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BIODEGRADABLE PACKAGING FOR PHARMACEUTICALS

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ABSTRACT

Pharmaceutical packaging is highly sophisticated since quality and safety issues are the most extreme need. Various materials are utilized for packaging in combination with more than one material as metals, glass, wood, paper or mash, plastic or composite. The wide usage of plastic packaging has caused concerns about the environmental problem in the world. The significant plastics which discover enormous packaging applications are High-Density Polyethylene (HDP), Polypropylene (PE), Poly Vinyl Chloride (PVC), Polyvinylidene chloride (PVDC), Polyester, Polystyrene, etc. The continuous utilization of synthetic plastic in the form of wastes is raising general worldwide concerns and has a terrible effect on the earth. Biodegradable polymers are a particular kind of polymer that separates through the activity of normally occurring microorganisms, such as bacteria and fungi, over a period of time result in natural by-products such as gases (CO_2 and N_2), water, biomass, and inorganic salts. Biodegradable pharmaceutical packaging materials are the protected materials for the earth which enclose the pharmaceutical item in any of the dosage forms.

KEYWORDS: Pharmaceutical packaging, biodegradable polymer, eco-friendly materials, plastics.

INTRODUCTION

"The case for rethinking plastics, starting with packaging"

Plastics have become the ubiquitous workhorse material of the modern economy. Plastics in bundling have demonstrated helpful for various reasons, incorporating the straightforwardness with which they can be framed, their high calibre, and the opportunity of plan to which they lend themselves. Plastic containers are extremely resistant to breakage and thus offer safety to consumers along with the reduction of breakage losses at all levels of distribution and use. Plastic containers comprise of at least one polymer together with certain additives. Those manufactured for pharmaceutical purposes must be free from substances that can be removed in significant amounts by the product contained. In this way, the risks of poisonous quality or physical and synthetic unsteadiness are avoided.[1,2]

MATERIALS AND METHODS

Purpose of using plastic packaging materials in pharmaceuticals include physical and chemical stability of the medicine (being an effective barrier to light, moisture, oxygen, bacteria, volatiles, etc. as appropriate), mechanical trauma–protection from damage, during transit, distribution and storage of the product, maintaining product integrity until it's in-use phase is completed or the expiry date stated on the label has passed.[3] At present, a great number of plastic resins are available for the packaging of drug products.[2] The more popular ones are described in Table 1.

Table 1: Plastic materials used in the packaging of drug products.

Sr no.	Material	Description
1	Polyethylene	Polyethylene is a good barrier against moisture. It lacks clarity and a relatively high rate of saturation of essential odors, flavors, and oxygen.
2	Polypropylene	Polypropylene is an excellent gas and vapor barrier. Its high melting point makes it reasonable for boilable packages and for sterilizable products. It does not stress-crack under any conditions
3	Polyvinyl Chloride (PVC)	PVC can be produced with crystal clarity, provide a fairly good oxygen barrier, and have greater stiffness. PVC can be softened with plasticizers.
4	Polystyrene	Polystyrene has been used for containers for solid dosage forms. It has a low melting point (190°F) and therefore cannot be used for high-temperature applications.
5	Nylon (Polyamide)	Nylon is not a good barrier to water vapor, but when this characteristic is required, nylon film can be laminated to polyethylene or to other materials. Its relative high-water transmission rate and the chance of medication plastic interaction have diminished the capability of nylon for long term stockpiling of medications. Some of the nylon approved by the FDA are Nylon 6, Nylon 6/6, Nylon 6/10, Nylon 11, and certain copolymers.
6	Polycarbonate	Polycarbonate can be sterilized repeatedly. The plastic is known for its dimensional steadiness, high effect quality, protection from strain, low water assimilation, transparency, and protection from heat and flame.

7	Acrylic Multipolymers (Nitrile Polymers)	These polymers represent the acrylonitrile or methacrylonitrile monomer. Their unique properties of the high gas barrier, good chemical resistance, excellent strength properties, and safe disability by incineration make them effective containers for products that are difficult to package in other plastic containers.
8	Polyethylene terephthalate (PET)	PET's excellent impact strength and gas and aroma barrier make it attractive for use in cosmetics and mouthwashes as well as in other products in which strength, toughness, and barrier are important considerations.

Technical issues of pharmaceutical packaging materials

Drug products come into direct contact with packaging systems that may result in interactions between the drug product and its packaging system.[3]

Product-Plastic interactions

Product-plastic interactions have been partitioned into five separate classes:

1. Permeation
2. Leaching
3. Sorption
4. Chemical reaction
5. Alteration in the physical properties of plastics or products

Plastic containers for pharmaceutical products are primarily made from the following polymers: polyethylene, polypropylene, polyvinyl chloride, polystyrene, and to a lesser extent, polymethyl methacrylate, polyethylene terephthalate, polytrifluoroethylene, the amino formaldehydes, and polyamides.

Plastic containers consist of one or more polymers together with certain additives.

Those manufactured for pharmaceutical purposes must be free of substances that can be extracted in significant quantities by the product contained. Thus, the hazards of toxicity or physical and chemical instability are avoided.

Table 2: Pharmaceutical packaging products obtained from various plastic materials.

Sr no.	Products
1	PET bottle
2	Cap and Closure
3	Dropper
4	Measuring Cup, Spoon, Cyliner
5	Stopper
6	Eye drop bottle
7	Eardrop bottle
8	Nasal drop bottle
9	PVC Film
10	PVDC Film
11	Large Volume Parenteral Container (Flexible and Non-Flexible)
12	Infusion Set
13	Pre-filled Syringe
14	Actuator
15	Applicator
16	Spray Pump
17	Special Tube-Type container

The packaging systems must secure and be compatible with drug products and not compromise their stability, efficacy or safety. The elements of a medication item should not be consumed into the surface or relocate into the body of the plastic packaging framework. However, top local manufacturers imports nourishment grade virgin dynamic elements for creating plastic packaging materials from Korea, Taiwan, Malaysia, Saudi Arabia, UAE, China, etc. which are a little costly and the pharmaceutical manufacturer have some quality parameters to select that same.

Table 3: The major suppliers.

Sr. no.	Company	Country of origin
1	Wuxi Sunmart	China
2	Nuplas	Dubai
3	Rexam	France
4	ACG	India
5	Struble	Germany
6	Bilcare	India
7	Bprex Pharma	India
8	Doctor Pack	India
9	Meditalia	Italy
10	F.D. Enterprise	Taiwan
11	JOMA	Austria
12	BestPack	UK

The pharmaceutical organizations who are exporting medication to semi-regulated and regulated markets are exceptionally cautious about the sources of plastic materials since there are exacting rules for packaging materials from the regulatory body.[3] Subsequently, they anticipate certain SOP (Standard Operating Procedure) and COA (Certificate of Analysis) from the plastic maker.

Therefore, these export-oriented companies limited their purchase only from top-class plastic manufacturers.

The plastic problem

We come across a variety of packaged products each and every day. From containers used to contain milk and grains, to medication bottles, drinks bottles, nourishment holders and bundling folded over apparel, we're presented to a wide range of various materials every day. Research led by the Ocean Conservancy shows that plastic traces were distinguished in 100% of turtle species and 60% of seabird species. [4]

Plastic waste — regardless of whether in a waterway, a sea, or ashore — can continue in the earth for a considerable length of time.

Fig. 1: Plastic wastes in river.

The River conveys almost 1.5 million tons of plastic waste into the Sea.

If current trends continue, our seas could contain more plastic than fish by 2050.[6]

Statistcs

a. Plastic enters in world's oceans

In 2010:

- Global primary production of plastic was 270 million tonnes;[6]
- Global plastic waste was 275 million tonnes (and can exceed annual primary production through wastage of plastic from prior years);
- Plastic waste most at risk of entering the oceans is generated in coastal populations; in 2010 coastal plastic waste amounted to 99.5 million tonnes;[8]

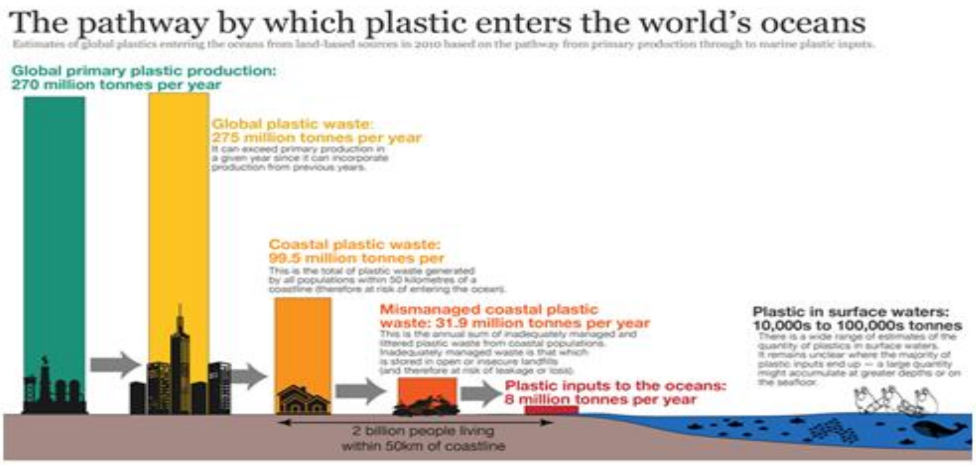

Fig. 2: Pathway by which plastic enters the world's oceans.

- Only plastic waste which is improperly managed (mismanaged) is at significant risk of leakage to the environment; in 2010 this amounted to 31.9 million tonnes;[6]
- Of this, 8 million tonnes – 3% of global annual plastics waste – entered the ocean (through multiple outlets, including rivers);
- An estimated 10,000s to 100,000s tonnes of plastics are in the ocean surface waters. This inconsistency is known as the 'missing plastic issue'.[7]

b. Cumulative global plastic production

In the diagram beneath we see the development of yearly worldwide plastic production, estimated in tons every year. This is shown from 1950 through to 2015.

In 1950 the world delivered just 2 million tons for each year.

From that point forward, yearly production has expanded to about 200-overlap, arriving at 381 million tons in 2015. For setting, this is generally comparable to the mass of 66% of the total population. The short downturn in yearly creation in 2009 and 2010 was transcendently the aftereffect of the 2008 worldwide financial crises — this mark is seen over a few measurements of resource production/consumption, including energy.[6]

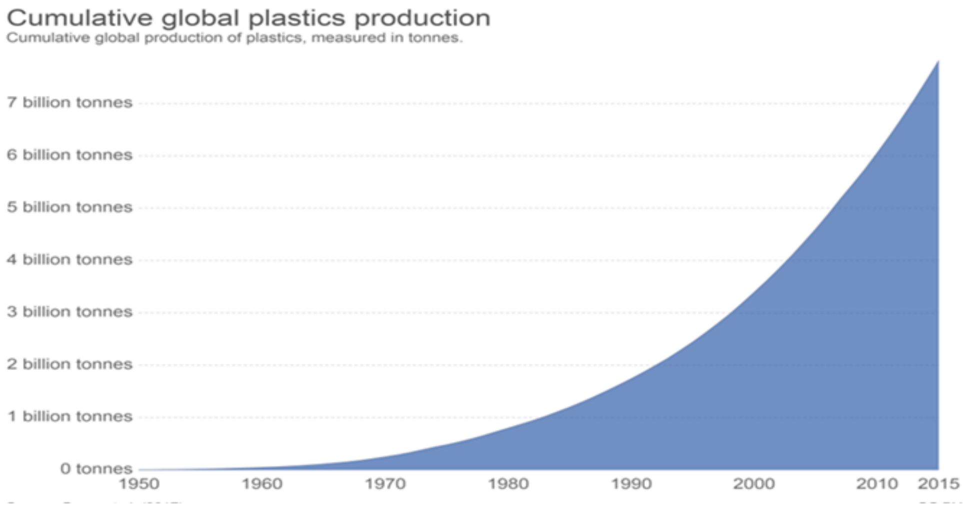

Fig. 3: Cumulative global plastic production.

Cumulative production by 2015, the world had produced 7.8 billion tonnes of plastic — more than one tonne of plastic for every person alive today.[6]

c. Disposal of plastic

Before 1980, reusing and burning of plastic were insignificant; 100 percent was in this way disposed of. From 1980 for burning and 1990 for reusing, rates expanded on normal by about 0.7 percent every year.

In 2015, an expected 55 percent of worldwide plastic waste was disposed of, 25 percent was burned, and 20 percent reused. On the off chance that we extrapolate chronicled drifts through to 2050 — by 2050, burning rates would increment to 50 percent; reusing to 44 percent, and disposed of waste would tumble to 6 percent. Notwithstanding, note this depends on the shortsighted extrapolation of historic trends and doesn't represent concrete projections. Global plastic production to fate;

In the figure underneath we summarise worldwide plastic production to definite destiny over the period 1950 to 2015.

This is given in cumulative million tonnes.

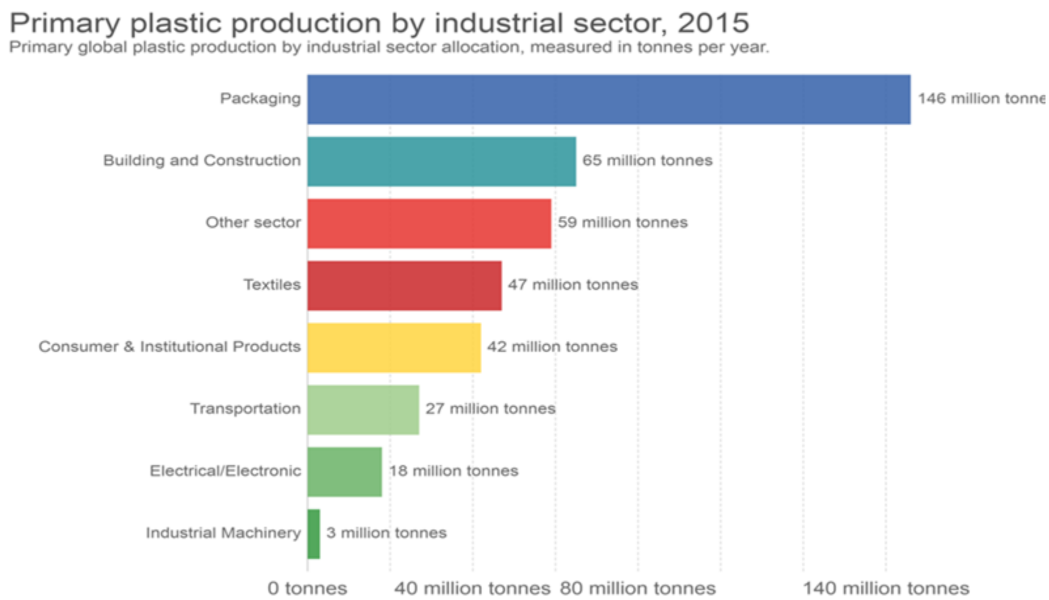

Fig. 4: Primary plastic production by industrial sector, 2015.

As shown

a) Cumulative production of polymers, synthetic fibers and additives was 8300 million tonnes;

b) 2500 million tonnes (30 percent) of primary plastics was still in use in 2015;

c) 4600 million tonnes (55 percent) went straight to landfill or was discarded;

d) 700 million tonnes (8 percent) was incinerated;

e) 500 million tonnes (6 percent) were recycled (100 million tonnes of recycled plastic was still in use; 100 million tonnes were later incinerated, and 300 million tonnes were later discarded or sent to landfill).

f) Of the 5800 million tonnes of primary plastic no longer in use, only 9 percent has been recycled since 1950.

g) The packaging was the dominant use of primary plastics, with 42 percent of plastics entering the use phase.[6]

d. Cumulative Plastic waste generation and disposal

We estimate that 2500 Mt of plastics—or 30% of all plastics at any point produced—are right now being used. Somewhere in the range of 1950 and 2015, combined waste generation of primary and secondary (reused) plastic waste added up to 6300 Mt.

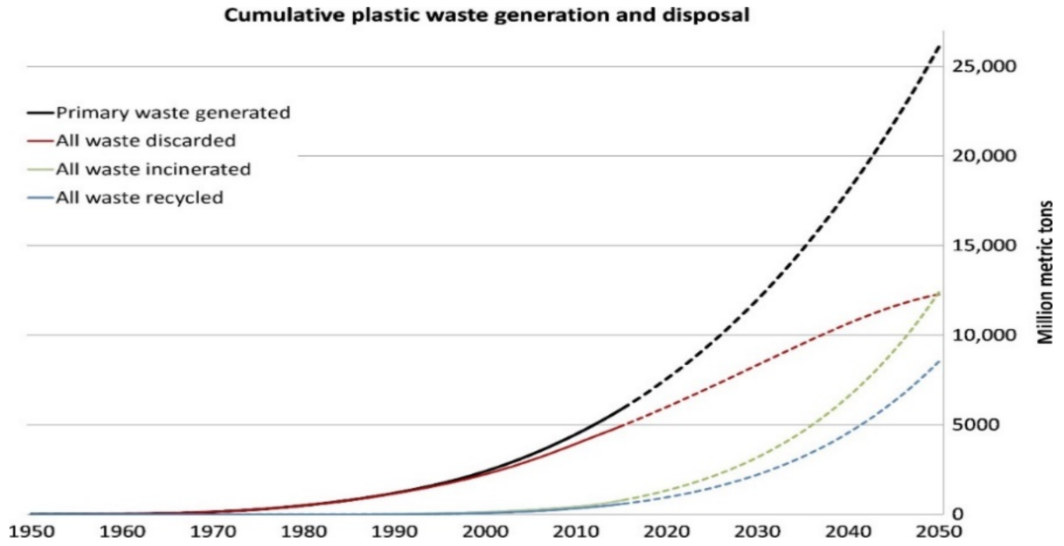

Fig. 5. Cumulative plastic waste generation and disposal (in million metric tons).

Strong lines show historic information from 1950 to 2015; dashed lines show projections of recorded patterns to 2050.

We estimate that 2500 Mt of plastics—or 30% of all plastics ever produced—are currently in use. Between 1950 and 2015, cumulative waste generation of primary and secondary (recycled) plastic waste amounted to 6300 Mt. of this, around 800 Mt (12%) of plastics have been burned and 600 Mt (9%) have been reused, just 10% of which have been reused more than once.[6]

Pharmaceuticals

The packaging is an emerging science, an emerging engineering discipline, and a successful contributor of pharmaceutical enterprises. Packaging requirements for pharmaceutical products are complex than those of other non-edible products. Pharmaceutical packaging is an art and science of preserving and protecting the pharmaceutical product from damage by enclosing them.[10] [11]

Functions served by packaging

- Protection Against Temperature
- Protection Against Moisture and Humidity
- Protection Against Light
- Physical/mechanical Protection
- Protection Against Compression
- Protection Against Impact

- Biological Hazards Protection
- Presentation of Information Regarding Product
- Providing Identification for Product
- Providing Convenience During Handling
- Tool for Advertising and Marketing of Product

Categories of pharmaceutical packaging materials

1. **The primary packaging system:** is the material that first envelops the product and holds it i.e., those package segments and subcomponents that interact with the product, or those that may have a direct effect on the product shelf-life e.g., ampoules and vials, prefilled syringes, IV holders, and so forth.
2. **The secondary packaging system:** is outside the primary packaging and used to group primary packages together e.g., cartons, boxes, shipping containers, injection trays, etc.
3. **The tertiary packaging system:** is used for bulk handling and shipping e.g., barrel, container, edge protectors, etc.[2]

Materials used for pharmaceutical packaging

Most of medicines (51%) have been taken orally by tablets or capsules, which are either packed in blister packs or fed into plastic pharmaceutical bottles. Powders, pastilles, and liquids additionally make up some portion of the oral medication intake. Notwithstanding, different methods for taking medicines are presently being all the more generally utilized. These incorporate parental or intravenous (29%), inhalation (17%), and transdermal (3%) methods.

These changes have made a major effect on the packaging industry and there is an increasing need to provide tailored, individual packaging solutions, which ensure the effectiveness of medicines.

The present review article details several key trends that are impacting the packaging industry and offers some predictions for the future packaging encompassing solid oral dosage forms and injectables.

Biodegradable materials for pharmaceutical packaging

Bio-packaging is important for future packaging.

Hydrocolloids and lipids are generally used for preparing biodegradable packaging materials. Glycerol, polyethylene glycol, and sorbitol are used in the film formulations as plasticizers, to impart flexibility.[12,13,[14]

Table 4: Eco-friendly material for pharmaceutical packaging.

Sr no.	Eco-friendly material	Source	Description	Available Polymer/Derivatives
1.	Starch	legumes, tubers, cereals Primary Source: Corn, Potato, Wheat and Rice	Starch, a polysaccharide, is a renewable, eco-friendly and widely available raw material. Biodegradable Plasticizers such as glycerol, polyether, urea, and polyhydroxy components are used to make starch materials less brittle.	Types of starch-based polymers: Starch-based thermoplastic products Starch-polyvinyl alcohol Starch-synthetic aliphatic polyester Starch polybutylene succinate
2.	Cellulose	Natural resources such as wood and glass	Cellulose-based materials, like paper and board, are commonly used in packaging. They are light-weight, tough, bio-based and effectively recyclable which have made them a well-known packaging material.	Various commercial products of cellulose derivatives Ethyl Cellulose Methyl Cellulose Cellulose acetate Hydroxyl ethyl Cellulose
3.	Xylan	Naturally occurring carbohydrate found in plant cell walls and algae. Also obtained as residue from agricultural industries	Biodegradable and compostable	It forms a group of substances known as hemicellulose.
4.	Gluten	Protein found in Wheat, barley and rye.	Gluten is an intense, rubbery and flexible substance, which has the ability to stretch and rise because of	Used in edible films, adhesives, molded biodegradable thermoplastic films for agricultural uses, windows in envelopes,

			the activity of preparing powder or yeast. At the point when flour is blended in with water, the gluten swells to form a continuous network of fine strands.	surface coatings on paper, water-soluble bags with fertilizers, detergents, cosmetics.
5	Soy protein	Protein that is isolated from soybean	Soy protein is the most widely used plant-derived protein for microencapsulation due to its good functional properties including gel-formation, emulsifying activity and surface tension reducing properties	Used as adhesives or biodegradable plastics produced from soy isolate and concentrate by them molding process, inks, paper coatings, oil for lubrication, soy films as coating materials for preservation.
6	Whey	The by-product of the cheese industry	Rich in α - lactoglobulin Collagen	Use in packaging as edible coatings and films
7	Zein	Corn endosperm	Comprises a group of alcohol-soluble proteins – “prolamine”	Zein based films used as biobased packaging and in pharmaceutical coatings
8	Casein	Milk derived protein	Easily processable	Used as a thermoset plastic, for bottle labeling due to excellent adhesive properties.
9	Keratin	Structural protein extracted from waste streams such as hair, nails, and feathers	Cheapest protein Poor mechanical properties	Used to produce fully biodegradable water-insoluble plastic.
10	Collagen	Found in animal tissues particularly tendons, skin, and bones.	Fibrous, flexible and structural protein with the common repeating unit: proline, glycine, and hydroxyproline	Used as packaging material in several pharmaceutical applications.
11	Gelatin	Obtained from skin and bones.	Used as a packaging material for improving moisture sensitivity	Used as a raw material for; Photographic films Microencapsulating aromas Vitamins Sweeteners

				And as gelatin films in the pharmaceutical industry to fabricate tablets and capsules

An eco-friendly future

The utilization and wastage of plastic over the pharma supply chain continue to be a major focus in 2019, after a warning by the UN our oceans will contain more plastic than fish by 2050 unless all industries take action. The eventual fate of pharma packaging will see a move towards increasingly sustainable materials, moving endlessly from plastic which the industry has been so heavily reliant on for design and manufacturing.[16-24]

Attempts to limit plastic waste will see the continued application of polyethylene terephthalate (PET), which can be broken down to the molecular level and converted back into PET. Presently the innovation has demonstrated effective in early testing, we'll begin to see it move into worldwide production. New techniques are likewise making it generally conceivable to decrease waste. For instance, 3D visualization techniques wipe out the requirement for multiple prototype designs and computer-aided manufacturing like 3D printing uses only exact materials, minimizing waste.[2]

Efforts of pharma companies to protect the environment

Pharmaceutical industries are leading the way in adapting the way they work to benefit the environment and diminish the danger of hurting the planet and its native wildlife species. [26] There are numerous ways by which pharma firms are putting forth an attempt to ensure and protect the planet.

Focusing on sustainability

Putting resources into sustainability is a positive advance forward for pharmaceutical industries regarding waste reduction and bringing down the hindering effect of specific materials. Industries that are effectively searching for practical methods for delivering packaging are directing their concentration toward creating materials that are either reusable or recyclable, decreasing the quantity of packaging required, urging customers to utilize packaging more than once and constraining the measure of waste created all through the supply chain. Think about the effect of purchasing and utilizing a cup or jar produced using practical materials contrasted with purchasing a container of water each day. This is the sort of model pharma industries are working on. By utilizing materials that can be used again and again, this eliminates the need for single-use plastic, contributing to significant waste reduction. It additionally brings down the danger of medication bottles, tablet pouches and bottle tops closure ending up in our oceans.[27,28]

RESULT

Developing new, more eco-friendly packaging materials

For a long time, similar materials have been utilized to make both external and primary packaging. Presently, as pharmaceutical industries strive to do their bit to protect the environment, many are focusing on developing new, more eco-friendly packaging materials.[27] Firms are searching for sustainable materials, but on the other hand they're sourcing and examining materials that have a significantly less harmful impact on the planet.

Examples of materials that are presently utilized by pharmaceutical industries include.

Pe or Pet

This is a material made from sugarcane. The process involves extracting ethanol from sugarcane and dehydrating it to create ethylene. The ethylene is then converted into PE or PET at a polymerization plant.[28]

Fig. 6: PET from Sugarcane.

PCR (Post consumer regrind)

PCR products are made utilizing plastic that has just been reused. The hypothesis lies in the way that reusing progressively plastic decreases the demand for new plastic. It conserves energy and non-renewable resources as recycling replaces the requirement for primary extraction and the production of new plastics. PCR tubes are accessible for use with PE starting at 25% PCR material. PCR labels are also available which are 100% recyclable and give the same high-performance levels as non-recycled labels.[28]

Pla (polylactic acid)

PLA is a recyclable, affordable, innovative packaging material made from renewable resources.

The lactic acid used to make it is derived from corn.[30] The procedure used to make it includes both chemistry and biotechnology. PLA is a thermoplastic, high-quality, high-modulus polymer that can be produced using yearly sustainable resources to yield articles for use in either the modern packaging field or the bio-compatible/bio-absorbable medical device market.

Fig. 7: Pla from Corn.

It doesn’t require corn; it only needs a sugar source. Alternative sugar sources for lactic acids are Sugar beet, Tapioca, Sugar cane and wheat are 100% renewable resources and available in plenty and cheaply.

DISCUSSION

One of the fundamental issues with plastic is that it takes hundreds of years to break down. Therefore, identifying biodegradable alternatives is probably going to have an immense effect. The aim is to replace traditional plastics with biodegradable materials that do a similar activity however decompose much faster. Developing biodegradable materials isn't the main methods for reducing plastic waste. Pharma firms are likewise exploring and working on design and manufacturing processes that are cleaner and all the more environmentally-friendly.

CONCLUSION

In the era of globalization, it would be a challenge for the packaging industries, as the years ahead would observer the opening of the worldwide channels, and to coordinate the international standards and quality, it is fundamental that packaging industry upgrades in research to have a holistic approach to packaging that would go beyond functional aspect of packaging. The conventional packages accessible don't effectively provide protection against counterfeiting and quality, and the industry seems to be sluggish in adopting the technical advances in the packaging, probably on account of the prohibitive cost factor. As the packaging industry is directly or indirectly involved in the drug manufacturing process, it becomes ethically mandatory to understand and incorporate scientific methods in packaging. The need of the hour is to arrive at a sustainable solution by the adoption of technologies, upcoming innovations and eco-friendly solutions. An organized development addressing cost-effective plastic processing, along with streamlining operations of recycling of plastics could pave a path for the growth of this industry.

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