



# OVER VIEW OF PHARMACEUTICAL PACKAGING

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# What is Packaging ?

## Definition:

Packaging can be defined as an art, science and technology to ensure the safer delivery of the product throughout its journey from manufacturing to the end use

## Functions of Packaging:

- **P**rotection
- **P**reservation
- **P**resentation

This is widely known as **3P** concept. The latest inclusion of the 4<sup>th</sup> **P** is **P**romotion of the product



## Role of Packaging in Pharmaceutical

- Use of the optimum Packaging which shall take care of the Pharmaceutical Preparations right through its shelf life and beyond . That too without any over packaging.
- Selection of Packaging for Pharmaceuticals is extremely crucial as it is directly related to life and death of a living element.
- Pharmaceutical Packaging requires special features like senior friendly and child resistant features
- Pharmaceutical packaging has become very critical as it requires to meet the law of the land especially when it is exported to regulated markets.



## Significance of Pharma packaging

- Product protection upto shelf life
- Legal compliance
- Pharmacopoeial standards
- Patient Protection
- Customer convenience
- Route of administration



# Choosing the most appropriate pack

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## BASIC REQUIREMENTS

- Protection
- Compatibility
- Regulatory
- In line with the Innovator product/pack
- Commercial
  - Image & design
  - Market requirements/trends
  - Dosing/patient compliance
  - Security/tamper evidence
  - Manufacturing
  - Economics - COG



# Classification of the Packaging materials

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- **Primary Packaging**

Direct contact with product, also known as critical packaging component. Tendency to have influence on the finished product quality.

Eg: Containers, closures, blisters, strips, space fillers, desiccant etc.

- **Critical Secondary Packaging**

To protect primary packaging

Eg: Pouches, Thermoform trays for pre-filled syringes etc..

- **Secondary Packaging**

This encloses one or more primary packs, also known as non-critical Packaging component

Eg: Cartons, e-flute boxes, e-fluted trays, etc.

- **Additional Packaging**

To hold primary packs

Eg: trays, display cartons.

- **Final external Packaging**

Transport pack, also known as non-critical Packaging component

Eg: Shippers, drums and Pallets.

# Primary Packaging

## Containers:

### Plastic

#### High Density Polyethylene (HDPE) Containers

Mostly used for tablets, capsules, dry powders and sometimes for liquids, suspensions

Properties:

- Good moisture barrier
- Easily moldable
- Protection from Light
- Good strength

#### Polyethylene Terephthalate (PET) Containers

Mostly used for liquid solutions

Properties:

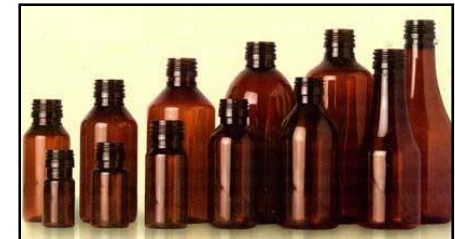
- Light weight
- Gas Barrier properties
- Chemically inert
- Unbreakable
- Wide range of designs
- Good strength

### Glass

Mostly used for the liquid solutions, Injections, PFOs

Properties:

- Complete barrier to moisture and gas
- Inert material
- Excellent Chemically resistant



# Primary Packaging

## Types of Closures:

- Child Resistant Closures
- Tamper Evident Child Resistant Closures
- Screw Closures
- Tamper Evident Screw Closures
- ROPP
- Rubber stoppers

## A good closures ,

- Preserves freshness
- Authenticates product integrity
- Prevents leakage
- Ensures Consumer Confidence
- Prevents product contamination throughout supply chain
- Graphic communication and promotion



# Primary Packaging

## Fillers:

Main purpose is to protect the product from transit hazards.

## Types of Fillers:

### Cotton:

- Natural Material
- Having Moisture content of 4 to 8%

### Rayon

- Semisynthetic Material
- Having Moisture content up to 11%

### Polyester Fiber

- Synthetic Fibers
- Having low moisture of maximum 1%.



# Primary Packaging

## Desiccants:

Main purpose is to protect the product from moisture / gases.

## Types of Desiccants:

- Silica Gel
- Silica Gel with Activated Carbon (2 in 1)
- Molecular sieve

**Oxygen Scavengers / Absorbers : Purpose is to protect the product from gases especially oxygen, nitrogen etc..**



# Primary Packaging



- **BLISTER PACKAGING**
- Blister packaging consists of forming material, which will take the form of the cavity to receive the product and lidding foil.

## Forming Materials:

- PVC
- PVC/PVdC (duplex), PVC/PE/PVdC (Triplex)
- PVC/Aclar (Aclar® film is a polychlorotrifluoroethylene (PCTFE) of Honeywell)
- Cold Form Laminate (Polyamide/Aluminum foil/ PVC film)
- Surlyn based Cold Form Laminate for Temperature sensitive products (Surlyn™ of DuPont, it is copolymer of ethylene)
- COC (Cyclic Olefin copolymer) combined with PE or PP or PVC or PETg very good in Moisture barrier to blister packs for deeper cavities



## Lidding Materials:

- Push through Foil (Aluminium)
- Peelable Lidding Foil (Paper/ Polyester/ Aluminum foil/ HSL)
- Peel push Lidding foil (Paper/ Polyester/ Aluminum foil/ HSL)

## Strip Packaging:

- Aluminium laminated with Polyethylene on the both sides
- Paper with Poly-coating





# Labeling Requirements

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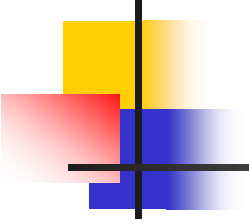
- Country specific requirements
- Barcode
- Pharmacode
- NDC No.
- Blister pocket to have barcode, lot no. & expiry
- Braille script on carton

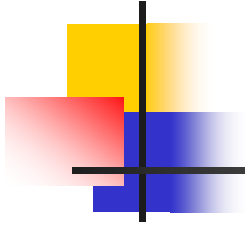


## **BASE MATERIAL / PACKAGING MATERIAL USED IN PHARMA INDUSTRY FOR PACKAGING**

<b>BASE MATERIAL</b>	<b>PACKAGING MATERIAL</b>
<b>Glass</b>	<b>Bottles, Ampoules, Vials, Syringes, etc.</b>
<b>Plastics eg. (Polyethylene, Polypropylene, PET,PVC, etc)</b>	<b>Bottles, Closures, Tubes, films etc.</b>
<b>Metals (Aluminium)</b>	<b>Collapsible Tubes, Foils etc.</b>
<b>Metal / Plastic</b>	<b>Flip Off Aluminium Seals</b>
<b>Paper</b>	<b>Labels, Leaflets</b>
<b>Board</b>	<b>Cartons, Display Units.</b>
<b>Rubber</b>	<b>Stoppers</b>

## ADDITIONAL DRIVERS & FUTURE CHALLENGES:

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- Moisture sensitive drugs increasing barrier requirements
  - Novel delivery systems
  - Emphasis on speed to market
  - Control of R&D Expenditure/resource - number of stability studies required
  - Global - Regional - Local packs
  - Anti-counterfeiting, illegal cross-border trading



**Thank you**

