



Shielding the Cure

Reliance Relpet® - The perfect packaging formula for the Pharma Industry.

Overview of the PET Industry

Global Scenario

PET production is increasing globally as usage has crossed 20 Mn MT annually. Ever since PET became commercially available in 1970, more than 300 Mn MT have been sold and consumed world-wide in the last four decades. PET packaging has a variety of usage in segments like CSD, drinking water, fresh, flavored and UHT milk, pharmaceuticals, etc. and demand is estimated to grow at more than 6% p.a. in the coming years.

Indian Scenario

Domestic demand of PET is expected to cross 700 KTA by the end of this financial year with more than 15% growth rate in coming years. The pharma packaging industry in the country is valued at a massive Rs. 10,000 crores. There are about 1500 PET converters spread all over India, resulting in easy and JIT availability of PET preforms and bottles for different end-use sectors across India. The major application areas of PET in India are packaging of CSD, mineral water, liquor, pharma liquids etc.

Uses of PET in Pharma Industry

Global

PET is non-toxic, safe for food and pharma contact packaging as per testing standards set by US FDA, USP and other regulatory bodies of pharmaceutical packaging. The developed countries like US, UK, Germany and Japan are using PET for packaging of different pharma products.

International Pharma Brands in PET Bottles

Brand, Manufacturer, Category

Benylin

The Boots Company Plc, UK
Children's Tickly Cough Syrup

Eno Liquid

GlaxoSmithKline
Consumer Healthcare Ltd.
Antacid

Eludril

Pierre Fabre Medcament
Oral Care

Nyquil Sever (Vicks)

P & G, US
Cold and flu

Robitus

Pfizer, US
Cough and chest congestion

Phillips

Bayer
Milk of Magnesia

This is just an illustrative list and not an exhaustive one.

India

Out of the 700 KTA of PET used in India, 15% accounts for the pharma sector. Around 20% of the Indian PET suppliers supply to pharmaceutical business along with other end usages. In India in the last two decades, more than 5 lakh MT of PET bottles have been consumed to pack more than 40 billion packs of oral liquids. PET usage in pharma industry is growing at the rate of 15% CAGR.

Different types of Plastics used in Pharma Industry

Different types of plastic have different polymer chemistries and properties based on the various types of monomers; hence each plastic is being processed differently. Thus, PET, HDPE, PVC, PP etc. are used for different applications. PVC is generally used for non-contact with human body applications like preparing blood storage bags etc. PET and PE are used in short and long term body contact applications like feeding tubes, surgical instruments, drug delivery devices etc.

PET Chemistry

PET is a co-polymer produced from Purified Terephthalic Acid (PTA), Mono-ethylene Glycol (MEG) monomers and IPA as a co-monomer. When PET resin is converted into PET bottles by ISBM, only physical change takes place in the composition. Production of PET bottles does not need the use of any additives while processing. As PET is a condensation polymer, no monomer leaches out at the end of the polymerization.

Medical Applications of PET in Pharma Liquid Oral Formulations

PET bottle packaging is used for most of the liquid oral formulations like cough syrups, antacids, vitamins etc. as it is food-contact safe, shatter-proof and light-weight, reducing the transportation cost and eliminating breakages.



Medical Instruments

FDA has confirmed that medical devices containing PET such as surgical sutures, esophageal dilators, surgical mesh etc. are safe and effective. PET is also safe for soft tissue approximation and/or ligation, including cardiovascular, ophthalmic and neurological tissue.

Blood Collection Tubes

These are globally used and some of the major suppliers include Becton-Dickinson & Company.

Characteristics of PET Packaging for Pharma

Resin

PET is non-toxic semi-crystalline thermo plastic material and meets the USFDA / EU / BIS Regulations. The residual content of metal elements are in trace levels and within permissible limits.

Colorants

The colors added to make colored PET bottles for packaging of Pharma products are completely food-contact safe. Colorants used in PET conform to Indian and global regulations on colorants for direct food-contact materials.

Bottles

PET bottles are manufactured by Injection Stretch Blow Molding (ISBM). They are rigid and unbreakable and so are easy to transport, thus eliminating any transportation losses. PET bottles have excellent oxygen and gas barrier propertise; thus making them suitable for longer shelf life of the packaged product. The noise level on the production lines is also reduced by 60%; thus resulting in lesser noise pollution. 30% more PET bottles can be transported as compared with other competitive packaging materials. This leads to savings in fuel cost and reduces air pollution too.

SCM of PET Pharma

The stability guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) have been adopted in many regions worldwide including the U.S, Europe, and Japan. The ICH guidelines recognize that the different climatic zones of various countries may impact the standard temperature and humidity conditions in which drugs will be stored during normal use. Therefore, different long-term stability conditions are recommended depending on the climatic zone in which a drug is intended to be marketed. Long-term stability studies conducted on oral drug product formulations stored in PET packaging components establish that the active pharmaceutical ingredient and drug product formulation is compatible with the chosen packaging materials.

It is worthwhile to note here that PET is widely used for hot filling of juices and jams. US FDA and EU PIRA have certified PET as a safe packaging medium for human consumption for juices filled at 85°C and above. Similarly, pre-cooked food packed in CPET containers can be heated to 200°C before consuming. Most of the food items (including juices) packaged in PET containers are exposed to hot conditions for prolonged periods, not only in transportation, but also during further distribution and at points of sale (POS).

Environment Friendly PET

PET is one of the most eco-friendly packaging materials with low GHG emissions. The used empty PET bottles are recycled easily to make value-added applications like fiber for pillows, carpets, clothing and paper industry.

Regulatory Standards for PET Packaging

FDA

The USFDA has set a Code of Federal Regulations in Title 21 under Section 177.1630 titled Polyethylene Terephthalate polymers. Since PET passes these requirements, the pharmaceutical industry refers the same while evaluating PET packaging. FDA has established in the U.S. Code of Federal Regulations (CFR) that as long as the materials meet certain specifications, PET polymers 'may be safely used as components of plastics (films, articles or fabric) intended for use in contact with food'.

USP

The U.S. Pharmacopeia (USP) Chapter 661 Containers-Plastics establishes 'Standards for plastic materials [including PET] and components used to package medical articles (pharmaceuticals, biologics, dietary supplements, and devices)'.

EU

It is a comprehensive regulation in Europe for the safety of PET in food contact applications. PET passes EU Regulation 10/2011/EC too. The European Pharmacopoeia (EP) (Sections 3.1.15, 3.2.2.1, 3.2.2) contain monographs for the use of PET containers in pharmaceutical packaging.

BIS

The Bureau of Indian Standards (BIS) has set the following standards for PET bottles meant for packaging of different food and beverage products including Pharma:

- i. IS 12252-1987: Specification for Polyalkylene Terephthalates (PET and PBT) for their safe use in contact with Foodstuff, Pharmaceuticals and Drinking water
- ii. IS 9845-1998: Determination of Overall Migration of constituents of Plastics Materials and articles intended to come in contact with Foodstuff method of analysis
- iii. IS 10171-1982: Guide on Suitability of Plastics for Food Packaging
- iv. IS 12229-1987: Positive list of constituents of Polyalkylene Terephthalate for their safe use in contact with Foodstuff, Pharmaceutical and Drinking water





Food-contact Packaging Limits

Antimony

The BIS Standard IS-12229 on 'Positive List of Constituents of Polyalkylene Terephthalates (PET and PBT) for their Safe use in Contact with Foodstuff, Pharmaceutical and Drinking water' permits <350 mg/kg of Antimony as 'Residual Catalyst' in PET. The PET resin complies with this requirement. Antimony is used in PET resin manufacture at a level of < 300 ppm. Apart from BIS, PET resins comply with Specific Migration Limit as per US FDA 21 CFR §177.1630 and EU 10/2011 regulation.

Update on Different Chemicals

Phthalates

Phthalates are used as Plasticizers in some PVC formulations. PVC plastics have been assigned a recycle code '3'. The Terephthalate polymer PET and the phthalate based plasticizers are chemically different substances as such. Although the word 'phthalate' appears in the name polyethylene terephthalate, PET does not contain phthalates at all. The recycling code for PET is '1' written inside a triangle.

BPA

Bisphenol-A (BPA) or other carcinogens are not used in PET resin. BPA is used as monomer in the manufacture of 'Polycarbonate' plastics. PET has different chemistry vis-a-vis these plastics.

EDC's

The United States Environment Protection Agency (USEPA) is running an Endocrine Disruptors Screening and Testing Program (EDSP) and PET does not appear in the list. There is also a report by EFBW (European Federation of Bottled Water) that negates the presence of endocrine disruptors in PET packaging.

Acetaldehyde

It is not added in PET. Acetaldehyde traces generated during PET processing have no effect on human health. It is interesting to note that Acetaldehyde occurs naturally in coffee, bread and ripe fruit at much higher concentrations.

Testing Process

The suitability of PET bottles for direct food contact packaging applications is demonstrated through various international standards and test reports. Some of the labs doing pharma related tests includes M/s Cipet, IIP, IITR, Intertek, SGS, Sipra, Vimta Labs etc. (listed in alphabetical order).

Conclusion

PET is light, food-contact safe, easy to use and transport and far more convenient to the end-user. It also uses much less energy right from manufacturing till final disposal. It is a cost-competitive packaging material and has one of the lowest carbon foot prints (CFP) and low GHG emissions. There are international studies available which establishes the suitability of PET packaging for different end use applications including environment friendliness.



Total Packaging Solution

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