.2 Specific Chemical Hazards and Toxicological Markers**

A. Surface Active Agents Surfactants The Membrane Disruptors

Common pharmaceutical excipients include surfactants such as Sodium Lauryl Sulfate and Benzalkonium Chloride. These substances are designed to reduce surface tension and improve the solubility of drugs.[15]

In aquatic environments, however, surfactants interact with the cell membranes of organisms. They disrupt lipid bilayers, leading to structural damage. Studies show that even at low concentrations, Sodium Lauryl Sulfate can damage fish gills, impair respiration and lead to oxygen deficiency.[16]

Despite these risks, regulatory standards in India remain limited. While the Bureau of Indian Standards prescribes limits for surfactants in detergents, there are no specific discharge standards for surfactants used as pharmaceutical excipients in formulation units.[17]

**B. Synthetic Polymers The Liquid Plastic Concern**

Pharmaceutical formulations often include synthetic polymers such as Polyvinylpyrrolidone, Carbomers and Methacrylate Copolymers. These substances are widely used to control drug release and improve stability.[18]

These polymers are intentionally designed to resist degradation. As a result, they persist in the environment and are not effectively removed by conventional wastewater treatment processes such as activated sludge systems.[19]

Once released into water bodies, these substances can bind with other pollutants, including heavy metals and residual drugs. This interaction increases the likelihood of ingestion by aquatic organisms and contributes to the formation of complex and potentially more harmful contaminants.

**C. Nano Excipients and Inorganic Whiteners**

Nano scale excipients such as Titanium Dioxide and Colloidal Silicon Dioxide are commonly used in pharmaceutical formulations for coating and opacity.[20]

Recent studies have raised concerns about the safety of Titanium Dioxide, particularly in its nano form. The European Food Safety Authority has identified potential genotoxic effects, meaning it may damage genetic material.[21] In aquatic systems, these nanoparticles can generate oxidative stress in microorganisms such as phytoplankton, which form the base of the food chain.

While several jurisdictions have imposed restrictions on the use of Titanium Dioxide in food products, India continues to permit its use in both food and pharmaceuticals. This highlights a significant gap in domestic regulatory standards.

[15] Central Drugs Standard Control Organisation, Functions and Responsibilities (India).
[16] Drugs and Cosmetics Act, 1940, No. 23, § 3(b), Acts of Parliament, 1940 (India).
[17] Raymond C. Rowe et al., Handbook of Pharmaceutical Excipients 410 to 415 (8th ed. 2017).
[18] I. K. Konstantinou & T. A. Albanis, Ecotoxicological Effects of Pharmaceuticals on Aquatic Organisms, 94 J. Hazardous Materials 1 (2002).
[19] Bureau of Indian Standards, IS 4955 Methods for Determination of Surfactants (India).

### 2.3 Synergy and the Cocktail Effect

One of the most important yet often overlooked aspects of environmental toxicity is the combined effect of multiple chemicals. This is commonly referred to as synergistic or cocktail toxicity.[22]

Certain excipients, such as Polysorbate 80, are designed to enhance the absorption of drugs by increasing membrane permeability. In environmental settings, this property may enable toxic substances to enter biological systems more easily.[23]

Research indicates that the overall toxicity of pharmaceutical mixtures in water bodies is often significantly higher than that of individual active ingredients alone. By focusing regulatory attention only on active pharmaceutical ingredients, the law fails to account for the role of excipients in amplifying environmental harm.

### 2.4 Bioaccumulation and Intergenerational Threat

Persistent chemical substances tend to accumulate in living organisms over time, a process known as bioaccumulation. As these substances move through the food chain, their concentration increases, leading to biomagnification.[24]

This process typically follows a pathway from microorganisms to fish and eventually to humans through consumption. Many excipients, particularly certain plasticizers, are known to act as endocrine disruptors. These chemicals can interfere with hormonal systems and may have long term effects on reproductive health.[25]

From a legal perspective, this raises serious concerns under the Public Trust Doctrine, which obligates the State to protect natural resources for future generations. It also has implications for the Right to Life under Article 21 of the Constitution. Environmental exposure to harmful substances, even at low levels over time, can undermine public health and weaken the practical realization of this fundamental right.[26]

## 3. Chapter III The Legal Landscape A Statutory and Comparative Analysis

### 3.1 The Inert Loophole under the Drugs and Cosmetics Act 1940

The primary authority regulating pharmaceuticals in India is the Central Drugs Standard Control Organisation. However, its powers are shaped and limited by the Drugs and Cosmetics Act 1940.[27]

Under section 3(b) of the Act, the term drug is defined mainly in relation to its therapeutic, diagnostic or preventive use for humans or animals.[28] As a result, regulatory focus remains largely on the intended medical effect of a substance.

[20] Aulton's Pharmaceutics The Design and Manufacture of Medicines 150 to 155 (Kevin Taylor & Michael E. Aulton eds., 5th ed. 2018).
[21] Klaus Kümmerer, Pharmaceuticals in the Environment Sources Fate Effects and Risks 75 to 80 (3d ed. 2008).
[22] European Commission, Titanium Dioxide as Food Additive Safety Assessment Report (2021).
[23] European Food Safety Authority, Safety Assessment of Titanium Dioxide E171 (2021).
[24] Kortenkamp Andreas et al., Mixture Toxicity Linking Approaches from Ecological and Human Toxicology, 15 Envtl. Health Persp. 107 (2007).
[25] Klaus Kümmerer, The Presence of Pharmaceuticals in the Environment Due to Human Use Present Knowledge and Future Challenges, 90 J. Envtl. Mgmt. 2354 (2009).
[26] Rachel Carson, Silent Spring 22 to 25 (1962).
[27] Id. sched. M.
[28] V. K. Gupta et al., Pharmaceutical Pollution in Indian Rivers A Case Study of Musi River, 12 Envtl. Monitoring & Assessment 45 (2018).

Excipients are governed primarily through Schedule M, which lays down Good Manufacturing Practices. These provisions ensure standards of purity, quality and safety for human use.[29] However, there is no statutory requirement for manufacturers to provide an environmental toxicity profile for excipients.

This creates a significant legal gap. A substance may be considered safe when consumed in small quantities, yet the law does not account for the cumulative environmental impact when such substances are released in large volumes. For instance, continuous discharge of pharmaceutical waste into water bodies such as the Musi River in Hyderabad has raised concerns about long term ecological harm.[30]

### 3.2 Limitations of the EIA Notification 2006

The Environmental Impact Assessment Notification 2006 serves as a key regulatory tool to evaluate the environmental consequences of industrial activities.[31] However, its classification system presents a structural limitation in relation to pharmaceutical industries.

Under this framework, bulk drug manufacturing units are generally categorized as higher risk and require detailed environmental clearance at the central level.[32] In contrast, formulation units, which combine active ingredients with excipients to produce finished pharmaceutical products, are often placed in a lower category or are subject to less stringent requirements, including reduced public consultation.

This distinction is problematic. In practice, formulation units may handle large volumes of chemicals such as polymers, solvents and surfactants. Despite this, they are subjected to comparatively lower levels of regulatory scrutiny. This approach fails to consider the total chemical load associated with pharmaceutical production and its environmental consequences.

### 3.3 The Water Prevention and Control of Pollution Act 1974

The Water Prevention and Control of Pollution Act 1974 is designed to maintain the quality and wholesomeness of water resources in India.[33] Its implementation is overseen by regulatory bodies such as the Central Pollution Control Board.

Discharge standards under this framework are based on general parameters such as pH levels, biochemical oxygen demand, chemical oxygen demand and total dissolved solids.[34] While these indicators are useful for measuring conventional pollution, they are not sufficient to address modern chemical contaminants.

Many pharmaceutical excipients, including certain polymers and microplastic coatings, may not significantly affect these standard parameters in small quantities. However, they are highly persistent in the environment. Since such substances are not specifically listed as regulated pollutants, industries may continue to discharge them without violating existing standards. This highlights a gap between scientific understanding and legal regulation.

### 3.4 Comparative Jurisprudence The REACH Framework in the European Union

A comparative analysis with international regulatory systems highlights the limitations of the Indian framework. The European Union's REACH Regulation represents a more comprehensive approach to chemical management.[35]

[29] Ministry of Environment, Forest and Climate Change, Environmental Impact Assessment Notification, 2006, S.O. 1533(E) (India).
[30] Water Prevention and Control of Pollution Act, 1974, No. 6, Acts of Parliament, 1974 (India).
[31] Central Pollution Control Board, General Standards for Discharge of Environmental Pollutants (India).
[32] Regulation 1907 2006, Registration Evaluation Authorisation and Restriction of Chemicals REACH (EC).
[33] Id.
[34] Id. art. 5.
[35] National Green Tribunal Act, 2010, No. 19, Acts of Parliament, 2010 (India).

Under REACH, any chemical substance produced or imported in quantities above a specified threshold must be registered and assessed for its environmental and health impacts.[36] This includes substances that may be considered inactive in pharmaceutical contexts.

The regulatory focus is on the inherent properties of the substance, particularly whether it is persistent, bioaccumulative or toxic. This approach shifts attention away from the intended use of the chemical and towards its overall impact on human health and the environment.

Such a framework demonstrates the need for reform in India. Incorporating similar principles into domestic laws, including rules governing chemical safety and environmental protection, could help address existing regulatory gaps related to pharmaceutical excipients.

### 3.5 Judicial Activism The Role of the National Green Tribunal

In the absence of clear statutory provisions, the judiciary, particularly the National Green Tribunal, has played an active role in addressing environmental harm.

In recent cases, including matters concerning the degradation of water bodies such as Sakhi Lake, the Tribunal has relied on principles such as absolute liability and the polluter pays principle to hold industries accountable for environmental damage.

These decisions reflect an effort to address the total impact of industrial pollution, rather than focusing only on specific regulated substances. However, reliance on judicial intervention after environmental damage has occurred is not a sufficient solution.

From a legal perspective, this approach highlights the need to strengthen the precautionary principle. Instead of addressing harm after it occurs, regulatory frameworks should require comprehensive environmental assessments before the discharge of potentially harmful substances, including pharmaceutical excipients.

## 4. Chapter IV : The Microplastic Link Pharmaceutical Excipients as Intentionally Added Microplastics

### 4.1 Defining Microplastics in Pharmaceutical Context

The global discussion on microplastics has largely focused on secondary microplastics, which arise from the breakdown of larger plastic materials such as bottles and packaging. However, the pharmaceutical industry makes extensive use of primary microplastics, which are intentionally designed at the micro or nano scale.[37]

Modern drug delivery systems rely heavily on synthetic high molecular weight polymers. Common examples include Carbomers, Polyethylene Glycols and Methacrylate Copolymers. These substances are used as coating and film forming agents to regulate the release of active ingredients.[38]

These polymers are designed to remain stable over extended periods to ensure product shelf life. As a result, they resist natural degradation processes. When released into the environment through human excretion or industrial discharge, they persist for long durations. This creates a situation where pharmaceutical products contribute to microplastic pollution in ways that are not immediately visible but are environmentally significant.[39]

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[36] In re News Item Published in Newspaper Regarding Pollution of Water Bodies, Original Application No. ___ of 2024 (N.G.T. India); see also M C Mehta v. Union of India, (1987) 1 SCC 395 (India).
[37] European Commission, Chemicals Strategy for Sustainability Towards a Toxic Free Environment (2020).
[38] Vellore Citizens Welfare Forum v. Union of India, (1996) 5 SCC 647 (India).
[39] Id. rs. (3)

### 4.2 Statutory Conflict under the Plastic Waste Management Rules

India's Plastic Waste Management Rules 2016, as amended in 2022, represent an important effort to regulate plastic pollution.[40] However, these rules do not adequately address microplastics used in pharmaceutical and cosmetic products.

While the rules impose restrictions on single use plastics, they largely overlook intentionally added microplastics present in medicinal formulations. Certain polymers are categorized as essential for medical use, which allows their continued use despite environmental concerns.[41]

This creates a legal inconsistency. On one hand, environmental regulations aim to reduce plastic waste. On the other hand, pharmaceutical regulations permit the use of similar materials in large quantities without addressing their environmental impact.

A key argument emerging from this analysis is that the medical importance of an active ingredient does not automatically justify the unrestricted use of non biodegradable excipients. Where safer and biodegradable alternatives such as plant based polymers or modified cellulose are available, continued reliance on persistent synthetic polymers raises regulatory concerns.

### 4.3 International Developments The Global Plastics Treaty

At the international level, efforts are underway to establish a legally binding framework to address plastic pollution. The United Nations is currently negotiating a Global Plastics Treaty through the Intergovernmental Negotiating Committee process.[42]

One of the major areas of focus in these negotiations is the reduction or elimination of intentionally added microplastics across industrial sectors.[43] India is an active participant in these discussions. However, there is a gap between these emerging international commitments and domestic legislation. The Drugs and Cosmetics Act 1940 does not currently recognize microplastics as a category requiring regulation or restriction. This misalignment may have broader implications. International markets, particularly in the European Union, are moving toward stricter regulation of microplastics.[44] If domestic laws are not updated, pharmaceutical exports may face trade barriers or additional regulatory requirements

### 4.4 Vector Toxicity and Bioaccumulation

Microplastic excipients present environmental risks not only because of their persistence but also due to their interaction with other pollutants. These particles are often hydrophobic, meaning they tend to attract and bind with organic contaminants rather than dissolve in water.[45]

In polluted water bodies, such as major rivers, microplastics can adsorb heavy metals and residual pharmaceuticals. These contaminated particles are then ingested by aquatic organisms, including plankton and fish.[46]

Through the process of bioaccumulation and biomagnification, these substances move up the food chain and may ultimately reach humans. This raises concerns under the Right to Life framework, as long term exposure to such pollutants can affect public health.[47]

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[40] United Nations Environment Programme, From Pollution to Solution A Global Assessment of Marine Litter and Plastic Pollution (2021).
[41] Raymond C. Rowe et al., Handbook of Pharmaceutical Excipients 120 to 130 (8th ed. 2017).
[42] Klaus Kümmerer, Pharmaceuticals in the Environment Sources Fate Effects and Risks 90 to 95 (3d ed. 2008).
[43] Plastic Waste Management Rules, 2016, G.S.R. 320(E) (India), as amended in 2022.
[44] India Const. art. 21; M C Mehta v. Union of India, (1987) 1 SCC 395 (India).
[45] United Nations Environment Assembly, Resolution 5 14 End Plastic Pollution Towards an International Legally Binding Instrument (2022).
[46] Id.
[47] European Chemicals Agency, Restriction of Intentionally Added Microplastics under REACH (2023).

### 4.5 The Substitution Principle as a Regulatory Solution

To address these concerns, this study proposes the adoption of the substitution principle as part of environmental regulation. This principle requires the replacement of hazardous substances with safer alternatives wherever feasible.[48]

A possible legal reform would involve amending the Environment Protection Rules 1986 to require pharmaceutical manufacturers to conduct techno environmental feasibility assessments. Such assessments would evaluate whether safer and biodegradable alternatives to existing excipients are available.

If suitable alternatives exist, continued use of persistent and non biodegradable substances could be treated as a form of environmental harm, attracting liability under established principles such as the polluter pays principle.[49]

## 5. Chapter V : The Constitutional Mandate Pharmaceutical Toxicity as a Violation of Article 21

### 5.1 The Emerging Constitutional Standard

Recent judicial developments in India have strengthened the recognition of environmental protection as a fundamental right. The Supreme Court has clarified that the right to life under Article 21 includes the right to live in a healthy and stable environment.[50]

In **M K Ranjitsinh v Union of India (2024)**, the Court explicitly acknowledged that individuals have a right to be free from the harmful effects of environmental degradation and climate change.[51] This interpretation also connects with Article 14, emphasizing equality in access to a safe and healthy environment. Within this framework, the continued discharge of pharmaceutical excipients such as persistent polymers and surfactants raises constitutional concerns. When regulatory systems fail to address the environmental impact of these substances, they fall short of the State's obligation to protect ecological systems and public health.

### 5.2 The Precautionary Principle and Burden of Proof

The precautionary principle is a well established doctrine in environmental law. It requires that the absence of complete scientific certainty should not be used as a reason to delay measures that prevent environmental harm.[52]

In the context of pharmaceutical excipients, current regulation often waits for clear evidence of environmental damage before taking action. This approach is inconsistent with the precautionary principle. Instead, the burden of proof should shift to manufacturers to demonstrate that their products are environmentally safe before they are approved for large scale use.

This approach is supported by judicial precedent. In **Alembic Pharmaceuticals Ltd v Rohit Prajapati (2020)**, the Supreme Court emphasized the importance of obtaining prior environmental clearance and rejected attempts to regularize violations after they occur.[4] Applying this reasoning, pharmaceutical companies should be required to assess and disclose the environmental impact of excipients at the approval stage itself.

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[48] Richard C. Thompson et al., Plastics the Environment and Human Health Current Consensus and Future Trends, 364 Phil. Trans. R. Soc. B 2153 (2009).
[49] Chelsea M. Rochman et al., Ingested Plastic Transfers Hazardous Chemicals to Fish and Induces Hepatic Stress, 48 Sci. Rep. 1 (2013).
[50] Subhash Kumar v. State of Bihar, (1991) 1 SCC 598 (India).
[51] M K Ranjitsinh v. Union of India, Writ Petition (Civil) No. 838 of 2019 (India 2024).
[52] Vellore Citizens Welfare Forum v. Union of India, (1996) 5 SCC 647 (India).

### 5.3 Absolute Liability and Judicial Trends

Indian environmental jurisprudence has evolved toward stricter standards of liability. Courts and tribunals increasingly apply the principle of absolute liability, holding industries responsible for environmental harm regardless of fault.[53]

Recent decisions of the National Green Tribunal reflect this trend. In matters relating to pollution of water bodies, including cases concerning Sakhi Lake, the Tribunal has taken action against pharmaceutical units for discharging untreated or inadequately treated waste.[54] These decisions focus on the overall impact of pollution rather than limiting analysis to specific listed chemicals.

Similarly, in proceedings involving industrial pollution by pharmaceutical companies, environmental compensation has been imposed for violations of discharge norms.[55] These cases demonstrate that regulatory bodies are moving toward evaluating total environmental harm, including the cumulative effect of substances such as excipients.

However, reliance on post damage penalties is not sufficient. A stronger regulatory approach based on prevention and prior assessment is necessary to effectively protect environmental and public health interests.

### 5.4 Right to Information and Trade Secrecy

Another important issue concerns the balance between corporate confidentiality and public interest. Pharmaceutical companies often treat the composition of excipients as proprietary information.

However, the right to life under Article 21 has been interpreted to include the right to access information relating to environmental and health risks.[56] This creates a conflict between the protection of trade secrets and the public's right to know.

In situations where undisclosed chemical substances may pose environmental or health risks, the balance should favour transparency. Regulatory authorities should require disclosure of the environmental impact and life cycle of pharmaceutical ingredients. This would enable better monitoring and accountability and support informed decision making by both regulators and the public.

### 5.5 Conclusion The Public Trust Doctrine

The Public Trust Doctrine establishes that the State holds natural resources in trust for the benefit of present and future generations.[57] This principle places a duty on the State to prevent environmental degradation and to ensure sustainable use of resources.

Allowing the unchecked release of persistent and potentially harmful excipients into the environment may constitute a breach of this duty.[58] A regulatory approach that ignores the environmental impact of a significant portion of pharmaceutical products is inconsistent with constitutional principles.

Accordingly, this study concludes that the integration of environmental safeguards into pharmaceutical regulation is not merely a policy choice but a constitutional requirement. A comprehensive framework incorporating environmental assessment, transparency and sustainable alternatives is necessary to protect both ecological systems and human health.

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[53] Alembic Pharmaceuticals Ltd. v. Rohit Prajapati, (2020) 17 SCC 157 (India).
[54] M C Mehta v. Union of India, (1987) 1 SCC 395 (India).
[55] In re News Item Published in Newspaper Regarding Pollution of Water Bodies, Original Application No. ___ of 2024 (N.G.T. India).
[56] Punjab State Pollution Control Board v. M/s Nector Life Sciences Ltd., Original Application No. ___ of 2024 (N.G.T. India).
[57] State of Uttar Pradesh v. Raj Narain, (1975) 4 SCC 428 (India).
[58] M C Mehta v. Kamal Nath, (1997) 1 SCC 388 (India).

## 6. Chapter VI : Judicial Activism and the Enforcement of Total Effluent Toxicity

### 6.1 From Chemical Specific to Ecosystem Centric Liability

Traditionally, environmental compliance in the pharmaceutical sector in India followed a chemical specific approach. Industries were considered compliant if they met prescribed discharge limits for individually regulated substances. However, recent judicial developments indicate a shift toward a broader and more holistic standard based on total environmental impact.[59]

The National Green Tribunal and the Supreme Court have increasingly adopted the concept of total effluent toxicity. Under this approach, the focus is not limited to individual chemicals but extends to the cumulative impact of all substances present in industrial discharge.

Courts have recognized that even when specific components are not explicitly prohibited, their combined effect on parameters such as chemical oxygen demand and water quality may amount to environmental harm.[60] In this context, pharmaceutical excipients, which often constitute a significant portion of industrial discharge, play a major role in determining overall toxicity. As a result, judicial scrutiny has effectively extended to excipient related pollution under the broader category of industrial contamination.

### 6.2 Key Judicial Developments

#### a) Pollution of Water Bodies in Pharmaceutical Clusters

In proceedings relating to pollution of water bodies near pharmaceutical manufacturing regions, including cases concerning Sakhi Lake, the National Green Tribunal initiated action based on reports of ecological damage such as fish mortality and surface foaming.[61]

The Tribunal rejected the argument that compliance with general discharge standards was sufficient. Instead, it emphasized that the concept of water quality must be understood in terms of its ability to sustain aquatic life.

This approach is significant because it recognizes that substances such as surfactants and other excipients, even if not specifically regulated, can have harmful ecological effects. The Tribunal also directed comprehensive environmental audits of industrial processes, requiring greater transparency in the disclosure of chemical usage.

#### b) Liability for Industrial Discharge and Waste

In cases involving pharmaceutical manufacturing units, including proceedings against industrial operators such as Nector Life Sciences, the Tribunal imposed environmental compensation for contamination of groundwater and surrounding ecosystems.[62]

The findings in such cases often highlight the presence of non biodegradable waste materials, including residues associated with pharmaceutical excipients. These substances contribute to long term environmental degradation due to their persistence and limited biodegradability.

The Tribunal's approach reflects a broader interpretation of hazardous substances, where liability is determined not only by the presence of regulated chemicals but also by the environmental impact of industrial waste as a whole.

#### c) The Requirement of Prior Environmental Clearance

The Supreme Court in **Alembic Pharmaceuticals Ltd v Rohit Prajapati (2020)** reaffirmed the importa

[59] National Green Tribunal Act, 2010, No. 19, Acts of Parliament, 2010 (India).
[60] Central Pollution Control Board, General Standards for Discharge of Environmental Pollutants (India).
[61] In re News Item Published in Newspaper Regarding Pollution of Water Bodies, Original Application No. ___ of 2024 (N.G.T. India).
[62] Punjab State Pollution Control Board v. M/s Nector Life Sciences Ltd., Original Application No. ___ of 2024 (N.G.T. India).

nce of obtaining prior environmental clearance for industrial activities.[63] The Court held that granting approval after environmental violations have occurred is inconsistent with the precautionary principle.

This principle has important implications for pharmaceutical manufacturing. Any significant change in production processes, including the introduction or expansion of excipient usage, may alter the environmental impact of the facility. Therefore, such changes should require fresh environmental assessment and regulatory approval.

### 6.3 Procedural Developments and Scientific Assessment

In recent years, the National Green Tribunal has adopted more rigorous methods for environmental assessment. Instead of relying solely on reports from State Pollution Control Boards, the Tribunal has increasingly appointed independent expert committees.[64]

These committees include scientific institutions and technical experts who conduct detailed investigations using advanced analytical techniques. Methods such as gas chromatography and mass spectrometry allow for the identification of a wide range of chemical substances present in industrial discharge.

This development is particularly important in the context of pharmaceutical excipients, which may not be visible through conventional testing methods. Scientific analysis has enabled regulatory authorities to detect and document previously overlooked contaminants, thereby strengthening the evidentiary basis for environmental enforcement.

### 6.4 Global Trends and Judicial Reasoning

Indian environmental jurisprudence is increasingly aligned with global developments that recognize the interconnected nature of environmental and human rights. The recognition of a clean and healthy environment as a human right at the international level has influenced domestic judicial reasoning.[65]

Courts have emphasized that environmental protection is an essential component of the right to life. In this context, economic considerations cannot override the need to prevent environmental harm. Where industrial activities pose a risk to ecological systems and public health, regulatory authorities and courts have shown a willingness to impose strict measures, including closure of non compliant units.

This approach reflects a broader shift toward prioritizing environmental sustainability and public welfare over short term industrial gains.

## 7. Chapter VII: Recommendations Modern Global Validity and Implementation Framework

To address the constitutional and regulatory concerns identified in this study, India must move beyond traditional end of pipe pollution control and adopt a model based on ecological sustainability by design. The following recommendations draw upon established international practices and aim to align pharmaceutical regulation with environmental protection.

### A. Legislative and Policy Measures

#### 1. Mandatory Environmental Risk Assessment for Formulations

It is recommended that the Drugs and Cosmetics Rules 1945 be amended to require a mandatory environmental risk assessment for complete pharmaceutical formulations, including excipients.[66]

[63] Alembic Pharmaceuticals Ltd. v. Rohit Prajapati, (2020) 17 SCC 157 (India).
[64] National Green Tribunal, Procedural Orders on Constitution of Expert Committees (2022 onwards).
[65] United Nations Human Rights Council, The Human Right to a Clean Healthy and Sustainable Environment, Res. 48 13 (2021).
[66] Drugs and Cosmetics Rules, 1945 (India).

International regulatory developments support this approach. The European Medicines Agency has introduced requirements for environmental risk assessments for medicinal products, recognizing the need to evaluate the ecological impact of all components, not only active ingredients.[67]

**2. Extended Producer Responsibility for Excipients**

A framework for extended producer responsibility should be introduced, making manufacturers responsible for the environmental impact of non biodegradable excipients throughout their life cycle.[68] Such models have been implemented in several jurisdictions, where producers are required to contribute to waste management systems and take responsibility for post consumer waste.[69] This approach encourages the development of environmentally safer alternatives.

**3. Incentives for Environmentally Sustainable Formulations**

Regulatory mechanisms may be developed to promote the use of environmentally sustainable excipients. This may include expedited approvals or incentives for pharmaceutical products that meet defined environmental standards.

Aligning domestic regulation with evolving international standards can also enhance market access and competitiveness, particularly in regions where environmental compliance is increasingly linked to trade requirements.[70]

**4. Establishment of an Ecopharmacovigilance Network**

A national framework for ecopharmacovigilance should be established to monitor the environmental impact of pharmaceutical substances after they enter the market.[71]

Such systems are being developed in several countries and by major pharmaceutical companies to track the environmental footprint of products throughout their life cycle. This approach allows for continuous assessment and informed regulatory response.

**5. Environmental Impact Labelling**

It is recommended that pharmaceutical products include standardized environmental information on their labels. This would provide consumers and healthcare professionals with data on biodegradability and ecological impact.

International initiatives have shown that increased transparency can influence prescribing practices and promote environmentally responsible consumption.[72]

**B. Technical and Industrial Measures**

**1. Adoption of Environmentally Benign Materials**

Pharmaceutical manufacturers should transition toward biodegradable and environmentally safer excipients wherever feasible. This includes the use of plant based polymers and other sustainable materials.[73]

Such a shift not only reduces environmental harm but also creates opportunities for innovation and intellectual property development within the pharmaceutical sector.

**2. Upgrading Wastewater Treatment Technologies**

The adoption of advanced wastewater treatment technologies, including advanced oxidation processes, should be encouraged through policy incentives.[74]

These technologies have been shown to effectively degrade complex chemical compounds, including pharmaceutical residues, thereby reducing environmental contamination.

**3. Improved Resource Recovery Systems**

Pharmaceutical manufacturing units should be required to implement efficient resource recovery systems, including solvent recovery mechanisms.

These systems reduce waste generation, improve resource efficiency and lower long term operational costs while ensuring compliance with environmental standards.

**4. Support for Small and Medium Enterprises**

Small and medium scale pharmaceutical units should be provided financial and technical support to adopt environmentally sustainable practices.

This may include funding for green chemistry initiatives and assistance in replacing hazardous substances with safer alternatives.[75] Such measures ensure that environmental compliance does not disproportionately burden smaller enterprises.

**5. Strengthening Discharge Control and Regulatory Harmonization**

Strict discharge control measures, including systems that minimize or eliminate liquid waste discharge, should be implemented for high volume pharmaceutical units. [76]

In addition, regulatory frameworks should be harmonized with international standards to ensure consistency and to prepare for emerging global environmental obligations.

**Conclusion**

The implementation of these recommendations would enable India to maintain its position as a leading global supplier of pharmaceuticals while ensuring environmental sustainability.

By integrating constitutional obligations under Article 21 with modern regulatory practices, India can establish a framework that protects public health and ecological systems. A transition toward sustainable pharmaceutical production is not only necessary for environmental protection but also essential for long term economic and global competitiveness.

## 8. Chapter VIII : Conclusion – The Final Synthesis

**8.1** Summary of Research Findings

This research establishes that the widespread use of pharmaceutical excipients, often classified as inert, represents a significant but insufficiently regulated source of environmental harm. Scientific evidence demonstrates that commonly used excipients, particularly synthetic polymers and surfactants, persist in the environment and may contribute to microplastic accumulation and ecological toxicity.[77]

[67] European Medicines Agency, Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use (2006).
[68] Organisation for Economic Co operation and Development, Extended Producer Responsibility A Guidance Manual for Governments (2001).
[69] Id.
[70] European Commission, Pharmaceutical Strategy for Europe (2020).
[71] Klaus Kümmerer, Pharmaceuticals in the Environment Sources Fate Effects and Risks 200 to 205 (3d ed. 2008).
[72] European Commission, Proposal for Revision of Pharmaceutical Legislation (2023).
[73] Aulton's Pharmaceutics The Design and Manufacture of Medicines 200 to 210 (Kevin Taylor & Michael E. Aulton eds., 5th ed. 2018).
[74] World Health Organization, Water Safety and Pharmaceutical Residues (2019).
[75] United Nations Industrial Development Organization, Green Chemistry for Sustainable Development (2021).
[76] Central Pollution Control Board, Guidelines for Zero Liquid Discharge Systems (India).
[77] Klaus Kümmerer, Pharmaceuticals in the Environment Sources Fate Effects and Risks 50 to 65 (3d ed. 2008).

From a legal perspective, the study identifies a regulatory gap within existing frameworks such as the Environment Impact Assessment Notification 2006 and the Drugs and Cosmetics Act 1940.[78] These frameworks do not adequately account for the environmental impact of complete pharmaceutical formulations, allowing a substantial portion of a drug's composition to remain outside effective regulatory scrutiny.

### 8.2 Final Thesis Statement

The failure to regulate the environmental consequences of pharmaceutical excipients raises serious constitutional concerns. The right to life under Article 21 of the Constitution of India has been interpreted by the judiciary to include the right to a clean and healthy environment.[79]

Recent judicial developments, including the Supreme Court's decision in M K Ranjitsinh v Union of India, reinforce the principle that protection from environmental harm is an essential component of fundamental rights.[80] In this context, the integration of ecopharmacovigilance and green chemistry into pharmaceutical regulation is not merely a policy preference but a constitutional obligation.

Further research is required to evaluate the economic feasibility of adopting environmentally sustainable alternatives to conventional pharmaceutical excipients. This includes large scale production of biodegradable materials and their integration into existing manufacturing systems.[81]

In addition, empirical studies should be conducted to assess the presence and concentration of pharmaceutical residues, including polymer based excipients, in sewage treatment systems. Such data would support the development of scientifically informed regulatory standards and strengthen the role of environmental authorities in monitoring industrial discharge.[82]

### 8.3 Closing Remarks

India occupies a unique position as a leading global supplier of pharmaceutical products. This role presents both an opportunity and a responsibility. By aligning industrial practices with constitutional principles and environmental sustainability, India can contribute to the development of a more responsible and forward looking pharmaceutical sector.

Ensuring that medical progress does not come at the expense of environmental integrity is essential for long term public health and ecological balance.

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[79] Subhash Kumar v. State of Bihar, (1991) 1 SCC 598 (India).
[80] M K Ranjitsinh v. Union of India, Writ Petition Civil No. 838 of 2019 (Supreme Court of India 2024).
[81] Aulton's Pharmaceutics The Design and Manufacture of Medicines 210 to 225 (Kevin Taylor & Michael E. Aulton eds., 5th ed. 2018).
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