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Review Article

QUALITY ASSURANCE FOR BIOPLASTIC IN PHARMACEUTICAL AND COSMETIC: A REVIEW

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ABSTRACT

Growing environmental concerns about sustainable packaging have led to a significant demand for biopolymer packaging worldwide. Biopolymer is the term used to describe naturally occurring polymers used in the manufacture of plastics, which are mostly sourced from renewable resources such as plants and animals. According to statistics from global market forecasts, the biopolymer packaging sector is anticipated to expand by about 22.68% between 2014 and 2019. Like everywhere else, packaging is where biopolymers are most frequently used. Additionally, it is projected that throughout the forecast period, the market will continue to grow due to continuing research and advancements in the field of biopolymers. Because of its advanced time-demanding properties, biopolymer packaging has recently seen a boom in the food, cosmetics, and pharmaceutical industries.

Keywords: Bioplastics, Biopolymers, Biodegradability, Sustainable packaging materials, Thermal analysis.

INTRODUCTION

Bioplastics are currently of great interest to many scientists and engineers throughout the world due to their low melting point in comparison to plastic petroleum, their fragility and water exposure, and their poor relationship. However, the cost of manufacture is higher for bioplastics than for conventional plastics, which hinders their development. In addition to being two to three times more expensive than traditional plastics, its production is beset by high expenses and poor yields. Basic raw materials include vegetable lipids, wood fibers, starch or lignin polymers, and other materials made from tapioca, sugarcane, maize, potatoes, cassava roots, soy, sugar beets, and any other plentiful and affordable bio-source. However, petroleum plastics are made from natural resources including cellulose, coal, natural gas, salt, and crude oil through the processes of polymerization or polycondensation. The bioplastics break down into simple components and compounds (carbon dioxide, water, carbon, etc.) considerably more quickly than the other plastics (typically less than 100 days to a year under optimal circumstances). mixing with the environment (soil, water, and air) as opposed to traditional plastics which, depending on their source and manufacturing method, take 100-1000 years to produce. Compared to traditional plastics, bioplastics often dissolve more quickly in natural or synthetic organic solvents, melt in water at a considerably lower temperature, and are far less safe. Furthermore, these bioplastics are less environmentally friendly and break down more slowly. Therefore, bioplastics might not be entirely made of vegetable material. They can occasionally be as low as 20%. Conventional materials could be used for the remainder.

BIOPLASTIC CLASSIFICATIONS

The four types of bioplastics that are currently on the market are based on the components employed in their production and the length of their end.

Bioplastic that broken down naturally

The biological activity of microorganisms like bacteria, fungi, and algae will cause them to decompose into carbon and water in a matter of weeks if the right conditions are met. Micro-organisms secrete enzymes that break the

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chemical bonds of polymers, which is the first step in decomposition. The greatest biodegradable Products can undergo full biodegradation in 90-100 days under the right circumstances.

Bioplastic that are not biodegredable

These are difficult for microbes to break down. Despite being derived from natural fiber-rich sources like sugarcane, they share molecular similarities with certain polymers derived from petroleum. Bioplastics are occasionally combined with petroleum-based materials to create robust, long-lasting, and corrosion-resistant products. Similar to traditional plastics, they will only break down slowly, which may take years, and they will leave behind both non-toxic and some hazardous remnants. Poly sheets, poly fibers, and other materials are made from these long-lasting plastics.

Compostible plastic

When bacteria are exposed to oxygen in the environment, these bioplastics break down entirely in about 90 days into natural components including water, carbon dioxide, and biomass. To completely breakdown, the majority of these polymers require industrial equipment. Over time, compostable waste will transform into nutrients that plants may consume, humus, or compost. They don't produce any residues. These plastics do not decompose quickly in a homestead compost pit.

CHEMICAL COMPONENTS OF BIOPLASTIC

Based on their chemical makeup, bio-based polymers can be divided into two main categories:

Polylactic Acids (PLA)

Ingredients such as maize starch, sugarcane, or arum (also known as taro) are fermented to make it. Right now, this is the most affordable bioplastic source available. PLA bioplastics have widespread applications in the production of cups, lids, cutlery, straws, tea bags, food packaging, apparel, cosmetics, and home furnishings.

Polyhydoxyalkaneoates (PHA)

PHA is more temperature-tolerant than PLA. Medical devices, agricultural items, and food packaging are all using these more and more. Because PHA is made by bacteria, it is a far more environmentally friendly polymer that breaks down in soil and streams and can withstand high temperatures. Today, the most widely used transparent bioplastic is PLA (polylactic acid).

Material analysis of degradation and quality assurance in bioplastic

What are bioplastics, and how can producers successfully integrate them into products using mechanical, rheological, and thermal analysis? There are two types of materials that can be referred to by the terms "bioplastics" or "bio-polymers": The raw ingredients used to make bio-based polymers are renewable and include corn and sugarcane. By using microbial or enzymatic decomposition processes, biodegradable plastics can be fully broken down into environmentally safe natural byproducts such water, biomass, inorganic salts, and gases (CO2, N2). Certain fossil fuel-based polymers, like polybutylene adipate terephthalate (PBAT) and polycaprolactone (PCL), can also undergo biodegradation. But bio-based plastics might present the same sustainable disposal issues as traditional plastics made from fossil fuels. Analyzing life cycle sustainability and reducing the amount of fuel and water used in the production of bio-based products provide additional challenges. Researchers developing innovative bio-plastics must strike a compromise between these sustainability requirements and preserving high-quality, efficient production.

Bioplastic quality control and testing

Plastics are now an essential component of human existence. With heat and pressure, these high molecular weight polymers can be shaped into films, trays, bottles, and jars, among other shapes. Their superior physical and barrier qualities, flexibility, toughness, and ease of manufacture have made them rival metals in terms of both application severity and scope of use (Fang and Fowler 2003; OrhaBioplastics quality control and testing.

METHODS FOR TESTING

Some of the main justifications for testing are as follows: To confirm design concept, to lay the ground work for reliability, Safety, Protection from allegations of product liability, Quality Control, to follow rules and specification, to verify the production process, to evaluate competitors' products.

Testing of physical properties

Bioplastics bulk, density, and dimensions are crucial physical characteristics. The fact that density can be computed using mass and dimension data makes the relationship between mass, density, and dimensions evident. The dimensional correctness of the components is one of the most basic quality control methods, and controlling the quantity of ingredients and other elements necessitates careful mass consideration. Another helpful control measure to keep an eye on material variation is density (Brown 2002).

Thickness

The distance between a material's two exterior surfaces measured perpendicularly is its thickness. A micrometer is used to measure the thickness of films (Rhim *et al*. 2007). The thickness of the sample is usually measured at different places, and the mean is calculated. A microscope can also be used to measure the thickness (microtome cut). Additionally, using a scanning electron microscope for extremely thin coatings (less than 1 μm). The average thickness of the polylactic acid (PLA) and soy protein isolate (SPI) control films was 89.5 µm and 78.8 µm, respectively (Rhim *et al*., 2007).

Density

Elevated density values signify elevated transportation expenses (for example, lightweight car components reduce energy usage) and might be crucial design factors. Additionally,a lighter material makes implementation considerably simpler and less dangerous. It is common practice to utilize density to calculate "specific properties" (i.e., to divide mechanical qualities by the appropriate density).

Mass

Mass creates a force during test processes. The test piece or object in question is weighed to ascertain its mass using the appropriate balance or scales. The required precision and magnitude, which vary, must be taken into consideration while selecting a weighing equipment. The required precision is sometimes stated as "accurate to 1 mg," while balance measurements up to 1 mg may be cited.

Testing of mechanical properties

Since almost all service conditions and most end-use applications involve some level of mechanical loading, mechanical properties are often the most important of all the properties of plastic materials (Shah 2007).

Tensile tests

Tensile test studies are performed to ascertain a bioplastic material's elastic modulus (GPa), tensile strength (MPa), and the percentages of elongation at yield (%) and break (%). According to ASTM D882, Standard Test Method for Tensile Properties of Thin Plastic Sheeting, these values are crucial for obtaining mechanical information for bioplastic materials that will be compared with commercial nonbiodegradable materials (Siracusa *et al*. 2008). In its broadest definition, a tensile test measures a material's resistance to forces that would otherwise tear it apart and how much it can stretch before breaking.

Tests of impact

Following the instructions in ASTM D1709, Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method (Siracusa *et al*. 2008), the impact properties test is a technique used to ascertain the energy that causes bioplastic to fail under particular impact conditions.

Compression test

An Analysis of Compression According to the Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads (ASTM D642), thermoformed samples are frequently used for compression tests. Siracusa *et al*. (2008) state that the compression strength is influenced by the material and design (size and form).

Puncture tests

In order to assess deformation and puncture force, this sample underwent a puncture test using a TAXT2iStable MicroSystem texture analyzer. A 3-mm cylindrical probe that moved at 1 mm/s was used to perform the puncture test in triplicate after circular sample films were fixed in a 40 mm diameter cell (Gontard *et al*. 1993).

Hardness test

A substance's hardness refers to how resistant it is to deformation, particularly permanent deformation, indentation, or scratching. The resistance to abrasion and wear. Polystyrene, for example, has a high Rockwell hardness rating but a low abrasion resistance. Hardness has been evaluated using a variety of tests. Since plastic materials differ greatly in terms of hardness, a single type of hardness test cannot fully capture the range of hardness properties encountered (Shah). The Rockwell and Durometer hardness tests are two of the most widely used tests for plastics. Acetals, nylons, acrylics, and polystyrene are examples of relatively hard polymers that are subjected to the Rockwell test. A Durometer hardness test is used for softer materials including polyethylene, thermoplastic rubbers, and flexible PVC.

Rockwell hardness

As the load on an indenter is varied from a specified minor load to a major load and back to a minor load, the Rockwell hardness test measures the net increase in depth impression (ASTM D785, Standard Test Method for Rockwell Hardness of Plastics and Electrical Insulating Materials). The determined hardness values are only numeric values without any units. Every time Rockwell hardness numbers are quoted, a scale symbol identifying the indenter size, load, and dial scale used is supplied.

Durometer hardness

The Durometer test (ASTM D2240, Standard Test Method for Rubber Property-Durometer Hardness: ISO 868) is used to measure the relative hardness of soft materials. The penetration of the indentor into the material under specific conditions forms the basis of the test procedure.

Barcol hardness

The Barcol hardness test can be used to determine the hardness of both reinforced and nonreinforced rigid plastics. The tester is a portable instrument used to gauge the hardness of manufactured components and test specimens. In Barcol hardness testing, an indicator in the shape of a 100-division dial and an indentor with a sharp, conical point are utilized.

Refractive index

The ratio of the speed of light in a clear medium to that of light in a vacuum (or air) is known as the refractive index, or index of refraction. The index of refraction is calculated by dividing the sin of the angle of incidence by the sin of the angle of refraction

Light transmittance and haze

Luminous transmittance, which is typically represented as a percentage of light transmitted, is the ratio of transmitted light to incident light (ASTM D1003, Standard Test Method for Haze and Lumi-nous Transmittance of Transparent Plastics). When light is dispersed from the specimen's surface or from inside it, it can give the illusion of haze to an otherwise transparent object. Haze is defined as the percentage of transmitted light that deviates from the incident beam by forward scattering as it passes through a specimen.

Color

Because they are reasonably easy to color and may be used to add color across the entire structure, plastics are one of the most successful materials of this century. A colorimeter is the name of the device created for color measuring. Red, green, and blue are the three primary colors that are used by a tristimulus colorimeter to measure color.

Instrumented color measurement

Measurement of Color Using Instruments A spectrophotometer is usually required for color formulation and other color development work, while a filter colorimeter or spectrophotometric colorimeter is used when the user is looking only for tristimulus values, chromaticity coordinates, and color difference information. These are the two basic types of instruments used for color measurements, depending on the needs. The main applications of colorimeters are in specifications, production control, quality control, and necessary color matching.

Specular gloss

ASTM D2457, Standard Test Method for Specular Gloss of Plastic Films and Solid Plastics, ASTM D523, Standard Test Method for Specular Gloss, defines specular gloss as the relative luminous reflectance factor of a specimen at the specular direction. A projection or source lens, a condenser lens, and an incandescent light source comprise the glossmeter's basic source-optical system. The specimen is the target of the incident beam created by this configuration. An analog or digital panel meter that displays the value in gloss units is powered by an electrical signal that is amplified after a sensitive photodetector detects the reflected light.

Testing of permeability

Packages manufactured of thermoplastic polymers are permeable to small molecules including gasses, water vapor, organic vapors, and other low molecular weight chemicals to varied degrees, unlike those made of glass or metal. Low permeability is a characteristic of an excellent barrier plastic polymer.

Test for water vapor permeability in bioplastics

The Water Vapor Permeability (WVP) test for bioplastics measures the rate at which water vapor passes through a substance. An overview of the test procedure for bioplastics is provided below: 1. Configuration of the test setting up the specimen: The bioplastic sample should be prepared in a standardized manner, usually as thin films with consistent thickness. Test Chamber: Typically, a permeation chamber is used for the test. While one side of the sample is exposed to a controlled humidified environment, often with a greater humidity, the other side is exposed to a desiccant (dry environment) or a lower humidity.

Bioplastic oxygen permeability

The oxygen permeability of a bioplastic can be influenced by its type, composition, and ambient conditions (such as humidity and temperature). Here are some typical bioplastics and how permeable they are to oxygen: PLA: One of the most widely used bioplastics, PLA typically has a moderate oxygen permeability.

Metrics of rheology

Viscosity is the measurement of the flow resistance caused by internal friction when one fluid layer is compelled to move relative to another layer, and rheology is the study of circulation. Shear force is the force needed to produce this movement. Thus, greater force is needed to move highly viscous fluids than less viscous materials. A fluid is said to be Newtonian if the ratio of shearing stress to shear rate stays constant, as it does in water. The stress that develops in the polymer melt when the layers in a cross-section glide past one another is known as shear stress.

Visocity testing

There are two unique features of viscosity: It is best to determine dynamic or absolute viscosity in a rotational viscometer with a modest gap clearance, regardless of the liquid sample's density or specific gravity. It is measured in centipoises (CP) and poises (P). Kinematic viscosity, which is very reliant on the density or specific gravity of the liquid and is measured in stokes (S) and centistokes (CS), is usually measured using a capillary bore or small hole that drains by gravity.

Melt index test

The Melt Index (MI) test, also known as the Melt Flow Index (MFI), is widely used to assess a polymer's flow characteristics when melted. A polymer's molecular weight, viscosity, and processability are all indicated by the pace at which it melts and flows under particular circumstances. hence it comes to bioplastics, this test is equally important for figuring out how the material would act during processing like injection molding or extrusion. Crucial elements of the Bioplastics Melt Index examination: Test requirements: The temperature: Typically, the test is carried out at a set temperature, such as 190°C for polyethylene (PE) and 230°C for polypropylene (PP). Bioplastics' significance: Processability The bioplastic is better suited for high-speed processing when it has a higher melt index because it is less viscous and flows more readily

Environmental stress cracking

Information about the effects of specific substances, such as oils, soaps, wetting agents, or detergents, on polymers is provided by this test. After subjecting the specimens to these conditions for a specified period of time, the cracks are observed.

Environmental stress cracking resistance

Resistance to Cracking Under Environmental Stress (ASTM D1693, Standard Test Method for Environmental Stress-Cracking of Ethylene Plastics, ISO 4599) Environmental stress cracking is the failure of a polyethylene specimen or part under polyaxial stress in contact with a medium without which fracture does not occur under the same stress conditions. It is a surface-initiated brittle fracture. Combinations of internal and/or external stressors may be present, and sensitizing mediums can be gaseous, liquid, semisolid, or solid. For environmental stress cracking to occur, certain conditions must be met. First and foremost, the presence of a "notch" or "stress riser" is essential. Stress of some form is inevitable, whether it is "molded-in" or external. Finally, without the pre-setice of an external sensitizing agent, environmental stress cracking cannot occur. Polyethylene goods are prone to premature fracture when exposed to water, sunlight, oil, detergents, and other dynamic conditions. Environmental stress cracking is the term for these phenomena, which usually happens in situations with comparatively significant strain.

ANALYTICAL TESTS

Solubility Assessment

The precise kinds of material present can be identified by observing how different organic solvents interact with bioplastic polymers. To distinguish between different forms of the same base polymer, it is especially helpful to perform a solubility assessment. For example, cellulose acetate and cellulose acetate butyrate can be distinguished from one another because the former is fully soluble in furfuryl alcohol, whereas the latter is only partially soluble. A tiny portion of the sample should be put in a test tube, followed by the addition of the solvent and careful stirring to carry out the solubility assessment

Biodegradability testing

Choosing a testing method that is appropriate for the plastic's properties and the research area's environmental conditions is crucial when evaluating biodegradation.

Soil Burial Method

One often used approach for determining the biodegradability of plastics is the soil burial method (Eya 2002, Yang *et al*. 2005). This method entails carrying out a biodegradation test in either a controlled laboratory setting or in a natural setting. Following the allotted time, the sample is taken out of the soil, properly cleaned with distilled water, submerged in distilled water, and then dried for 24 hours at 50°C in a vacuum oven. After that, the sample is given at least 24 hours before the measurement to acclimate to ambient temperature and humidity. In one investigation, starch-based plastic films buried in forest soil exhibited rapid colonization by fungal hyphae within 15 days, along with noticeable degradation of the starch granules present on the films (Lopez-Llorca and Valiente 1993; Singh and Sharma 2008).

Pure Culture Method

Certain bacteria and fungi are used in the pure culture approach to aid in the breakdown of polymers. Disinfected films are first weighed before being aseptically added to a culture medium that has been sterilized. To maintain aseptic conditions, these films are shaken for 24 hours before injection. After that, spores from a specific microorganism are added to the culture medium, and it is shaken at 125 rpm for four weeks at the temperature that is ideal for that microorganism's growth. For every kind of pretreatment film, four duplicates are made. Following the incubation period, the samples are weighed after being cleaned with 70% ethanol and dried at 45°C until they reach equilibrium

Compost Method

This method involves combining a certain weight of dry plastic with a predetermined amount of mature compost, then incubating the mixture at 58 degrees Celsius while maintaining a moisture level of 65%. The amount of carbon transformed into gaseous carbon dioxide is used to measure the biodegradation process (Corti *et al*. 1992The biodegradation of plastics in compost that has been held at -20 degrees Celsius, 4 degrees Celsius, and 20 degrees Celsius for varying lengths of time has shown unexpected patterns)

METHODS FOR THERMAL ANALYSIS

The phrase "thermal analysis" (TA) describes a class of analytical techniques in which the temperature of a sample is controlled and a property is monitored over time or temperature to identify processing problems and assess a material's suitability for use, thermal analyzers are employed. DSC, or differential scanning calorimetry, TGA, or thermogravimetric analysis, TMA, or thermomechanical analysis Combining all three methods to characterize a polymer will maximize the benefits of thermal analysis. Dynamic Mechanical Thermal Analysis

Differential Scanning Calorimetry (DSC)

This technique tracks the heat exchange that takes place as a sample pass through a controlled temperature program in order to assess the thermal properties of materials. When used to bioplastics, DSC provides important information on the material's thermal transitions, such as its specific heat capacity, glass transition temperature (Tg), melting temperature (Tm), and crystallization temperature (Tc).

DSC applications for bioplastics

When it comes to bioplastics, DSC is very advantageous in a number of ways.

Melting Temperature (Tm)

For semi-crystalline bioplastics, DSC determines the temperature at which the crystalline portions of the material melt.

Crystallization Behavior

DSC can also quantify the temperature at which a bioplastic crystallizes during cooling

Thermogravimetric Analysis (TGA)

A technique called thermogravimetric analysis (TGA) is used to track changes in a sample's mass over time as it is heated gradually. As the temperature rises, either steadily or in predetermined intervals, the sample's weight is continuously monitored.

Thermomechanical Analysis

A sample's dimensions vary as it is heated because to thermal expansion, stress realignment, and deformation brought on by applied stress. By exerting a steady stress on the sample, thermomechanical analysis (TMA) measures these changes. TMA measures the dimensional changes in the vertical direction while regulating the sample's temperature under both no-load and fixed-load scenarios.

Dynamic Mechanical Thermal Analysis

One of the most versatile thermal analysis methods is dynamic mechanical thermal analysis (DMTA), also known as dynamic mechanical rheological testing. In a single evaluation, no other testing technique provides as much information on a sample. Apart from providing essential information on material characteristics, DMTA creates a clear link between a material's mechanical performance and its chemical makeup. Any kind, physical state, or application form of material can be described using this method.

CONCLUSION

Bioplastics are becoming more and more used in the cosmetics and pharmaceutical industries as a sustainable substitute for conventional polymers. They are viable materials because of their biodegradability, lower environmental effect, and use of renewable resources. However, issues like reduced mechanical strength and increased expenses need to be resolved. To guarantee their safe and efficient use, extensive quality assurance testing employing mechanical, thermal, and biodegradability techniques is necessary. Bioplastics have a great potential to replace traditional plastics in many delicate applications with more research and development.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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