Unit- 5 Cosmetics :-

→ The term cosmetics is derived from the Greek word kosmetikos which means the embellishment.

→ Any thing which are used for the attractiveness of skin is called cosmetics.

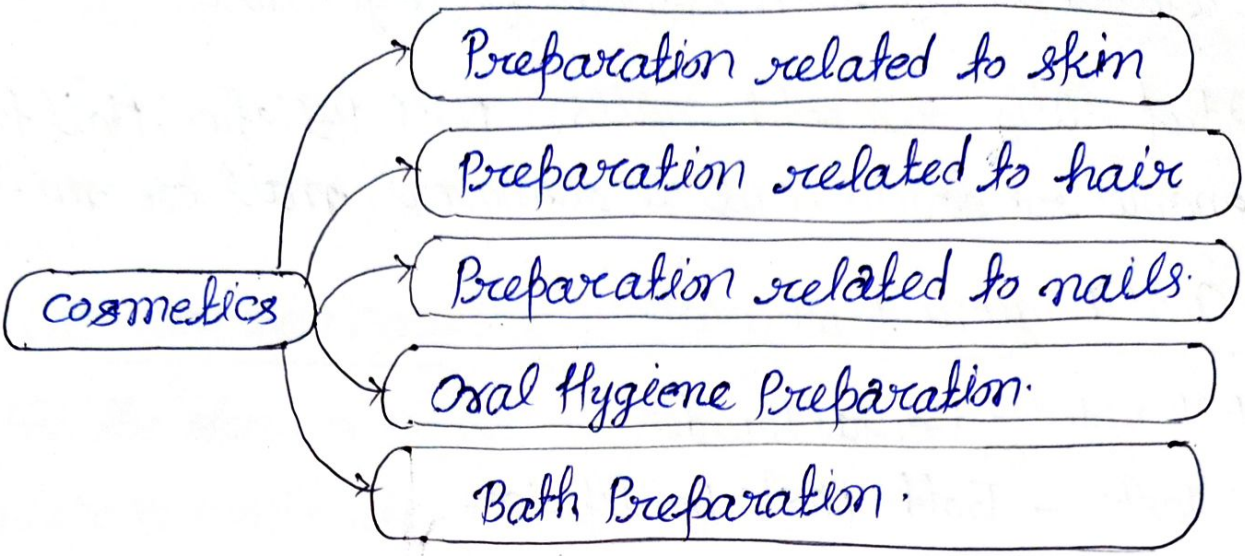
→ As per drug and cosmetic act 1940 -

" Means any articles intended to be rubbed, poured sprinkled or sprayed on or introduced into or otherwise applicated to the human body or any part of for cleansing, beautifying promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

Functions of Cosmetics :- There are the following function of the cosmetics.

- → cleaning
- → Coloring
- → Increase Attraction
- → Covering
- → Protection
- → Alteration of Appearance
- → Beautification.

Classification of Cosmetics :-



(1) Preparation related to skin

(A) Powders :- Face and body powder, Prickly heat Powder skin powder for infants after shave powders.

(B) Creams :- Cold creams hand creams, sunscreen, Vanishing creams and all other skin creams.

(C) Lotions :- Body lotions, Hand lotions, Skin-toner lotions astringent lotions.

(D) Colourants :- Lipsticks, liquid rouges.

(2) Preparation related to hair :-

(A) Hair Care Products :- Hair Dressings, Conditioner, Brilliantines, Shampoos, Hair dyes, Hair wave preparation

(B) Hair Removers :- Depilatories epilatories, Shaving Creams.

(c) Eye related Preparation:- Mascara, Preparation related to eye lash, Pencils for eye brow.

(3) Preparation related to nails:- Nail Palishes, Nail bleaches enamel removers, cuticle removers, nail creams.

(4) Oral Hygiene Preparation:-

(A) Powder - Dental Powder

(B) Paste - Tooth paste Dentifrices.

(C) Mouthwashes

(5) Bath Preparation:- Bath salts, Bath oils, Bath Powders.

÷ Cosmetic Preparation ÷

→ Introduction:- → Cosmetic word derived from Greek word kosmeticos 'means to adorn.

→ According to drug and cosmetics act and Rules, 1945 Cosmetic is defined as an item intended to be rubbed, poured, sprinkled on, Introduced into or applied to the human body or any part for cleansing, Protecting, beautifying, Promoting, attractiveness or altering the appearance

÷ Functions of Cosmetic Preparation ÷

→ Maintain body health and hygiene
→ Avoid Premature ageing of skin.
→ Give a sense of well being
→ Improve overall looks & Personality.

Classification of Cosmetics :-

(1) According to their use.
(2) According to their Function
(3) According to their Physical Nature

← Cosmetics According to their Use :-

→ For the skin ex. Cream, Powders, lotions deodorants, Antiperspirants etc.
→ For the nails ex - nail Polish, Nail Polish removers etc.
→ For the teeth and mouth ex Dentifrices and mouth washes.
→ For the eye ex - Eye cream, eye lashes, Eye liners.
→ For the hairs ex. Shampoo, Hair dyes, Hair removers, Hair tonic, Hair Sprays.

Cosmetics According to their Function :-

→ Therapeutic function ex - Antiperspirants and hair Preparations
→ Protective Function ex - Face Powders.
→ Corrective Function ex. Face Powders.
→ Decorative function ex. Lipsticks, Nail Polishes & Eye liners etc.

:- Cosmetics According to their Physical Nature :-

→ Aerosols Ex - After shave lotion, Hair Perfumes.
→ Cakes ex - Rouge Compacts. Make up Compacts.
→ Emulsions ex - Cold cream, Vanishing cream cleansing cream etc
→ Oils ex Hair oils.
→ Pastes ex tooth Paste.

→ Powders ex - Tooth Powders, Face Powders etc.

→ Solutions ex - After shave lotions, Hand lotions etc.

→ Soaps ex - Shaving soap, toilet soap etc.

→ Sticks ex - lipsticks, deodorant sticks.

÷ Facial Cosmetics ÷

→ Some face cosmetics used for facial Purpose for cleansing refreshing and nourishing effects.

→(1) Face Powders.

(2) Compact Face Powders.

(3) Rouges.

(4) Cold Creams

(5) Cleansing Creams

(6) Vanishing Creams.

(7) Moisturizing Creams

(8) Foundation Creams.

(9) Eye make up Preparations -

(A) Eye shadow.

(B) Eye brow Pencils.

(C) Mascara.

(10) Lipsticks.

(11) Bleaches

(12) Shaving Media -

(A) Lather shaving Creams.

(B) Brushless shaving Creams.

(C) Shaving Soaps

(D) Shaving Sticks

(E) After shave Products.

÷ Face Powders ÷

→ **Face Powder ÷** Face Powder is a cosmetic Preparation meant for improvement of overall attractiveness of the face.

- It is applied on the face by means of a Powder Puff & Provides visual covering to the skin and imparts smooth finish.

→ In that contains talcum Powder, Kaolin, mgg. carbonate, zinc oxide, titanium oxide, Starch, Colors & Perfumes.

Type ÷ (1) **Light Type ÷** Used for dry skin, large Quantity of talc.

(2) **Medium Type ÷** Used for normal or oily skin, lesser Quantity of talc with zinc oxide.

(3) **Heavy Type** Used for very oily skin, it contain lesser quantity of talc and higher quantity of zinc oxide

÷ General Method of Preparation of Face Powder ÷

(1) All the solid ingredients are powdered and Pass through sieve number 120.

(2) Mix them thoroughly incorporate the required quantity of Perfumes and Packed in Powder box.

Formula ÷

Talcum Powder	75.0g
Kaolin	5.0g
Chalk Precipitated	5.0g
Zinc oxide	10.0g
Zinc Stearate	5.0g
Perfumes & Color	Q.S

Cold Cream O/W

- Cold cream is an emulsion, which when applied on the skin a cooling effect is produced due to slow evaporation of water present in the emulsion.
- This are generally prepared by emulsification of oil and water
- In olden days animal fat and vegetable oils was used but vegetable oils have rancid tendency so they replaced by mineral oils.

← General Method of Preparation of Cold Cream :-

Formula :- Bees Wax 5.0 g
- Liquid Paraffin - 45.0 g
- With soft Paraffin - 10.0 g
- Hard Paraffin - 7.0 g
- Borax - 0.2 g
- Water - 32.8 ml
- Perfumes & Preservative Q.S

(1) Melt the wax, white soft Paraffin, hard Paraffin on a water bath.
(2) Add liquid Paraffin and heat the mixture to 70°C.
(3) Dissolve the borax in water at 75°C and add to melted fats with continuous stirring.
(4) Cool with stirring to 40°C.
(5) Add the required Quantity of Preservative & Perfumes.
(6) Transfer the cream to the container while hot.

÷ Vanishing Cream ÷

→ These are the o/w emulsion which when applied to the skin leave an almost invisible layer on it hence, this are called as vanishing cream.

→ The main ingredient used is stearic acid which gives pearly white shining appearance to the cream.

→ These creams can be quickley washed off because its o/w type.

→ In that, oil phase (temprature) which mealts at above body temprature so it provides an invisible and non greasy layer and provide very attractive appearance.

Formula ÷

- Stearic Acid – 18.0g
- Glycerin – 3.0g
- Lanolin – 2.0g
- Triethanalamine – 1.0g
- Water – 80.0ml
- Preservative – 1.0g
- Perfumes – Q.S

Method ÷

→ Melt stearic acid and lanolin.

→ Then, mix water, glycerin and triethalonamine and warm to same temprature as that of method stearic acid and lanolin

→ Mix the to with continuous stirring and add Perfumes and Preservative

→ Mix them thoroughly in order to obtained a uniform product.

÷ Lipsticks ÷

→ Most widely used cosmetic item by women to give an attractive color and appearance to lips.

→ In that pigments dissolved or dispensed in fatty base it means Fats, Waxes with suitable perfume.

⇒ Ideal qualities →

⇒ Nontoxic
⇒ Non-Irritant
⇒ Stable both Physically and chemically.
⇒ Free from gritty particles
⇒ Free from sweating.
⇒ Should not break easily.
⇒ Shiny and smooth appearance
⇒ Maintain color of lips for long period and remove easily
⇒ Should not break during storage.

÷ Formulation of Lipsticks ÷

(1) Bases ÷ Oily, Fatty material and waxes like mineral oil veg oil, cocoa butter, lanolin, Carnauba wax, beeswax etc.

(2) Coloring Material ÷ Titanium dioxide, Soluble eosin, Halogenated derivatives of fluorescein and tetra bromofluo fluorescein.

(3) Perfumes ÷ Floral fruity and light spicy fragrances.

(4) Antioxidants ÷ They are used for prevent rancidity BHA, BHT, Propyl gallate etc.

Formula:- Carnauba Wax 1.0
Beeswax — 15 g
Lanolin - 5 g
Cetyl Alcohal — 5 g
Castor oil — 65.0 ml.
Coloring matter and Perfume Q.S.

:- Shaving Media :-

→ They are used to remove hair, Particularly from men's faces.
→ Some women's are also used for removal of hairs from legs Under arms.
→ Shaving media are three types :-

(i) Pre-Shave Products :- For Softening of beard.

(ii) Shaving Products :- Shaving Cream, leather Shaving Cream

(iii) After-Shave Products :- To refresh the skin.

:- Antiperspirants & Deodorants :-

→ Antiperspirants are play to inhibit the flow of Perspiration
→ Deodorants are play to inhibit the formation of bad odour in perspiration by suppressing the growth of bacteria or mask the unpleasant odour.
→ Aluminium Carbohydrate shows both qualities.

Antiperspirants Mechanism of Action :- → Antiperspirants contains substance having astringent action & on reacting with skin proteins it causes coagulation which is accompanied by a swelling at the opening of sweat glands.

→ This helps in blocking the openings of sweat glands thus reduce the flow of sweat.

Ideal Properties :- → Non-Toxic
- Non-Irritant
→ It should have pH between 4 to 4.5
→ It should have no effect on fabrics.
- It should have astringent propertys.

← Shampoos :-

→ Shampoos defined as a preparation containing surface active agents which are used to remove dirt, grease and debris from the hair, scalp & other part of the body without affecting the natural gloss of hair.

→ It also helps to give fragrant softness to the hairs.

→ It is available in solution or suspension form prepared by dissolving cleansing agent and other agents to improve the quality of shampoo.

:- Qualities of Ideal Shampoos :- → Non-toxic, Non-Irritant

→ It should be capable of removing grease, dirt and skin debris from hair and scalp.

- It provides sufficient fragrance to the hair after it's use

→ It should effective in small amount.
→ It should get easily removed by washing.
→ It should produce sufficient foam bath in hard & soft water.
→ It make the hair soft and shiny.

Types of Shampoo:- → Medicated dandruff shampoo.
→ Powder Shampoo.
→ Clear liquid shampoo.
→ Gel Shampoo.
→ Soap shampoo.
→ Cream or Paste Shampoo.
→ Liquid cream or lotion shampoos.
→ Baby shampoos.
→ Aerosol shampoos.

÷ Formulation of Shampoos ÷

Surfactant:- The following types of surfactants used in various types of shampoos-

(1) Anionic:- Anionic Types of surfactants are widely used as detergent in shampoos ex. sodium lauryl sulphate.

(2) Non-Ionic:- Non ionic surfactants are used in combination with other surfactants Ex. Lauric Mono ethanoamide

(3) Cationic:- C. Surfactant are used as additives in small quanti. Because they have low cleansing and foam Property compared to anionic. Ex. Cetylpyridinum salt.

(4) Amphoteric :- Amphoteric Surfactants are used for mild shampoos such as baby shampoos ex. derivatives of amino acids.

Conditioning Agents (Conditioners) :- Used for improve the texture of the hair. Ex. Mineral oils, Humectants Etc.

Thickening Agents :- They provide viscosity and desired consistency to the preparation ex. Methyl Cellulose, CMC, Sodium stearate. Etc.

Opacifiers :- Used to shampoo opaque ex Glyceryl stearate, calcium or Zinc salts of stearic acid etc.

Sequestering Agents :- To make the shampoo effective in hard water ex. EDTA

Preservatives :- Ex- Methyl and Propyl Paraben.

:- Hair Dyes :-

→ Hair dyes classified accordingly of action.
- Temporary
- Semi-Permanent
- Permanent.

→ Hair dyes also classified into dyes nature.
- Vegetable dyes e.g henna and chamomile
- Metallic dyes Ex Bismuth citrate, Silver Nitrate, Copper Chloride etc.

→ Synthetic organic dyes ex - Para - amino - Diphenylamine para - Tolulylene diamine . Sulpho - ortho - Aminophenal etc.

Depilatories (Hair Removers) : The unwanted hairs from the skin can be removed by following 3 - Method -

(1) Epilation Method.
(2) Depilation Method
(3) Electrolysis Method.

(1) Epilation Method : In that wax, rosin etc used for Plucking the hair but this method is very painful and have the chances of skin damage and also have the chance for skin infection.

→ In that formulation contains rosin beeswax with mineral or vegetable oils, Cooling agent, Antibacterial Agent

(2) Depilation Method : In this method use the chemicals for removing of hair without pain and injury the skin

- For that purpose calcium sulphide is most commonly used in formulation also, calcium, thioglyceral barium sulphide etc.
- The formulation Present in Powder and Paste form.

Formula :

Barium Sulphide	- 8 gm
Calcium Carbonate	- 32 gm
powdered Soap	- 4 gm
Glycerin	- 2 ml
Water	- 54 ml
Perfumes	- Q.S

Method :- Powder Soap + Water Glycerin + Barium Sulphide + Calcium carbonate & Mix with above solution and then add perfume and triturate till smooth paste is obtained

(3) Electrolysis :- In this method the inserting of needle into the hair follicle and hair root is completely destroyed by weak current.

- In this method hair removed permanently.
- This method is very time consuming and Expensive.

÷ Antidandruff Preparations :-

- The mayor causes of dandruff are -
  - Dysfunction of the scalp.
  - Microbial Attack.
  - Combination of Above two.
- They can be controlled by using shampoo, it should be allowed to remain in the hair half and hour & then washed with warm water and water proper drying of hair, it should be massaged to increase the blood circulation of the scalp.

Formula :-

Selenium Disulphide	-	2.5 gm
Stabilizer	—	5 gm
Surfactant	-	17.5 gm
Water	—	75 ml

÷ Rouges ÷

→ Rouges are applied to the cheeks for enhancing the face beauty.

→ it imparts rosy freshness also add beauty.

→ Rouges are available in solid, liquid and cream form

→ Color of rouge vary from pink to red or reddish brown

→ The shade of the rouge depends on the type and quantity of color mixed with it.

→ The dry compact rouge is applied with help of powder puff.

÷ General Method of Preparation of Dry Rouge ÷

Formula ÷ Talcum Powder – 80 gm
Zinc Oxide – 5 gm
Zinc Stearate – 5 gm
Rice Starch – 10 gm
Perfumes and Colour – Q.S

Method ÷ (1) All powders mix & incorporate with perfume and colour.

→ The moulded mass is pressed to expel the air from the powders.

(2) After compact they dried at specific temp. to avoid dry mist & an undesirable lop cast.

÷ Pharmaceutical Aerosal ÷

→ Pharmaceutical Aerosal is a type of Aerosol inwhich the medicament is dissolve in the mixture of Solvent and Propellent in a well suitable container. and when the pressrised Pumb is press then the liquid comes out in the forms of vapour. this is called aerosal.

→ In 1942 used as a bactericidal

→ In 1950 used as a topical form.

→ In 1955 used as a inheller.

Advantages ÷ → Due to air tiet and well closed container there is no chances of contamination.

→ It stable during the self life.

→ Direct apply on the affected area.

→ There is less chances of irritation.

→ Ease and convineous to applicalion.

→ Rapid Action.

→ Decrease the first pass metabolism.

Disadvantage ÷ → It is very highly expensive.

→ It contain Chloro fluoro carbon (CFC) which may cause the depletation of ozone layer.

→ Propellent should Produce toxic responce.

→ And it shows some allergic Responce.

→ Difficult in disposal

÷ Desired Charectastics of Aerosol÷ There are should be at least five charectastics in the aerosol.

(1) Can be use directly affected area.
(2) Uniform and constant delivary
(3) Rapid Process.
(4) Protect drug from 1st pass metabolism.
(5) Systemic and local Action.

÷ Types of Phaomaceutical Aerosal÷

(1) MDI (Metered dose inheller)
(2) DPI (Dry Powder inheller)

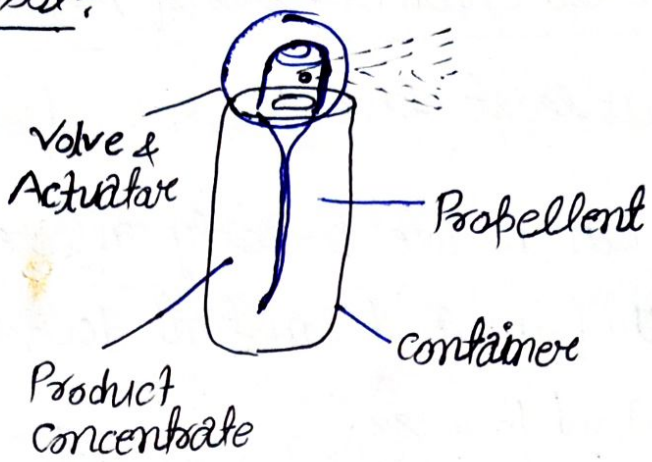
(1) MDI (Metered Dose Inheller)÷ This is basically used for the inheller in the case of lungs problem and asthma patients.

- In this type of inheller the dose of the drug is fixed on each ejection. so they are called metered dose inheller
- They eject the same amount of the drug content from begining to from the last

(2) DPI (Dry Powder inheller)÷ This is also used for the asthmetic patients lungs problem and when the actual medicament concentrate is available in the dry form then they are called dry powder inheller.

÷ Component of Aerosol ÷

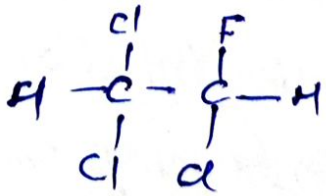
(1) Propellent
(2) Container
(3) Valve and Actuator
(4) Product concentrate



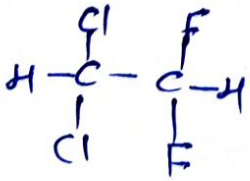
(i) Propellent ÷

- Propellent are the main constituent of any aerosol because they are basically used for the creating pressure inside the container
- Propellent are basically available in two form.
- first of all Liquifide gas.
- And Second one is compressed gas.
- And liquifide gas are available in liquid form but when they release they convert into gaseous form.
- And in the second type compressed gas propellent the are available in gaseous form and release also in the gaseous form Ex- (i) CFC → Trichloro mono fluro ethane

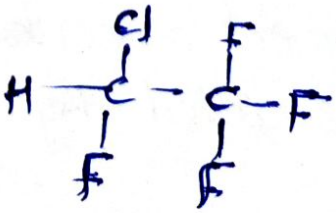
(i) C_2Cl_3F



(ii) $C_2Cl_2F_2$



(iii) C_2ClF_4



(2) Hydrocarbon:- Propane, Isobutane, Butane.

(2) Container:-

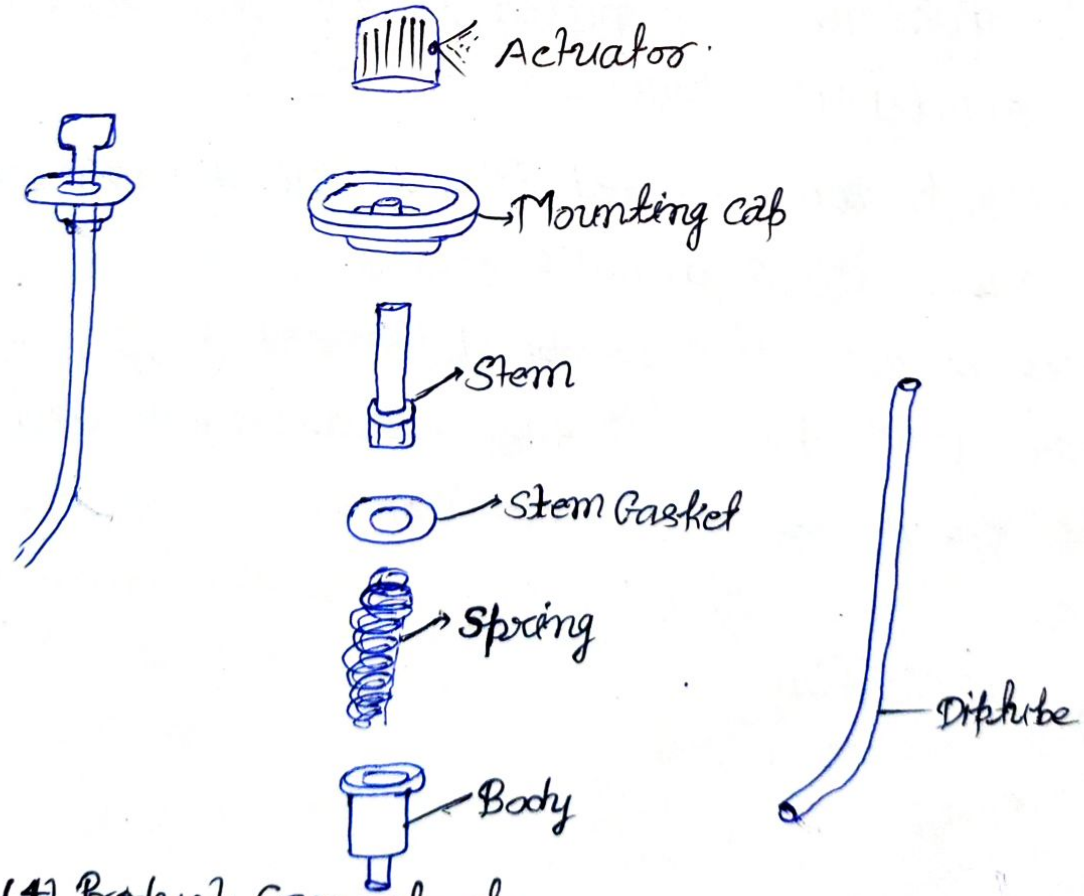
→ Container are those part of aerosal in which the Propellent, Solvent and drug are Filled

→ The container should have the property to bear the pressure of 140 to 180 PSIG.

→ Container are basically of three type -

(i) Tin
(ii) Alluminum
(iii) Stainless steal

(3) Valve and Actuator



(4) Product Concentrate

÷ Formulation of Aerosols ÷

⇒ It consist of two essential components.

(1) Product concentrate and
(2) Propellant

(1) Product Concentrate ÷ Active ingredient or mixture of active ingredients and other necessary agent such as solvent, Anti oxidants and surfactants.

(2) Propellant ÷ · Single or blend of various propellants is used.

⇒ Blend of solvent is used to achieve desired solubility characteristics

⇒ Various surfactants are mixed to give the proper HLB value for emulsion system.

⇒ The propellants are selected to give the desired vapar pressure solubility and particle size

⇒ Pharmaceutical aerosol may be dispensed as fine mist, wet spray, quick breaking foam, stable foam solid etc.

⇒ Type of system selected depends on.

(1) Physical, Chemical and Pharmacological Properties of drug.
(2) Side of Application

÷ Types of Systems ÷

→ Types of Aerosol Systems ÷

(i) Solution System
(2) Water based system
(3) Suspension or Dispersion Systems.
(4) Foam Systems.
(i) Aqueous Stable foams.
(ii) Non Aqueous Stable foams.
(iii) Quick-Breaking Foam
(iv) Thermal foams.
(5) Intranasal Aerosols.

(1) Solution System ÷

→ This system is also referred to as two phase system consists of vapar and liquid phase.
→ If active ingredient is soluble in propellant no other solvent is required
→ The vapour pressure of system is reduced by the addition of less volatile solvents such as ethanol, acetone, Propylene glycol, Glycerin, ethyl acetate.
→ This results in production of larger particle upon spraying
→ Amount of propellant may vary from 5% (for foams) to 95% (For inhalations).

General Formula	Weight %
Active drug	- to 10-15
Propellant	- to 100

Inhalation Aerosol

Formulation	Weight %
Isoproterenol HCl	-0.25
Ascorbic Acid	-0.1
Ethanol	-35.75
Propellant 12	- 63.9

→ Packed in 15-30 ml Stainless steel, Aluminium or glass container.

Hydrocarbons in Topical Aerosal Pharmaceutical Preparation

Formulation	Weight %
Active Ingedient	-Up to 10-15
Ethanol	-UP to 10-15
Water	- 10-15
Hydro Carbon Propellant (A-46)	- 55-70

→ Depending on water content the final product may be solution or three phase system.

→ Solution Aerosols produce a fine to coars spray.

→ Hydrocarbon propellant A-70 produces drier particles while propellents A-17 and A-31 tend to produce a wetter spray

→ These are useful for topical preparations.
→ Packaged in plastic coated glass container.

2. Water Based System :-

→ Large amounts of water can be used to replace all or part of the non aqueous solvents used in aerosol.
→ Produce Spray or foam.
→ To produce spray, formulation must consist of dispersion of active ingredients and other solvents in emulsion system in which the propellant is in the external phase.
→ Since propellant and water are not miscible, a three phase aerosol forms (Propellant, water and vapor phases).
→ Ethanol can be used as cosolvent to solubilize propellant in water. it also reduces surface tension aiding in the production of smaller particles.
→ 0.5 to 2% of surfactant is used to produce a homogenous dispersion
→ Surfactants with low water solubility and high solubility in non polar solvents will be most useful ex- Long chain fatty acid esters of polyhydric compounds including glycol glycerol and sorbitan esters of oleic, stearic, Palmitic and lauric acids.
→ Propellants concentration varies from about 25 to 60%

→ Aquasol system (Aquasol Valve) dispensing fine mist or spray of active ingredient dissolved in water

→ No chilling effect, since only active ingredient and water are dispensed, propellant is in vapor state.

→ Difference between aquasol system and three phase system is aquasol dispenses fairly dry spray with very small particles, non flammability of the product.

÷ (3) Suspension System ÷

→ It involves dispersion of active ingredient in the propellant or mixture of propellants.

→ To decrease the rate of settling of dispersed particles surfactants or suspending agents can be added.

→ Primarily used for inhalation aerosals.

Example ÷

Formulation	Weight %
Epinephrine bitartrate (1-5 M)	0.50
Sorbitan trioleate	0.50
Propellant - 114	49.50
Propellant - 12	49.50

→ Epinephrine bitartrate has minimum solubility in propellant system but soluble in fluids in the lungs.

→ Physical stability of aerosol dispersion can be increased by

(1) Control of Moisture content (< 300 ppm)

(2) Reduction of initial particle size to less than 5 μm.

(3) Adjustment of density of propellant and suspensoid so that they are equalized.

(4) Use of dispersing agents.

(5) Use of derivatives of active ingredients with minimum solubility in propellants system.

→ Physical stability of a dispersed system depends on rate of agglomeration of the suspensoid.

→ Agglomeration results in valve clogging in accuracy of dosage and depending on the nature of active ingredients it may cause damage to the liner and metal container

→ Agglomeration is accelerated at elevated temp. and it is also affected by particle size of drug (1-5 μ, never > 50 μ)

→ Isopropyl myristate and mineral oil are used to reduce agglomeration.

→ Surfactants of HLB values less than 10 are utilized for aerosol dispersions (Sorbitan monooleate, Monolaurate, trioleate, Sequioleate).

→ Surfactants are effective in a concentration of 0.01 to 1%

(4) :- Foam Systems :-

→ Emulsion and foam aerosols consist of Active ingredients aqueous or non aqueous vehicle surfactant, propellant and are dispersed as a stable or quick breaking foam depending on the nature of the ingredients and the formulation

÷ Aqueous Stable Foam ÷

Formulation	% W/W
Active ingredient oil waxes o/w Surfactant Water	95-96.5
Hydrocarbon Propellant (3-5%)	3.5-5

→ Quick Breaking Foam ÷

→ Propellant is in the external phase.
→ When dispensed the product is emitted as a foam, which then collapses into a liquid
→ Especially applicable to topical Medications

Formulation	% W/W
Ethyl Alcohal	46-66
Surfactant	0.5-5
Water	28-42
Hydrocarbon Propellant	3-15

→ Surfactant should be soluble in both alcohal and water and can be non ionic or cationic or anionic type.

÷ Thermal Foam ÷

→ Used to produce warm foam for shaving.
→ Used to dispense hair colors and dyes but were unsuccessful due to the corrosion problems and are expensive, inconvenient to use and lack of effectiveness.

÷ Intranasal Aerosols ÷

→ Intended to deposit medication into nasal passages for local or systemic effect.

÷ Advantages ÷ → Deliver measured dose of drug.

→ Require lower doses compared to other systemic products.

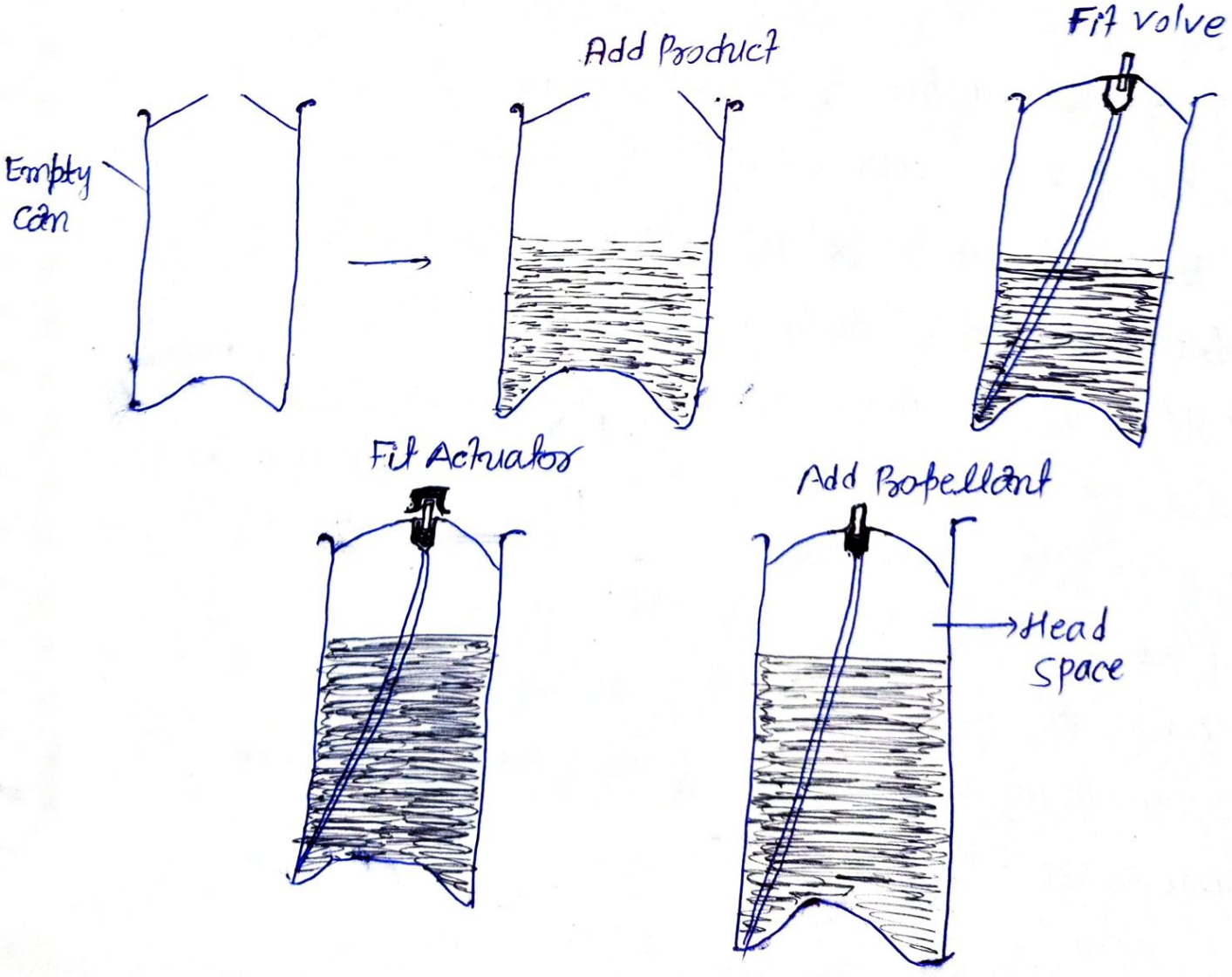
→ Excellent depth of penetration into the nasal passage way

→ Decreased mucosal irritability.

→ Maintenance of sterility from dose to dose

→ Greater flexibility in the product formulation.

÷ Manufacture of Aerosols ÷



÷ Manufacture of Pharmaceutical Aerosol ÷

→ Pressure filling Apparatus.
→ Cold filling apparatus.
→ Compressed gas filling Apparatus.

(i) Pressure filling Apparatus ÷

→ It consist of a pressure burrette capable metering small volumes of liquefied gas into the aerosol container under pressure.
→ Propellant is added through an inlet valve located at the bottom or top of the pressure burette.
→ The propellant is allowed to flow with its own vapor pressure in the container through aerosol valve
→ The trapped air escapes out from the upper valve.
→ The propellants stops flowing when the pressure of burette and container becomes equal.
→ If further propellant is to be added a hose (Rubble pipe) leading to a cylinder of nitrogen is attached to the upper valve, the pressure exerted by nitrogen helps in the flow of the propellants into the container.
→ Another pressure filling device makes use of piston arrangement and is capable of maintaining positive pressure.

→ This type of device cannot be used for filling inhalation aerosols which have metered valves.

÷ Procedure ÷ → This method involves filling of the concentrate into the container at the room temperature

→ Then the value is placed in the container and crimped.

→ Through the opening of the value the propellant are added or it can be added " under the cap.

→ Since the opening of the valve are smaller in size ranging from 0.018 - 0.030 inches, it limits the production and the process become slow.

→ But with the use of rotary filling machines and newer filling heads where the propellants are filled through valve stem, the production rate is increased

→ The trapped air in the container and air present in head space is removed beffore filling the propellant to protect the products from getting adversely affected

→ Various units used in pressure filling line are arranged in the following order.

Unscramber, Air cleaner, Concentrate filler, Valve placer purger, Valve crimper, propellant filler, water bath, Labeler, Coder and Packing table.

→ Purger, Vacuum crimper and pressure filler are peplaced with a single unit if filling is carried by 'under' the cap method.

÷ Cold filling Apparatus ÷

→ It consist of an insulated box fitted with copper tubings and the tubings are coiled to increase the area exposed to cooling.

→ The insulated box should be filled with dry ice or acetone prior to use.

→ The apparatus can be operated with or without metered values

→ Hydrocarbon propellant cannot be filled into aerosol containers using this apparatus because large amount of propellant escapes out and vaporizes.

→ This may lead to formation of an explosive mixture.

→ Fluorocarbon vapors do not form any explosive or flammable mixture though their vapors are heavier than air

Procedure ÷ Non Aqueous products and products which can withstand low temperatures of -40°F are used in this method.

→ The product concentrate is chilled to a temperature of -40°F and filled into already chilled container.

→ Then the chilled propellent is added completely in 1 to 2 stages, depending on the amount

→ Another method is to chill both the product concentrate and propellant in a separate pressure vessel to -40°F and then filling them into the container

→ The valve is placed and crimped on to the container.
→ Then test for leakage and strength of container is carried out by passing container into a heated water bath, where the contents of the container are heated to 130° F. After this the containers are air dried, capped and labeled.
→ Various units used in cold filling methods are Unscramber air cleaner, Concentrate filler, Propellent filller, Valve Placer, Valve crimper, Water bath, Labeler Coder and Packing table.
→ The cold filling methed is no longer being used, as it has been replaced by pressure filling method.

Advantages:- Easy Process.

Disadvantages:- Aqueous products emulsion and those products adversely affected by cold temperature can't be filled by this method.

:- Cold filling Apparatus :-

÷ Compressed Gas Filing Apparatus ÷

→ Compressed Gases have high pressure hence a pressure reducing valve is required.
→ The apparatus consists of delivery gauge.
→ A flexible hose pipe which can withstant 150 pounds per square inch gauge pressure is Attached to the delivery gauge along with the filling head.
→ A flow indicator is also present in specialized equipments

Procedure ÷ → The product concentrate is filled into the containe.
→ Valve is placed and caimped on the container.
→ With the help of vacuum pump the air is removed from the continer.
→ Filling head is put in the opening of the value and the value is depressed and the gas is allowed to flow into container.
→ The gas stops flowing if the delivery pressure and the pressure within the container become equal.
→ Carbon dioxide and nitrous oxide is used if more amounts of gas is required.
→ High salubility of the gas in the product can be achieved by shaking the container manually or with the help of mechanical shakers.

← (5) Leak Testing :-

÷ Quality Control Tests ÷

It includes the testing of -

(1) Propellants.
(2) Valves, Actuators and dip tubes -
(3) Containers.
(4) Weight Checking
(5) Leak Testing
(6) Spray Testing.

÷ (1) Propellants :-

- Vapar pressure and density of the propellant are determined and compared with specification sheet.

Parameter	Tested by -
Identification	Gas Chromatography IR Spectroscopy.
Purity and Acceptability	Moisture, Halogen, Non-Volatile Residue, determination.

(2) Valves, Actuators And Dip Tubes :-

→ Sampling is done according to standered Procedures as found in Military Standards "Mil-Std-105D"

For metered dose aerosol valves, test method were developed by →

→ Aerosol Specifications Committee.
→ Industrial Pharmaceutical Technology Section.
→ Academy of Pharmaceutical Sciences.

→ The objective of this test is to determine magnitude of valve delivery and degree of uniformity between individual valves.
→ Standard test solutions were proposed to rule out variation in valve delivery

:- (3) Containers :-

→ Containers are examined for defects in lining.
→ Quality control aspects includes degree of conductivity of electric current as measure of exposed metals.
→ Glass containers examined for flaws.

:- (4) Weight Checking :-

→ Is done by periodically adding to the filling line tared empty aerosol containers, which after filling with concentrate are removed & weighed.
→ Same procedure is used for checking weight of propellants being added.

← (5) Leak Testing :-

→ It is a means of checking crimping of the valve and detect the defective containers due to leakage.

⇒ Is done by measuring the Crimp's dimension & comparing

→ Final testing of valve closere is done by passing the filled. containers through water bath.

← (6) Spray Testing :-

→ Most Pharmaceutical aerosol are 100% Spray tested

→ This serves to clear the dip tube of pure propellant and pure concentrate

→ To check for defects in valves and spray pattern.

← Evaluation Test :-

(A) Flammability and Combustibility.

(1) Flash Point
(2) Flame Projection.

(B) Physicochemical Characteristics :-

(1) Vapor Pressure (3) Moisture content
(2) Density (4) Identification of Propellants.

(C) Performance :-

(1) Aerosol Value discharge rate (2) Spray pattern
(3) Dosage with metered valves (4) Net contents (5) Foam Stability.
(6) Particle size determination

(D) Biological Testing :-

(1) Therapeutic Activity
(2) Toxicity Studies.

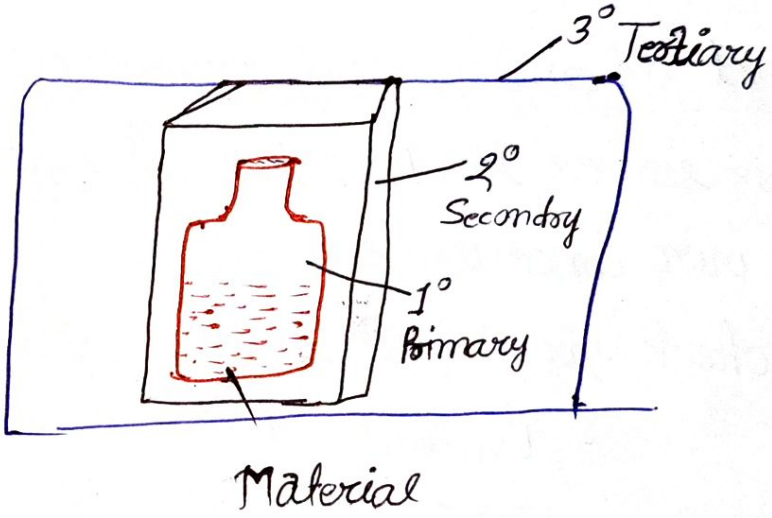
÷ Pharmaceutical Packaging ÷

Packaging ÷ Packaging are those external factor are subs which covers the products and safe the product for external environment and make them attractive

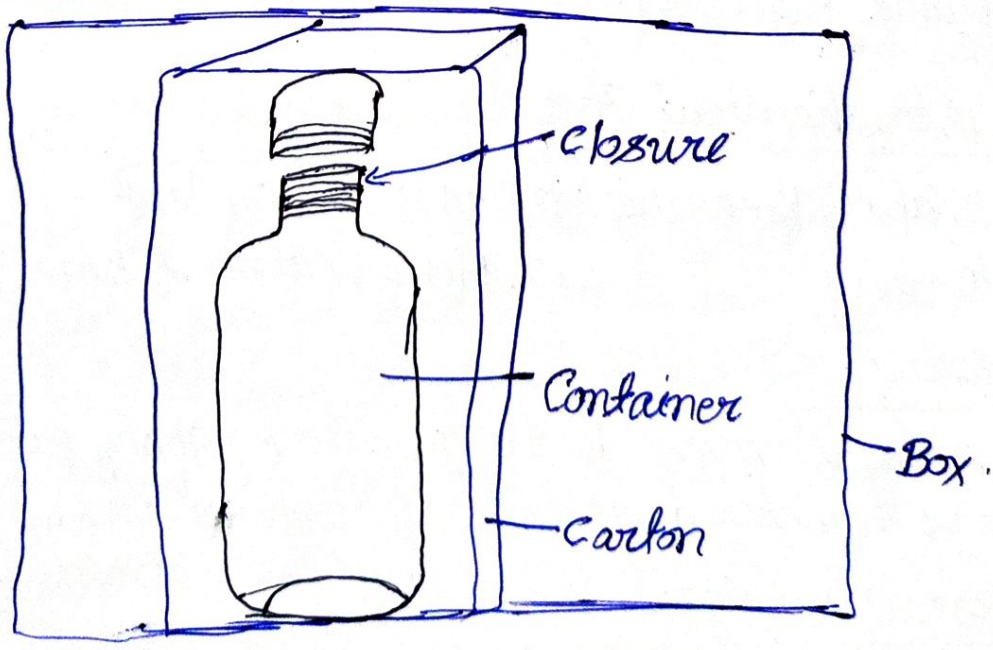
÷ Types of Packaging ÷

Packaging is of three types -

(1) Primary
2° Secondry
3° Tertiary



÷ Comporent of Packaging Material ÷ (C3B)



* Charectarstics of Container :-

→ Sufficient Strong → It should be sufficient strong so they can bear all kind of fource.

→ Does not allow loss or leakage.

→ It should be inert.

→ With stand heat :- It should be stand the heat so during the heat sterilization process it can bear the maximum heat.

→ Surface clear for the labeling.

→ Must not absorb.

→ Light protectar.

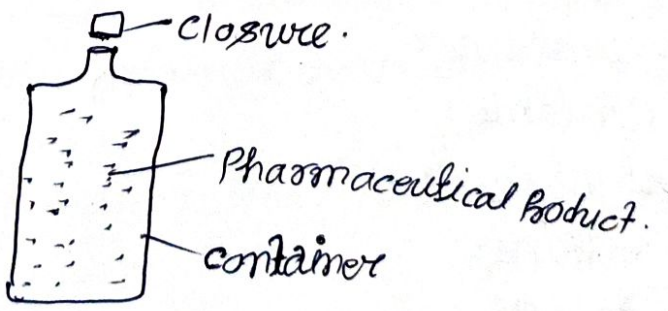
→ Size variable

:- Closure and container :-

→ Container is a device which hold the substance.

→ Pharmaceutical container is an device which hold the drug and direct connect with the pharmaceutical product.

→ Closure is a device that close the container.



÷ Closure Container Provide ÷

- Safety
- Protection from external
- Identification.
- Transportation.
- Information.
- Convenience and stability to the drug.

÷ Classification of Container ÷

On the basis of closure of container with drug it is classified in 3 types -

÷ Types of container ÷

- On the basis of use of container it is of following types -

1) Well closed container.
2) Single dose container
3) Multidose container
4) Light resistant container.
5) Air tight container.
6) Aerosol container
7) Child resistant container.

(i) Well closed Container: A well closed (closed) container protect the content from loss during transportation handling and storage and etc.

Ex- Ampule, Vial.

2) Single dose container: These container are used to supply only one of medicine and it hold generally parenteral dose.

Ex- Ampule.

3) Multidose Container: These containers allow with the drawer of dose at various interval without changing the strength, quality and purity of remaining product.

→ The containers hold more than one dose and use for injectiva

Ex- Vial.

4) Light Resistant container: These containers protect the medicine from harmful effect of light.

→ These container are use to store those medicine which are phato sensitive.

5) Air tight container: These are also called hermetic container. These container have air tight sealing on closing.

→ These container protect the product from dust moisture and air.

→ These air tight container are used for injectibles.

6) Aerosol Containers :- These containers are used to hold aerosol product.

- These container have adequate mechanical to bear the pressure of aerosol packing.

7) Child resistant container :- Child resistant container that is fixed with a closure that prevent opening by children.

← Material Used for Container :-

- They are mainly four types of material for preparation of container.

→ Glass
→ Plastic
→ Metal
→ Rubber.

÷ Glass container ÷

Glass container is widely used as a packaging material it is use for oral local administrations.

- Mainly Glass container is made by silicon dioxide tetra hydrogen oxide.

Types of Glass

Glass is of two type-

(1) Transparent glass container.

(2) Color glass container.

÷ Types of Glass container ÷

→ On the basis of nature and function glass is a four types.

→ Type one glass - Highly resistant boosilicate glass

→ Type two glass - Treated sodalime glass.

→ Type three - Soda lime glass.

→ Type Four glass — General purpose sodalime glass.

÷ Glasses used in pharmaceutical practices ÷

Glass Type	General Discription	Test method	Uses.
Type-1	Highly resistant boosilicate glass	powdered glass	Buffered & Unbuffered aqueous solution.
Type-2 -	Treated soda lime glass	Water attach	Buffered aqueous soln. with pH below 7.0 dry powder oleagenous soln.
Type-3.	Soda lime glass	Powdered Glass	Dry powders, oleagenous solution.
Type-4.	General Purpose Soda lime glass.	Powdered glass.	Not for parenterals oral soln. For tab. and suspensions ointments & external liquids.

÷ Advantages of Glass Containers ÷

⇒ It allow easy inspection of the containers contents
⇒ It also have the great advantages of preserving a certain temp. for a longer period of time. They do not dilute when it is too warm or shrink. when exposed to lower temp: they are available in various shape and sizes.
⇒ They are economical and readily available.
⇒ They can protect the photosynthetic medicaments from light during their storage.
⇒ They do not deteriorate with age.

÷ Disadvantages of glass Containers ÷

⇒ They are brittle and break easily
⇒ They may crack when subject to sudden changes in temp.
⇒ They are heavier in comparison to plastic containers
⇒ They can cause light transmission.

Special Labelling requirement

→ Labelling is the useful instruction and information which is prepaid

→ In this label following information should be given.

1) Brand name
2) Quantity
3) Indication.
4) Composition
5) Company details < Manufactured by
   Marketed by.

Herbal — Green
Animal — Red
Drug — Red line.

6) Product details
   - Batch no ____
   - Drug Lic. no ____
   - Mfg Date ____
   - Expiry date ____

7) Instruction
   - Schedule 'X' drug ____
   - Shake well before use ____
   - Each ml contains ____

Diastage - 200mg
pepsin - 400mg
Oparcine - 100mg

MFG by → 3. No - 4055D
KCL Pharma → KclZyme Lic no - AT392
Kamna bazar →
Mfg Date → 3/06/15
Exp. date → 03/07/2021
Marketed by
Dr A.K Pharma
Naini All.

Do not take without physician
shake well before use.
→ away far child.

TYPES OF PACKAGING MATERIALS USED FOR PHARMACEUTICAL PACKAGING

- Glass
- Plastics
- Rubbers
- Paper/card boards
- Metals

PLASTIC

- Plastics may be defined as any group of substances, of natural or synthetic origins, consisting chiefly of polymers of high molecular weight that can be moulded into a shape or form by heat and pressure.

Advantages

- Less weight than glass,
- flexible
- Variety of sizes and shapes
- Essentially chemically inert, strong, rigid Safety use, high quality, various designs
- Extremely resistant to breakage

Disadvantages

- Absorption permeable to moisture
- Poor printing, thermostatic charge

TYPES OF PLASTICS

Thermosetting type –

When heated they may become flexible but they do not become liquid

e.g. Urea formaldehyde (UF),Phenol formaldehyde ,Melamine formaldehyde (MF), Epoxy resins (epoxides), Polyurethanes (PURs)

Thermoplastics type-

On heating they are soften to viscous fluid which harden again on cooling.

e.g. Polyethylene{HDPE – LDPE}, Polyvinylchloride(PVC),Polystyrene Polypropylene, Nylon(PA), Polyethylene terepthalate(PET) ,Polyvinylidene chloride(PVdC), Polycarbonate Acrylonitrile butadiene styrene(ABS)

METALS :

Metals are used for construction of containers. The metals commonly used for this purpose are aluminium ,tin plated steel, stainless steel, tin and lead

Advantages:

- They are impermeable to light, moisture and gases.
- They are made into rigid unbreakable containers by impact extrusion.
- They are light in weight compared to glass containers.
- Labels can printed directly on to their surface.

Disadvantages:

- They are expensive.
- They react with certain chemicals

COLLAPSIBLE TUBES METAL

- The collapsible metal tube is an attractive container that permits controlled amounts to be dispensed easily, with good reclosure, and adequate protection of the product.
- It is light in weight and unbreakable and lends itself to high speed automatic filling operations.
- Most commonly used are tin, aluminium and lead.

Tin:

- Tin containers are preferred for food, pharmaceuticals and any product for which purity is considered.
- Tin is the most chemically inert of all collapsible metal tubes .

Aluminium:

- Aluminium tubes offer significant savings in product shipping costs because of their light weight .
- They are attractive in nature

Lead:

- Lead has the lowest cost of all tube metals and is widely used for non food products such as adhesives, inks. paints and lubricants.
- Lead should never be used alone for anything taken internally because of the risk lead poison .
- With internal linings, lead tubes are used for products such as chloride tooth paste.

RUBBER:

- Rubber is used mainly for the construction of closure meant for vials, transfusion fluid bottles, dropping bottles and as washers in many other types of product.

BUTYL RUBBER:

Advantages:

- Permeability to water vapour .
- Water absorption is very low.
- They are relatively cheaper compared to other synthetic rubbers.

Disadvantages:

- Slow decomposition takes place above 130 ◦ C.
- Oil and solvent resistance is not very good.

NITRILE RUBBER:

Advantages : Oil resistant due to polar nitrile group. Heat resistant.

Disadvantages:

Absorption of bactericide and leaching of extractives are considerable.

CHLOROPRENE RUBBERS :

Advantages: Oil resistant. heat stability is good.

PACKAGE TESTING

- Drop test
- Vibration test
- Shock test
- Inclined impact test
- Revolving drum test