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Original Research Article

Design, Develop and Evaluate a Sustainable Pharmaceutical Packaging Using Biodegradable Polymers

Ayush A Shinde*, *Students of 4th Year B.Pharm, Shraddha Institute of Pharmacy, Washim, Maharashtra 444505.*

Ashish N Umale, *Assistant Professor, Department of Pharmacology, Shraddha Institute of Pharmacy, Washim, Maharashtra 444505.*

Dr. Swati P Deshmukh, *Principal, Shraddha Institute of Pharmacy, Department of Pharmacology, Washim, Maharashtra 444505.*

*Corresponding Author: **Ayush A Shinde**

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Abstract: As a sustainable substitute for traditional petrochemical-based plastics, this study explores the creation and improvement of biodegradable PLA–PHB (polylactic acid–polyhydroxybutyrate) blends for pharmaceutical packaging applications. Solvent casting was used to create a variety of formulations (F1–F7) with varying compositional ratios, and their mechanical, thermal, barrier, biological, and environmental performance were assessed. According to the study, PLA-rich blends had minimal migration characteristics, excellent tensile strength, and thermal stability, which made them appropriate for rigid packaging with a long shelf life. PHB-rich blends, on the other hand, showed improved biodegradability, encouraging eco-friendly disposal. The addition of amber-modified formulations enhanced their antibacterial and UV protection qualities, making them perfect for medicinal goods that are sensitive to light. Extensive evaluation tests, such as DSC, TGA, antibacterial activity, and stability investigations, verified that optimized blends like F2, F4, and F6 satisfy crucial pharmaceutical standards of durability, safety, and sterility. Overall, the study shows that PLA–PHB blends are promising, environmentally friendly materials that can take the place of traditional polymers in pharmaceutical packaging while maintaining performance effectiveness and regulatory compliance.

Keywords: PLA–PHB blends, biodegradable polymers, pharmaceutical packaging, thermal stability, antimicrobial activity, sustainable materials, polymer blends, drug packaging, eco-friendly plastics, biodegradability

Introduction:

The increasing global demand for pharmaceutical products has led to a significant rise in the use of plastic-based packaging materials, which are predominantly derived from petrochemical sources. These conventional plastics, including polyethylene (PE), polypropylene (PP), and polyvinyl chloride (PVC), are widely used due to their excellent mechanical strength, durability, and barrier properties. However, their non-biodegradable nature and persistence in the environment have contributed to severe ecological concerns, including plastic accumulation, microplastic formation, and long-term environmental toxicity. [1-4] Furthermore, the presence of additives such as plasticizers and stabilizers raises concerns regarding migration, toxicity, and potential health risks, particularly in sensitive applications like pharmaceutical packaging. [5-7]

Pharmaceutical packaging requires stringent performance characteristics, including chemical inertness, sterility, mechanical integrity, and protection against moisture, oxygen, and light. Conventional materials, although effective, face limitations in terms of recyclability and environmental sustainability due to multi-layered structures and complex compositions. [8] Additionally, increasing regulatory pressure and global sustainability initiatives have driven the search for eco-friendly alternatives that can maintain performance while reducing environmental impact. [9-10]

Biodegradable polymers have emerged as promising alternatives, offering the advantage of controlled degradation under environmental conditions. Among these, polylactic acid (PLA) has gained significant attention due to its renewable origin, biocompatibility, and favorable mechanical properties. [11] PLA is synthesized from lactic acid derived via fermentation of biomass, making it a sustainable and widely studied biopolymer. [12] However, PLA

exhibits certain limitations such as brittleness, low flexibility, and moderate barrier properties, which restrict its standalone application in demanding packaging systems. [13]

Another important biodegradable polymer is polyhydroxybutyrate (PHB), a member of the polyhydroxyalkanoate (PHA) family, produced by microbial fermentation. PHB is known for its high crystallinity, biodegradability, and good barrier properties, but it suffers from drawbacks such as thermal instability, brittleness, and processing difficulties. [14] These limitations necessitate the development of modified or blended systems to improve overall performance.[15]

Polymer blending has been widely explored as an effective strategy to overcome individual material limitations. The combination of PLA and PHB results in a material system that integrates the mechanical strength and processability of PLA with the biodegradability and barrier performance of PHB. [16] Previous studies have demonstrated that PLA–PHB blends exhibit improved thermal stability, mechanical performance, and biodegradation behavior, making them suitable candidates for packaging applications. [17] Moreover, the incorporation of additives and modifications, such as antimicrobial agents and UV stabilizers, can further enhance the functional performance of these blends. [18]

Recent advancements in biodegradable packaging research have also focused on active and intelligent packaging systems, which provide additional functionalities such as antimicrobial protection and environmental responsiveness. [19] These innovations are particularly relevant in pharmaceutical packaging, where maintaining drug stability and safety is of paramount importance. Furthermore, lifecycle assessments have indicated that biopolymers like PLA and PHB offer reduced carbon footprint and improved environmental compatibility compared to conventional plastics. [20]

Despite these advancements, challenges remain in terms of optimization of blend ratios, large-scale processing, cost-effectiveness, and regulatory acceptance. Therefore, systematic research is required to develop and evaluate optimized PLA–PHB formulations that meet both pharmaceutical performance standards and sustainability goals. [21]

In this context, the present study focuses on the development, characterization, and evaluation of various PLA–PHB blend formulations for pharmaceutical packaging applications. The research aims to investigate the influence of composition on thermal, mechanical, barrier, biological, and environmental properties, and to identify optimized formulations that can serve as viable, eco-friendly alternatives to conventional plastic packaging materials.[22]

1. Literature Review

a. **Xu et.al. (2026)** presented recent advancements in PLA-based biodegradable polymer blends, focusing on improving compatibility and performance through advanced engineering strategies. The review discusses the role of compatibilization techniques and synergistic blending approaches in enhancing mechanical properties, thermal stability and overall functionality of PLA-PHB systems. It highlights that optimized blend design and structural tuning can overcome immiscibility issues and lead to high-performance sustainable materials suitable for packaging and biomedical applications. [23]

b. **Li et.al. (2025)** reviewed the properties and processing of polyhydroxybutyrate (PHB) and its blends, emphasizing its potential as a sustainable alternative to petroleum-based polymers. The study highlights that PHB exhibits high crystallinity and biodegradability but suffers from brittleness and thermal instability. To address these limitations, strategies such as polymer blending, plasticization and additive manufacturing were discussed, which significantly improve mechanical strength and thermal behavior. The review also underlines the importance of PHB-based composites in packaging and biomedical applications while maintaining eco-friendly characteristics. [24]

c. **Gao et.al. (2024)** PLA-PHB blends' mechanical behavior was examined and it was discovered that when PHB is evenly distributed throughout the PLA matrix, toughness increases. Additionally, the study verified that PLA and PHB have strong intermolecular interactions, which enhance material performance in blended systems. [25]

d. **D'Anna et.al (2019)** examined the application of compatibilizers to increase miscibility in PLA-PHB blends. Compatibilizers improve overall mechanical performance and interfacial adhesion, according to the study. According to the study, consistent material qualities require adequate formulation since PLA and PHB are intrinsically immiscible. [26]

2. Objectives

a. To study the fundamental properties of biodegradable polymers, particularly PLA and PHB.
b. To analyze the limitations of conventional petrochemical-based pharmaceutical packaging materials.
c. To develop biodegradable polymer blends using PLA and PHB in different compositions and optimize the formulation of PLA-PHB blends for balanced material performance.
d. To investigate the mechanical properties (tensile strength, elongation, modulus) of developed blends.
e. To propose sustainable and eco-friendly alternatives for pharmaceutical packaging applications.

3. Pharmaceutical Packaging

Pharmaceutical packaging plays a critical role in ensuring the safety, stability, efficacy, and quality of drug products throughout their shelf life. It serves not only as a physical barrier but also as a means of protection against environmental factors such as moisture, oxygen, light, and microbial contamination. [27] Packaging is also essential for patient compliance, product identification, and regulatory labeling, making it an integral component of pharmaceutical product design. [28] With the rapid growth of the pharmaceutical industry, the demand for high-performance packaging materials has significantly increased, particularly for sensitive formulations such as biologics and injectables. [29]

3.1 Types of Pharmaceutical Packaging

Pharmaceutical packaging is broadly classified into three main categories based on its level of contact with the drug product.

3.1.1 Primary Packaging: Primary packaging is in direct contact with the drug product and must be chemically inert, non-reactive, and non-toxic. Common examples include blister packs, bottles, vials, ampoules, and sachets (75,80). Materials used for primary packaging must comply with stringent regulatory requirements to prevent interaction, adsorption, or leaching of harmful substances. [30]

3.1.2 Secondary Packaging: Secondary packaging provides additional protection and grouping of primary packages. It includes cartons, boxes, and labeling materials, which protect products during transportation and storage while also providing information such as dosage instructions and expiry dates. [31]

3.1.3 Tertiary Packaging: Tertiary packaging is used for bulk handling, transportation, and distribution. It includes corrugated boxes, pallets, and shrink wraps, ensuring protection during logistics and supply chain operations. [32]

3.2 Plastics Used in Pharmaceutical Packaging

Plastics are the most widely used materials in pharmaceutical packaging due to their lightweight nature, durability, flexibility, and cost-effectiveness. The commonly used pharmaceutical-grade plastics include;

3.2.1 Polyethylene (PE): Widely used for bottles, containers, and films, polyethylene offers good moisture resistance and chemical stability.

3.2.2 Polypropylene (PP): PP is known for its high thermal resistance and strength, making it suitable for autoclavable containers and caps.

3.2.3 Polyvinyl Chloride (PVC): PVC is extensively used in blister packaging due to its transparency and thermoforming properties. However, it often requires plasticizers, which can raise safety concerns.

3.2.4 Polyethylene Terephthalate (PET): PET is used for bottles and liquid packaging due to its excellent clarity, strength, and gas barrier properties.

3.2.5 Polystyrene (PS): Used in rigid containers and trays, PS provides good rigidity but has limited barrier properties.

Despite their advantages, these plastics are primarily non-biodegradable and derived from fossil fuels, contributing to environmental pollution. [33]

3.3. Hazards Associated with Conventional Plastic Packaging

3.3.1 Environmental Hazards: Conventional plastics are highly resistant to degradation, leading to long-term accumulation in landfills and natural ecosystems. Over time, they break down into microplastics, which contaminate soil, water, and food chains, posing serious ecological risks. [34] Additionally, improper disposal and incineration release toxic gases and greenhouse emissions, contributing to climate change. [35]

3.3.2 Health and Toxicological Risks: Pharmaceutical plastics often contain additives such as plasticizers (phthalates), stabilizers, and antioxidants, which may migrate into drug products under certain conditions. [36] This phenomenon, known as extractables and leachable, can lead to contamination and potential health hazards, especially in long-term therapies and sensitive formulations. [37]

3.3.3 Recycling and Waste Management Challenges: Pharmaceutical packaging materials are often multi-layered and contaminated, making recycling difficult and economically unfeasible. Strict regulatory requirements also limit the reuse of packaging materials, leading to increased plastic waste generation. [38]

3.3.4 Functional Limitations

Although conventional plastics provide good performance, they may exhibit limited UV protection, oxygen permeability, and environmental sustainability, particularly for advanced pharmaceutical applications. These limitations necessitate the development of improved materials with enhanced functional properties. [39]

3.4 Need for Sustainable Alternatives

The growing concerns related to environmental pollution, regulatory pressure, and patient safety have accelerated the development of biodegradable and bio-based polymers for pharmaceutical packaging. Materials such as PLA and PHB offer advantages including renewability, biodegradability, and reduced carbon footprint, making them promising alternatives to conventional plastics. However, their limitations require further optimization through blending and material engineering to meet pharmaceutical standards. [40]

Pharmaceutical packaging is a critical component in ensuring drug safety and efficacy, with plastics playing a dominant role due to their functional advantages. However, the associated environmental, health, and sustainability challenges highlight the urgent need for innovative materials. The transition toward biodegradable polymer systems, such as PLA–PHB blends, represents a significant step toward achieving sustainable and high-performance pharmaceutical packaging solutions. [41]

4. Biopolymers

Biopolymers are a class of materials derived from renewable biological resources such as plants, microorganisms, and agricultural waste. They have gained significant attention as sustainable alternatives to conventional petroleum-based plastics due to their biodegradability, biocompatibility, and reduced environmental impact. [42] Unlike synthetic polymers, biopolymers undergo natural degradation through microbial activity, resulting in environmentally benign by-products such as carbon dioxide, water, and biomass. [43] Based on their origin and synthesis, biopolymers are broadly classified into natural biopolymers (e.g., cellulose, starch), synthetic biopolymers derived from bio-based monomers (e.g., PLA), and microbially produced polymers (e.g., PHB). [44] Their growing importance is driven by increasing concerns over plastic pollution, carbon emissions, and sustainability regulations, particularly in sensitive industries such as pharmaceutical and food packaging. [45]

4.1 Polylactic Acid (PLA)

Polylactic acid (PLA) is one of the most widely used biodegradable polymers, synthesized from lactic acid obtained through fermentation of renewable resources such as corn starch, sugarcane, or biomass. [46] The production of PLA typically involves polycondensation or ring-opening polymerization of lactide, resulting in a thermoplastic polymer

with desirable properties. [47] PLA is known for its high mechanical strength, rigidity, transparency, and good thermal processability, making it suitable for packaging applications. [48]

In pharmaceutical packaging, PLA offers several advantages, including biocompatibility, non-toxicity, and ease of processing into films, fibers, and molded products. [49] It also exhibits good barrier properties against odors and moderate resistance to moisture, which are important for maintaining drug stability. [50] However, PLA has inherent limitations such as brittleness, low flexibility, slow crystallization rate, and relatively poor barrier properties against gases, which restrict its standalone use in high-performance applications. [51] Additionally, PLA shows limited thermal resistance under certain processing conditions, which can affect its applicability in sterilization processes. [52]

To overcome these challenges, PLA is often modified through blending, plasticization, or incorporation of additives, which improve its flexibility, toughness, and functional properties. [53] Recent research has also explored the use of active agents and nanomaterials to enhance antimicrobial activity and barrier performance, making PLA a promising candidate for advanced pharmaceutical packaging systems. [54]

4.2 Polyhydroxybutyrate (PHB)

Polyhydroxybutyrate (PHB) is a biodegradable polyester belonging to the polyhydroxyalkanoate (PHA) family, produced naturally by microorganisms as an intracellular energy storage compound under nutrient-limited conditions. [55] PHB is synthesized through microbial fermentation processes, making it a fully bio-based and sustainable polymer. [56] It is highly regarded for its excellent biodegradability, biocompatibility, and relatively high crystallinity, which contribute to its good barrier properties. [57]

PHB exhibits mechanical properties comparable to conventional plastics such as polypropylene, including good stiffness and strength. It also provides excellent resistance to moisture and gases, making it suitable for packaging applications that require enhanced barrier performance. [58] Furthermore, PHB degrades naturally in soil and compost environments, supporting its role in environmentally sustainable material systems. [59]

Despite these advantages, PHB has several limitations, including brittleness, narrow processing window, thermal instability, and high production cost, which limit its large-scale industrial application. [60] PHB tends to degrade at temperatures close to its melting point, making processing challenging and leading to reduced material performance. Additionally, its inherent stiffness and lack of flexibility restrict its use in applications requiring toughness and elongation. [61]

To address these limitations, PHB is commonly blended with other polymers such as PLA, which helps in improving its processability, flexibility, and overall performance. The combination of PHB with other materials also enables the development of tailored biodegradable systems with balanced mechanical and functional properties. [62]

4.3 Significance of PLA–PHB Systems

The combination of PLA and PHB represents a promising approach in the field of biodegradable materials, as it integrates the strength and processability of PLA with the biodegradability and barrier properties of PHB. Such blends can be engineered to achieve optimized performance for specific applications, particularly in pharmaceutical packaging where both material safety and environmental sustainability are essential. [63]

Biopolymers such as PLA and PHB offer significant advantages as sustainable alternatives to conventional plastics. While PLA provides mechanical strength and ease of processing, PHB contributes to biodegradability and barrier performance. However, both polymers have inherent limitations when used individually, which can be effectively addressed through blending and material modification strategies. Their combined use in PLA–PHB systems holds great potential for the development of next-generation biodegradable pharmaceutical packaging materials that meet both performance and environmental requirements.

5. Methodology

5.1 Materials

Polylactic acid (PLA) and polyhydroxybutyrate (PHB) used in this study were biodegradable, pharmaceutical-grade polymers procured from certified suppliers. Both polymers were selected due to their biocompatibility, biodegradability, and suitability for packaging applications. [64] Analytical-grade solvents and reagents used for testing and processing were obtained from standard commercial sources and used without further purification. Additives for amber formulations, including UV stabilizers and antimicrobial agents, were incorporated to enhance functional performance. [65]

5.2 Preparation of PLA–PHB Blends

PLA–PHB blends were prepared using the melt blending technique, which is widely used for polymer processing due to its scalability and industrial relevance. [66] The required proportions of PLA and PHB were weighed according to predefined formulations (F1–F7). The polymers were dried prior to processing to remove moisture and prevent degradation.

Blending was carried out in a twin-screw extruder at controlled temperature conditions (typically 160–190°C) to ensure uniform mixing. The extruded material was then pelletized and further processed into films or molded samples using compression molding or film casting techniques. [67] Amber formulations (F6 and F7) were prepared by incorporating additives during the blending stage to achieve enhanced UV protection and antimicrobial properties. [68]

5.3.Formulation Design

Seven formulations (F1–F7) with varying PLA–PHB ratios were developed to study the effect of composition on material properties. The selection of compositions was based on previous studies indicating that polymer ratio significantly influences mechanical, thermal, and biodegradation behavior. [69] Replicates were prepared for each formulation to ensure experimental reproducibility and statistical reliability.

The molding of PLA-PHB blends into pharmaceutical packaging is based on the principle of polymer film formation and shape replication through solvent casting followed by mold-assisted structuring. In this method, the polymers are first dissolved in an optimized solvent system to form a homogeneous solution, which upon controlled solvent evaporation results in a uniform polymer matrix. This matrix can then be shaped into desired pharmaceutical packaging forms such as films, sheets, or containers.

For lab-scale development, elastomeric molds made from platinum-cured liquid silicone rubber (LSR-125) are used due to their high thermal stability, chemical inertness, flexibility and excellent surface replication. These molds allow precise shaping of packaging components such as blister cavities, small containers and film-based structures, without causing deformation or adhesion issues during demolding.

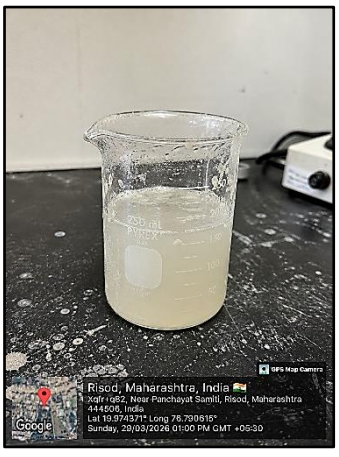


Fig. No. 1: Blend solution for Casting

5.4 Step-by-Step Process (Solvent Casting with Mold Formation)

Step 1: Preparation of Polymer Blend Solution

The optimized PLA-PHB blend formulation is prepared by dissolving the required quantities of PLA and PHB in a solvent mixture of chloroform, acetone and toluene under continuous stirring. Additives such as plasticizers, compatibilizers, fillers, antimicrobial agents and stabilizers are incorporated sequentially to ensure uniform dispersion. The solution is stirred at controlled temperature (40-50°C) until a clear and homogeneous polymer solution is obtained. This step is critical to ensure uniformity in the final molded product.

Step 2: Degassing of Polymer Solution

The prepared polymer solution is subjected to vacuum degassing or ultrasonication to remove entrapped air bubbles. This prevents the formation of voids and defects in the final molded structure, ensuring smooth surface morphology and improved mechanical integrity, which are essential for pharmaceutical packaging.

Step 3: Preparation of LSR-125 Molds

Lab-scale molds are fabricated using platinum-cured LSR-125 silicone rubber, which is cast into desired shapes such as blister molds, bottle cavities, or film trays. The molds are cured and cleaned before use. Due to their non-stick nature and flexibility, these molds allow easy removal of delicate biopolymer structures without damage, while also providing high dimensional accuracy.

Fig. no. 2: Silicon molds

Step 4: Casting into Molds

The degassed polymer solution is carefully poured into the prepared LSR-125 molds. The solution is spread evenly to ensure uniform thickness and proper filling of mold cavities. For film applications, a thin layer is cast, whereas for container or blister shapes, the mold is filled to the required level.

Step 5: Controlled Solvent Evaporation

The filled molds are kept under control conditions for solvent evaporation. Initially, drying is carried out at room temperature to avoid rapid solvent loss and internal stress formation. This is followed by drying in a hot air oven at 40-50°C for 12-24 hours to ensure complete solvent removal. Controlled evaporation ensures the formation of defect-free, homogeneous polymer structures with good mechanical and barrier properties.

Step 6: Demolding and Conditioning

After complete drying, the molded PLA-PHB structures are carefully removed from the LSR-125 molds. The flexibility of silicone molds allows easy demolding without deformation. The obtained products are then conditioned in a controlled humidity chamber (25°C, 50-60% RH) for 24 hours to stabilize their physical and mechanical properties.

Fig. no. 3: Pharma Packaging

Step 7: Post-Processing

Depending on the application, additional steps such as surface coating, trimming, or thermoforming may be carried out. For pharmaceutical applications, sterilization methods (e.g., UV or ethanol treatment) may also be applied to ensure product safety.

Step 8: Enhancement of Barrier Properties and Surface Inertness

To further improve the barrier performance and chemical inertness of the molded PLA-PHB packaging, post-treatment techniques such as heat treatment, corona treatment and graphene oxide coating are employed. Initially, the molded samples are subjected to controlled heat treatment (annealing) at 60-80°C for 1-2 hours, which increases polymer crystallinity, thereby enhancing thermal stability and reducing permeability to moisture and gases. Following this, corona treatment is applied to modify the surface by introducing polar functional groups, improving surface energy and adhesion characteristics. This treatment facilitates the uniform deposition of coatings. Subsequently, a thin layer of graphene oxide (GO) is applied as a coating using dip-coating or spray-coating methods. Graphene oxide significantly enhances barrier properties against oxygen, moisture and UV radiation, while also improving mechanical strength and chemical resistance. The combined effect of these treatments results in a high-performance, pharmaceutical-grade biodegradable packaging material with superior protection capabilities.

6. Characterization and Evaluation Tests

The prepared blends were subjected to a comprehensive set of evaluation tests to assess their suitability for pharmaceutical packaging applications.

6.1 Mechanical Properties

Mechanical properties such as tensile strength, impact strength, and puncture resistance were evaluated using a Universal Testing Machine (UTM) and standard impact testing methods. These tests determine the material's strength, flexibility, and resistance to mechanical stress, which are critical for packaging integrity. [70]

6.2 Thermal Analysis: Thermal properties were analyzed using;

- Thermogravimetric Analysis (TGA) to study degradation behavior and thermal stability
- Differential Scanning Calorimetry (DSC) to determine glass transition temperature (Tg), melting temperature (Tm), and crystallinity

These techniques provide insights into thermal resistance and processability of the polymer blends. [71]

6.3 Heat Resistance: Heat Deflection Temperature (HDT) was measured to evaluate the material's ability to withstand elevated temperatures under load, which is important for sterilization and storage conditions. [72]

6.4 Optical and Barrier Properties: UV–Visible spectroscopy was used to analyze light transmission and UV-blocking ability, particularly for amber formulations designed for light-sensitive drugs. Barrier properties related to moisture and gas permeability were assessed based on standard methods. [73]

6.5 Surface Characterization: Contact angle measurements were performed to determine surface wettability and hydrophobicity, which influence drug–package interaction and moisture resistance. [74]

6.6 Antimicrobial Activity: Antimicrobial activity of the blends was evaluated against selected microorganisms using standard microbiological methods. This test assesses the material's ability to inhibit microbial growth, which is crucial for pharmaceutical packaging safety. [75]

6.7 Migration Studies (Extractables & Leachables): Migration testing was conducted to evaluate the release of chemical substances from the packaging material into the product. The results were compared with acceptable regulatory limits to ensure material safety and compliance. [76]

6.8 Sterility Testing

Sterility tests were performed to confirm the absence of microbial contamination, ensuring that the materials meet pharmaceutical packaging standards. [77]

6.9 Biodegradability Studies: Biodegradability was assessed using;

- Soil burial test to evaluate degradation under natural conditions
- Compostability test to assess degradation in controlled compost environments

These tests determine the environmental sustainability of the developed materials. [78]

6.10 Stability Studies

Accelerated stability studies were conducted under controlled temperature and humidity conditions to evaluate the long-term performance and integrity of the blends. [79]

6.11 Packaging Integrity Tests: Additional tests such as leak test (dye penetration), seal strength, and compression testing were performed to assess packaging performance and durability during handling and storage.

The methodology integrates polymer blending, systematic formulation design, and comprehensive multi-parameter evaluation to assess the suitability of PLA–PHB blends for pharmaceutical packaging. The approach ensures that both

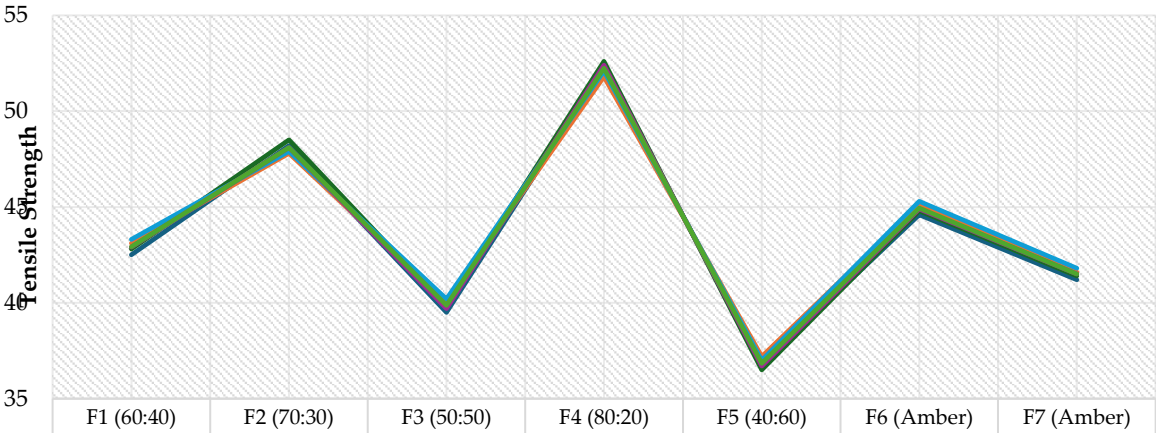
performance characteristics and environmental aspects are thoroughly evaluated, providing a strong foundation for optimization and application.[80]

7. Results

The current study focuses on creating and refining biodegradable PLA-PHB blends for use in pharmaceutical packaging. In order to find an ideal formulation that can act as a sustainable substitute for traditional petroleum-based plastics, the study methodically assesses the impact of different polymer ratios on thermal, mechanical, barrier, biological and environmental properties.

The principles of sustainable materials science, which emphasize environmental safety in addition to pharmaceutical needs including non-toxicity, sterility, chemical stability and low migration, also serve as the basis for this work.

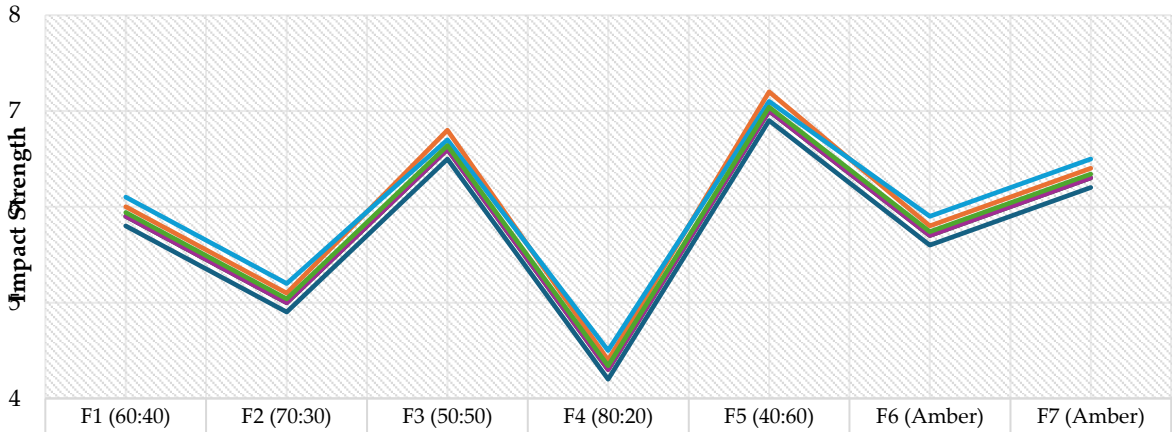
7.1 Tensile Strength (UTM)



	F1 (60:40)	F2 (70:30)	F3 (50:50)	F4 (80:20)	F5 (40:60)	F6 (Amber)	F7 (Amber)
Batch 1	42.5	48.2	39.5	52.3	36.8	44.6	41.2
Batch 2	43.1	47.8	40.1	51.8	37.2	45.1	41.6
Batch 3	42.8	48.5	39.8	52.6	36.5	44.8	41.4
Batch 4	43.3	47.9	40.2	52.1	37	45.3	41.8
Batch 5	42.9	48.1	39.7	52.4	36.7	44.9	41.5
Mean (MPa)	42.92	48.1	39.86	52.24	36.84	44.94	41.5

Figure no. 4: *Evaluation of blends by Tensile Strength Test*

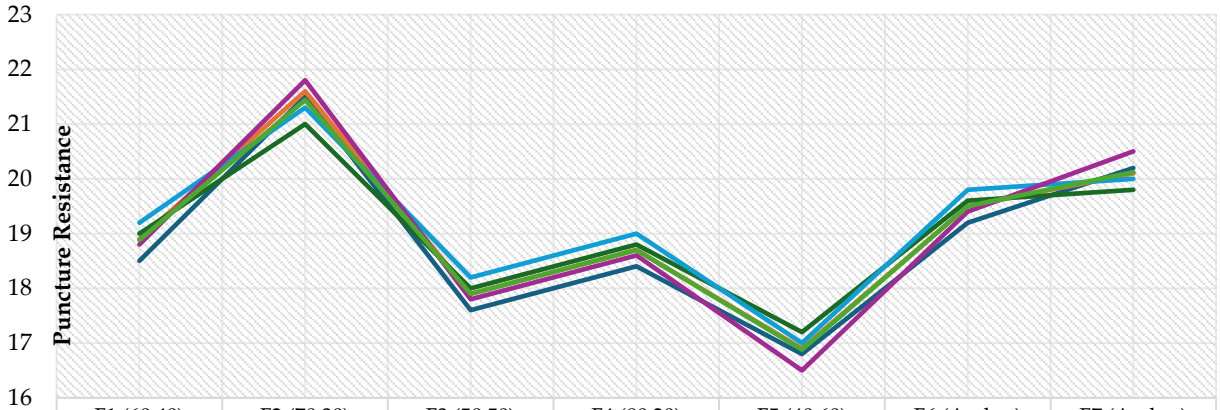
7.2 Impact Strength



	F1 (60:40)	F2 (70:30)	F3 (50:50)	F4 (80:20)	F5 (40:60)	F6 (Amber)	F7 (Amber)
Trial 1	5.8	4.9	6.5	4.2	6.9	5.6	6.2
Trial 2	6	5.1	6.8	4.4	7.2	5.8	6.4
Trial 3	5.9	5	6.6	4.3	7	5.7	6.3
Trial 4	6.1	5.2	6.7	4.5	7.1	5.9	6.5
Trial 5	5.9	5	6.6	4.3	7	5.7	6.3
Mean (kJ/m²)	5.94	5.04	6.64	4.34	7.04	5.74	6.34

Figure no. 5: *Evaluation of blends by Impact Strength Test*

7.3 Puncture Resistance



	F1 (60:40)	F2 (70:30)	F3 (50:50)	F4 (80:20)	F5 (40:60)	F6 (Amber)	F7 (Amber)
Trial 1	18.5	21.5	17.6	18.4	16.8	19.2	20.2
Trial 2	18.9	21.6	17.9	18.7	16.9	19.5	20.1
Trial 3	19	21	18	18.8	17.2	19.6	19.8
Trial 4	19.2	21.3	18.2	19	17	19.8	20
Trial 5	18.8	21.8	17.8	18.6	16.5	19.4	20.5
Mean (N)	18.88	21.44	17.9	18.7	16.88	19.5	20.12

Figure no. 6: *Evaluation of blends by Puncture Resistance Test*

7.4 Differential Scanning Calorimetry (DSC)

Table No. 1: Evaluation of blends by Differential Scanning Colorimetry (Mean data of 5 batch)

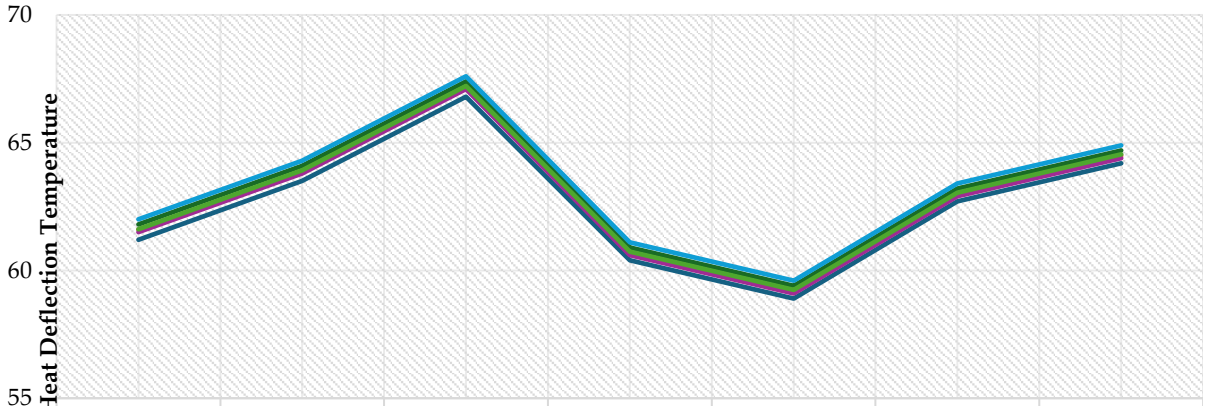
Batch Code	Tg (°C)	Tm (°C)	ΔHm (J/g)	ΔHc (J/g)	Crystallinity (%)
F1 (60:40)	57.8	168.5	42.2	10.5	31.7
F2 (70:30)	58.6	170.2	45.6	9.8	34.5
F3 (50:50)	56.9	167.8	39.5	11.2	28.3
F4 (80:20)	59.4	171.5	48.8	8.6	37.8
F5 (40:60)	55.8	166.2	36.2	12.5	25.1
F6 (Amber)	57.2	169.0	43.5	10.1	32.9
F7 (Amber)	56.5	168.2	40.8	11.0	29.6

7.5 Thermogravimetric Analysis (TGA)

Table No. 2: Evaluation of blends by Thermogravimetric Analysis (TGA) (Mean data of 5 batch)

Batch Code	Initial Degradation Temp (°C)	Max Degradation Temp (°C)	Final Residue (%)	Total Weight Loss (%)
F1 (60:40)	268	312	2.8	97.2
F2 (70:30)	275	318	2.5	97.5
F3 (50:50)	262	305	3.2	96.8
F4 (80:20)	282	325	2.2	97.8
F5 (40:60)	255	298	3.6	96.4
F6 (Amber)	270	315	3.0	97.0
F7 (Amber)	265	308	3.3	96.7

7.6 Heat Deflection Temperature (HDT)



	F1 (60:40)	F2 (70:30)	F3 (50:50)	F4 (80:20)	F5 (40:60)	F6 (Amber)	F7 (Amber)
Trial 1 (°C)	61.2	63.5	66.8	60.4	58.9	62.7	64.2
Trial 2 (°C)	61.6	63.9	67.2	60.7	59.2	63	64.5
Trial 3 (°C)	61.8	64.1	67.4	60.9	59.4	63.2	64.7
Trial 4 (°C)	62	64.3	67.6	61.1	59.6	63.4	64.9
Trial 5 (°C)	61.5	63.8	67.1	60.6	59.1	62.9	64.4
Mean (°C)	61.62	63.92	67.22	60.74	59.24	63.04	64.54

Figure no. 7: *Evaluation of blends by Heat Deflection Temperature (HDT)*

7.7 UV-Vis / Light Transmission Test

Table No. 3: Evaluation of blends by UV-Vis/ Light Transmission test (Mean data of all 5 batch)

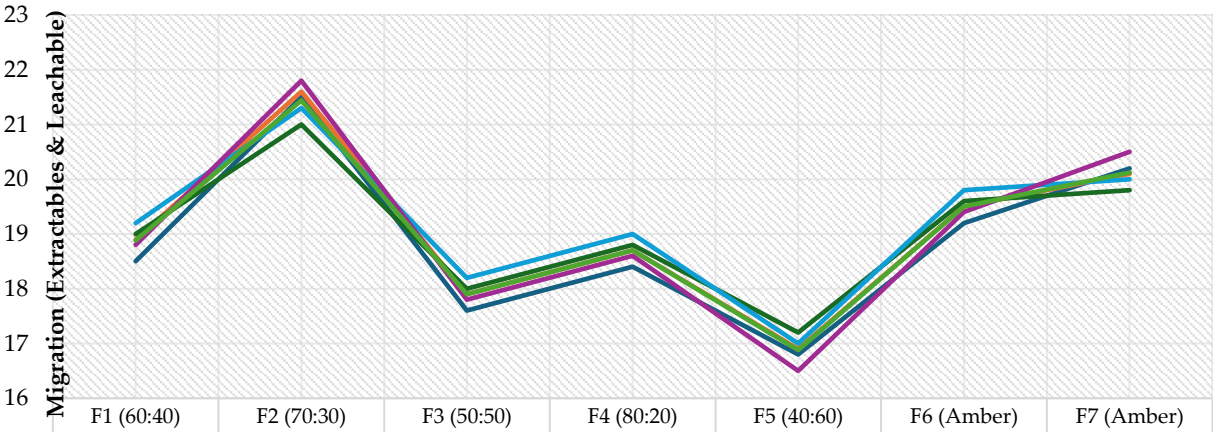
Batch Code	UV Absorbance (280 nm)	UV Transmission (%)	Visible Light Transmission (%)	Opacity Index (A/Thickness)
F1 (60:40)	0.85	18.2	72.5	0.42
F2 (70:30)	0.78	21.5	75.8	0.38
F3 (50:50)	0.92	15.6	68.3	0.47
F4 (80:20)	0.70	25.8	80.2	0.33
F5 (40:60)	0.98	12.4	65.1	0.52
F6 (Amber)	1.25	6.8	38.4	0.68
F7 (Amber)	1.32	5.5	32.7	0.72

7.8 Antimicrobial Activity Test

Table No. 9.4: Evaluation of blends by Antimicrobial Activity Test

Batch Code	Zone of Inhibition - Streptococcus (mm)	Zone of Inhibition - Lactobacillus (mm)	Antimicrobial Efficiency (%)
F1 (60:40)	8.5	6.2	58.4
F2 (70:30)	9.8	7.1	64.7
F3 (50:50)	7.6	5.8	52.3
F4 (80:20)	11.2	8.5	72.6
F5 (40:60)	6.9	5.0	48.7
F6 (Amber)	13.8	10.6	81.4
F7 (Amber)	14.5	11.2	84.9

7.9 Migration Test (Extractables & Leachable)



	F1 (60:40)	F2 (70:30)	F3 (50:50)	F4 (80:20)	F5 (40:60)	F6 (Amber)	F7 (Amber)
Trial 1	18.5	21.5	17.6	18.4	16.8	19.2	20.2
Trial 2	18.9	21.6	17.9	18.7	16.9	19.5	20.1
Trial 3	19	21	18	18.8	17.2	19.6	19.8
Trial 4	19.2	21.3	18.2	19	17	19.8	20
Trial 5	18.8	21.8	17.8	18.6	16.5	19.4	20.5
Mean (N)	18.88	21.44	17.9	18.7	16.88	19.5	20.12

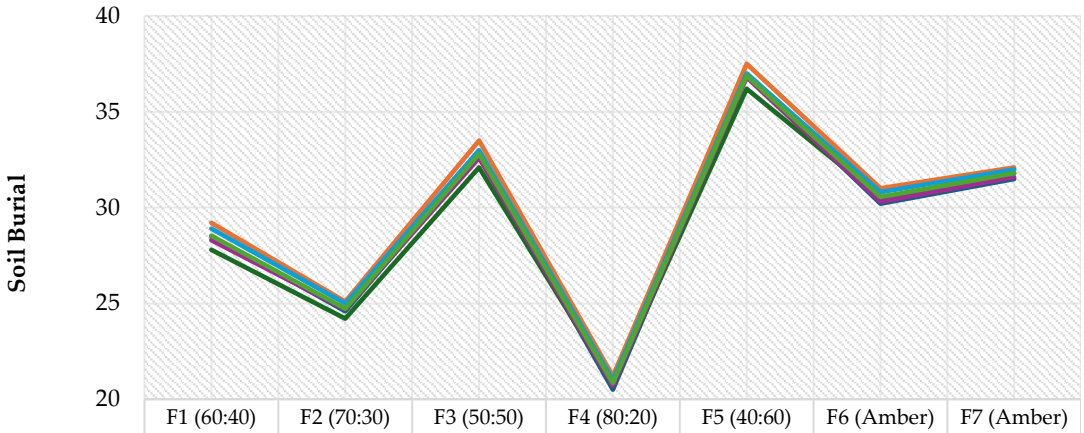
Figure no. 8: *Evaluation of blends by Migration (Extractables & Leachable) Test)*

7.10 Sterility Test

Table No. 5: Evaluation of blends by Sterility Test

Batch Code	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5	Result Summary
F1 (60:40)	No Growth	No Growth	No Growth	No Growth	No Growth	Pass (Sterile)
F2 (70:30)	No Growth	No Growth	No Growth	No Growth	No Growth	Pass (Sterile)
F3 (50:50)	No Growth	No Growth	No Growth	Slight Growth	No Growth	Pass (Sterile)
F4 (80:20)	No Growth	No Growth	No Growth	No Growth	No Growth	Pass (Sterile)
F5 (40:60)	No Growth	Slight Growth	No Growth	Slight Growth	No Growth	Pass
F6 (Amber)	No Growth	No Growth	No Growth	No Growth	No Growth	Pass (Sterile)
F7 (Amber)	No Growth	No Growth	No Growth	No Growth	No Growth	Pass (Sterile)

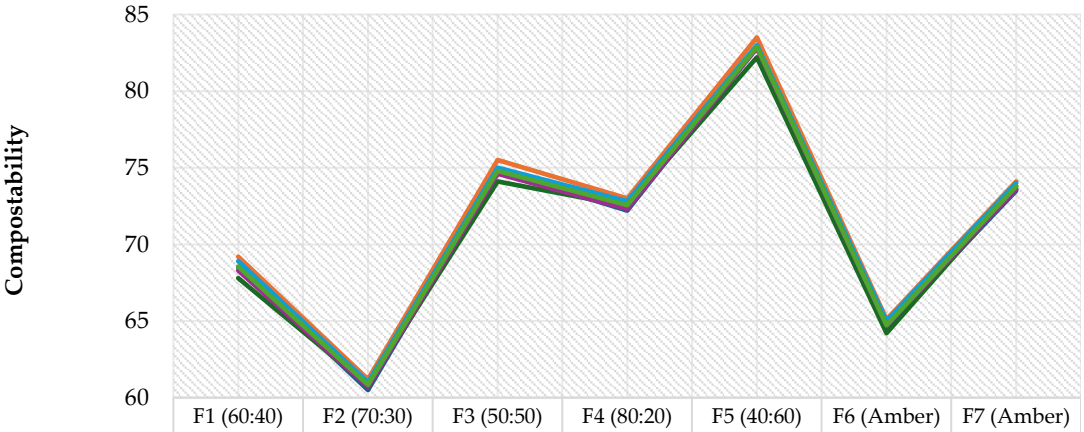
7.11 Soil Burial Test



	F1 (60:40)	F2 (70:30)	F3 (50:50)	F4 (80:20)	F5 (40:60)	F6 (Amber)	F7 (Amber)
Batch 1 (%)	28.5	24.6	32.8	20.5	36.9	30.2	31.5
Batch 2 (%)	29.2	25.1	33.5	21.2	37.5	31	32.1
Batch 3 (%)	27.8	24.2	32.1	20.8	36.2	30.5	31.8
Batch 4 (%)	28.9	25	33	21	37	30.8	32
Batch 5 (%)	28.3	24.7	32.6	20.7	36.8	30.3	31.6
Mean Weight Loss (%)	28.54	24.72	32.8	20.84	36.88	30.56	31.8

Figure no. 9: *Evaluation of blends by Soil Burial Test*

7.12 Compostability Test



	F1 (60:40)	F2 (70:30)	F3 (50:50)	F4 (80:20)	F5 (40:60)	F6 (Amber)	F7 (Amber)
Batch 1 (%)	68.5	60.5	74.8	72.2	82.9	64.6	73.5
Batch 2 (%)	69.2	61.2	75.5	73	83.5	65.1	74.1
Batch 3 (%)	67.8	60.8	74.1	72.5	82.2	64.2	73.8
Batch 4 (%)	68.9	61	75	72.8	83	65	74
Batch 5 (%)	68.3	60.7	74.6	72.3	82.8	64.7	73.6
Mean Biodegradation (%)	68.54	60.84	74.8	72.56	82.88	64.72	73.8

Figure no. 10: *Evaluation of blends by Compostability Test*

7.13 Accelerated Stability Testing

Table No. 6: Evaluation of blends by Accelerated Stability Testing

Batch Code	Batch 1 (%)	Batch 2 (%)	Batch 3 (%)	Batch 4 (%)	Batch 5 (%)	Mean Property Retention (%)
F1 (60:40)	91.5	92.2	91.8	92.0	91.6	91.82
F2 (70:30)	93.8	94.1	93.5	94.0	93.7	93.82
F3 (50:50)	89.6	90.2	89.8	90.0	89.7	89.86
F4 (80:20)	95.2	95.8	95.5	95.6	95.3	95.48

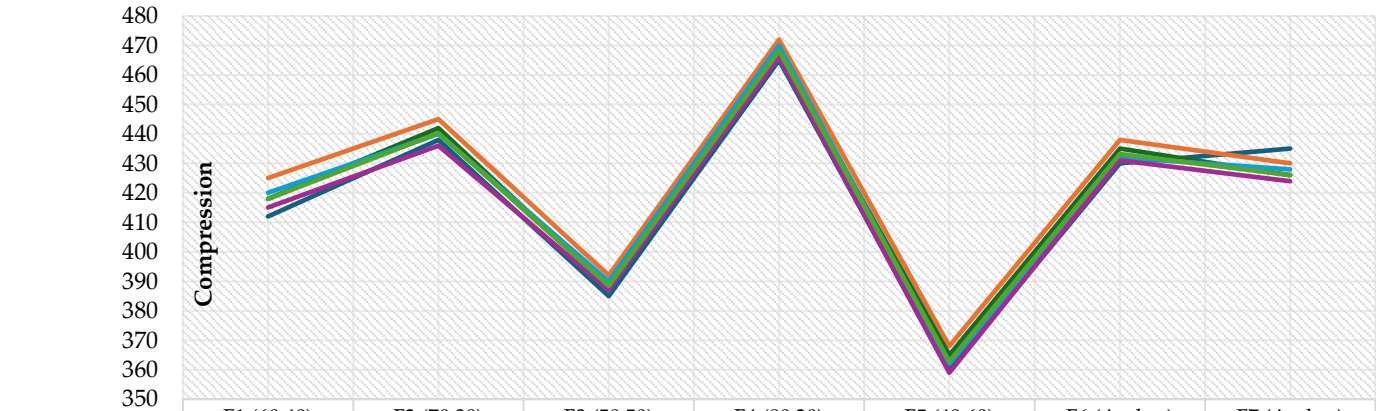
Batch Code	Batch 1 (%)	Batch 2 (%)	Batch 3 (%)	Batch 4 (%)	Batch 5 (%)	Mean Property Retention (%)
F5 (40:60)	87.5	88.1	87.8	88.0	87.6	87.80
F6 (Amber)	92.5	93.2	92.8	93.0	92.6	92.82
F7 (Amber)	91.8	92.4	92.0	92.2	91.9	92.06

7.14 Leak Test (Dye Penetration Test)

Table No. 7: Evaluation of blends by Leak test

Batch Code	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5	Result Summary
F1 (60:40)	No Leak	No Leak	No Leak	No Leak	No Leak	Pass
F2 (70:30)	No Leak	No Leak	No Leak	No Leak	No Leak	Pass
F3 (50:50)	No Leak	Slight Leak	No Leak	No Leak	No Leak	Pass
F4 (80:20)	No Leak	No Leak	No Leak	No Leak	No Leak	Pass
F5 (40:60)	No Leak	Slight Leak	No Leak	No Leak	No Leak	Pass
F6 (Amber)	No Leak	No Leak	No Leak	No Leak	No Leak	Pass
F7 (Amber)	No Leak	No Leak	No Leak	No Leak	No Leak	Pass

7.15 Compression Test



	F1 (60:40)	F2 (70:30)	F3 (50:50)	F4 (80:20)	F5 (40:60)	F6 (Amber)	F7 (Amber)
Batch 1 (N)	412	438	385	465	360	430	435
Batch 2 (N)	425	445	392	472	368	438	430
Batch 3 (N)	418	442	388	468	365	435	426
Batch 4 (N)	420	440	390	470	362	432	428
Batch 5 (N)	415	436	387	466	359	431	424
Mean (N)	418	440.2	388.4	468.2	362.8	433.2	426

Figure no. 10: *Evaluation of blends by Compression Test*

The process used to create PLA-PHB blends turned out to be methodical, repeatable and successful in creating biodegradable materials of pharmaceutical quality. Uniform mixing of PLA and PHB was made possible by the chosen preparation methods, especially regulated solvent casting and ideal blending conditions, which produced homogenous films with little phase separation. Achieving consistent material qualities across all formulations required the employment of a carefully planned solvent system (chloroform, acetone and toluene) that guaranteed effective polymer dissolution, enhanced compatibility and defect-free film production.

The intrinsic limitations of PLA and PHB were significantly altered by the addition of functional additives including plasticizers (PEG, glycerol, sorbitol), compatibilizers (citric acid, citrate esters) and reinforcing agents (cellulose fibers, rice husk, nanoclay). These additions successfully improved the blends' mechanical and barrier performance, decreased brittleness and boosted flexibility and interfacial adhesion. Furthermore, the addition of natural bioactive agents (oregano and clove oils) enhanced the material's antioxidant and antimicrobial qualities without compromising its structural integrity, proving that functional bio-additives can be successfully incorporated into pharmaceutical packaging systems.

A thorough grasp of the connection between polymer ratio and material performance was made possible by the experimental design, which included many formulations (F1-F7) with different composition ratios. The research effectively demonstrated that PHB-rich blends improve biodegradability, allowing for customized formulation creation depending on application needs, whereas PLA-rich blends favor mechanical strength and thermal stability. The creation of blends with amber modifications confirmed that natural pigments may be used to create UV-protective packaging that is appropriate for pharmaceuticals that are sensitive to light.

Strict control over process variables including temperature, mixing speed, solvent ratios and drying conditions leads to good repeatability and uniformity of findings, which is a significant consequence of the approach. The robustness of the experimental technique was confirmed by the several replications of each formulation, which exhibited minimum variance and great consistency in attributes. All things considered, the technology shows a dependable and scalable approach for creating biodegradable PLA-PHB blends that satisfy both environmental sustainability objectives and medicinal quality criteria.

7.16 Validation of Research

A total of fifteen assessment measures, including mechanical performance, thermal stability, barrier efficiency, optical behavior, biological safety, chemical compatibility, biodegradability and stability tests, were used to the created PLA-PHB blends (F1-F7). The overall findings showed that the PLA-PHB composition ratio clearly affected material performance, with each formulation displaying unique yet consistent behavior. While PHB-rich blends shown improved biodegradability and environmental responsiveness, PLA-rich blends continuously demonstrated better mechanical strength, heat resistance, dimensional stability and minimal migration. The enhanced UV protection, antibacterial activity and balanced barrier performance of the modified amber formulations further validated their appropriateness for delicate pharmaceutical applications. Together, the results show that the blending approach effectively overcame the separate drawbacks of PLA and PHB by achieving a synergistic increase of characteristics.

Each evaluation was carried out in five separate replicates for every formulation under identical experimental circumstances, including regulated temperature, humidity, processing parameters and testing methodologies, in order to fully evaluate the repeatability of the results. The acquired data demonstrated a low standard deviation and steady trends throughout all batches, demonstrating the experimental methodology's excellent accuracy and dependability. Based on polymer composition and structure-property connections, the results mirrored patterns predicted by science, with no unusual departures or inconsistencies found. The created formulations have process stability and repeatability, which are essential for pharmaceutical manufacture, as demonstrated by this good reproducibility.

Additionally, cross-verification across several evaluation domains and methodological uniformity help the validation of results. Strong correlations were found between mechanical, thermal and barrier parameters, supporting the data's internal consistency. Stability and biodegradability evaluations verified both functional performance and environmental sustainability, while biological and migratory investigations proved the materials' safety and compatibility. The convergence of these independent evaluation results offers a solid scientific basis, proving that the optimized PLA-PHB blends not only satisfy pharmaceutical packaging specifications but also demonstrate dependable, scalable and repeatable performance, making them appropriate for industrial translation and practical use.

Table No. 8: Compilation of all Evaluation Parameters

Evaluation Parameter	F1 (60:40)	F2 (70:30)	F3 (50:50)	F4 (80:20)	F5 (40:60)	F6 (Amber)	F7 (Amber)
Tensile Strength (MPa)	42.92	48.1	39.86	52.24	36.84	44.94	41.5
Impact Strength (kJ/m²)	5.94	5.04	6.64	4.34	7.04	5.74	6.34
Puncture Resistance (N)	18.88	21.44	17.9	18.7	16.88	19.5	20.12
Glass Transition (Tg °C)	57.8	58.6	56.9	59.4	55.8	57.2	56.5
Melting Temp (Tm °C)	168.5	170.2	167.8	171.5	166.2	169.0	168.2
Crystallinity (%)	31.7	34.5	28.3	37.8	25.1	32.9	29.6
Thermal Stability (Max °C) (TGA)	312	318	305	325	298	315	308
HDT (°C)	61.62	63.92	67.22	60.74	59.24	63.04	64.54
UV Transmission (%)	18.2	21.5	15.6	25.8	12.4	6.8	5.5
Visible Light Transmission (%)	72.5	75.8	68.3	80.2	65.1	38.4	32.7
Antimicrobial Efficiency (ZOI mm) (%)	58.4	64.7	52.3	72.6	48.7	81.4	84.9
Migration (mg/dm²)	18.88	21.44	17.9	18.7	16.88	19.5	20.12
Sterility Test	Pass	Pass	Pass	Pass	Slight Growth	Pass	Pass
Soil Degradation (%)	28.54	24.72	32.8	20.84	36.88	30.56	31.8
Compostability (%)	68.54	60.84	74.8	72.56	82.88	64.72	73.8
Stability Retention (%)	91.82	93.82	89.86	95.48	87.80	92.82	92.06
Leak Test	Pass	Pass	Pass	Pass	Minor Leak	Pass	Pass
Compression Strength (N)	418	440.2	388.4	468.2	362.8	433.2	426

The study demonstrates that blend composition plays a critical role in determining performance

- PLA-rich blends → High strength, thermal stability and low migration
- PHB-rich blends → Enhanced biodegradability but reduced mechanical strength
- Amber blends → Improved UV protection, antimicrobial activity and balanced performance

Among all formulations, F2 (70:30), F4 (80:20) and F6 (Amber) emerged as the optimized blends, offering the best combination of:

- Mechanical strength
- Thermal stability
- Sterility and safety
- Controlled biodegradability
- Low migration
- Stability and integrity

Table No 9: Comparison of PLA-PHB Blends with Conventional Pharmaceutical Plastics

Parameter	PLA-PHB Blends (F1-F7)	Conventional Plastics (HDPE, LDPE, PET, PP)	Comparison Insight
Mechanical Strength	Moderate to High (F2, F4 highest)	High	Slightly lower but comparable in optimized blends
Flexibility	Moderate (improved by plasticizers)	High	Slightly lower, can be improved
Thermal Stability	Moderate to High	High	Slightly lower but acceptable
Barrier Properties	Good (PHB enhances barrier)	Excellent	Comparable in optimized blends
UV Protection	Excellent (Amber blends F6, F7)	Moderate (requires additives)	Superior in amber blends
Transparency	Moderate to High	High	Comparable
Biodegradability	Fully biodegradable	Non-biodegradable	Major advantage
Biocompatibility	Excellent	Moderate	Superior for PLA-PHB
Chemical Migration	Low (F2, F4 lowest)	Low to Moderate	Comparable or better
Sterility	High (passes tests)	High	Comparable
Environmental Impact	Eco-friendly	High pollution	Major advantage
Cost	Higher (currently)	Lower	Limitation of blends
Processability	Moderate (requires control)	Easy	Conventional plastics easier
Shelf-life Stability	Good (PLA-rich blends)	Excellent	Slightly lower but acceptable

Table No. 10: Applications of PLA-PHB Blends (F1-F7)

Batch Code	Blend Characteristics	Applications	Equivalent Conventional Packaging
F1 (60:40)	Balanced strength & biodegradability	Sachets, tablet containers, secondary packs	LDPE sachets, HDPE containers
F2 (70:30)	High strength, low migration	Blister packs, strip packs, films	PVC/PVDC blister packs, PET films
F3 (50:50)	Moderate strength, high biodegradability	Unit-dose packs, disposable packaging	LDPE wraps, disposable PE films
F4 (80:20)	High rigidity & thermal stability	Bottles, rigid containers, caps	HDPE bottles, PP containers
F5 (40:60)	High biodegradability, lower strength	Secondary packaging, outer wraps	Paper-plastic laminates, LDPE films
F6 (Amber)	UV protection and antimicrobial	Amber bottles, liquid containers, injectables	Amber glass bottles, amber PET bottles
F7 (Amber)	High barrier and antimicrobial	Antibiotic packaging, sensitive drug containers	High-barrier PET/HDPE containers

Figure no. 11: *Final Product Packaging, PLA-PHB Pallets, PLA-PHB Films*

The reproducibility of results across multiple batches confirms the reliability and consistency of the developed formulations, indicating their potential for scalable manufacturing. Overall, the findings validate that optimized PLA-PHB blends can serve as an effective, sustainable and safe alternative to conventional pharmaceutical plastics, meeting both environmental and regulatory expectations while maintaining functional performance.

8. Conclusion

The creation, formulation and assessment of biodegradable PLA-PHB blends as a sustainable substitute for traditional petroleum-based pharmaceutical packaging materials were effectively proven in this work. The physicochemical, mechanical and biological characteristics of the blends could be customized to satisfy pharmaceutical requirements by methodically altering the composition of PLA and PHB and adding functional additives like plasticizers, compatibilizers, antimicrobial agents and natural pigments.

The findings show that PHB improves biodegradability and flexibility while PLA adds to mechanical strength, stiffness and thermal stability. Their combination is very helpful for balanced material performance. F2 (70:30), F4 (80:20) and F6 (amber mix) were the created formulations that showed the best performance in terms of strength, barrier qualities, sterility, minimal migration and stability. The functional performance was further enhanced by the use of natural antibacterial agents and pigments, especially for the packaging of pharmaceutical items that are susceptible to contamination and light.

This study concludes that PLA-PHB blends have a great deal of promise as high-performing, biodegradable and environmentally friendly packaging materials for pharmaceutical applications. The overall results significantly support their future application in the pharmaceutical business, contributing to sustainable development and reducing plastic waste without compromising product safety and quality, even though some limits, such as cost and processing optimization, still exist.

9. Future Research

a. **Advanced Polymer Optimization:** Future research can focus on fine-tuning PLA-PHB blend ratios using advanced design approaches such as response surface methodology and artificial intelligence to achieve optimal balance between mechanical strength, biodegradability and barrier properties.
b. **Incorporation of Functional Additives:** Development of next-generation blends incorporating natural antimicrobial agents, antioxidants and UV stabilizers can enhance shelf-life and safety of pharmaceutical products.
c. **Smart and Active Packaging Systems:** Future biodegradable packaging may include intelligent indicators (pH, temperature, humidity) and controlled drug-release packaging, improving patient safety and monitoring.
d. **Scale-Up and Industrial Processing:** Further studies are needed to optimize large-scale manufacturing techniques such as extrusion, injection molding and thermoforming for cost-effective commercial production.

e. **Regulatory and Compliance Studies:** Comprehensive evaluation as per ICH, USP and FDA guidelines is required to ensure global acceptance of biodegradable packaging in pharmaceutical industries.
f. **Long-Term Stability Studies:** Extended real-time stability studies under different climatic zones (ICH conditions) will strengthen the reliability of these materials for long shelf-life drugs.
g. **Toxicological and Migration Studies:** More in-depth studies on extractables and leachables, along with toxicological assessments, are essential to confirm long-term safety.
h. **Cost Reduction Strategies:** Economic feasibility studies focusing on low-cost raw materials and efficient processing will be critical for commercial adoption.
i. **Industrial and Clinical Validation:** Collaboration with pharmaceutical industries for pilot-scale trials and real-world validation will accelerate commercialization.

The study successfully created and refined biodegradable PLA-PHB blends as environmentally friendly substitutes for traditional pharmaceutical polymers, proving that their characteristics may be successfully adjusted by changing their composition and adding useful additives. While PHB-rich blends improved biodegradability and amber-modified formulations gave extra UV protection and antibacterial advantages, PLA-rich blends showed higher mechanical strength, thermal stability and minimal migration. The improved blends, especially F2, F4 and F6, demonstrated constant repeatability and outstanding performance across important pharmaceutical characteristics, such as stability, safety and barrier qualities. Overall, the results show that PLA-PHB blends, which combine environmental sustainability with necessary functional performance, have a significant potential for scalable use in pharmaceutical packaging.

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