INDUSTRIAL PHARMACY - I

UNIT 5 NOTES

COSMETICS

- LIPSTICKS, SHAMPOOS
- COLD CREAM, VANISHING CREAM
- TOOTHPASTE, HAIR DYES, SUNSCREEN

PHARMACEUTICAL AEROSOLS

- PARTS OF AEROSOLS
- MANUFACTURING OF AEROSOLS
- EVALUATION OF AEROSOLS

PACKAGING MATERIALS

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IMPERFECT PHARMACY

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Cosmetics

- Cosmetic is a Greek word term that means 'to Decorate'
- It refers to products that are applied to different part of the body, such as the skin, hair, nails, lips & mucous membranes.
- Cosmetic products can alter the body's appearance & improve its scent.
- They also help protect the skin and maintain its health.
- Overall, cosmetics are external products used on the outside of the body.
- Examples: Powder, Lotions, Skin creams, Deodrant etc.

Uses Of Cosmetics

- They cleanse, moisturise & enhance the body's appeal.
- Sunscreen enhance body appearance by protecting skin from UV rays.
- Beauty products can help treat acne, wrinkles & dark circles.
- It's help with skin infections.

Lipsticks

- Lipsticks are mix of colour & a base made from oils, fat and waxes, often with added scents & flavours.
- They are shaped into sticks to give a shiny look & colour when applied to the lips.
- Lipsticks also make lips took moist & help cover any imperfections.

IDEAL CHARACTERISTICS OF LIPSTICKS

- The product should deliver full colour coverage & long-lasting shine, maintaining its shade & intensity.
- The product should adhere well to this lips without greasiness & allow for easy colour application with good shear thinning properties.
- It should be smear-proof, maintain plasticity & quality during storage & dry smoothly.
- The stick must endure temperature upto 55°C without drying, or breaking & have a pleasant scent.
- It must safe for lips & should not cause my swelling or moisture on the lips.

FORMULATION OF LIPSTICKS

COMPOSITION

INGREDIENTS	EXAMPLES
The solid component waxes :	
- Hydrocarbon Waxes	White Beeswax
- The Mineral Waxes	Ozokerite wax, ceresin wax
- Hard Waxes	Carnauba wax, Candellila wax
- Microcrystalline Waxes	
The liquid Component	Mineral Oil, Vegetable Oil, Castor oil
The Softening Agent	Anhydrous Lanolin, Lecithin
The Colouring Agent	Carmine, Pigmented stain
Pearlescent Pigment	Guanine Crystal
Opacifying Agent	Titanium dioxide
Perfumes	Rose Oil, Cinnamon Oil
Miscellaneous Agents :	
- Preservative	Parabenes
- Antioxidant	BHA, BHT
- Flavouring Agent	Cinnamon Oil, Spearmint oil etc.

① The Solid Components / Waxes

- The main solid part of lipstick is the waxes, that helps shape, stabilize & give it a smooth texture.
- Waxes are crucial for maintaining lipstick's shape at room temperature & ensuring smooth application, preventing crumbling or melting.
- The main solid parts of the formulating are mainly natural waxes, which can be grouped like this.

ⓐ Hydrocarbon Waxes:

- White Bees Wax - A common wax & serves as the oily base in lipstick formulation.
- Use - Essentail for capturing castor oil, offering strong plastic qualities for easy shaping & commonly used as stiffening agent.

ⓑ Mineral Waxes:

- Ozokerite wax - It is a natural amorphous hydrocarbon from bituminas materials that creates a smooth crystalline wax gel, maximizing oil matrix retention, easily transformed into required shapes.

ⓒ Hard Waxes:

- These waxes are mainly determine the shape & firmness of the lipsticks.
- Use - Increase the stick's rigidity to faciliate size reduction.

ⓓ Microcrystalline Waxes:

- They have long-chain hydrocarbons with melting points ranging from 60°C to 120°C.
- Use - Keep the lipsticks crystal shape intact.

② THE LIQUID COMPONENT

- These mainly consist of oils like mineral oils, vegetable oils, castor oil & Alcohol etc.

ⓐ **Mineral Oil :** It consist of Petroleum Hydrocarbons in light or heavy mineral oil forms.

ⓑ **Vegetable Oil :** Sesame oil & Olive oils can be used, but their low solubility with staining dyes limits their usage.

ⓒ **Castor Oil :** Ricinus Communis, from the Castor plant, is an ideal lipstick base due to its thick texture, solubility, oxidation stability & ease of mixing.

③ THE SOFTENING AGENT

- The soften lipstick for easier application. The most common softening agents are :

ⓐ **Lanolin :** Also known as hydrous wool fat, it improves film coverage but contains 25-30% water, leading to sticky & greasy products.

ⓑ **Cocoa Butter :** Once popular as a moisturizer, its use has declined due to spoilage & surface crystals, leading to a shiny, oily appearance on lips.

ⓒ **Petrolatum :** It is a tasteless, odorless hydrocarbon from oil, primarily used to enhance shine.

(d) **LECITHIN:** It is used to small amounts to enhance smoothness & ease of application.

(e) **Anhydrous Lanolin:** It is applied at a low concentration of around 0.25% to provide softness, moisture & protection for the lips.

(4) COLOURING AGENT

- Lips can be coloured by either applying a dye to stain them or by layering on colour.

(a) **Soluble Colours:** They are colouring agents that dissolve in oil, water & Alcohol.

(b) **Insoluble Colours:** They are pigments that can be either organic or inorganic & dont dissolve.

(5) PEARLSCENT PIGMENTS

- They create a shiny, pearl-like look using natural pearlscent pigments from fish scales or bismuth oxychloride, blended with 70% castor oil for glass.

(6) OPACYFYING AGENT

- It makes lipstick opaque or white & alters the pigments main colour.

⑦ PERFUMES

- Floral scents like roses, cinnamon and lavender oils can be added to lipsticks, along with family-fruity flavours to mask the waxy smell.

PREPARATION OF LIPSTICK

- The preparation of lipstick involves several key steps including melting, mixing, molding & finishing.

MELTING

- First the raw materials like solid fats & waxy materials are melted in separate stainless steel containers.
- Gradually add oils & liquid fats to the melted wax mixture while stirring.

MIXING

- Mix the colour pigments with a small amounts of the oil to form a smooth paste.
- The mixture is then passed through roller mill for grindings the pigments for uniform dispersion.
- Slowly add the pigment mixture to the melted base while continuously stirring to avoid clumping.

MOLDING

- Pour the hot mixture into pre-heated lipstick molds to prevent cracking or air bubbles.
- Allow the molds to cool & set at room temperature or in a refrigrator for fresh - faster solidification.

FINISHING

- Remove the lipstick from the molds carefully.
- Inspects for imperfections & polish the surface if needed.
- Fit the lipstick into cases or tubes.

Evaluation Of Lipsticks

- Evaluation studies assess the efficiency, stability & consistency of the final product.
- Lipsticks test may include :

① Melting Point Determination Test

- Finding the melting point helps to understand how to store the product.
- The lipstick base should start at 60° to 65°C to avoid friction or dryness during application.
- The techniques used to test it Capillary Tube Method.

② Breaking Load Point Test

- This test measures lipstick strength & hardness by placing it flat & adding weights 1 inch from the base.
- The breaking load point is where the lipsticks begins to break, tested at around 25°C.

③ Storage Stability

- This test is conducted to assess how stable the product is while being stored.

④ Test For Rancidity

- The oxidation of oils like castor oils can cause unpleasant smells, flavours & a sticky nature.

SHAMPOO

- Shampoo is generally a liquid or semi-liquid formulation, designed for cleansing the hair & scalp.
- It principle function is to clean the scalp.
- It also makes the hair shiny & good looking.
- It is a critical segment of cosmetic & pharmaceutical industries, developed to meet both financial & therapeutic needs.
- It is used by both male & Female.

IDEAL CHARACTERISTICS OF SHAMPOO

- It should have good spreading properties.
- It should produce sufficient lather after application.
- It shouldn't form any kind of film on scalp.
- It should rinse out completely after washing.
- It should faciliate ease of combing after shampooing.
- After drying, hair should not give rough appearance.
- It should provide luster to the hair.
- It shouldn't support any microbial growth.
- It should be stable.
- It should be economical.
- It should produce good odour.
- It shouldn't produce any kind of irritation or itching to the scalp.

Types Of Shampoo

- Shampoo can be classified into various types based on their purpose, ingredients & target audience.

① Based On Functionally

- Cleansing Shampoos : Designed for everyday use to remove dirt, oil & buildup from hair & scalp.
- Clarifying Shampoos : They are deep cleansing formulas that remove that residue from styling products or hard water & used ocassionally.
- Conditioning shampoo : Contain conditioning agents to moisturize & soften hair, reducing the need for separate conditioners.

② Based On Therapeutic Agents

- Anti - Dandruff Shampoo : They contain zinc punithione, ketoconazole or selenium sulfide for treating dandruff.
- Anti - Hairfall Shampoo : It can contain biotin or minoxidil to prevent hair loss.

③ Based On Special Features

- Sulfate free Shampoo: They are mild formulations free from harsh surfactants like Sodium Lauryl Sulphate ided for sensitive or damaged hair.

- pH Balanced Shampoo: Designed to match the scalp's natural pH (5.5) to prevent irritation.

- Organic Natural Shampoo: Made with plant based or herbed ingredient free from synthetic chemicals.

④ Based On Form

- Liquid Shampoo: The most common type easy to use & widely available.

- Dry Shampoo: Powder or Aerosol sprays that absorb oil without need of water.

- Solid / Shampoo Bars: Compact & Eco-friendly, made with minimal packaging.

- Cream Based Shampoo: Richer formulation for added hydration.

FORMULATIONS

These ingredients used in the formulation of Shampoos are enlisted here:

INGREDIENTS	EXAMPLES
Surfactants	
Anionic Solutions	Alkyl Sulphate & Alkyl Ether Sulphate
Non-ionic solutions	Alkalonamides
Cationic Solutions	Alkyl amines & Alkyl Imidazoles
Amphotenic Solutions	Acyl Amino Acids
Foam Booster	Monoethanolamides, Lauramides DEA & Cocamide DEA
Germicide & Anti-Dandruff Agent	Benzalknonium chloride, Cetrimide, Selenium sulphide & cadmium sulphide
Conditioning Agent	Lanolin, egg & Amino acids
Thickners	Alginates, Polivinyl Alcohol & Methyl Cellulose
Perfuming Agents	Herbal Fruits & Floral Fragrance
Colour	FD & C Dye
Preservatives	P-Hydroxyl Benzoic Acid & Phenyl Mercuric nitrate.

The following raw materials are used in the formulation of shampoo :

① SURFACTANTS

- These are agents used to produce foam & clean the scalp. They are of four types :

- **Anionic Surfactants :** These have good foaming property, hence are the principle surfactant & the main ingedient of shampoos.
- **Non - ionic Surfactants :** These are secondary surfactants, they are used to produce foam because they have less foaming power ; however they are used as viscosity inducers, emulsions stabilizers & opacifiers.
- **Cationic Surfactants :** These contain positive charge, they are considered as both principle & secondary surfactants as they have a good foaming & cleaning properties but are also toxic to eyes (thus used in low concentrations).
- **Amphoteric Surfactants :** These posses both cationic & anionic charges. They are used as secondary surfactants as they produce mild actions, are compatible with other surfactants, & exhibit excellent hair conditioning property.

② FOAM BOOSTERS

- These agents, e.g. fatty acid alkanolamides & amine oxides, are used to stabilise or strengthen the foam produced by the surfactants.
- They make the foam dense so that they remain for a long duration.

③ Germicide And Anti-Dandruff Agents

- These agents prevents the microbial growth on the scalp & removes dandruff.

④ Conditioning Agent

- These agents, e.g. Lanolin, oils, herbal extracts, eggs, amino acids, etc. improve the hair condition.
- They reduce the electric charges on the hair, thus making them shiny & easily manageable.
- They also exhibit a bactericidal effect.
- Amino acids are most commonly used as they provide an efficient conditioning effect.

⑤ Thickening Agent

- These agents, e.g. Methyl Cellulose, Alginates polyvinyl alcohol, Polyethylene glycol etc. make the preparation viscous to facilliate ease of handling & prevent wastage during application.

⑥ Perfumes

- These agents, e.g. Herbal fruits etc. are obtained from natural sources such as flowers, fruits, herbs, etc.
- They mask the understable odour of other ingredients & impart a good fragrance to the Shampoo.

⑦ Preservatives

- These agents, eg. P-hydroxybenzoic Acid & Phenyl Mercuric Acetate, prevent microbial growth & maintain the product stability for a desired time period.
- Since shampoo is a wet preparation, it provides a media for various micro-organisms & should be added with appropriate preparations.

⑧ Colours

- These agents impart a pleasant appearance to the shampoos.
- They should be water-soluble & shouldn't impart any colour to hair & scalp.

Method Of Preparation

- Heat Purified water to 70°-80°C in a mixing tank.
- Add water soluble ingredients like thickners & preservatives and stir until dissolved.
- Gradually add surfactants to the water phases while stirring to avoid foaming.
- Mix until a homogenous solution is achieved.
- If required Heat all soluble ingredients & then slowly incorporate the oil phase into the water phase.
- Take remaining quantity of water & add hexamethyl cellulose, glycerine, perfume & other ingredients.
- Mix all the substances to form a uniform shampoo.

COLD CREAM

- These water-in-oil emulsions provide a cooling sensation as the water evaporates, moisturizing without clogging the skin, hence the name "creams".

FORMULA	QUANTITY FOR 100g
White Beeswax (Emollient)	20g
Mineral Oil (Lubricant)	50g
Distilled Water (Vehicle)	28.8g
Borax (Buffer)	0.7g
Perfume (Odour)	0.5g
Colour	-
Water	-

METHOD OF PREPARATION

- Beeswax is heated in water bath to about 70°C, then mixed with mineral oil, it is first mixture.
- Heat water about 70°C in a separate container & mix in borax until dissolved, it is second mixture.
- Borax mixture slowly added into first mixture.
- In the last add perfume to the formulation.

VANISHING CREAM

- Vanishing cream are oil-based emulsions that form a thin, invisible layer on the skin, helping powder adhere better.

PROPERTIES OF VANISHING CREAM

- It should have a high melting point & be pure white.
- It should've a mild smell & lower iodine content.

PREPARATION METHOD OF VANISHING CREAM

- Stearic acid is heated in a water bath, while potassium hydroxide is mixed with water & glycerin.
- Blend is heated to about 75°C, forming the water phase.
- Gradually mix the liquid phase into the melted stearic acid while stirring.
- Perfume is added at 40°C.

TOOTHPASTE

Toothpaste clean, stains & freshen breath using gentle abrasives & flavours, making them the most common dental products.

FORMULATION OF TOOTHPASTE

INGREDIENTS	EXAMPLES
Agents responsible for cleansing agent: (i) Polishing agent / Abrasive agents	i) Precipitated Calcium Carbonate ii) Phosphates of Calcium iii) Dental graded silica / polymers of silica i) Trihydrated Alumina
(ii) Foaming Agents / Surfactants	ii) Sodium Lauryl Sulphate ($RASO_3Na$) iii) Sodium Lauryl Sarcosinate
Agents responsible for the formation of toothpastes: (i) Humectants	i) Sorbitol 70 ii) Glycerine iii) Propylene glycol
(ii) Ceiling Agents / Binding agents	i) Sodium Carboxyl Methyl Cellulose (SCMC) ii) Cellulose ethers
Agents responsible for improving palatability: (i) Sweetening Agents	i) Sodium saccharin ii) Chloroform
(ii) Flavouring Agents	i) Cinnamon bark ii) Spearmint Oil

Miscellaneous Agent

i) Colouring Agents
ii) Whitening Agents
iii) Preservatives
iv) Therapeutic Agents

The ingredients used to make toothpastes include :

① Polishing Or Abrasive Agents

- These agents clean teeth & remove food particle, used in concentrations of 20 - 50 %.
- Ex - Precipitated Calcium Carbonate etc.

② Humectants

- These agents cleen teeth & reduce moisture loss to prevent quick drying of teeth & enhance flaxibility, included at 20 - 40 %. concentration.
- Ex - Sorbitol 70, Glycerine etc.

③ Ceiling Or Binding Agents

- It creates a smooth paste by blending solids & liquids, ensuring consistency & enhancing thickness.
- Ex - Carboxy Methyl Cellulose (CMC), Sodium CMC etc.

④ Sweetening Agents

- Agents like Saccharin sodium, Chloroform, Aspartame, Cyclamates & Potassium acesulfame enhance sweetness & mask bitter flavours, improving oral aceptability.

⑤ Flavouring Agents

- These agents include edible volatile oils, primarily, spearmint & pipermint along with optional ingredients like thymol, anethole, eucathol, aniseed oil & wintergreen oil, used at 0.5% - 1.5% concentrations, making them the formulations most experience component.

⑥ Colouring Agents

- These agents, permitted at concentrations below 0.01% under the EEC cosmetics directive, can be blended into a while creamy base to enhance consumer appeal & drive purchases.

⑦ Whitening Agents

- Agents like Titanium dioxide (TiO_2) should be added to enhance the products whiteness & brightness.

⑧ Preservatives

- These agents enhance product quality & shelf-life, with a 5% Methyl Paraben & 0.02% Propyl Paraben blend being the most effective, Sodium Benzoate is avoided due to incompatability.

⑨ Therapeutic Agents

- These agents provide additional benefits beyond standard cleansing.
  Ex - Tetra Sodium pyrosulfate, Disodium dihydrophosphate etc.

Preparation Of Toothpaste

① Dry Gum Method

- In this method, all solid components, like the abrasive & binding agents, are mixed in a dry mixer, excluding surfactants.
- The mixer may use slow - spinning blade to gradually add liquids, like humectants & water, to the dry mixture.
- The mixing continuous until a paste is created.
- The other ingredients, such as surfactants & flavouring agents, are mixed into the smooth paste while under vaccum.

② Wet Gum Method

- All the liquid parts are combined to create liquid phase.
- The binding agent is mixed with the liquid phase while stiming evenly to create mucilage.
- The solid ingredients, excluding surfactants, are gradually mixed into the mucilage with an agitation mixer to form a smooth paste.
- Leftover ingredients like surfactants, flavouring, & colouring agents are added to the smooth paste under vaccum.

HAIR DYES

- Hair dyes are chemical products used to change the colour of hair.
- These days are formulated to contain various active ingredients that alter the natural pigment of hair.

IDEAL PROPERTIES

- It should be stable.
- They should colour the hair evenly.
- The shaft of hair must not damaged.
- They should not to lead to loss of natural shine of hair.
- The natural moisture of hair must not be lost.
- It should be not irritant.
- It must be non-toxic.

TYPES OF HAIR DYES

1. Temporary Hair Dyes
2. Semi-Permanent Hair Dyes
3. Permanent Hair Dyes
4. Natural Dyes

1. TEMPORARY HAIR DYES

- It only last 1-2 washes.
- It only coat the hair shaft but do not peneterate the hair cutide.

② SEMI - PERMANENT HAIR DYES

- It last 6-8 washes.
- They wouldn't peneterate deeply into the hair & typically last through several washes.

③ PERMANENT HAIR DYES

- They last until hair growth out.
- They involve a chemical reaction that permanently alters the hair structures.

④ NATURAL DYES

- They uses plant -based ingredients like henna, indigo, coffee.
- They do not contain any synthetic ingredients.

METHOD OF PREPARATION

- Obtain the neccessary raw materials (Plant materials, Chemicals, etc.)
- Preparing the starting materials.
- Carry out the specific chemical reactions or extraction process.
- Isolate & purify the dye from any impurities or byproducts.
- Formulate the into a usable form (e.g. Powder, Liquid, Paste).

SUNSCREENS

- Sunscreen are product that absorb or reflect some of UV rays on the skin (exposed to sunlight), thus they provide protection against sunburns.
- They are available in the form of lotions, sprays, gels or creams.
- They are also added in the skin lightening products because light skin is more suspectible to sun damage the darker skin.
- Many sunscreens on the other hand are added with tanning powder to help the skin to darken or tan.

IDEAL PROPERTIES

- It should be non-toxic & non-irritant.
- It should be natural.
- It should be stable to heat, light & perspiration.
- It should absob UV rays over the range of 200 - 320 nm.
- It shouldn't get rapidly absorbed.
- It should be readily soluble in suitable vehicles.

INGREDIENTS

- Organic chemical compounds that Absorb UV light.
- Inorganic particulates, eg. Titanium dioxide, Zinc oxide or a combination of both, that reflect, scatter & absorb UV light.

FORMULATIONS

Some example of common sunscreens preparations, their formulations & method of preparation are given below :

SUNSCREEN LOTION (SPF 25)

FORMULA	% W/W
Phase A	
Demethicone	1·50
Wheatgerm oil	3·00
Octyl Palmitate	4·50
Isohexadecane	6·00
Cetyl dimethicone Copolyol	2·00
Cyclomethicone Aluminium / Magnesium Hydroxide Stearate	10·00
Candellila wax	1·0
Phase B	
Sodium Chloride (NaCl)	0·50
Water, Pure	51·30
Phase C	
Titanium Dioxide [and] 12-15 Alkyl Benzoate	20·00

METHOD

- Phase A & B are heated separately at 75°C temperature.
- Phase C is heated at more than 60°C temperature.
- The heated Phase C is allowed to cool up to 45°C temperature & added to the mixture of Phase A & B with continuous stirring to form a homogeneous system.

PHARMACEUTICALS AEROSOLS

- Aerosols are pressurized products that release active ingredients when activated.
- This is used for applying treatment to burns, small cuts, infections, & different skin conditions.
- Aerosol products release their contents as a fine mist, spray, continuous stream or foam.
- Pharmaceutical Aerosols deliver medication directly to the lungs for treating conditions like Asthma, COPD, Cystic fibrosis etc.

ADVANTAGES OF AEROSOLS

- A dose can be removed without impacting the rest, which is essential for delivering sterile forms like saline products aerosols for wound cleaning.
- Oxygen - and Moisture - sensitive medicines remain stable due to adequate protection.
- A clean dose of medication is provided, ensuring it remains uncontaminated.
- It has temper - proof closing system.
- A pressure package is simple & easy to use.
- Aerosols can be applied both overall & specific uses.

Disadvange Of Aerosols

- It's an expensive & disposing of empty aerosols cans is difficult.
- Their restrictions mainly stem from the highly flammable fuels they use.
- Due to trace metals found, that why sometimes drugs are contaminated.
- In MDIs, it is important to coordinate the valve activation with inhaling.
- Topical application cools quickly, potentially harming the injured skin further.

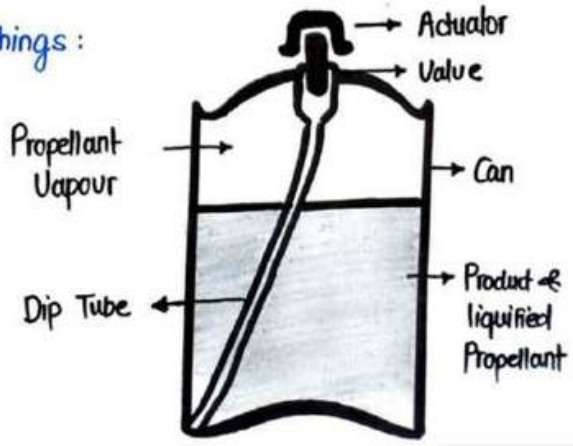
Components Of Aerosols

① Containers

- Aerosols containers must withstand pressures of 140 - 180 psig at 130°f & typically cosist of a shell, valve, diptube & pressurized liquified - gas, propellant, which is combined with the liquid product.
- Container have two types:
  i) Metal
  ii) Glass

ⓘ Metal: Metals have some types of things:

ⓐ Tin - Plated steel
ⓑ Tin - free steel
ⓒ Aluminium
ⓓ Stainless steel



@ Tin Plated Steel Containers

- These are steel containers coated with tin on both sides, with tin thickness indicated by numbers like #25, #50 & #100.
- Their size is measured by diameter & hiegth.

ⓑ Tin - free Steel Containers

- TFS or electrolytic chromium / Chromium oxide coated steel, consists of a mild steel base coated with chromium & chromium oxide, providing corrosion protection before shaping or processing.

© Aluminium Containers

- These lightweight containers are less reactive, reducing compatibility issues & enhancing corrosion resistance.
- Coatings like phenolic, vinyl or epoxy resins further improve this resistance, while anodization creates a stable aluminium oxide layer an aluminium containers.

ⓓ Stainless Steel Containers

- These smaller, durable containers requires no internal coating & can handle various materials, making them ideal for inhalation aerosols.

② Glass Containers

- Glass containers may have a plastic coating, either fully attached or vented, which prevents breakage, aids indentification, provides UV protection, absorb shocks, reduces compatibility issues, & resists corrosion.

VALVES

An aerosols valve controls the flow of liquid or gas from a container & aims to dispense the contents into a fine mist upon release.

TYPES OF VALVE

① CONTINUOUS SPRAYING VALVE

Mainly used as tropical aerosols, it consist of some part as : Stem, Valve body, Gasket, Spring, Mounting cap etc.

② METERING VALVES

It delivers strong medicine using a chamber that controls the dosage, dispensing 50 to 150 mg ± 10% liquid at once.

ACTUATOR

- The Actuator adjusts the spray's angle, amount, shape & fineness, while the cap seals the product until use.
- Types of Actuator :
  i) Spray Actuator
  ii) Foam Actuator

① SPRAY ACTUATOR

- These Actuator release product concentrate & propellant as tiny particles through one to three openings, utilizing, vaporization, actuator opening & internal pathways to control particle size.

② FOAM ACTUATOR

- These Actuators have large openings (0.070) to 0.125) inches that allow product flow into a chamber for expansion & release.

LIQUIFIED GASES

- Liquified gases used as propellants, are gases at room temp. but can be liquified by cooling or pressure increase
- Boiling points are below 70°C (21°C) & Vapour pressure are b/w 14 & 85 psig.
- They are safe & non-toxic.
- It has two types:

i) Chloroflurocarbon
Eg. - Dichlorofluoromethane
Dichlorotetrafluoromethane etc.

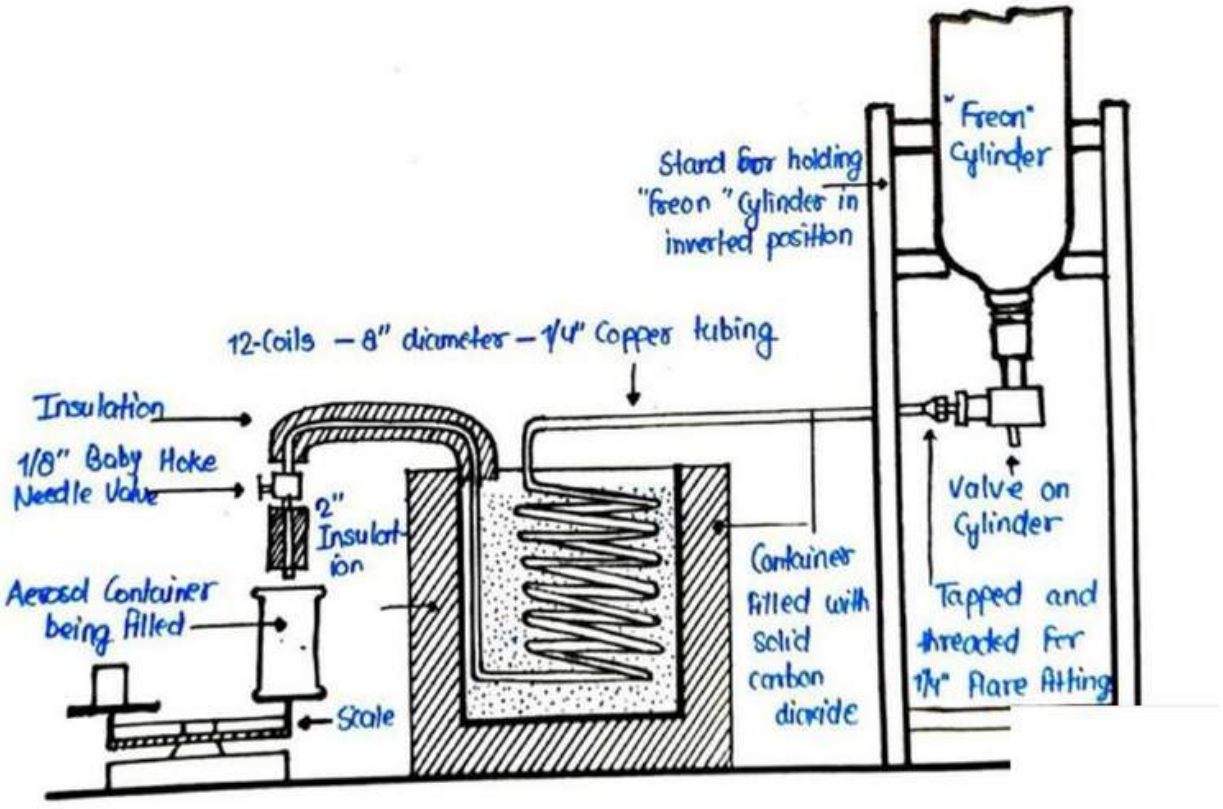
ii) Hydrocarbon
Eg. - Propane, Isobutane,
Butane etc.

MANUFACTURE OF AEROSOLS

- Pharmaceutical aerosols need specialized knowledge, skills & equipment for proper preparation and packaging under strict supervision & quality controls, which must also account for the propellant added during pregnancy.
- Different devices used to make aerosols:

i) Cold filling Apparatus
ii) Pressure filling Apparatus
iii) Compressed Gas filling Apparatus

① COLD FILLING APPARATUS



PROCEDURE

This method is not used for Hydrocarbon aerosols due to explosion risk.

↓

Both the product & propellant must be cooled to -30°C to -40°C (this temp. is required to liquefy the propellant gas with dry ice or refrigeration).

↓

Cooled product concentrate is measured into a cold aerosol container & liquefied gas is added.

↓

Thick vapour from the cold propellant expels the air from the containes.

↓

The propellant is added, and the valve assembly is secured.

ADVANTAGES

- Process is easy.

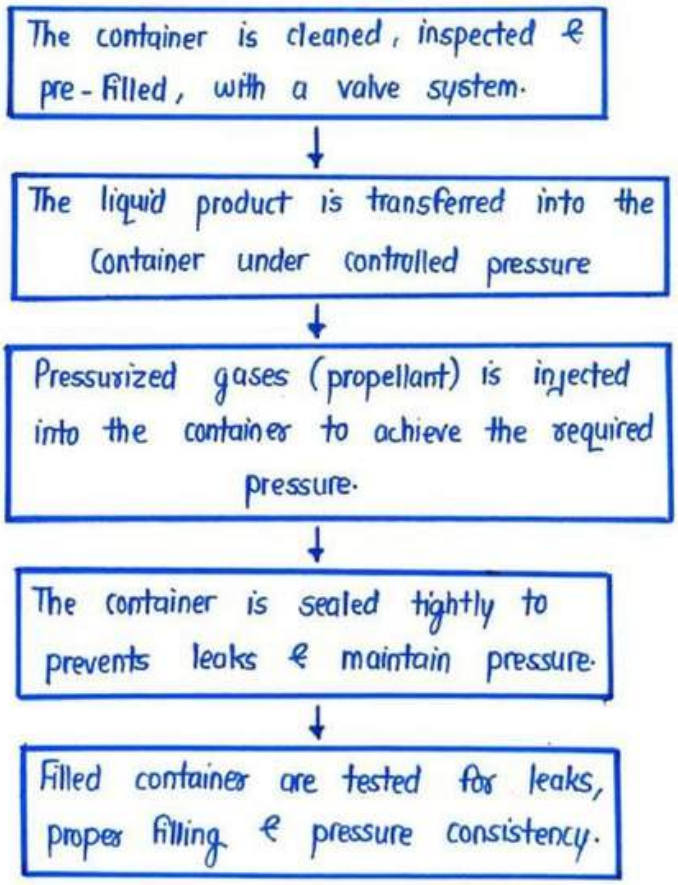
DISADVANTAGES

- This method doesn't fill aqueous products, emulsions or temperature-sensitive items.

② Pressure Filling Apparatus

A Pressure Filling Apparatus is used to fill pressurized containers, such as aerosol cans with liquids, gases or both.
It ensures precise & safe filling under pressure.
These apparatus are commonly emloyed in industries like pharmaceuticals, cosmetics & households products.

Procedure



Evaluation Of Aerosols

- The Evaluation of Aerosols involves various tests to ensure their safety, efficacy & performance.
- These tests assess the physical, chemical & functional properties of aerosol products.

① Valve Functionality Test

- Purpose : Ensure the proper operation of the valve system.
- Procedure : - Check for smooth operation of the Actuator.
  - Test for leakage or clogging in the valve.
- Evaluation : Valves should open & close properly without leakage.

② Pressure Test

- Purpose : Measures the internal pressure of the aerosol container to ensure it's within safe limits.
- Procedure : - Use a pressure gauge to measure the pressure inside the can.
  - Check at room temperature & elevated temperature (55°C - 1 hours).
- Evaluation : The pressure should meet regulatory standards and remain stable under specified conditions.

③ LEAKAGE TEST

- Purpose : Checks for leaks in the container, valve or seams.
- Procedure : - Submerge the aerosol container in water & look for bubbles.
  - Alternatively, use a pressure decay or vaccum test.
- Evaluation : There should be no leakage.

④ CONTENT UNIFORMITY TEST

- Purpose : Ensures consistent product delivery per actuation.
- Procedure : - Actuate the aerosol several times & collect the procedure.
  - Weigh or analyze the amount of product dispensed.
- Evaluation : The amount dispensed should remain consistent.

⑤ FLAMMABILITY TEST

- Purpose : Asseses the flammability of the aerosol spray.
- Procedure : - Spray the product near an open flame at a specified distance.
  - Observe whether the spray ignites & how far the flame propagates.
- Evaluation : Products should comply with safety regulations for flammability.

⑥ MICROBIAL TESTING

- Purpose : Ensures the product is free from microbial contamination.
- Procedure : Perform microbial limit tests or sterility test.
- Evaluation : Results should comply with phamacoepial standards.

⑦ pH And Viscosity Test

- Purpose: Ensure the product's pH & viscosity are within acceptable ranges.
- Procedure: - Measure pH using a pH meter.
  - Use a viscometer to determine viscosity.
- Evaluation: pH & Viscosity should match product specifications.

⑧ Stability Test

- Purpose: Assess product stability under various conditions.
- Procedure: - Store aerosols at different temperatures & humidity levels.
  - Evaluate changes in pressure, content or physical appearance over time.
- Evaluation: No significant changes should occur during the storage period.

PACKAGING MATERIALS SCIENCE

- Packaging involves the techniques for wrapping & protecting products for shipping, storage, sale, along with the creation & evaluation of packages.
- Packaging prepares products for offering protection, preservation, information & promotion.
- Choosing a package begins with assessing the products physical & chemical properties, protection requirements & marketing needs.

OBJECTIVES

① Protection

- Packaging protects products from harm during handling, transport & storage, sheilding them from impacts, vibrations & crushing.
- Packaging for perishiable products protects against gases & light, keeping them fresh, tasty & nutritious.

② Prevention & Shelf-life Extension

- Packaging keeps food safe from germs & spoilage by creating a sealed or airtight space.
- Food & drink packaging keeps item fresh by reducing air & moisture exposer, often using preservatives or special gas mixtures.

③ Convenience :

- Clear labels on packaging provide essential information on product use, dosage & preparation.
- Packaging simplifies products with features like easy-open seals, tear strips, & reseanable zippers for better user experience.

④ Marketing

- Consistent packaging fosters brand loyalty as customers learn to trust their favourite brands.
- Good packaging design is vital for sales, as it attract attention, influence buying decisions, & boosts visibility on store achieves.

⑤ Security

- Packaging reduces shipping security risks with tamper-resistant features that indicate if tampering has occured.
- Packages are designed to reduce theft risk, featuring tamper-resistant seals that show if they've been opened.

⑥ Portion Control

- Single serving packs provide convenient partitions, while bulk items like salt simplify supply management for households.
- For example - Selling 1-litre sealed milk bottles mean customers don't have to bring their own containers.

Characteristics Of Packaging

- They must be FDA - approved & free of harmful effects.
- They must not interact with the product or its ingredients & shouldn't add any smell or flavour (e.g. some plastics can emit odors).
- The packages must be tamper - proof to ensure integrity & prevent tampering or replacement.
- They must protect materials from temperature, humidity, oxygen & light and can be compatible with packaging equipment.

Materials Used For Pharmaceutical Preparations

- Pharmaceutical products are packaged using various materials, including:

① Glass
② Plastic
③ Rubber
④ Metals
⑤ Fibrous Metals
⑥ Foils, Films and Laminates

① Glass

- Glass is commonly used for pharmaceutical packaging because of its protective qualities, aesthetic appeal & variety of sizes & shapes.
- Glass is chemically stable, impermeable, strong & EDA - approved, but it is also fragile, heavy & costly.

Types Of Glass

① Type I Borosillicate Glass

- Compotition : High percentage of silica & Boric Oxide.
- Properties : - Highly resistance to thermal shock & chemical interactions.
  - Low alkali content, making it ideal for sensitive drugs.
- Applications: - Preferred for acidic & neutral solutions.
  - Used for injectables solutions, vaccines & other parenteral products/ preparations.

② Type II Treated Soda - Lime Glass

- Composition : Soda - Lime Glass treated with sulfor or Ammonium sulfate to improve chemical resistance.
- Properties : - Moderate resistance to chemical reactions.
  - Suitable for storing products with a pH below 7.
- Applications: - Used for aqueous sol^{n} & some parenteral drugs that are not highly sensitive.

③ Type III Soda Lime Glass

- Composition : Regular Soda - lime glass without surface treatment.
- Properties : - Suitable for non- critical applications.
  - Less resistant to chemical & thermal stress compared to Type I & Type II.
- Applications: Used for Oral medications, solid dosage forms (tablets, capsules) & non - parenteral products.

④ Type IV General Purpose Soda-Lime Glass

- Composition: Basic Soda-lime glass minimal processing.
- Properties: - Lowest chemical resistance among the four types.
  - Not suitable for pharmaceutical preparations with high sensitivity.
- Applications: Used for Non-Medicinal products or general storage purpose.

Specialized Glass Containers

① Amber Glass

- Used for light-sensitive preparations to protect against UV radiation.

② Clear Glass

- Used for preparations that don't require that protection against light.

③ Coloured Glass

- Used for specific applications, such as protecting against UV radiation or providing a specific colour for branding purpose.

④ Coated Glass

- Has a specialized coating to improve durability, reduce alkalinity or provide a specific release profile.

ADVANTAGES

- It has superior protective qualities.
- It is available in various colours.
- Amber colowed glass provide protection against light.
- Transparent glass allows visual inspection of the products.
- It can be easily cleaned.

DISADVANTAGES

- It is of fragile & brittle nature.
- It is heavy in weight & occupies more volume
- It cannot undergo operations involving pressure & vaccum.
- Once broken, it cannot be joined back.

② PLASTIC

- Plastic refers to a synthetic or semi-synthetic material composed of polymers that can be molded into various shapes and forms.
- Plastics are widely used in pharmaceutical packaging due to their versatility, lightweight nature, durability & cost-effectiveness.

CHARACTERISTICS OF PLASTICS

- **Flexibility:** Can be shaped into bottle, containers & films.
- **Barrier Properties:** Offers protection against moisture, oxygen, light etc.
- **Inertness:** Designed to avoid interactions with packed drugs.
- **Cost Effectiveness:** Affordable for large scale production.

TYPES OF PLASTICS USED IN PHARMACEUTICAL PACKAGING

There are various types of plastics used in pharmaceutical packaging as follows:

① **POLYETHYLENE:**
- Used for bottle, bags, and films.
- It is mainly known for its flexibility and moisture resistance.

② **POLYPROPYLENE:**
- It is common in caps, closures and syringes due to its chemical resistance and high melting point.

③ **POLYVINYL CHLORIDE** :
- It is inexpensive, clear and stiff.
- It is mainly used in blister packs.

④ **POLYETHYLENE TEREPHTHLATE** :
- It is lightweight & strong, often used for packaging cosmetics, ples bottles & mouthwashes.

⑤ **POLYSTYRENE** :
- It is utilized for jars, trays and small containers.
- It is not suitable for dispensing liquid products.

ADVANTAGES

- Lightweight
- Flexible
- Cost - Effective
- Easy to Seal
- Moisture Barrier

DISADVANTAGES

- Permeability for certain gases
- Chemical Interaction
- Environmental concerns.
- Regulatory Requirments

③ RUBBER

- Rubber refers to a natural or synthetic elastic polymeric material used primarily for closure and sealing of pharmaceutical packaging.
- It is mainly known for its flexibility & ability to form airtight and watertight seals, ensuring integrity and sterility of pharmaceutical products.

CLASSIFICATION

It can be classified into following two types :

① **Natural Rubber** : It is derived from latex obtained from rubber trees (Hevea brasiliensis).

② **Synthetic Rubber** : They are resistant to oxidation, solvents, oils.
Examples : Butyl Rubber, Nitrile Rubber etc.

TYPES OF RUBBER USED IN PHARMACEUTICALS

① **Butyl Rubber** : They are excellent for airtight seals and resistant to moisture and gases. They are commonly used as vial stoppers and syringe plungers.

② **Nitrile Rubber** : It is known for its resistance to oils, chemicals and temperature variations.

③ SILICON RUBBER :
- It is highly biocompatible and chemically inert
- It is used for specialized closures & medical devices.

④ Chlorobutyl or Bromobutyl Rubber :
- They are modified versions of butyl rubber with enhanced performance.

ADVANTAGES

- Effective Sealing
- Durability
- Flexibility

④ METALS

Metals are valued for their strength, durability and barrier properties, providing protection against physical damage, contamination and environmental factors.

TYPES OF METALS USED IN PHARMACEUTICALS

- **Aluminium :**
  - It is one of the most widely used metals in pharmaceutical packaging, especially for blisters, foils and caps.
  - It is lightweight, non-corrosive and offers excellent barrier properties against moisture, oxygen and light.

- **Steel :**
  - It is known for its strength and resistance to corrosion
  - It is used for closures, container linings and in medical devices.
  - It is highly durable & maintain its integrity under various conditions.

- **Tinplate :**
  - It is used primarily in the production of cans and some closures.
  - It is resistant to corrosion.

Application Of Metals In Pharmaceuticals

- Blister Packs
- Caps & Closures
- Containers & Cans
- Secondary Packaging
- Syringe Needles

Advantages

- Effection Protection
- High Strength
- Aesthetic Appeal
- Long Shelf Life

Types Of Packaging

Packaging can be classified into following 3 types:

① Primary Packaging
② Secondary Packaging
③ Tertiary Packaging

① Primary Packaging

- This is the first layer of packaging that comes into direct contact with the product.
- It serves to protect the product and often provides consumer convenience and information.

Examples

- Bottles for Beverages
- Blister Packs for tablets & capsules
- Tins for canned foods
- Plastic wrappers for snacks
- Sachets for shampoors

Key Functions

- Protect the product from contamination or damage.
- Maintain freshness & shelf life.
- Provides Information
- Attracts consumers with branding & design.

② SECONDARY PACKAGING

- This is the outer packaging that groups multiple primary packages together.
- It facilitates handling, storage and transportation.

Examples

- Boxes containing individual blister packs of medicines.

key Functions

- Provides additional protection to primary packaging
- Aids in organization & bulk handling.
- Enhances product's presentation.

③ TERTIARY PACKAGING

This is the bulk or transport packaging used to move large quantities of products from manufacturers to retailers or warehouses.

Examples

- Crates for transporting goods.
- Drums for transporting chemicals.

key Functions

- Ensures safe transportation & storage.
- Protects product from environmental or physical damage.

FACTORS INFLUENCING CHOICE OF CONTAINERS

- The choice of containers in pharmaceuticals is crucial for ensuring the stability, safety & efficacy of product throughout its shelf life.
- Here are factors that influence choice of containers :

① **Material** : Containers can be made of plastic, glass, metal or cardboard. The material affects durability, cost and suitability for the contents.

② **Size & Capacity** : Containers must be appropriately sized to hold the amount of product or material without wasting space.

③ **Cost** : The price of containers should align with the budget, considering both purchase and long term usage.

④ **Storage Conditions** : Factors like temperature, humidity and exposure to light can influence the choice, such as choosing airtight or UV protective containers.

⑤ **Transportation Needs** : Containers should be easy to handle & transport without causing damage to contents.

⑥ Environment & Sustainibility : Preference for eco friendly, recyclable or biodegradable containers is growing.

⑦ Sealing & Safety : Some containers require airtight or tamper-evident seals for safety, especially for food & chemicals.

⑧ Regulatory Requirments : Certain products may require containers that meet specific health and safety standards, such as FDA-approved packaging for food.

Stability Aspects Of Packaging Materials

The stability of packaging materials is crucial in ensuring that products are protected, preserved and safe throughout their lifecycle.

① Mechanical Stability

- The material must resist mechanical stresses, such as compression, tension and impact, during handling, storage and transportation.

② Chemical Stability

- The material should not react chemically with the product it contains, especially for food, pharmaceuticals or chemicals.
- It should resist degradation from moisture, oxygen, UV light and other environmental agents.

③ Thermal Stability

- The material should maintain its properties under the expected temperature range for storage and transportation.
- For Example: Some materials must withstand extreme cold or heat

④ Barrier Properties

- Packaging should prevent or control the permeation of gases and vapours to maintain product quality.

⑤ Light Stability

- Materials must protect products from light, which can cause degradation, discoloration or loss of efficacy.

⑥ Microbial Resistance

- For sterile or food-grade packaging, materials must resist microbial growth to prevent contamination.

QUALITY CONTROL TEST

Quality Control Test for materials used in packaging of pharmaceutical products are critical to ensure the safety, efficacy and quality of the products.

① QUALITY CONTROL TEST FOR GLASS

@ HYDROLYTIC RESISTANCE TEST

It determines the glass's resistance to water-induced leaching, which can affect product stability.

Methods

- Powdered Glass Test
- Water Attack Test

Powdered Glass Test :

- Glass containers are crushed into a fine powder to increase the surface area exposed to testing conditions.
- The sample is then heated in water at 121°C in autoclave for 30 minutes to accelerate the leaching process.
- The solution is then titrated with sulfuric acid using a methyl red indicator to determine the amount of alkali leached.

Water Attack Test :

- Entire glass containers are immersed in water and heated in an autoclave at 121°C for 30 minutes.
- The amount of alkali leached into the water is then measured by titration.

ⓑ THERMAL SHOCK RESISTANCE

- It assesses the glass's ability to withstand rapid temperature changes without cracking, ensuring durability during process like sterilization.
- Glass containers are subjected to sudden temperature variations and their resistance to cracking or breaking is observed.

② Quality Control Test For Plastic

Ensuring the quality of plastic materials used in pharmaceutical packaging is crucial for maintaining the safety, efficacy and integrity of pharmaceutical product.

ⓐ Leakage Test

- It is perform to ensure that plastic containers do not leak, maintaining sterility & integrity of pharmaceutical products.
- Fill to containers with water. fit them with intended closures. and invert them for 24 hours.
- Examine for any sign of leakage

ⓑ Transparency Test

- To ensure that plastic container allows for visual inspection of contents, which is important for identifying degradation or contamination.
- In this we simply visually inspect the container to confirm it is sufficiently transparent.

ⓒ Penetration Test

- To assess the ease with which a needle can penetrate the closure of the plastic containers, which is important for containers designed for injectable products.
- In this, we use a standardized needle to penetrate the closure & measure the force required.

THANK YOU

FOR CHOOSING IMPERFECT PHARMACY AS YOUR STUDY PARTNER

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