Closures and containers for Dispensed Products

Container & Closure

Container may refer to:

Items used to contain, store, and transport products, such as:

Carton,Bottle,Can

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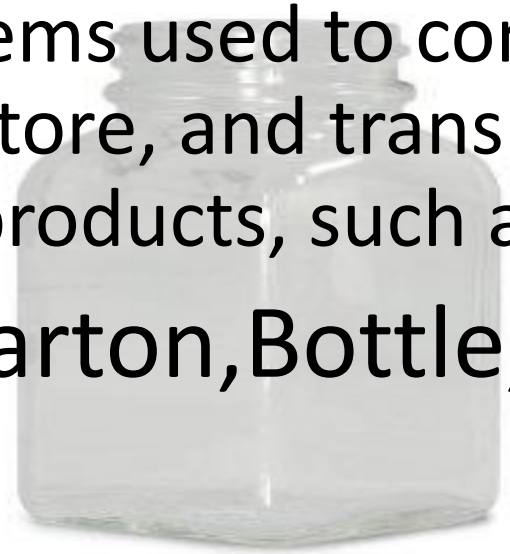


CLOSURES

ARE devices and techniques used to close or seal a *bottle, jug, jar, tube, can,* etc. **Closures can be a cap, cover, lid,** etc.

Introduction

- A container for pharmaceutical use is an article

  Which holds or is intended to contain and protect a drug and is or may be in direct contact with it.

- The closure is a part of container. The container or closure must not interact physically or chemically with the substance within in any way that would alter its quality.

Desirable Features For Containers

- Container Must Be Rigid Enough To prevent The Damage To The Contents
- Material of Container must not be Reactive to the Content packed in it
- The closure must prevent
  - Access of moisture
  - Loss of moisture for or volatile component from semisolid preparation
  - Unintentional escape of content
  - Entry of dirt other contamination like odorous vapours

Conti….

- Closure must be easily removed and replaced
- Must not be difficult to abstract the content or to empty the container
- Protection from sunlight must be given
- Medicaments or adjuncts must not be absorbed by container material nor diffuse through walls
- Must be easy to label
- Give pharmaceutically elegance appearance

TYPES OF CONTAINER

British Pharmaceutical Codex Defines 4 Types Of Container

Well closed	Air tight	Securely closed	Hermetically sealed
Container protects the contents from contamination with extraneous solids under normal condition of handling, storage and transportation. 	Containers give protection from extraneous solids, liquids and vapours and, under normal condition of handling prevents change due to efflorescence, deliquescence and evaporation. 	Air tight container with means of preventing unintentional displacement of closure. 	It is impervious to air and other gases under normal conditions of handling, storage and transport. E.g. glass ampoule sealed by fusion 

Liquid Oral Preparations

Types Liquid Oral Preparations

- Oral preparations intended to be swallowed

- Oral preparations Not intended to be swallowed

Oral liquid preparations Intended to be swallowed

- Draughts
- Elixirs
- Emulsions
- Certain types of gargle
- Oral gels
- Linctuses
- Syrups

Choice of container

❖Features

- For cheapness: It is made from lime soda glass
- It is ovoid in section but the back is flatter than the front
- free from the molded graduation
- It has a special lip that facilitates pouring.

Glass Medicine Bottle

Features CONT……..

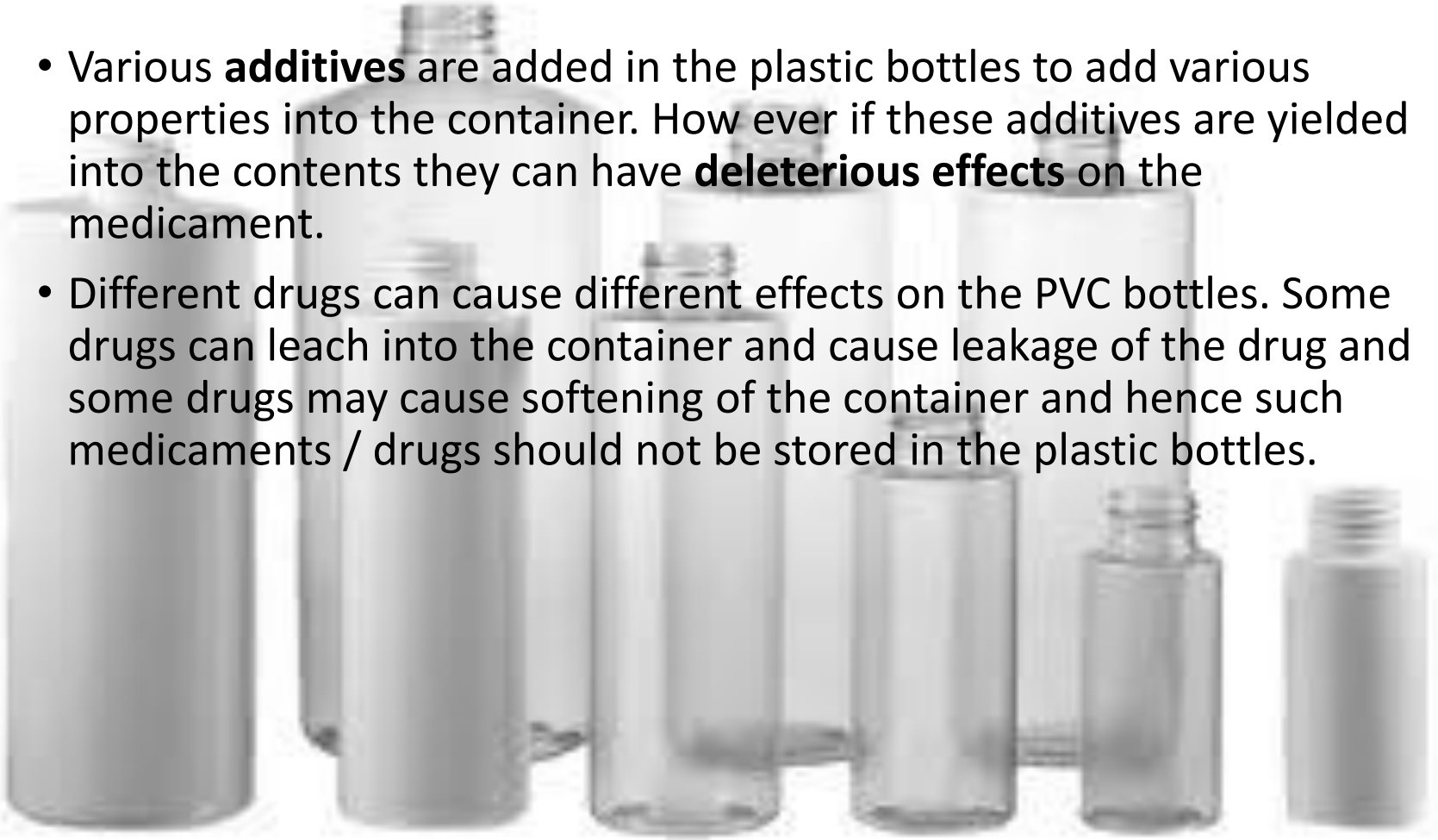
- It is colorless but when the protection from light is necessary light resistant i.e. amber color bottles
- It is available in six sizes (50, 100, 150, 200, 300 and 500ml

Types of Closure

- White Polypropylene
- Black thermosetting plastic

PRECAUTIONS

- Various **additives** are added in the plastic bottles to add various properties into the container. How ever if these additives are yielded into the contents they can have **deleterious effects** on the medicament.
- Different drugs can cause different effects on the PVC bottles. Some drugs can leach into the container and cause leakage of the drug and some drugs may cause softening of the container and hence such medicaments / drugs should not be stored in the plastic bottles.



ACTIONS OF CONTENTS ON PVC MEDICINE BOTTLES

CONTENTS	ACTIONS
CHLOROFORM, MORPHINE TINCTURE B.P.C	RAPID SOFTENING AND DISTORTION
ANISE, CLOVE AND PEPPERMINT OIL	RAPID SOFTENING AND DISTORTION
PREPARATIONS CONTAINING UNDISSOLVED CHLOROFORM, ETHER ALONE OR TOGATHER	SOFTENING EVEN WHEN THE CONC. IS LOW
BENZOIC ACID SOLUTIONS	MIGRATION INTO THE CONTAINER

Not intended to be Swallowed

- Mouthwashes
- Throat paints
- And most of the gargles
- Although these preparations are used in the mouth or throat they should not be swallowed in large amounts

Type of Container for Liquid Oral Preparations

- **Container bottles** are the **fluted or ribbed ovals**
- Ribbed ovals are closed with the plastic screw caps requiring impervious liners
- **Colorless bottles are used** unless protection from light is necessary
- A wide mouthed ribbed jar is more satisfactory for throat paints

Ribbed bottles

OTHER LIQUID PREPARATIONS

OTHER LIQUID PREPARATIONS

- For application to the skin or use in body cavities
- For Inhalation

FOR APPLICATION TO THE SKIN OR USE IN BODY CAVITIES:

- Examples include lotions , paints ear drops, nasal drops etc
- The containers used are **coloured, fluted bottles.**
- The **difference** b/w the containers used for oral purposes and those involved in external purposes is the colour. While both are fluted.

APPLICATIONS

- For viscous applications that are to be applied with brush, colured fluted wide mouthed container / jar is used.

VOLATILE DRUGS

- The closure must be air tight and the containers must be small usually about **5ml** because in case of larger bottles more loss of volatile content and hence the concentration of the drugs changes.
- The cap is usually fitted with a brush or plastic applicator.

Liquid Preparations for Application to the Skin or Use in the Body Cavities

- Collodions
- Liniments
- Lotions
- Paints
- And some solutions are applied on the skin while douches, ear drops, sprays and other solutions are used in the body cavities.

For Inhalation

- Inhalations and sprays should be packed in colorless fluted bottles.
- Because made from thin glass, must packed in boxes that give good physical protection

SEMI-SOLID PREPARATIONS

For Application To The Skin Or Mucosa

- This group includes creams, jellies , ointments, pastes etc.
- A satisfactory container should :

➢ **Prevent evaporation** of moisture or volatile constituents.

➢ **Not absorb active ingredients** or allow their diffusion into the walls of the containers. For e.g methyl salicylate and phthalate dissolve polystyrene

➢ **Do not liberate irritating or sensitizing substances into the product** for e.g. nickel and chromium esters are skin sensitizers and hence their container material should not contain these

➢ Should have **mechanical strength** and provide an effective seal

A. Collapsible metal or plastic tubes

- Creams must be prepared **with hygienic conditions** to prevent the contamination by microbes.
- A jar into which the fingers may be dipped is not ideal but **a tube is acceptable because:**

➢ **Narrow orifice**

➢ **Wastage is reduced**.

➢ When the part of preparation is removed it **is not replaced by air** and hence oxidation, hydrolysis and contamination is reduced to an extent.

how ever **this advantage is not obtainable by the plastic tubes** as they tend to return back to their shape and position.

Low density polyethene tubes exhibit suck back quality.

- **Nozzle type applicators** can be fitted. They further have a narrow orifice and hence less chances of contamination plus can be applied more carefully.
- Most collapsible tubes are made up of **aluminium, tin, lead etc**. however **aluminium is mostly used as they have better resistance to corrosion because a film of oxides**. However **mercury** solutions may dissolve this layer and hence further corrosion may occur until internal lacquer.
- Hence collapsible tube are not suitable for creams containing mercury as their preservative. And hence **cetomacrogol cream and fluocinolone** cream are preserved with **thiomersal** when dispensed in aluminium tubes.

- Aluminium is also **attacked by acids and alkalis and ethyl alcohol**.
- It also includes a **trace of iron** and if used for products containing **electrolytes especially chlorides** corrosion may take place.
- The **hydrogen evolved** may cause decomposition, bleaching of the medicaments.

Corrosion may be prevented by

- **Coating** the tube internally:

➢ **Microcrystalline waxes** may be used but **epoxy resins lacquers are better which adhere wall** and provide chemical resistance. For e.g in case of buffered creams.

➢ Including a **buffer** for e.g in case of hydrocortisone and neomycin creams a buffer is added i.e 0.1 %anhydrous disodium hydrogen phosphate and 0.02%sodium dihydrogen phosphate

- When a strong protection against air , moisture and leakage is required , the end of the **tube is sealed using pressure sensitive latex.**

B. Glass or plastic pots

- **The creams** must be free of contamination as they are to be applied on larger areas on skin and hence **dispensed in tubes.**
- The **ointments, pastes and poultices** are however applied on a **smaller scale** hence The tubes are usually avoided because they are comparatively **expensive** and it **is difficult to fill them**.
- Suitable alternatives are wide mouthed pots made up of glass or plastics and occasionally metal.
- **Screw caps are used having a liner**. For glass containers it is usually waxed paperboard and in case of plastics it is vinyl in nature.
- For many years paperboard boxes were used but later on they were prohibited

- Clear
- Either colourless or opaque white or amber coloured

GLASS POTS

- Inert
- Hygienic
- expensive

Plastics used can be

- **Low density polyethene**:

Containers are too flexible

PLASTIC POTS

- **Low impact polystyrene**

  Fracture easily and coal tar diffuses though it

- **High impact polystyrene**:

  Less brittle, good structural rigidity and satisfactory for coal tar

- **Polypropylene:**

  Can be Flexible or rigid

Example: kaolin poultice

- It is **packed in a tin** which has a **handle** and a lid
- The lid is loosened and the tin is placed in **hot water** to heat the contents to the temperature for use.
- Removal from the water is facilitated with the handle.
- The container must be airtight as the poultice contains volatile ingredients.

Solid unit dose preparation

Types of Solid unit dose preparation

A. Intended to be swallowed or sucked

B. Intended for use in body cavities

A. Intended to be swallowed or sucked

- Cachets,
- Hard and soft capsules,
- Most of Tablets and
- Pills are swallowed

Where as

- Lozenges,
- Pastilles,
- And few tablets are sucked

Features of container Solid unit dose preparation

- **Robust and unbreakable**
- Protect from fracture and crushing
- Prevent unintentional release of contents
- Prevent deformation

- **Impermeable to moisture/ oxygen/ light**

Types of container Solid unit dose preparation

Four types

- Paperboard
- Glass
- Plastics
- Aluminum

Paper Board Boxes

- Until comparatively recent, solid unit dosage forms were often packed in paper board containers. These are available in many types and sizes.
- Drums with metal or paperboard bases and press in or slip-over lids.
- Rigid boxes with lift-off is hinged lids, or with a sliding drawer
- Collapsible cartons with tuck-in end (skillets).


The Medicine Shoppe
ORIGINAL STRENGTH
ACID CONTROL
Famotidine Tablets, 10 mg
Acid Reducer
Just One Tablet
Prevents & Relieves
Heartburn Due to
Acid Indigestion
GUARANTEED
30 TABLETS
OPEN OTHER END
CONVENIENT RECLOSING TAB

Cont…..

- Cheapness and the small storage space needed for the collapsible form made these particularly popular. However because they release their contents rather easily and a careless patient may damage the flaps, they are the least satisfactory of all types.

- Nevertheless since reasonably cheap and much more reliable alternative container are available, the pharmaceutical society of Great Britain has long recommended, and the drug tariff now directs that solid oral dosage forms shall be dispensed in containers of glass rigid plastic or aluminum. The only. **exceptions are foil or blister packed tablets.**


DISPRIN ORIGINAL - fast and effective
CONTACT LINE
DISPRIN
DISPRIN
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DISPRIN
DISPRIN

Glass

- Oval or rectangular bottles or tubular vials, closed with plastic or metal screw that contain a suitable insert or, for metal caps, are internally lacquered.

- The pharmaceutical society recommends amber glass jars or vials for all tablets and capsules to prevent accidental packaging of light sensitive products in a container allowing free light transmission.


Masterfile

Plastics

- Plastic tablet containers made from polystyrene, high density polythene and poly propylene and concluded that most gave protection from moisture for short period to all but highly moisture sensitive tablets. Vials of polyvinyl chloride are also available. This polymer provides a much better barrier to water vapor than polystyrene and less expensive than polypropylene.

- British standards also covers tablet containers and specifies a test for water vapor permeablility and test for mechanical, strength, and light protection. The pharmaceutical society recommends that when plastic containers are used for tablets and capsules they should be amber or opaque.

- **Different plastics** are used but the problem occurs that one type of plastic does not give the complete satisfactory result.
- **Thin walled polystyrene and polypropylene** gives good protection against water because their moisture permeability is low but are too flexible to prevent the crush resistance. If thickness of walls is increased than price is effected.
- **PVC less water permeable than polystyrene and less expensive than polypropylene.**

- **Press in closures** exert a pressure on the mouth of the container and hence create a dust proof seal.
- The pharmaceutical society recommends that when plastic containers are used they should be amber or opaque


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Conti…

- In plastic PRESS-IN and SLIP-OVER closures are usual. They exert slight pressure on the mouth of the container and so maintain a substantially dust-proof seal.

PRESS-IN

SLIP-OVER

Aluminium

- The aluminium containers used in pharmacy are made by impact extrusion, a process that avoids a seam in the side of tin. They can be reliably sealed because they accept a variety of closures, e.g. an aluminum screw cap with a resilient wad, or slip-over or press- in, plastic caps.
- They are **popular** in patients because they are **unbreakable** and hence can be easily carried in pockets/hand bags and there is less chance of unintentional leakage of content.


CYBER
TECHNOLOGY LIMITED
Pill Box

Advantages of Aluminium Containers

- They are unbreakable; this is especially advantageous in packaging of large numbers of tablets.
- They are light in weight and this reduces transport costs.
- They require less storage space than alternative containers.
- Mechanical filling is simple.
- The label can be printed directly on the container.
- They provide protection from light.
- They are also liked by patients because they cannot be broken when carried in the pockets or handbags and there is little risk of content escaping or being damage by crushing.

Minor disadvantages include

- Sometimes the screw caps are difficult to engage and gritty in action. In addition the edges of tin can are really sharp.

- Unless lacquered internally, which adds to cost, they leave gray marks on certain tablets (particularly sugar coated tablets) due to abrasive rubbing against the wall. They should be lined with paper before use

ADVANTAGES

- **Robust** and unbreakable
- **Light in weight** and hence reduces transport cost
- **Less storage space** as compared to other alternative containers
- Mechanical f**illing is simple**
- **Label** can be printed directly on the container
- Provide **protection from light**

DISADVANTAGES

- Screw caps are sometimes gritty in action and the **edges may be sharp**
- Unless lacquered, they **leave grey marks** on the tablets and hence should be lined with paper.
- **expensive**

B. Intended to Use in Body Cavities

Examples are

- Pessaries
- Suppositories
- Solution Tablets

Compressed Pessaries and Suppositories

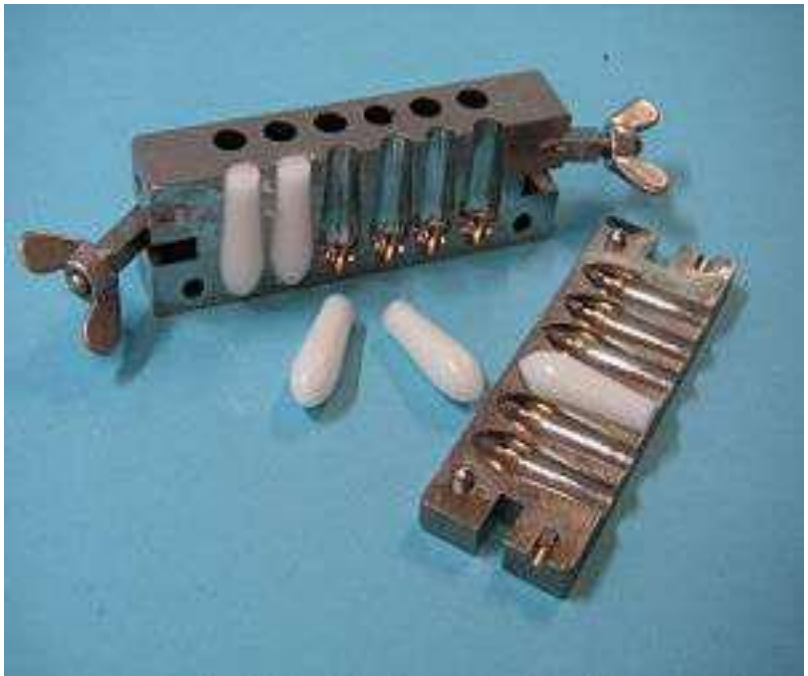
They are dispensed in the type of container used for tablets with appropriate labeling to indicate that **contents should not be taken in the mouth.**

Molded Pessaries and Suppositories

- They are dispensed in the shallow partitioned, rigid, paperboard boxes, lined with waxed or suitably treated paper, or in plastic or metal containers.
- Sometimes the manufactures make suppositories by pouring the molten base into a strip of disposable plastic moulds in which the products are then marketed. This technique has advantage that the finished products are not touched by hand.
- Unplasticised polyvinyl chloride and low density polythene have been used for moulds.

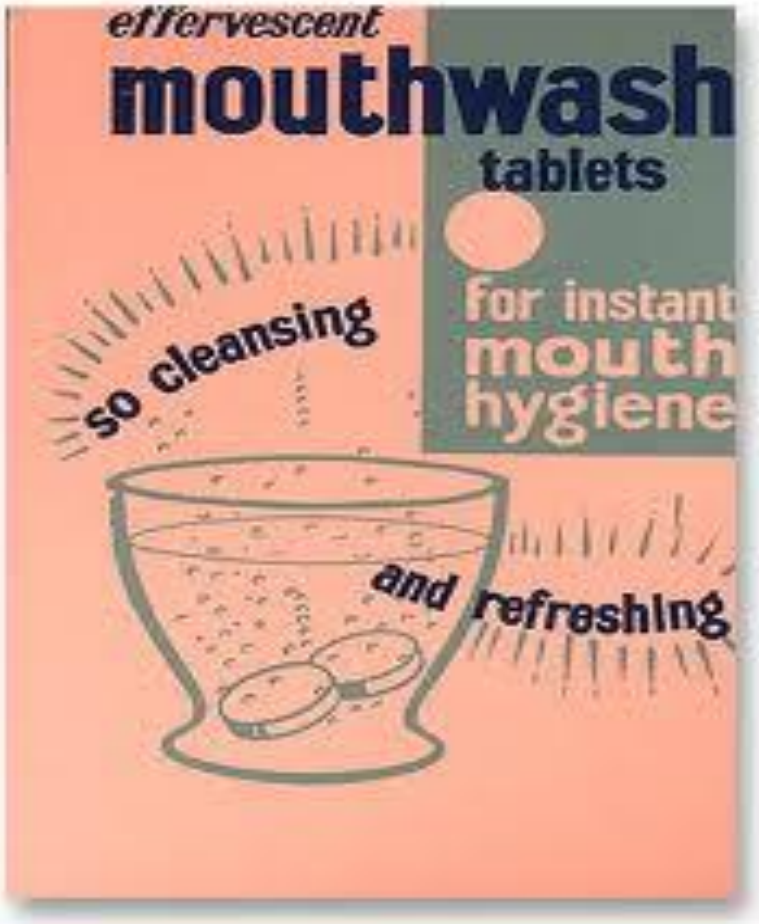
Conti…

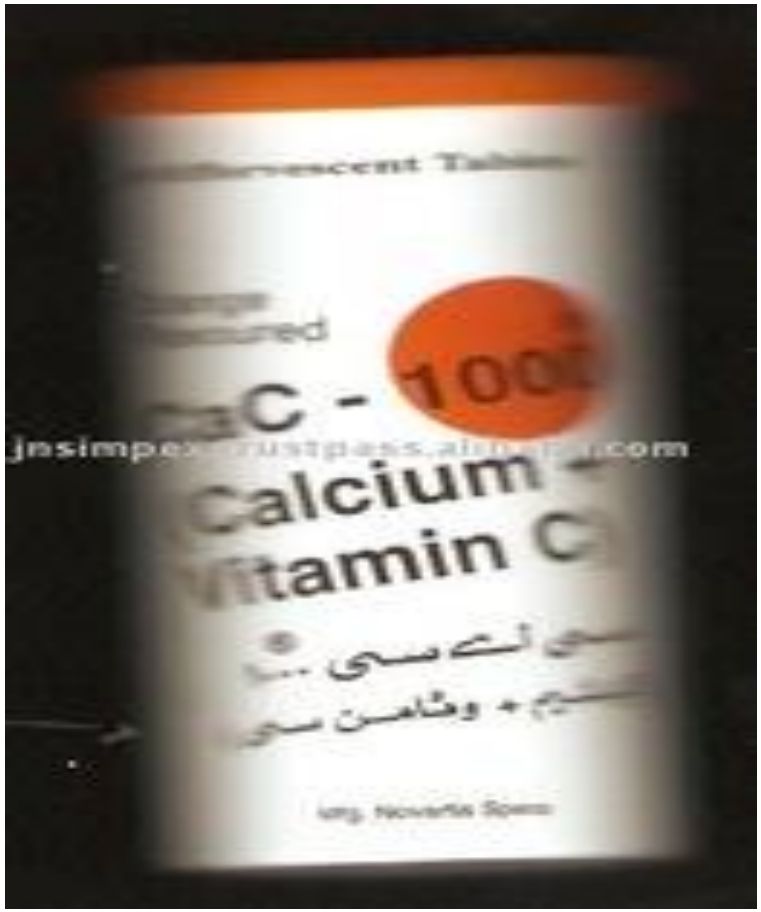
Those containing volatile or hygroscopic ingredients, or intended for use in tropical or subtropical countries, should be wrapped singly in waxed or suitably treated paper, or metal foil, or enclosed in a form of strip packing.



Some Solution Tablets

- e.g; mouthwash tablets, do not contain poisons and are packed in the way as ordinary tablets.
- But others contain poisonous ingredients e.g; tablets for making antiseptic or disinfectant solutions, and their containers should be distinguishable by touch.
- Since, as would be expected, solution tablets deteriorate if exposed to moisture so air tightness is essential.


effervescent
mouthwash
tablets
for instant
mouth
hygiene
so cleansing
and refreshing


Calcium
Vitamin

CHILD RESISTANT CCONTAINERS

Child resistant containers

- Introduction
- Wear
- Susceptibility To Opening By mouth
- Testing Panels
- Method
- Interpretation

Introduction

- These have ben produced in response to demands for greater protection of children against accidental poisoning
- They take advantage of the greater strength of adults and generally incorporate a locking mechanism e.g PALM & TURN TABLET

- Gartside (1971) showed that after palm & turn containers had been opened and closed, rather roughly, fifty times, they could be opened within 5 minutes by children between 2 & 5 years old.
- Because the points of the locking wedges had been worn away.

Susceptibility To Opening By Mouth

- Use of jaws to break off the lid.
- By preventing the child from getting its teeth under the lip of the lid e.g MEDISAFE TYPE.

Strip & Blister Packs

- Difficult to tear
- Strong but soft & pliable
- Impermeable to saliva
- Completely sealed
- Easily separated into individual units

CLOSURES

CLOSURE

- Closures are devices and techniques used to close or seal a bottle, jug, jar, tube, can, etc
- Closures can be a cap, cover, lid, plug, etc

- The closure is normally the most critical component of a container
- An effective closure must prevent the contents from escaping and allow no substance to enter the container

FUNCTION OF A CLOSURE

- Provide a totally hermetic seal
- Provide an effective seal which is acceptable to the products
- Provide an effective microbiological seal

CHARACTERISTICS OF CLOSURE

- It should be resistant and compatible with the product
- If closure is of re closable type, it should be readily operable and should be re-sealed effectively
- It should be capable of high speed application
- It should be decorative and of a shape that blends with the main containers

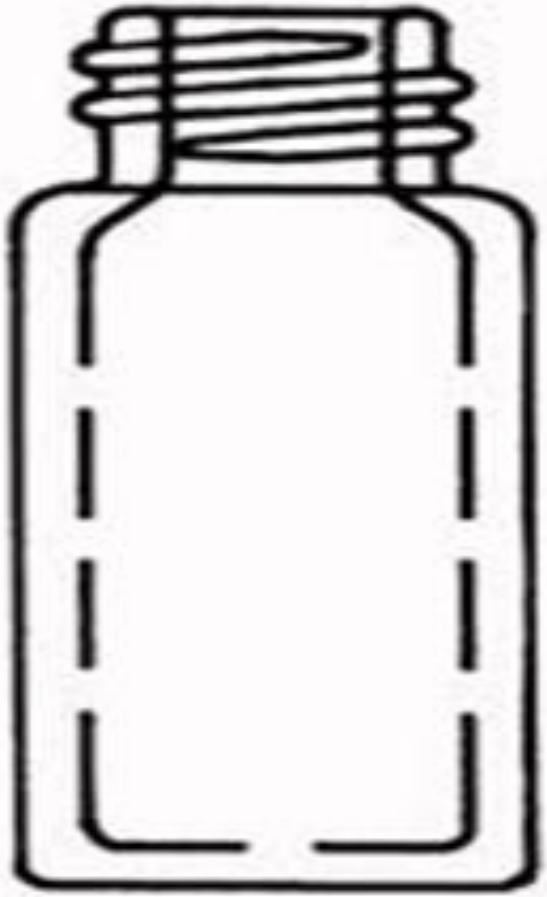
TYPES OF CLOSURES

- Closures are available in five basic designs
    1. Screw-on, threaded, or lug
    2. Crimp-on (crowns)
    3. Press-on (snap)
    4. Roll-on
    5. Friction.

- Many variations of these basic types exist, including
  - Tamperproof
  - Child resistant
  - Dispenser applicators

THREADED SCREW CAP

- The screw cap provides physical and chemical protection to content being sealed.
- The screw cap is commonly made of metal or plastic
- The metal is usually tinplate or aluminum, and in pla both thermoplastic and thermosetting materials are



LUG CAP

- The lug cap is similar to the threaded screw cap and operates on the same principle
- It is simply an interrupted thread on the glass finish, instead of a continuous thread
- Unlike the threaded closure, it requires only a quarter turn
- The cap is widely used in the food industry

CROWN CAPS

- This style of cap is commonly used as a crimped closure for beverage bottles and has remained essentially unchanged for more than 50 years

ROLL-ON CLOSURES

- The aluminum roll-on cap can be sealed securely, opened easily, and resealed effectively
- It finds wide application in the packaging of food, beverages, chemicals, and pharmaceuticals
- The roll-on closure requires a material that is easy to form, such as aluminum or other light-gauge metal


On Duty
24

PILFER PROOF CLOSURES

- The pilfer proof closure is similar to the standard roll-on closure except that it has a greater skirt length
- When the pilfer proof closure is removed, the bridges break, and the bank remains in place on the neck of the container
- The torque is necessary to remove the cap.


MPORTED

SNAP ON

- Some closures snap on. For opening, the top is designed to pry off or, break off, or have a built in dispenser.

FRICTION FIT

- Some containers have a loose lid for a closure. A friction fit requires some force to close and open, providing additional security. Paint cans often have a friction fit plug.

TAMPER RESISTANT

Resistance to tampering is required for some types of products.

DISPENSING

- A wide variety of convenience dispensing features can be built in to closures. Spray bottles and cans with aerosol spray have special closure requirements.

CHILD-RESISTANT

- Child-resistant packaging or C-R packaging has special closures designed to reduce the risk of children ingesting dangerous items **Tamper-evident**

CLOSURE LINES

- A liner may be defined as any material that is inserted in a cap to effect a seal between the closure and the container.
- Liners are usually made of a resilient backing and a facing material. The backing material must be soft enough to take up any irregularities in the sealing surface and elastic enough to recover some of its original shape when removed and replaced.

FACTORS IN SELECTING A LINER

- The most important consideration is that the liner should be chemically inert with its product.

- Gas and vapour transmission rates are usually relative and depend chiefly on the shelf life required for the product.

- **Homogenous Liner:**

  These one piece liners are available as a disk or as a ring of rubber and plastic.

  - Expensive
  - Complicated to apply
  - Widely used in pharmaceuticals
  - Uniform properties
  - Can withstand high-temperature sterilization

- **Heterogenous liner or composite liner:**

  They are composed of layers of different materials.

  - It consists of two parts
  - A facing and a backing

COMPOSITION OF CLOSURE

- Closures are made of
  - Rubber
  - plastics
  - Glass
  - Metal
  - Cork

PLASTIC CLOSURES

- The two basic types of plastic generally used for closures are
  - Thermosetting
  - Thermoplastic resins
  - Urea
  - phenols

RUBBER CLOSURES

- Rubber is used in the pharmaceutical industry to make closures, cap liners and bulbs for dropper assemblies.
- The rubber stopper is used primarily for multiple dose vials and disposable syringes.
- Rubber closures for containers for aqueous parenteral
- Preparations for powders and for freeze-dried powders

GLASS CLOSURE

METAL CLOSURE

CORK


Thank you.