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Case Report

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Polylactic Acid (PLA) for Pharma & Nutraceutical Products Packaging

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Abstract

Polylactic acid, known as PLA, is a thermoplastic monomer derived from renewable, organic sources such as corn starch or sugar cane. Using biomass resources makes PLA production different from most plastics, which are produced using fossil fuels through the distillation and polymerization of petroleum. Despite the raw material differences, PLA can be produced using the same equipment as petrochemical plastics, making PLA manufacturing processes relatively cost efficient.

The concept of "Pharma & Nutraceutical products packaging" describes systems and materials used to contain, protect and preserve. while they are being used, stored and transported. The focus is on the most important biodegradable polymer that have gained popularity in packaging in recent years due to their beneficial features, including their mechanical strength, light weight and flexibility for customization.

The Benefits of PLA

PLA have many advantages, particularly in the context of environmental sustainability and human health.

Renewable Source

Unlike conventional plastics derived from petroleum, PLA is made from renewable resources. This reduces the dependency on finite fossil fuels and lowers the overall carbon footprint.

Biodegradability

One of the most compelling features of PLA is its ability to biodegrade under specific conditions. This end-of-life attribute makes it an ideal candidate for single-use applications, reducing the burden on landfills and minimizing pollution.

Biocompatibility

PLA is generally recognized as safe by regulatory agencies, making it suitable for medical applications such as sutures, implants, and drug delivery systems. Its biocompatibility means it can comfortably coexist within the human body without eliciting adverse reactions.

Regulatory approvals of PLA for Pharma & Nutraceutical products

a) USFDA
b) EMA

Properties of PLA for Pharma Packaging

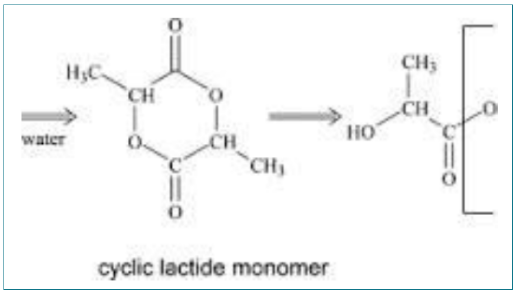
PLA possesses several properties that make it suitable for pharmaceutical packaging applications. Firstly, its biodegradability ensures minimal environmental impact compared to conventional plastics. This characteristic aligns with the growing demand for sustainable practices within the pharmaceutical industry. Additionally, PLA exhibits excellent barrier properties, protecting pharmaceutical products from moisture, oxygen, and other external factors that may compromise their efficacy. Moreover, PLA can be tailored to meet specific requirements, such as transparency for visibility of the packaged product or rigidity to ensure structural integrity.

Advantages of PLA in Pharma Packaging

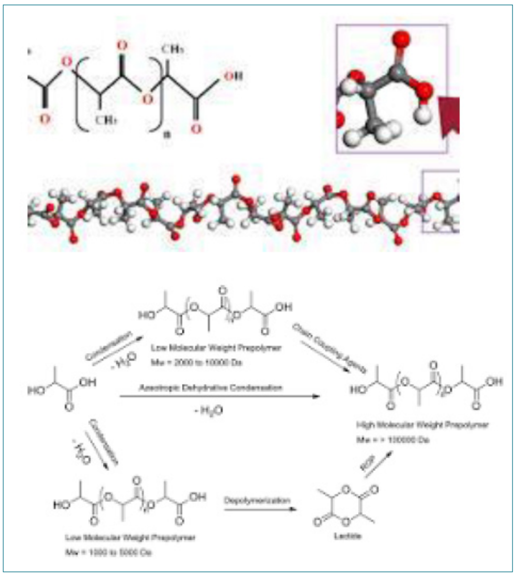
The adoption of PLA in pharmaceutical packaging offers numerous advantages. One significant benefit is its biocompatibility, which ensures that the packaging material does not leach harmful substances into the drugs it contains. This is particularly crucial for sensitive pharmaceutical formulations where contamination risks must be minimized. PLA's versatility allows for the creation of various packaging formats, including bottles, blister packs, and films, catering to diverse pharmaceutical products. Additionally, PLA's compatibility with recycling processes contributes to the circular economy by reducing waste and promoting resource efficiency.

Challenges

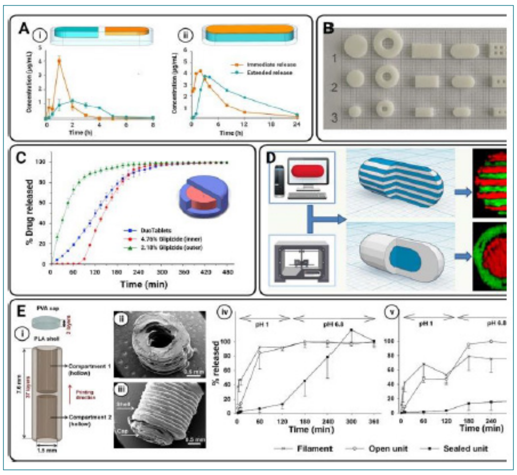
Despite its many benefits, the widespread adoption of PLA in pharmaceutical packaging faces certain challenges and considerations. One such challenge is the cost competitiveness of PLA compared to traditional plastics. While PLA production costs have been decreasing with advancements in technology, it still remains relatively more expensive. Moreover, concerns regarding PLA's mechanical properties, such as brittleness and heat resistance, may limit its applicability in certain packaging formats or environmental conditions. Additionally, ensuring the purity and consistency of PLA resin for pharmaceutical use requires rigorous quality control measures throughout the manufacturing process.



PLA Structures

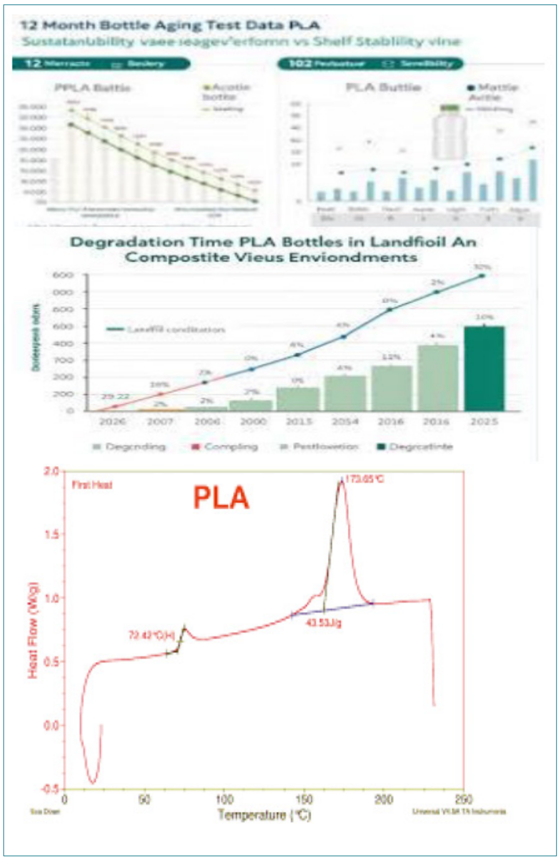


PLA Primary Packaging images



Smart Pills and Drug Delivery Devices by PLA

Leachable Graphs for PLA Bottle



PLA Injection Moulding Conditions

Conditions	Values
Adapter temperature	185 - 200 °C
Dew point	(-)40 - (-)35 °C
Die temperature	185 - 200 °C
Drying temperature	45 - 100 °C
Feed temperature	165 - 185 °C
Melt temperature	154.4 - 243.3 °C
Mold temperature	10 - 105 °C
Nozzle temperature	171.1 - 220 °C
Back pressure	0.345 - 1.724 MPa
Injection pressure	55.16 - 137.9 MPa
Moisture content	0.01 - 0.025%
Screw speed	20 - 200 rpm
Drying air flow rate	14.16 l/pm

Neat PLA and its oligomers are widely recognized as non-toxic substances. Lactic acid, the monomer building block of PLA, is classified as Generally Recognized as Safe by the US Food and Drug Administration and EU.

Many PLA grades comply with long-standing global legislation for food contact requirements in the US and EU.
Additionally, specific grades of PLA have been approved and used for decades in medical applications such as sutures, tissue scaffolds, and drug administration substrates. After use in the body, these PLA polymers are absorbed and degraded by the human body.

Beyond the chemistry, the physical impact on the environment and its organisms caused by the presence of a plastic article made from or with PLA is the same as of other plastics with a similar form or shape, be it as an intact object or as micro- and nanoparticles.

PLA Bottle is Sustainable Alternative of PET(For Solid and Liquid Orals)

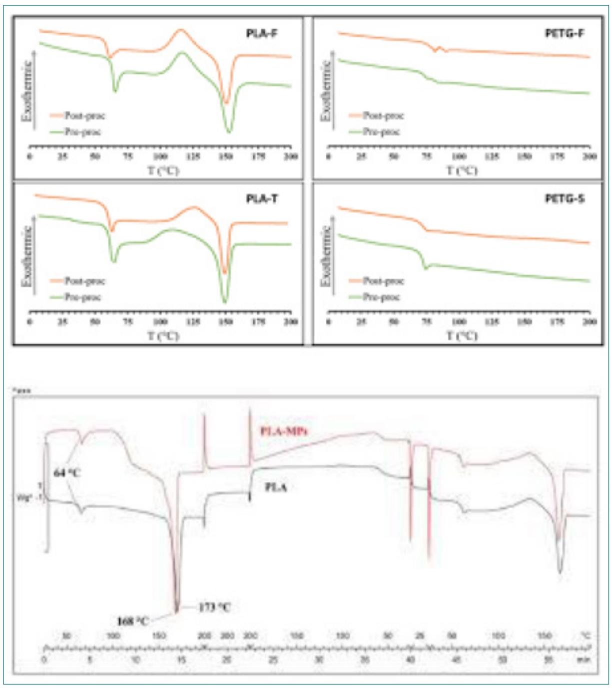
Polyethylene terephthalate (PET) is a widely used material in container manufacturing, particularly in bottle production. It is characterized by its low cost and widespread availability. However, its improper disposal has significantly exacerbated global plastic pollution. For instance, less than 50% of plastic bottles are recycled. Moreover, studies indicate that this issue has led to a significant accumulation of plastic waste in the oceans, which continues to grow annually and could be considered floating islands of debris. This study proposes replacing PET with polylactic acid (PLA), a biodegradable and biocompatible polymer with suitable properties for bottle production. PLA also has a shorter decomposition time compared to PET, contributing to the reduction of carbon footprint and greenhouse gas emissions. The research methodology included a diagnostic phase to define objectives, identify constraints, and determine variables based on an extensive literature review. The design phase focused on modeling a PLA-based bottle with detailed specifications and innovative structural features.

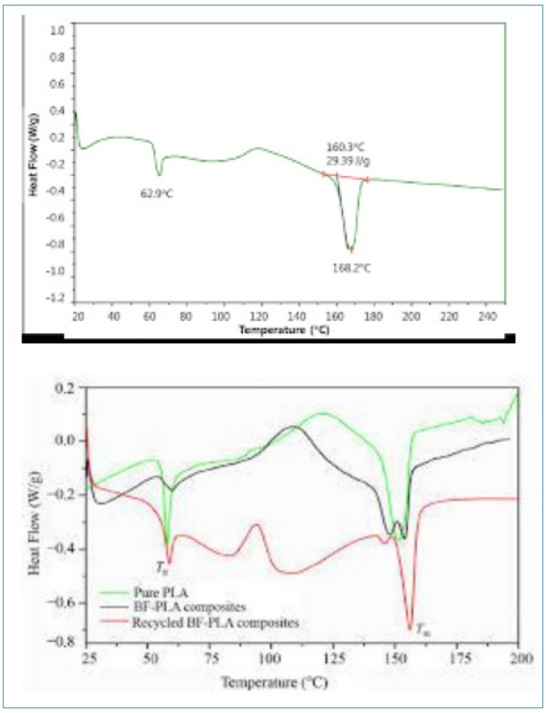
Additionally, experimental evaluations of biodegradability, compressive strength, and tensile strength were conducted to compare PET and PLA. The study incorporated technical standards and engineering protocols to evaluate critical properties such as material permeability and stress behavior. As a result, it was confirmed that PLA exhibits properties that make it a competitive material compared to PET. In conclusion, this research presents a technically viable alternative to PET bottles through the use of PLA, with the potential to significantly mitigate environmental impacts while maintaining the functional requirements of packaging.

PLA Toxicity Studies

However, in contrast to non-biodegradable plastic, which will persist and permanently accumulate as micro- and nanoplastics in the environment, PLA in the environment will hydrolyze into molecules of ever smaller size, becoming soluble and eventually fully biodegraded (mineralized). PLA's non-persistency will allow the environment to recover with time, and its potential impacts can be seen as temporary [1-5].

PET & PLA Identification Graphs by DSC





Recent Publications (minimum 5)

1. Delamination of Glass and Probable Solution – Drug Packaging
2. Importance of Extractable and Leachable study for Primary Packaging Materials.
3. Criticality of Rubber stopper for Biologics and Biosimilar products.
4. Role of Borosilicate Glass for "oncology products(cancer)
5. Role of packaging for NDDS (Neval drug delivery system) and NCE(New chemical entity)products.