

Eco-friendly Approach to Reclaim APIs from Pharmaceutical Waste



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Eco-friendly Approach to Reclaim APIs from Pharmaceutical Waste

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Abstract

Active Pharmaceutical Ingredients (APIs) from such waste can leach into soil and water, causing contamination and ecological imbalance. At the same time, discarded APIs still retain potential therapeutic value if recovered through sustainable processes. This project presents an eco-friendly approach for reclaiming APIs from expired vitamin B12 tablets, emphasizing their recovery, purification, and reuse in alignment with circular economy principles. The methodology involves a sequence of pretreatment and separation techniques. Initially, solid-liquid extraction is employed to dissolve the active compounds, followed by characterization using UV-visible spectroscopy to monitor spectral changes and confirm the presence of vitamin B12 derivatives. The extracted solution is filtered and subjected to Thin Layer Chromatography (TLC) for separation and identification of active components. Purification is achieved through antisolvent crystallization, which enables the selective recovery of pure crystalline API. Finally, drying and collection steps ensure stable recovery of the compound. This recovery process simulates natural environmental degradation pathways, such as dissolution in water, oxidation by air, and photo degradation by light, thereby offering insight into contamination studies. Purity testing validates the quality of the reclaimed API. Beyond laboratory recovery, the work highlights the role of a circular economy in the pharmaceutical sector—minimizing waste, reducing raw material dependency, and lowering environmental burden. By demonstrating a sustainable method for API recovery from expired vitamins, this project underlines the dual benefits of pollution prevention and resource reuse, paving the way for greener pharmaceutical practices.

Keywords: Pharmaceutical waste; API recovery; Vitamin B12; Solid-liquid extraction; Green chemistry; Circular economy

1. Introduction

Active Pharmaceutical Ingredients (APIs) are the biologically active components in medicines responsible for producing therapeutic effects, typically obtained through chemical synthesis, fermentation, or biotechnological processes [1]. Pharmaceutical waste refers to expired, unused, or discarded medicines and associated by-products originating from households, pharmacies, hospitals, and manufacturing industries. This waste includes not only expired drugs but also leftover raw materials, laboratory chemicals, packaging materials, and unused prescriptions [2]. Improper disposal practices, such as flushing medicines into drains or discarding them in landfills, pose a serious environmental challenge. Once APIs enter natural ecosystems, they contribute to soil and water contamination, ultimately threatening biodiversity and human health [3].

Pharmaceutical residues in soil can disrupt microbial diversity and reduce soil fertility, while contaminated aquatic systems threaten fish, invertebrates, and other organisms through bioaccumulation and trophic transfer [4]. A particularly alarming impact of improper disposal is the rise of antimicrobial resistance (AMR). The persistence of antibiotics and other pharmaceuticals in soil and water creates selective pressure on microorganisms, enabling resistant strains to develop and spread, which poses a global threat to public health [5]. Furthermore, residues of vitamins, antibiotics, and other APIs can disturb ecological balances, affecting plant growth, altering nutrient cycles, and endangering species dependent on uncontaminated water [6].

API recovery from pharmaceutical waste offers a sustainable strategy to mitigate these challenges. Recovery processes help reduce environmental pollution, conserve valuable resources, lower manufacturing costs, and support sustainable pharmaceutical practices [1]. The approach also aligns with green chemistry principles by minimizing waste generation, employing safer solvents, and implementing environmentally benign processes [7]. Moreover, API recovery supports the circular economy by enabling the reuse of active compounds, reducing reliance on virgin raw materials, and lowering the ecological footprint of pharmaceutical production [8]. Previous studies demonstrated Vitamin B12 recovery from expired supplements, and investigated eco-friendly API extraction from discarded antibiotics, reinforce the importance of API recovery in addressing soil and water contamination, antimicrobial

resistance, and ecological imbalance. These examples highlight its potential role in advancing sustainable resource management and protecting the environment.

2. Eco-friendly Approaches for API Recovery

2.1. Bioremediation

Bioremediation uses microorganisms and fungi to degrade or transform active pharmaceutical ingredients (APIs) in wastewater, offering a green and sustainable alternative to conventional treatment methods. Specific microbial strains such as *Pseudomonas* and *Bacillus* have demonstrated the ability to break down antibiotics, analgesics, and anti-inflammatory drugs through enzymatic action or biosorption [9].

Fungal species like *Aspergillus niger* and *Trametes versicolor* are especially effective due to their production of extracellular enzymes such as laccases and peroxidases. These enzymes oxidize complex pharmaceutical compounds into less harmful or biodegradable forms [10]. Enzyme-mediated bioremediation is particularly valued for its selectivity, efficiency, and minimal toxic by-products [11]. Despite challenges like variability in degradation efficiency and the need for optimized conditions, bioremediation remains a promising approach for eco-friendly API recovery in pharmaceutical waste management.

2.2. Adsorption & Bio-sorption

Activated carbon, biochar, and agricultural residues have been extensively studied as low-cost and efficient adsorbents for removing Active Pharmaceutical Ingredients (APIs) from wastewater streams (Figure 1). Their high specific surface area, porosity, and surface functional groups enable effective binding and removal of diverse pharmaceutical compounds [12]. For instance, biochar derived from agricultural waste not only adsorbs APIs effectively but also supports sustainable waste valorization [13]. Furthermore, biosorption using living or dead biomass such as algal cells and fungal mycelia offers an eco-friendly alternative by utilizing natural biological mechanisms like ion exchange, complexation, and physical adsorption to reduce pharmaceutical pollutants [14]. These biosorbents have demonstrated high removal efficiencies for a range of APIs, including antibiotics and anti-inflammatory drugs, without generating harmful secondary waste, making them promising candidates for green wastewater treatment technologies.

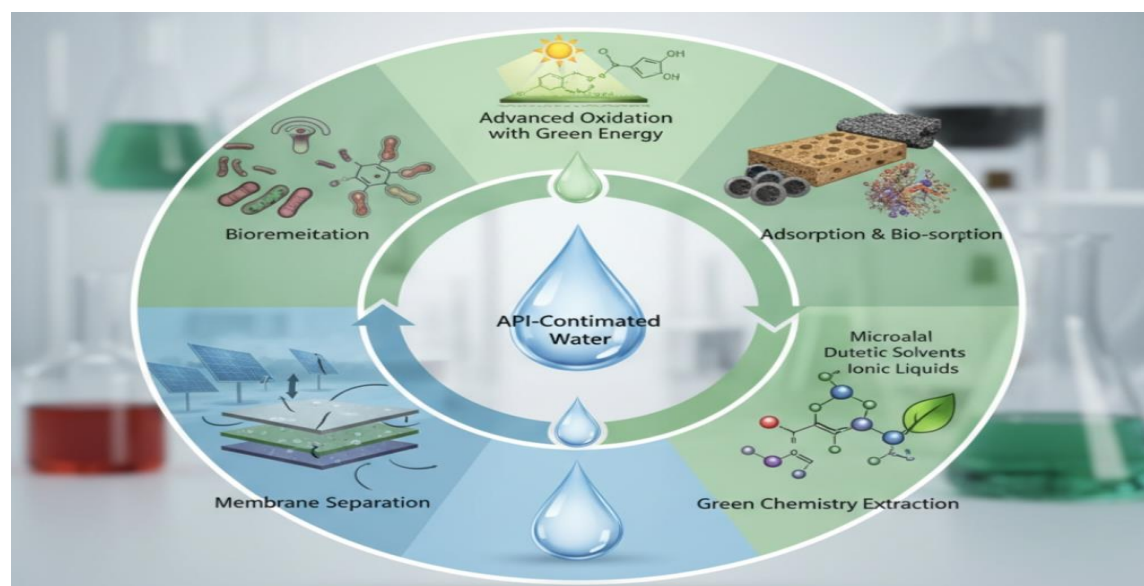


Figure1: Overview of Eco- friendly Approaches for Active Pharmaceutical Ingredient(API) Recovery in Wastewater Treatment

2.3. Membrane Separation Technologies

Membrane filtration technologies, including nanofiltration (NF), ultrafiltration (UF), and reverse osmosis (RO), provide highly selective and effective separation of APIs from pharmaceutical wastewater. Nanofiltration membranes, with pore sizes typically in the nanometer range, can reject molecules based on size exclusion and charge repulsion, efficiently removing small organic molecules such as many APIs [15]. Ultrafiltration membranes offer a barrier to larger molecular weight compounds, while reverse osmosis membranes provide near-complete removal of dissolved organic contaminants, including pharmaceuticals [16]. Moreover, the integration of these membrane systems with renewable energy sources, such as solar-powered desalination and filtration units, reduces operational carbon footprints and energy costs, contributing to more sustainable wastewater treatment frameworks [16]. Despite their high efficiency, membrane fouling and maintenance costs remain challenges, prompting ongoing research into membrane surface modification and hybrid systems to enhance long-term performance and economic feasibility.

2.4. Green Chemistry Extraction

The use of green solvents such as deep eutectic solvents (DESs) and ionic liquids is gaining prominence in the sustainable extraction of Active Pharmaceutical Ingredients (APIs). DESs are eutectic mixtures of naturally derived components that exhibit low volatility, biodegradability, and low toxicity, making them attractive alternatives to conventional organic solvents, which often pose environmental and health risks. Ionic liquids, composed entirely of ions, also provide excellent solvent properties, including high thermal stability and tunable polarity, facilitating efficient dissolution and selective extraction of APIs from complex pharmaceutical matrices [17]. These green solvents reduce hazardous waste generation and improve safety in pharmaceutical manufacturing and waste processing, aligning with the principles of green chemistry by minimizing environmental footprint and exposure to toxic chemicals. Their ability to be recycled and reused further enhances process sustainability, offering a promising route for eco-friendly API recovery [17].

2.5 Advanced Oxidation with Green Energy

Advanced oxidation processes (AOPs) are crucial in degrading persistent pharmaceutical contaminants that conventional treatments often fail to remove effectively. Among AOPs, photocatalysis using titanium dioxide (TiO_2) under solar irradiation stands out as a green and energy-efficient approach. TiO_2 acts as a semiconductor catalyst that, upon exposure to sunlight, generates reactive oxygen species capable of breaking down complex API molecules into less harmful compounds [19]. This method benefits from using abundant and renewable solar energy, eliminating the need for additional chemical reagents. Furthermore, recent advances in bio-inspired catalysts—materials engineered to mimic enzymatic functions—have improved photocatalytic efficiency and specificity, enabling targeted degradation of APIs with reduced formation of toxic by-products. Integrating these photocatalytic systems with sustainable energy sources offers a viable solution to pharmaceutical waste management by combining effective contaminant removal with minimal environmental impact [19].

3. Proposed Pipeline for Eco-friendly API Reclamation

A structured and eco-conscious pipeline can effectively integrate multiple green technologies for the sustainable recovery of Active Pharmaceutical Ingredients (APIs) from pharmaceutical waste streams. The goal is to minimize environmental burden while maximizing resource recovery in alignment with circular economy principles [12]. The proposed pipeline consists of the following steps shown in Figure 2.

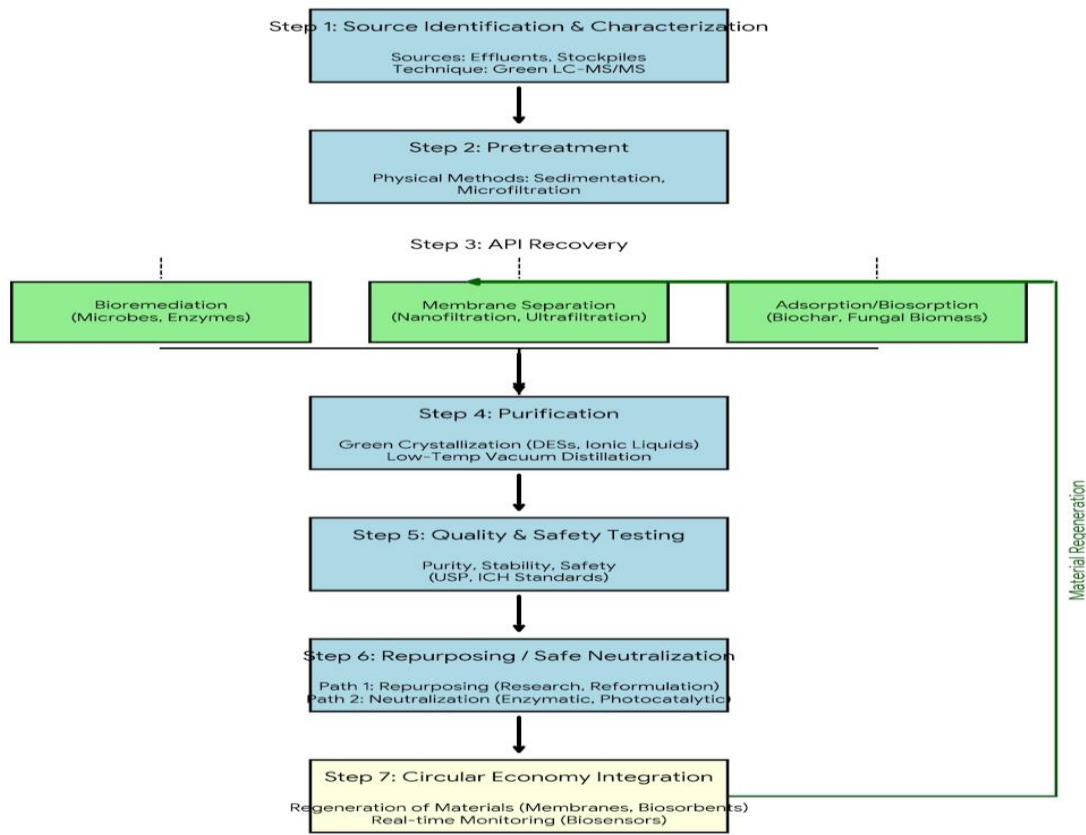


Figure2: proposed pipeline for Eco- friendly API reclamation(Integrated Circular Economy Approach)

Step 1 – Source Identification & Characterization

The first stage involves identifying potential API-containing waste sources such as pharmaceutical manufacturing effluents, hospital discharges, and expired drug stockpiles. Analytical quantification of target APIs is performed using green techniques like LC-MS/MS with reduced solvent usage, in line with green analytical chemistry principles [12].

Step 2 – Pretreatment

This step includes the removal of packaging materials, particulate matter, and other bulk contaminants using low-energy physical methods such as sedimentation and microfiltration [16]. Pretreatment ensures that downstream recovery processes operate more efficiently.

Step 3 – API Recovery

Eco-friendly recovery is facilitated through multiple parallel strategies. Bioremediation using selected microbial strains (e.g., *Pseudomonas*, *Bacillus*) or enzymes like laccases and peroxidases enables selective degradation or biotransformation of APIs [11]. Membrane separation techniques—such as nanofiltration and ultrafiltration—allow for effective concentration of APIs from aqueous matrices [15]. Additionally, adsorption and biosorption using low-cost, sustainable materials like biochar, activated carbon, or fungal biomass offer efficient API capture without harmful by-products [12,14].

Step 4 – Purification

Following recovery, purification is achieved using green crystallization methods involving deep eutectic solvents (DESs) or low-toxicity ionic liquids, which reduce environmental hazards. Energy-efficient operations such as low-temperature vacuum distillation can further purify APIs while conserving energy.

Step 5 – Quality & Safety Testing

Recovered APIs are evaluated for pharmaceutical-grade purity, stability, and biological safety. Analytical validation ensures compliance with pharmacopeial standards such as those outlined by the USP and ICH [18].

Step 6 – Repurposing / Safe Neutralization

Recovered APIs may be repurposed in preclinical research, educational laboratories, or reformulated into secondary pharmaceutical products. APIs deemed unfit for reuse are safely neutralized using enzymatic or photocatalytic degradation pathways [19].

Step 7 – Circular Economy Integration

To enhance sustainability, reusable materials such as membranes and biosorbents are regenerated and reintegrated into the process. Additionally, biosensor-based monitoring systems can be employed for real-time API detection and automated process control, supporting continuous operation with minimal waste.

This integrative pipeline not only contributes to environmental protection through pharmaceutical pollution reduction but also enables resource efficiency by recovering APIs for potential reuse—an approach that supports the goals of the circular economy and sustainable development.

3.1. Outcome: Reduced Pollution and API Recovery for Reuse

The implementation of eco-friendly API reclamation strategies leads to dual benefits: the reduction of pharmaceutical pollution in the environment and the sustainable recovery of valuable Active Pharmaceutical Ingredients (APIs) for potential reuse.



Figure 3: Integrated Benefits of sustainable API Reclamation: Environmental Protection and Resource Circularity (Highlights both environmental and economic benefits more explicitly).

These methods minimize the release of biologically active compounds into aquatic and terrestrial ecosystems, thereby mitigating ecotoxicological risks associated with pharmaceutical contamination [9]. Concurrently, reclaimed APIs—when purified and validated—can be repurposed for research, industrial formulations, or educational use, promoting circular resource flows and reducing reliance on new raw materials [12]. Overall, the integration of green technologies

into pharmaceutical waste management not only safeguards environmental and public health but also enhances the economic and material efficiency of the pharmaceutical sector.

4. Strengths and Limitations of Eco-friendly Approaches for API Recovery

Eco-friendly strategies for the recovery of Active Pharmaceutical Ingredients (APIs) from pharmaceutical waste present both promising opportunities and operational challenges. These methods align with green chemistry and circular economy frameworks, but practical implementation still faces several hurdles.

4.1. Strengths

Sustainability and Circularity:

Eco-friendly API reclamation approaches support sustainable development goals by promoting resource efficiency and minimizing environmental pollution. The reuse of APIs recovered from expired or discarded drugs contributes to a circular economy by reducing the need for virgin raw materials and minimizing pharmaceutical waste. This shift from a linear to a circular model enhances long-term sustainability in the pharmaceutical sector [9].

Lower Energy Demand Compared to Thermal Disposal

Unlike conventional disposal methods such as incineration, which require high energy input and often emit greenhouse gases and toxic by-products, methods like adsorption, biosorption, and enzymatic degradation operate at ambient conditions and require significantly less energy [12]. These approaches reduce the carbon footprint of pharmaceutical waste management while maintaining environmental safety.

Recovery of Valuable APIs

Eco-friendly processes not only mitigate environmental contamination but also allow for the recovery of therapeutically active compounds. Reclaimed APIs can be reused for research, reformulation, or educational purposes, thereby adding economic value to what would otherwise be waste. In cases where the recovered compounds meet pharma co-poeial standards, they may even be considered for reintegration into the supply chain under regulatory oversight.

4.2 Limitations

Scale-up and Operational Challenges

Most eco-friendly API recovery techniques—such as enzymatic treatment, membrane separation, and biosorption—have been demonstrated primarily at laboratory or pilot scales. Transitioning these methods to industrial-scale operations requires technological refinement, infrastructure investment, and process standardization [11]. Variables like membrane fouling, enzyme degradation, and biosorbent regeneration remain unresolved at scale.

Economic Feasibility Uncertain

While environmentally beneficial, many of these green technologies entail high initial capital costs and operational complexities. For instance, the cost of producing high-purity biosorbents or maintaining enzymatic activity can be significant [16]. Additionally, the absence of market incentives or regulatory mandates for API recovery may reduce the motivation for industry-wide adoption.

Regulatory and Safety Gaps

One of the major hurdles in API reuse is the lack of well-defined regulatory frameworks. Questions about the safety, efficacy, and traceability of recovered APIs pose barriers to their approval for reintegration into the pharmaceutical supply chain. Currently, most pharmacopoeias and environmental laws focus on pollutant removal rather than material recovery, highlighting a significant policy gap.

5. Future Perspectives

The future of eco-friendly API reclamation lies in combining advanced technologies to improve efficiency, scalability, and control. Hybrid systems integrating bioremediation with membrane filtration offer synergistic benefits—enzymes or microbes degrade APIs while membranes capture residual contaminants [11,15]. AI-enabled biosensors, integrated with IoT systems, are emerging tools for real-time monitoring of pharmaceutical pollutants, enhancing precision and automation in treatment processes [10].

Broader industrial adoption will depend on regulatory frameworks that enable safe API reuse. Current gaps in policy hinder scale-up, and clear guidelines for validation and certification are needed [9]. Additionally, the development of low-cost biosorbents from agro-waste like rice husks or banana peels offers a sustainable, accessible solution for many regions, particularly in developing economies [13].

These innovations, if implemented holistically, can significantly advance green pharmaceutical waste management.

6. Conclusion

Eco-friendly approaches to recover Active Pharmaceutical Ingredients (APIs) from pharmaceutical waste provide a sustainable and effective alternative to conventional waste treatment methods. By integrating processes such as bioremediation, membrane separation, adsorption, and green purification, the proposed pipeline enables systematic recovery, purification, and reuse of APIs, thereby minimizing environmental pollution and promoting resource circularity. These strategies not only reduce pharmaceutical contaminants in soil and water but also conserve valuable resources. Despite their potential, challenges remain regarding economic feasibility, regulatory frameworks, and ensuring the quality and safety of reclaimed APIs. Addressing these issues through further research, technological optimization, and clear policy guidelines is essential for successful large-scale implementation. Overall, eco-friendly API recovery holds significant promise for greener pharmaceutical waste management and sustainable industry practices.

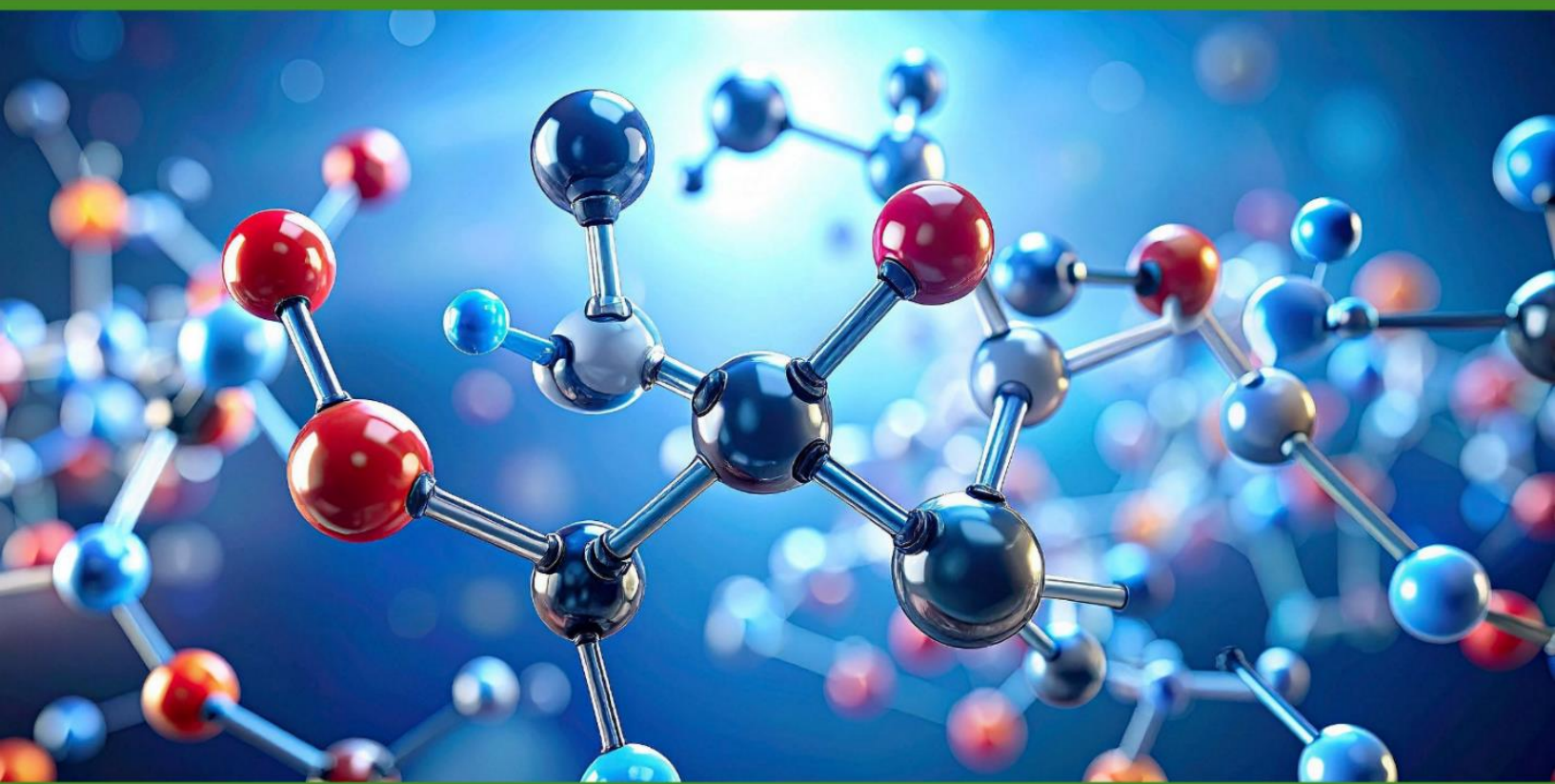
Acknowledgement

The authors would like to express their sincere gratitude to **Rapture Biotech, Bengaluru**, and the entire team for their invaluable support and guidance throughout the preparation of this review. We also gratefully acknowledge the financial assistance provided by Rapture Biotech, Bengaluru, which made this work possible.

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