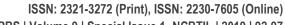
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Envoltura Farmacéutica—An Eco-Friendly Wrapping

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Abstract

Human health is being an increasing global concern. All countries across the globe are investing a major portion of their expenditure on the healthcare both in research and production. Tablets and capsules are the most common dosage formulation which are either packed in aluminum foils or few come out in tinted bottles as well. Packaging of each pharmaceutical product under this category is stringent depending on the composition and shelf life of the components. And hence the relevance of compatible and economic packaging without compromising the quality and durability of the contents inside is of utmost significance. Apart from aluminum foils; polyethylene terephthalate (PET), a non-biodegradable entity is another widely used material for packaging tablets and capsules. This a major concern for the environment as well. A possible solution would be a biodegradable packing material which would also be economically viable. This work aims to design and bring out one such feasible packaging material for these category (tablets and capsules) of medicines. The developed product would also be intended to offer maximum endurance to the product to be held inside despite of its categorization. The work plan includes the extraction of few biopolymers from various sources, testing for its quality and endurance in pilot scale, selecting the best, followed by scaling up the production.

Aluminum foils, Biodegradable packing, Biopolymer, Economically viable, Polyethylene terephthalate

1. INTRODUCTION

Plastics and Aluminum foils have become a vital asset for humanity. Though extensive research and new technologies have led to the development of new and safer plastics; the drawbacks and challenges of plastics have never been resolved till date. As the demand for these drugs increased, the raw material for the

wrapping also faced a demand. Once used these wrappers and not reusable and ultimately ends up in landfills and Fire pits. The manufacturers are least bothered about these unwanted leftovers which was used by them some time back and their ill effects on the environment. Tablets and capsules are the most common dosage formulation which are either packed



in aluminum foils or few come out in tinted bottles as well. Packaging of each pharmaceutical product under this category is stringent depending on the composition and shelf life of the components. And hence the relevance of compatible and economic packaging without compromising the quality and durability of the contents inside is of utmost significance. Apart from aluminum foils; polyethylene terephthalate (PET), a non-biodegradable entity is another widely used material for packaging tablets and capsules. This work aims to design and bring out one such feasible packaging material for these category (tablets and capsules) of medicines. The developed product would also be intended to offer maximum endurance to the product to be held inside despite of its categorization. [1]

Packaging of food and pharmaceutical products is stringent depending on the composition of the material to be packed. A compatible and economic packaging material without compromising the quality and durability of the contents inside is of

utmost significance. In the recent past traditional drugs (Ayurvedic medicines and nutraceuticals) also hit the market with colourful wrappers made of biodegradable synthetic materials. These packaging materials are inappropriately disposed after use which is a major environmental concern in the present days. Developing and replacing this packing material with a novel, economically viable biodegradable material without compromising the quality is the idea of this project. The material developed is intended to offer maximum endurance to the product (tablet/capsule) to be held inside despite of its categorization. The quality with which the drug is delivered to the user depends upon the shelf life of the drug as well as the quality of the packaging, and hence the quality of the packaging material cannot be compromised at any cost. But a second thought, over the environment conservation is also the prime need of the day. A Biodegradable packing material could aid in minimizing the usage of plastic packaging at least over the drug industry. The inert nature of the packing material is the major consequence that needs to be tackled. There are no products presently in the market with this specific purpose, and hence is the first and one of its kind. The demand for this biodegradable material would be high as drug manufacturers are committed to social responsibilities of environmental

conservation as well. This also reduces the use of plastic and aluminum to a great extent. Hence this product is commercially feasible.

Bio-based materials such as polynucleotides, polyoxoesters, polyamides, polysaccharides, polythioesters, polyanhydrides and polyisoprenoids potential candidates for substitution of synthetic plastic. An important family of biomaterials is which are usually built from hydroxy-acyl-CoA derivatives through different metabolic pathways. The term polymers represent compounds produced by microorganisms under different environmental conditions and are chemically non-related. Bio-plastics vary in their basic structure, structure of molecules and physical properties depending on their microbial origin, and most of them are characterized as biodegradable and biocompatible, making it extremely important in terms of biotechnology. Bio plastic is a special type of biomaterial. They are polystyres, produced by a number of microorganisms that develop under certain environmental conditions and under different nutrients. Polyhydroxyalkanoate (PHA) is one of these biomaterials, which belongs to the group of polyoxoesters has received intensive attention because it possesses biodegradable thermoplastic properties. Polyhydroxyalkanoates (PHAs) bacterial products are characterized by natural, renewable and biologically active polymers. PHAs extracted from bacterial cells show material properties that are similar to polypropylene. Many microorganisms have the ability to degrade these macromolecules enzymatically. Other advantages of these materials over petrochemical plastics are that they are natural, renewable and biocompatible. The main candidates for the large-scale production of PHAs are plants and bacteria. Plant cells can only cope with low yields [<10% (w/w) of dry weight] of PHA production. In contrast, within bacteria, PHAs are accumulated to levels as high as 90% (w/w) of the dry cell mass.

The general consensus in industry and academia to address this petrochemical based plastic waste menace is the production of biodegradable plastics. Biodegradable plastics unlike traditional low-density polyethylene (LDPE) produced from petrochemicals when exposed to the functional properties of starch films can be improved by blending with other biopolymers like polyvinyl alcohol (PVA),



polycaprolactone (PCL), polylactide (PLA) and Chitosan. The addition of PVA and Chitosan biopolymers to pure starch results in increase strength due to the introduction of cross linking between the starch bonds. The PVA starch forms a strong copolymer by reacting through their free hydroxyl (-OH) groups, thereby increasing the tensile strength of the blends formed. Cassava (Manihotesculenta) starch has a discontinuous phase because of its constituent amylopectin which is highly branched. PVA binds itself very well with cassava starch to convert its discontinuous phase to a continuous one thereby increasing the tensile properties of the starch based biodegradable plastic. Cassava flour is one of the most commonly used biopolymers as food packaging material because it is nontoxic, biodegradable, biocompatible, low cost, renewable and abundantly available in nature. Its major component is starch, but it may content small amount of lipid, protein, fiber and ash1.The starch plays important role in bioplastic forming. Today starch based bioplastic dominates 66% of the global bioplastics market. Starch based bioplastic is made by gelatinizing starch2. In general, smaller starch granule needs longer time and higher temperature to undergo gelatinization process3. For tapioca starch, a common name for starch extracted from cassava, gelatinization temperature is quite low, only about 52-64oC. To obtain a flexible starch-based bioplastic, sorbitol, glycerol, and xylitol are often added as plasticizers. The molecule of plasticizers can insert themselves into three dimensional networks of biopolymers and lower the interaction force between the molecules of biopolymers [1].

The goal of this development is to obtain biodegradable plastics that perform as well as traditional plastics when in use and which completely biodegrade at disposal. Starch foam is one of the major starch-based packaging materials. It is produced by extrusion or compression/explosion technology. Chitin is the second most abundant polysaccharide and produced annually as much as cellulose. It is the main structural component of the exoskeletons of animals like insects and crustaceans. Crab, shrimp, squilla and fish scale waste is ideal raw material for chitin production. The extracted chitin can be used to produce chitin-derived products, such as chitosan also for bioplastic and nanostructured film production. The present work is aimed at extraction of chitin from crab

shells. Minimization of waste material and its reuse into valuable and biologically sustainable material is a challenge to researchers and scientistExtracted chitin from crab shells can be used to produce chitin-derived products, such as chitosan also for bioplastic and nanostructured film. The crab shells contain 25-30% chitin. 25% protein, 40-50% calcium carbonate. The disposal of this waste creates sever problem for human life so that the present work is aimed at investigating utilization of waste crab shells in synthesis of chitin. "Nanostructured biocomposite film of high toughness based on native chitin nanofibres and chitosan" reports the synthesis of chitin and its utilization in nanostructured film.

Biopolymers of Plant Origin. [2]

Starch and cellulose are the two main carbohydrates in plants (algae included). Conventionally, starch is formed in a concentric arrangement around the hilum and consists of two components, namely amylose (linear) and amylopectin (hyper-branched). The formation of the starch takes place in the in the chloroplasts and their storage in the amyloplasts. Starch and starch derivatives are leading when it comes to biopolymers. Strengths are the availability of a large scale (in 2014: 10.5M tonnes) and inexpensive, rapidly renewable raw materials. This makes starch competitive with mineral oil. In addition, the European Starch Industry Association AAP predicts for the chemical sector, an increase in the production of polymers based on starch of nearly 50% in 2025 (in reference to 2010) expected. Starch and its derivatives have a wide application range. Edible films and biologically completely degradable films can be produced. These films can also be combined with functional additives, such as antimicrobial, antioxidant, essential oils, phenols and active nanoparticles. Thus, these films may be adjusted depending on the application. To produce starch films a combination of heat, pressure, time and plasticiser are required. Over time, significant improvements in strength were achieved on starch films. To show the influence of plasticisers that it is thus possible reduce the brittleness of starch films. PVA/starch blends are mechanically resistant but have a poor moisture barrier properties and tensile strengths. Currently PVA/starch blends do not have commercial importance due to high production costs compared to mineral oil-based packaging materials. To improve the



tensile strength and mechanical properties of starches it is widely used in starch blends, too. PLA can also be added to bio-nanocomposite films to increase their gas barrier properties and thermal stability. PLA can also be processed well to tissues and serves as teabags and higher priced products. Frequently it is also used in cosmetics for the production of jars [2]. The use of cassava starch films was promising, giving a good appearance, without stickiness, exhibiting shininess and transparency and developed edible coatings derived from cassava starch to minimize postharvest losses. Bioplastics made with natural ingredients of cassava that utilize the lactic acid with microorganisms to form PLA. The PLA (polylactic acid) is a result of esterification obtained by fermentation from cassava starch. The main process of bioplastic making from cassava by hydrolysis of starch to glucose. The flour produced from the cassava plant, which on account of its low content of non-carbohydrate constituents might well be called a starch, is known in world trade as tapioca flour. It is used directly, made into a group of baked or gelatinized products or manufactured into glucose, dextrins and other products.

Biodegradable plastics are seen by many as a promising solution to this problem because they are environmentally-friendly.

Cellulose & Cellulose derivate [3]

Cellulose, which makes up 20 to 40% of the plant's cell walls, is a homopolymer of glucose (β -1,4 linkage) . Primarily it is obtained from wood, although there are microorganisms that synthesise cellulose (e.g. Gluconacetobacter). There is great potential for cellulose for the coming years expected because it is the mostly abundant polymer on our planet. Since cellulose itself is hydrophilic in its structure, insoluble in water and crystalline, no films can be produced from it. In the food industry, there are therefore only two known forms of application, Cellophane and cellulose acetate. Both are commonly used for the packaging of processed meats, baked goods, cheese and confectionery, due to its good barrier properties.

Usually Cellophane is provided with a coating of PVDC or nitrocellulose wax. These coatings aim to improve the moisture barrier properties

Biopolymers of Animal Origin

Chitin and chitosan are in a number of organism's present (e.g. exoskeleton of insects, fungi (no animal), crustacean). In industrial production mainly, by-

products of shellfish processing are used for the production of chitin/chitosan, like cancer armor, crab shell, lobster shells. Increasingly, fungi or microorganisms are used. However, in the last year an increasing interest occurred in the production of biopolymers out of chitin/chitosan. Several studies have shown that chitin/chitosan films have antimicrobial and antifungal effects and is therefore well suited for the packaging of food and agricultural products. In addition, it is an ideal material for the development of active packaging solutions and coatings [4].

Biopolymers of Microbiological Origin

PHA, PHB, PHBV: There are currently more than 300 known microorganisms producing polyhydroxy alkanoates (PHA) and its derivatives (PHB, PHBV, PLLA etc.). It is used in microorganisms for energy and carbon storage properties. Brittleness and poor thermal and mechanical properties currently prevent commercial use as packaging material. These poor properties can be improved in use for starch blend or in the presence of plasticiser. Recent research, however, are focused on nanocomposites on bacterial cellulose-based, so as to develop active packaging. Biodiversity and occurrence of polymer-degrading microorganisms vary depending on the environment, such as soil, sea, compost, activated sludge, etc. It is necessary to investigate the distribution and population of polymer-degrading microorganisms in various ecosystems. Majority of the strains that are able to degrade PHB belong to different taxa such as and Gram-positive Gram-negative Streptomyces and fungi. It has been reported that 39 bacterial strains of the classes Firmicutes and Proteobacteria can degrade PHB, PCL, and PBS, but not PLA. The most important organisms in biodegradation are fungi, bacteria and algae. Natural polymers (i.e., proteins, polysaccharides, nucleic acids) are degraded in biological systems by oxidation and hydrolysis.

They can be derived from renewable feedstocks, thereby reducing greenhouse gas emissions. For instance, polyhydroxy alkanoates (PHA) and lactic acid (raw materials for PLA) can be produced by fermentative biotechnological processes using agricultural products and microorganisms. Biodegradable plastics offer a lot of advantages such as increased soil fertility, low accumulation of bulky plastic materials in the environment (which invariably



will minimize injuries to wild animals), and reduction in the cost of waste management. Furthermore, biodegradable plastics can be recycled to useful metabolites (monomers and oligomers) by microorganisms and enzymes. A second strategy involves degradation of some petroleum-derived plastics by biological processes [5].

II. MATERIALSANDMETHODS

Cassava

- Sample collection.
- Settling process.
- Filtration of starch
- Ethanol precipitation.
- Gelatinization of starch by heating for 60 min at 90°C
- Centrifugation
- Recovery of bioplastic.

Crab shell

- Sample collection
- Demineralization process using 7% Hydrochloric acid
- Deproteinization step using sodium hydroxide to reduce nitrogen content of protein, followed by washing.
- Filtration
- Drying at 70 deg C
- Bleaching using hydrogen peroxide.
- The filtered sample was then dried in an oven at 700C for 3 hours.
- The dried demineralized, deproteinized and deodorized white sample of chitin was obtained.

Pseudomonas putida

- PHA granules present in microbial cells would be observed by using Dye Nile blue A under anUV light microscope.
- Extraction and purification of PHA would be done by chloroform extraction results in a high level of polymer purity without polymer degradation.
- Sodium hypochlorite is awell known cell solubiliser which has been used for extraction of poly (3-hydroxy butyrate).
- Centrifugation
- A modified method of recovery using a dispersion solution of sodium hypochlorite and chloroform.
- Among these chemicals, SDS, NaOH and KOH wew more efficient in recoveringP(3HB) from recombinant E coli.

III. CONCLUSION

In accordance with the methodologies mentioned in the steps above, the novel material could be developed on combination of small units from individual sources. The analysis of their durability could be enough to substantiate the result.

Further enhancements could be done on to the product by the introduction of biodegradable materials which has got maximum shelf life and minimal environmental abberations.

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Fig 1: Bioplastic from cassava starch

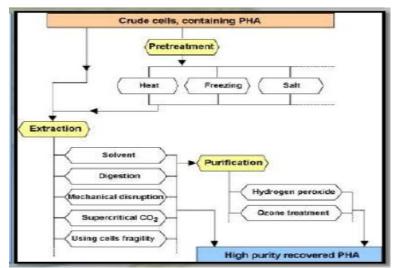


Fig 3: Extraction and Purification of PHA



Fig 2: Bioplastic from crab shell under dissolved state