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BIODEGRADABLE POLYMERS IN DRUG DELIVERY AND TISSUE ENGINEERING

CHAPTER-1

Foundation of Biodegradable Polymers in Pharmaceuticals

Prevesh Kumar^{1*}, Diksha¹, Iqra Hasan², Akriti Singh³, Navneet Verma¹

¹Pharmacy Academy, Faculty of Pharmacy, IFTM University, Moradabad-244102, Uttar Pradesh, India

²Research Scholar, School of Biotechnology, IFTM University, Moradabad-244102, Uttar Pradesh, India

³Assistant Professor, Lingaya's Vidyapeeth, Faridabad-121014, Haryana, India

Corresponding Author: Prevesh Kumar

Email:- drkpravesh92@gmail.com

Abstract

Biodegradable polymers can be regarded as one of the essential components of contemporary pharmaceuticals due to such characteristics as biocompatibility, controllable degradation, and wide applicability in the manufacture of drug delivery devices, tissue engineering products, and regenerative medicines. These polymers are capable of being completely degraded into harmless compounds in the biological medium; thus, it becomes unnecessary to resort to surgical removal of such polymers, and their toxicity is minimized. Natural polymers like chitosan, alginate, gelatin, and starch, as well as synthetic polymers such as polylactic acid (PLA), polyglycolic acid (PGA), and poly (lactic-co-glycolic acid) (PLGA), draw the considerable interest of researchers and engineers in the pharmacological industry. Physicochemical properties of biodegradable polymers, such as molecular weight, crystallinity, hydrophilicity, and degradation rates, greatly affect their performance in terms of encapsulating and releasing drugs. Modern innovations made it possible to develop smart biodegradable materials with a possibility of controlled drug delivery. Furthermore, biodegradable polymers have found their application in producing various nano-, micro-, and macro-particles, which may be used in biomedical devices and other medical purposes. Despite all the benefits, there are certain disadvantages like high production cost, inconsistency in terms of degradation, and other regulatory problems that make them commercially unviable. This paper presents a general introduction to the basics of biodegradable polymers in pharmaceuticals, including their classification, characteristics, degradation process, pharmaceutical uses, strengths, weaknesses, and future potential. Increasing interest in environmentally friendly and people-oriented pharmaceutical technologies makes biodegradable polymers increasingly important for creating novel drug delivery systems.

Keywords: - Biodegradable Polymers, Drug Delivery Systems, Biocompatibility, Controlled Release, Pharmaceuticals.





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1. Introduction

Biodegradable polymers refer to chemicals that are utilized in pharmaceuticals and can degrade into non-toxic products in the human body. Biodegradable polymers find a wide range of applications in pharmaceuticals, being widely used in drug delivery systems. They could either be natural or synthetic polymers, including PLA, PGA, and PLGA. The use of biodegradable polymers is preferred since they pose no adverse effects on the body because of their degradation characteristics (Kumari et al., 2010).

1.1 Overview of Polymers in Pharmaceuticals

Polymers are an important component in pharmaceuticals due to their versatility in pharmaceutical applications. They are important for drug delivery and formulation. Polymers can be used in the design of drugs to improve their bioavailability, stability, and drug release profiles. They can also be used in the formulation of tablets, capsules, and nanoparticle formulations (Henke et al., 2017).

1.2 Concept of Biodegradability

Polymer is an important component of pharmaceuticals because of its importance in pharmaceutical uses. It is essential for drug formulation and delivery. The polymers can be utilized in making drugs where they help to increase the bioavailability and stability of drugs, besides controlling the drug delivery rates (Bulatović et al., 2021).





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1.3 Historical Development of Biodegradable Polymers

Biodegradable polymers first appeared when natural substances like starch and gelatin were used for drugs during earlier times. The creation of synthetic biodegradable polymers was introduced later on during the middle of the 20th century with the use of PLA and PGA as biodegradable polymers. These biodegradable polymers achieved their importance medically during the 1970s as they were used for drugs delivery and absorbable sutures. Afterward, PLGA became popular for its good biocompatibility and adjustable degradation rates (Zhang et al., 2014).

2. Classification of Biodegradable Polymers

The biodegradable polymers can be categorized into three major types based on the origin of the polymer. The types include natural polymers, synthetic polymers, and combined polymers. Examples of natural polymers include chitosan, alginate, gelatin, and starch. Natural polymers are naturally occurring in living organisms and show excellent biocompatibility. Synthetic polymers, such as PLA, PGA, and PLGA, can be chemically manufactured. It becomes easy to control the degradation rate and mechanical properties of the synthetic polymers shown in Table No. 1) (Künkel et al., 2016).

3. Physicochemical Properties

The physical and chemical nature of biodegradable polymers makes enormous contributions to the application of these materials in the field of pharmaceutical sciences. Some of these factors include the molecular weight of the polymer, the chemistry of the polymer, crystallinity, hydrophilicity, and thermodynamics. The molecular weight factor is very significant because it determines the degradation time. High molecular weight requires more time for degradation. Hydrophilic polymers have a higher affinity for water, hence the rate of degradation. Thermodynamic properties define processing methods when developing pharmaceutical formulations.





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Table 1: Classification of Biodegradable Polymers along with their applications

Category	Examples	Key Characteristics	Major Pharmaceuticals Applications
Natural Biodegradable Polymers	Chitosan, Alginate, Gelatin, Starch, Collagen	Biocompatible, biodegradable, renewable, low toxicity	Drug delivery systems, wound healing, tissue engineering, and hydrogels (Balaji et al., 2017), (Karthika et al., 2019).
Synthetic Biodegradable Polymers	PLA, PGA, PLGA	Controlled degradation, good mechanical strength, reproducible properties	Controlled drug delivery, implants, microspheres, nanoparticles (Luckachan & Pillai, 2011).
Hybrid/Composite Polymers	Chitosan–PLGA, Gelatin–PLA composites	Combines advantages of natural and synthetic polymers; improved stability and functionality	Targeted drug delivery, regenerative medicine, advanced biomedical devices (Niemelä & Kellomäki, 2011).





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3.1 Molecular Weight and Structure

Molecular weight and structure of the polymers are two other parameters that influence the behavior of biodegradable polymers in pharmaceuticals. A polymer with a higher molecular weight has a tendency to degrade slowly; therefore, it has a high capacity for sustained release of the drug. Polymer with low molecular weight degrades fast. Structures of the polymers may be linear, branched, or cross-linked. The physical characteristics of these materials, like strength and solubility, depend upon the structures of the polymers.

3.2 Crystallinity and Thermal Behaviour

The role played by crystallinity and thermal behaviour in the functioning of biodegradable polymers that are used in pharmacological applications is quite important. The term "crystallinity" defines the extent of ordered structures in the polymers; therefore, polymers that are more crystalline have increased strength but undergo a slow degradation process since less water passes through them. Amorphous polymers, on the other hand, undergo fast degradation and allow quick drug release. Additionally, thermal properties such as the glass transition temperature and melting point determine the processability of drug-delivery systems based on polymers.

3.3 Mechanical and Biological Properties

Tensile strength, elasticity, and flexibility are just some examples of physical properties that define the capability of biodegradable polymers for use in various medical uses, including implants, sutures, and drug delivery devices. Mechanical stability becomes necessary for the stability of the substance during the administration process and release in the body. Some physical properties that must be present to ensure safe usage include biocompatibility, safety, and interactions with the body tissues (Di Maio & Iannace, 2012).

4. Mechanism of Biodegradation

Polymer biodegradation in pharmaceuticals is achieved by degrading polymer molecules to form smaller, non-harmful units that can be readily excreted out of the body. This process usually





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takes place via hydrolysis and enzyme degradation depending on the nature of the polymer. Hydrolysis occurs by the ingress of water in the polymer network, resulting in chain breakage until there is loss of structure. In addition to hydrolysis, enzymes found in living organisms speed up the degradation process, particularly of natural polymers. Factors affecting the biodegradation process include the nature of the polymer, degree of crystallization, molecular weight, and the level of pH in the surrounding environment (Shown in Figure No.1) (Samir et al., 2022).

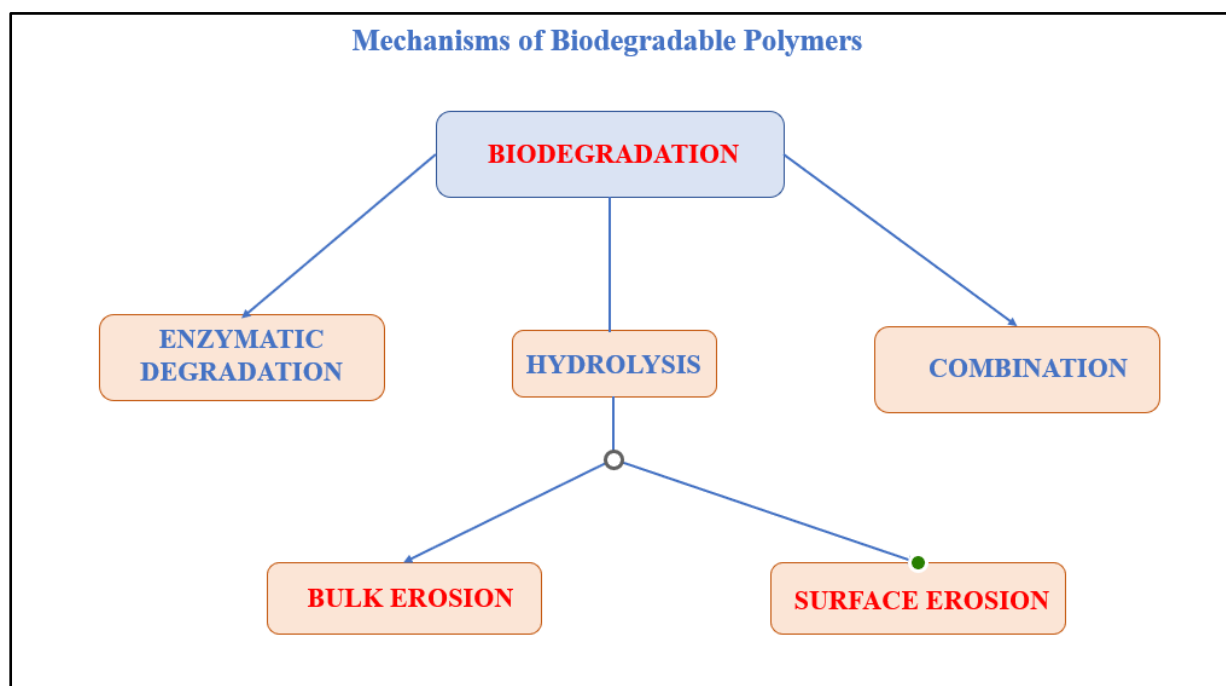


Figure 1: Mechanism of Biodegradable Polymers

4.1 Hydrolytic Degradation

Hydrolytic degradation constitutes one of the primary types of degradation for biodegradable polymers under physiological conditions. Hydrolytic degradation consists of water penetrating into the polymeric material and degradation of bonds, including ester, anhydride, and amide bonds. The breaking down results in the breakdown of the polymer's molecular weight and ultimately leads to loss of the polymer's structural integrity and the formation of small





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molecules, which are safe for disposal from the body. Hydrolysable polymers include poly lactic acid (PLA), poly glycolic acid (PGA), and poly lactic co-glycolic acid (PLGA), among others. Their rates of degradation can be manipulated using different techniques such as manipulation of crystallinity, hydrophilicity, or copolymerization of polymers.

4.2 Enzymatic Degradation

Enzymatic degradation is one in which degradation of biodegradable polymers takes place using the biological enzymes for the degradation of the material into harmless particles. Enzymatic degradation is more frequently observed in the case of natural polymers like chitosan, gelatin, collagen, and starch, where enzymes such as lysozyme, protease, and amylase are used to degrade the natural polymer chains. The speed of the reaction will depend upon the quantity of enzymes used, the nature of the polymer used, and the availability of the reactive sites of the material. Unlike hydrolytic degradation, enzymatic degradation is less aggressive and can take place under mild physiological conditions.

4.3 Factors Affecting Biodegradation

Several physicochemical and biological parameters affect the rate of degradation of polymers. The several physicochemical characteristics of the polymers such as molecular weight, crystallization, hydrophilic nature, and chemical structure have a great effect on the rate of degradation of polymers. Highly crystalline and hydrophobic polymers have slow speeds of degradation when compared to amorphous and hydrophilic polymers due to higher levels of water diffusion in the latter. pH level, temperature, and the effect of enzymes are environmental factors that affect degradation. Morphology of the polymers as well as drug composition also affects the speed of degradation.

5. Pharmaceutical Applications

Biodegradable polymers have often been used in pharmaceuticals because of the safety and compatibility associated with them, along with their ability to be degraded under control. The importance of biodegradable polymers can be understood by looking at controlled drug





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delivery systems that gradually release medicines into the body. Other than that, another major usage of biodegradable polymers involves the design of drug delivery devices in the form of nanoparticles, microspheres, hydrogels, and implants. These polymers are also widely used in tissue engineering applications.

5.1 Controlled and Sustained Drug Delivery

Biodegradable polymers will have an important role in the administration of drugs through controlled processes. Here, the degradation of these polymers within the body occurs slowly, resulting in the controlled release of the drug. This mechanism helps in maintaining the ideal drug concentration in the body for a prolonged period of time. Common polymers used include polylactic acid (PLA), polyglycolic acid (PGA), and poly (lactic-co-glycolic acid) (PLGA) (Wang et al., 2016).

5.2 Nanoparticles and Microspheres

The usage of nanotechnology in the field of drug delivery has brought into use nanoparticles and microspheres prepared from biodegradable polymers. Drug stability, enhancement in drug bioavailability, and targeted drug delivery are possible through this method (Li & Yu, 2023). The drug delivery with the help of polymeric nanoparticles takes place at the cellular and tissue level, whereas microspheres provide sustained release of the drug. Polymers that are used include PLGA, PLA, or chitosan, which is a natural polymer, since these polymers are biocompatible and do not release toxic substances upon degradation (Ye et al., 2023).

5.3 Hydrogels and Implants

Hydrogels based on biodegradable polymers are extensively applied in fields such as drug delivery and tissue engineering. Hydrogels comprise hydrophilic polymers having the capability to imbibe enormous amounts of water and, therefore, can be utilized as vehicles in administering drugs. Creation of hydrated conditions facilitates tissue repair and regeneration. Polymers that are incorporated in implants like polylactic acid, polyglycolic acid, and poly





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(lactic-co-glycolic) acid help in the continuous delivery of the drug without the requirement of undergoing surgery due to their slow degradation rate (Ghanbarzadeh & Almasi, 2013).

5.4 Tissue Engineering and Regenerative Medicine

The use of biodegradable polymers in tissue engineering and regenerative medicine is very important because they offer temporary scaffolds for the cells that attach and grow. This allows tissue regeneration, and the scaffold material degrades inside the body to be eventually substituted by the new tissue without any need for its surgical removal. Materials like PLA, PGA, PLGA, collagen, and chitosan are often chosen for these applications since they are biofriendly materials and have the property of controlled degradation.

6. Advantages of Biodegradable Polymers

There are several advantages in terms of biodegradable polymers in pharmaceuticals. Biodegradable polymers are biocompatible and generate non-toxic metabolites after undergoing the process of degradation. There is a lack of toxicity risks associated with using such materials, which eliminates the necessity of removing them surgically once the drug release procedure is completed. In addition, biodegradable polymers allow controlling the process of drug release, increasing its effectiveness and ensuring greater patient compliance by reducing the frequency of administration. In addition, these polymers are flexible and can be customized according to the purpose through modification in their composition and rate of degradation (Shown in Table No 2) (El Foujji et al., 2023).

Table 2: Comparison of Advantages and Disadvantages of Biodegradable Polymers

Advantages	Limitations
Biocompatible and safe	High production cost
Degrades into non-toxic products	Variable degradation rates
Eliminates the need for surgical removal	Stability issues during storage
Enables controlled and sustained drug release	Complex manufacturing processes
Improves patient compliance	Regulatory approval challenges





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Environmentally friendly	Limited long-term clinical data for newer polymers
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6.1 Biocompatibility and Safety

Safety and biocompatibility are the most prominent advantages provided by biodegradable polymers in pharmaceuticals. These polymers are developed in such a manner that they do not have a negative impact on biological systems and are not toxic, inflammatory, or immunogenic in nature. They are also broken down into non-toxic elements like water and carbon dioxide or smaller compounds, which will be metabolized in the body itself, hence preventing any chances of accumulation in the body. That is why biodegradable polymers find wide application in the field of pharmaceuticals (Leão et al., 2022).

6.2 Reduced Toxicity and Environmental Impact

The high level of biodegradability in biodegradable polymers leads to reduced levels of toxicity and environmental impacts because of their tendency to break down into non-toxic substances that are found naturally in the environment. In terms of the application of pharmaceuticals, biodegradable polymers are advantageous because of their low likelihood of developing toxicity and accumulating in the tissues. In the environmental sector, biodegradable polymers have lower levels of plastic wastage as compared to non-biodegradable polymers (Parthasarathy & John, 2022).

6.3 Improved Patient Compliance

Biodegradable polymers aid in patient compliance because they help in the sustained and controlled release of drugs; hence, there is no need for frequent drug dosages. This makes the treatment process easy, especially when treating chronic illnesses requiring the use of drugs for long periods of time. As biodegradable polymers break down inside the body, there is no requirement for surgically removing the drug delivery system, thus increasing the patient's comfort level (Hata, 2024).





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7. Limitations and Challenges

The biodegradable polymers have various limitations and challenges that limit their full potential. Variability in degradation rates under changed physiological conditions can lead to unpredictable drug release profiles. Some polymers may also face stability issues during storage and processing. High production and growth costs, along with complex manufacturing techniques, further limit large-scale commercialization. Additionally, regulatory approval and long-standing safety evaluation remain challenging due to limited clinical data for some novel polymer systems. These factors collectively require further research and optimization to recover their reliability and extensive use in pharmaceuticals (Langer & Peppas, 1981).

7.1 Stability and Storage Issues

Biodegradable polymers often face storage, stability and challenges that can affect their performance in pharmaceutical applications. These materials may undergo premature degradation when exposed to moisture, heat, or light, leading to changes in molecular weight and drug release behaviour. Absorption of water during storage can also initiate hydrolytic failure, especially in polymers like PLA and PLGA. Therefore, proper packaging, controlled temperature, and low-humidity situations are essential to preserve their stability. These issues can confuse long-term storage and limit their shelf life in pharmaceutical preparation (Liechty et al., 2010).

7.2 Manufacturing and Cost Constraints

The production of biodegradable polymers-based drug delivery systems involves multifaceted processing techniques that require specialized equipment and controlled conditions. Processes such as polymer synthesis, purification, drug encapsulation, and formulation scaling can be technically challenging and time-consuming. In addition, preserving batch-to-batch constancy is difficult, which can affect product quality and reproducibility. The high cost of raw materials, coupled with advanced production methods, makes these systems more expensive compared to conventional drug delivery platforms. These factors collectively boundary large-scale





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industrial production and widespread commercialization of biodegradable polymer-based pharmaceutical products (Jain et al., 2024).

7.3 Regulatory and Safety Concerns

The main challenges in developing and approving biodegradable polymer-based pharmaceutical products are regulatory and safety issues. Regulatory agencies require extensive preclinical and clinical data confirming the biocompatibility, safety and efficacy of these materials over the long term. Variability in polymer composition, degradation behaviour, and possible contaminants may further complicate the approval and standardization processes. Further, safety concerns can be raised because of incomplete understanding of long-term metabolic effects of degradation byproducts. These factors often result in long approval times and stringent regulatory requirements that hinder the rapid commercialization of new biodegradable polymer systems. (Menossi et al., 2025).

8. Recent Advances and Future Prospects

Recent advances in biodegradable polymers have significantly expanded their applications in modern pharmaceuticals, in particular in the development of smart drug delivery systems and personalized medicine. Current research is directed to the improvement of responsive and accurate drug release by polymer function. The future of biodegradable polymers is to incorporate advanced technologies such as nanotechnology, biotechnology and artificial intelligence to develop highly efficient and targeted therapeutic systems (Cheng et al., 2024).

8.1 Smart and Stimuli-Responsive Polymers

Smart or stimuli responsive biodegradable polymers are designed to react to specific internal or external triggers like pH, temperature, enzymes or magnetic fields. These systems facilitate the site-specific and on-demand release of drugs, enhancing therapeutic efficiency and minimizing side effects. Extensively studied for cancer therapy and targeted drug delivery applications (Olonisakin et al., 2025).





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8.2 Personalized Medicine Applications

In the last decade, the use of biodegradable polymers in personalized medicine has been increased to develop patient-specific drug delivery systems. Tuning polymer properties to individual genetic, metabolic and disease profiles allows therapies to be optimized for maximum efficacy and minimal adverse effects. This method enables precision dosing and improved clinical outcomes (Shaikh et al., 2021).

8.3 Future Research Directions

Future directions in biodegradable polymers are in multifunctional, bioactive and highly tunable systems. The key areas are the improved predictability of degradation, enhanced targeting efficiency, reduced production costs, and wider applications in regenerative medicine and nanomedicine. Integration with advanced biomedical technologies is expected to be the driver for the next generation of smart therapeutic systems (Ncube et al., 2020).

9. Conclusion

Biodegradable polymers represent a cornerstone in modern pharmaceuticals due to their ability to safely degrade into non-toxic byproducts while enabling controlled and targeted drug delivery. Their diverse origin, including natural and synthetic sources, allows flexibility in designing advanced drug delivery systems such as nanoparticles, microspheres, hydrogels, and implants. These materials have significantly improved therapeutic outcomes by enhancing drug stability, reducing dosing frequency, and increasing patient compliance. Despite their numerous advantages, challenges such as manufacturing complexity, cost constraints, and regulatory hurdles still need to be addressed. Continued research and technological advancements are expected to further optimize their performance and expand their applications in personalized medicine, tissue engineering, and smart drug delivery systems.





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