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PHARMACEUTICS 1

IMPORTANT QUESTIONS AND ANSWERS

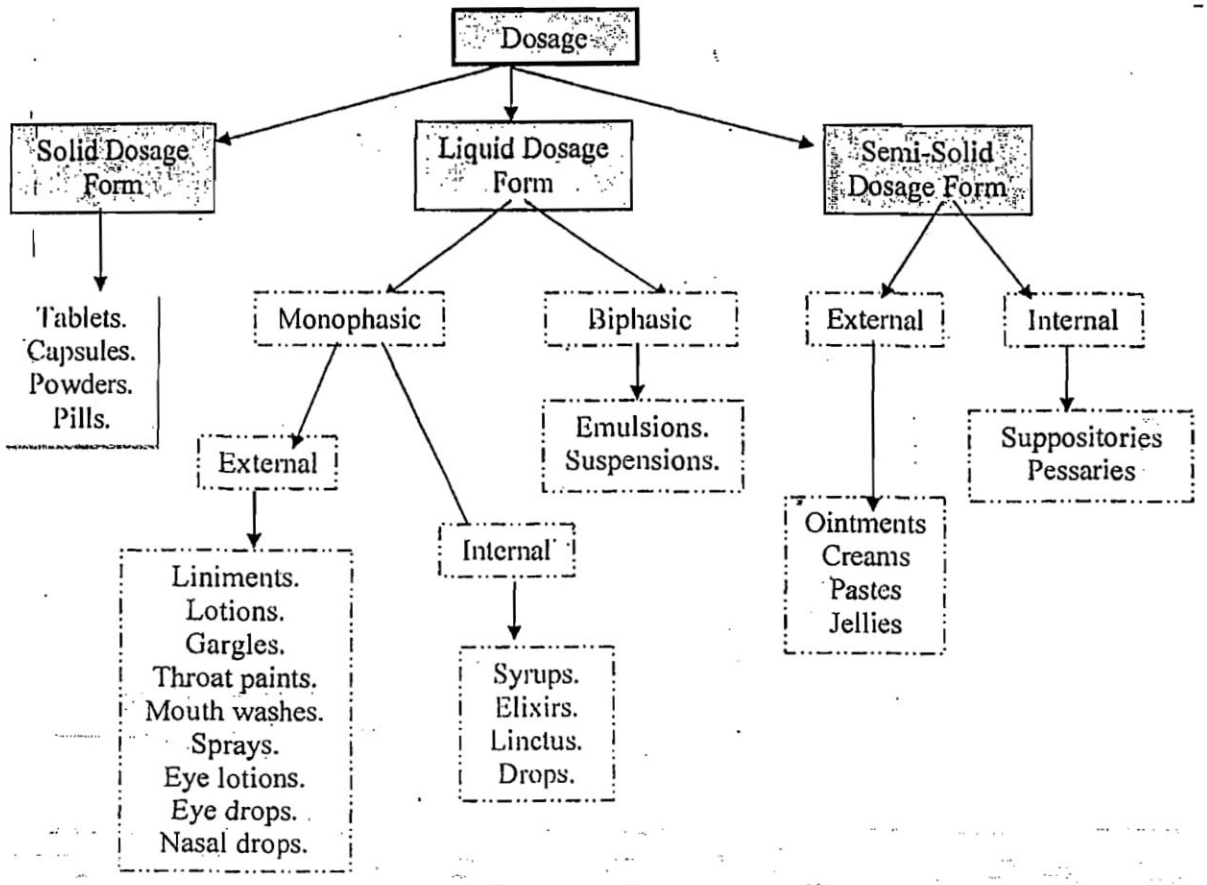
CONTENTS

CHAPTER.1
DIFFERENT DOSAGE FORMS

Q.1 Define dosage forms and classify different dosage form with examples.

Ans: A dosage form may be defined as a combination of medicament and non medicament components with mixture of suitable excipients.

Classification of dosage forms:



Solid Dosage Form: The solid dosage forms are available mostly in unit dosage forms (consisting of doses which are taken by numbers) such as tablets, capsules, pills, cachets or powders etc.

Liquid Dosage Form: Liquid dosage forms are meant for internal, parenteral or external use. They are available in Monophasic or biphasic form.

Semi-Solid Dosage Form: Semi-solid dosage forms are meant for external application.
E.g. ointments, creams, pastes, jelly etc.

Q.2 What are new drug delivery systems?

Ans: In the last few years, many novel dosage forms (New Drug Delivery Systems) have been developed and are being used now.

Some of the Important New Drug Delivery Systems:

1. Films & Strips: Buccal Strips, Zero order release films, Sprayable bandages.
2. Implants (Magnetically Controlled) eg: Insulin.
3. Nanoparticales: FITC (Fluorescein Isothiocyanate)
4. Erythrocytes: Allow Drugs to Flow for longer period.
5. Prodrugs: eg: Procaine-Penicillin G.
6. Liposome Drug Carriers: eg: Protein.
7. Controlled Drugs Delivery Modules: eg: Cellulose Esters.
8. Magnetic Microspheres.

CHAPTER. 2
INTRODUCTION TO PHARMACOPOEIAS

Q.1 What is Pharmacopoeia & write its importance.

Ans: Pharmacopoeia is a book containing a list of drugs and formula for medicinal preparations, together with descriptions of these substance, tests for identification and purity, and description of method of standardization for each drug either chemical and biology method. The pharmacopoeia is first used in 1580 in a book on drug standards printed in Italy.

Importance of pharmacopoeia:

The importance of pharmacopoeia is to select substances which possess medicinal power, convert them into preparations of suitable composition in order to enhance their power to the maximum advantage. Ex: U.S.P.

List of various pharmacopoeias:

Indian Pharmacopoeia (I.P)
British pharmacopoeia (B.P)
United Stated Pharmacopoeia (U.S.P)
National Formulary (N.F)
European Pharmacopoeia
International Pharmacopoeia

Monograph of I.P.

Main Title
Subsidiary Titles
Chemical Formula, Mol.Wt. Systematic Chemical Name, Quantity Standards of Purity or Strength
Description
Solubility
Identification of Specific or Non-Specific Tests.
Method of Assay
Methods of Storage and Labeling
Preparations
Action and Use
Doses

Q.2 Write a note on historical background of Indian pharmacopoeia.

Ans: Historical backgrounds of Indian pharmacopoeia are as follows: In 1946 The Government of India published the Indian Pharmacopoeia list which served as Supplement of British Pharmacopoeia. The Pharmacopoeial list contained about 180 monographs. After Publication of this list, Govt. of India Constituted a Permanent Indian Pharmacopoeial Committee.

In 1948, this committee assigned the work to prepare the Indian Phamacopoeia to keep it up to date. The first edition of Indian Pharmacopoeia was published in 1955 and a supplement of it was published in 1960.

The work of Version of the Indian Pharmacopoeia as well as the Compliance of New Edition was taken up simultaneously under the chairmanship of Dr. B.N.Gosh, Professor of Pharmacology, R.G.Kar, Medical College, and Calcutta.

.The Second Edition of Indian Pharmacopoeia was published in 1966 and a supplement of it was published. A Working group was constituted by the Committee to Prepare the Monograph, Appendices and general notice that were finalized by the Pharmacopoeial Committee. The same was published in the form of Pharmacopoeia of India in 1985, in two volumes i.e. volume-I and volume-II.

The first Indian Pharmaceutical codex was published in 1953. The codex consists of two part. Under the Drugs and Cosmetics Act 1940, The Indian Pharmacopoeia is an official book which contains the standards for drugs and other related substances included in the pharmacopoeia.

Q.3 Write a note on british pharmacopoeia

Ans: History of British pharmacopoeia: The medicinal act of 1858 brought the drastic changes in the medical profession. Under section of this act General Council of Medical Education and Registration enacted and was given this work. The book was named as British Pharmacopoeia. The first British Pharmacopoeia was published in 1864. More useful and successful reprint was published in 1874.

Medicine commission in accordance with the same act reconstituted the British Pharmacopoeia Commission, and Under Section 99 (1) of the Medicine Act. Preparation of the British Pharmacopoeia is the responsibility of British Pharmacopoeia Committee.

The thirteen edition of B.P was published in 1980, 14th in 1988 and 15th in 1993.

Q.4 What are the silent features of the sixth edition of Indian pharmacopoeia?

Ans: The 6th edition of the Indian Pharmacopoeia 2010 is published by the Indian Pharmacopoeia Commission (IPC) in accordance with a plan and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years.

The Indian Pharmacopoeia 2010 is presented in three volumes. Volume I contains the Notices, Preface, the Structure of the IPC, Acknowledgements, Introduction, and the General Chapters. Volume II contains the General Notice, General Monographs on Dosage Forms, Monographs on drug substances, dosage forms and pharmaceutical aids (A to M). Volume III contains Monographs on drug substances, dosage forms and pharmaceutical aids (N to Z) followed by Monographs on Vaccines and Immunosera for Human use, Herbs and Herbal products, Blood and blood-related products, Biotechnology products and Veterinary products.

The scope of the Pharmacopoeia has been extended to include products of biotechnology, Standards for new drugs and drugs used under National Health Programmes are added and the drugs as well as their formulations not in use now a days are omitted from this edition. A new chapter on Liposomal products and a monograph of Liposomal Amphotericin B injection is an added advantage in view of latest technology adopted for drug delivery. A chapter on NMR is incorporated in Appendices. The chapter on microbial contamination is also updated to a great extent to harmonise with prevailing international requirements.

CHAPTER.3
WEIGHTS AND MEASURES

Q.1 Define and classify different system of weights and measures followed in pharmacy with suitable examples.

Ans: **Weights**: It is a measure of gravitational force acting on a body and is directly proportional to its mass.

Measures: It is the measurement of volume of any substance.

There are two systems of Weights and Measures. They are:

1.Imperial system and 2.Metric system.

Imperial System: The Standard of Imperial system is Pound (lb)

The Imperial system consists of: 1) Avoirdupois System, and
2) Apothecaries System

1) Avoirdupois System of Weights and Measure.

1 Ounce (Oz)	=437.5 Grain (Gr)
1 pound (Ib)	=16 ounce (7000 gr)
1 pound (Ib)	=7000 grains
1 fluid ounce	=8 fluid drachm (fl dr)
1 fluid drachm	=60 minims
1 pint (pt)	=20 fluid ounce
1 quart	=40 fluid ounce
1 gallon	=160 fluid ounce=4 quart.

GALLON: It is define as the volume occupied by ten imperial standards.

2) Apothecaries System of Weights and Measure.

20 grains	=1 scruple
60 grains	=1 drachm
8 drachm	=1 ounce
12 ounce	=1 pound

Measure of volume is same as avoirdupois system

Metric System: Standard unit of measures of mass (weight) is kilogram and all other measures of capacity are derived from kilogram.

1 Ton	=1000 Kilogram
1 Quintal	=100 Kg
1 Kilogram	=1000 Grms
1 Hectogram	=100 Gram
1 Decagram	=10 Gms
1 Decigram	=0.10 Gms
1 centigram	=0.001 gms
1 milligram	=0.0001 gms
1 microgram	=1/1000mg
1 nanogram	=1/1000 microgram
1 picogram	=1/1000 nanogram

Measures of capacity: Standard unit of measures of capacity (volume) is litre and all other measures of capacity are derived from litre.

1 Litre (lt) = 1000 millilitre(ml)
1 hectoliter =100 litre
1 litre =1000.028 cubic centimeter
1 litre =33.8 fl. ounce

Relation of imperical system with metric system:

4 Millilitre =1 fluid drachm
1 gram =15.432 grain
1 kg =2.2046 pounds
1 ounce =28.35 gms
1 pound =453.59 gms
1 grain =0.064 gms
1 litre =35.196 fl-ounce
1 ml =16.9 minim
1 min/im =0.0592 ml
1 fl-ounce =28.41 ml

Approx. equvalents:

30 ml =1 fluid ounce
30 gms=1 ounce
1 G =15 grains
1 ml =15 min
1 teaspoonful =4 ml
1 desert spoonful =8 ml
1 table spoonful =15 ml.

CHAPTER.4
PACKAGING OF PHARMACEUTICALS

Definitions:

Packing: It is the process by which the pharmaceuticals are suitably packed so that they should retain their therapeutic effectiveness from the time of their packing till they are consumed.

Container: A container is a vessel or devices which hold the drugs or pharmaceutical dosage form.

Closure: The closure is a part of the container. Closure is a device, by means of which the container can be opened and closed.

Q.1 Write the desirable features of a container and write the different types of material used for the construction of containers.

Ans: Desirable features of container:

1. A container must give sufficient mechanical strength to withstand when emptying, filling, closing, and processing, transport and storage.
2. It must be able to withstand heat during sterilization.
3. It should not react with the product.
4. It should not alter the stability of the medicament.
5. It should protect the preparation from environmental hazards.
6. It should be low in cost.
7. The surface of the container should be uniform for easy labeling.
8. The container must be so designed so as to facilitate withdrawal of dose in a convenient manner as and when required.

The following materials are used for the construction of containers:

They are used either singly or sometimes in combination with each other. (1) glass (2) plastics (3) metals (4) paper

(1) glass: Glass is mostly produced by heating of silica (SiO_2), soda ash (Na_2CO_3) and lime stone ($CaCO_3$) in about 1400^0C.

(2) Plastics: Plastics are high polymers weight possessing long carbon chains.

There are two types of plastics **(i)** Thermosetting Type **(ii)** Thermoplastic Type

(3) Metals: Metals containers are not very popular for packing for pharmaceutical products because they may react with the preparations. For this purpose tin plated steel, stainless steel and aluminium containers are used.

(4) Papers: It is widely used in pharmaceutical industries in one form or the other. Their properties can be modified by treating it with plastic, wax and other materials.

Q.2 Write the desirable features of closure and which are the materials used for the constructions of closures:

Ans: Desirable features of a closure:

1. It must give sufficient mechanical strength to withstand when closing, and storage.
2. It must be enough elasticity and hardness.
3. It must be able to withstand heat during sterilization.
4. It should not react with the product.
5. It should not alter the stability of the medicaments.
6. It should be low in cost.
7. It must prevent loss of the product by volatilization.
8. It must prevent loss of the product during transportation and handling.

Materials used for the constructions of closures are:

1) Cork: It is essentially a wood obtained from the bark of oak tree. It is used as stoppers for narrow mouth bottles.

2) Glass: It is an ideal material for making stopper but these stoppers have the difficulties that they do not provide leak proof closures.

3) Plastics: Plastics closures are becoming more popular day by day because of their ease & convenience.

4) Rubber: Natural rubber consists of latex. Rubber closures are mainly used for vials, multidose containers & IV fluid bottles.

5) Metals: Tin plates and aluminium are most widely used.

Q.3 Write a note on glass containers.

Ans: Glass is the most popular material used in pharmaceutical packaging because it is transparent., available in various shapes and sizes, withstand in temperature and pressure during sterilization, protect the light sensitive medicament., they do not detoriate with age.

Glass is mostly produced by heating a mixture of silica, soda ash, limestone in a furnace at about 1400^0C. The fused mass on rapid cooling founds glass.

Different types of glass used are:

a) Type I-borosilicate glass
b) Type II-treated soda-lime glass
c) Type III-soda-lime glass
d) Type NP-non-parenteral glass
e) Colored glass
f) Neutral glass

Advantages:

1. Glass has more superior protective property.
2. Economical.
3. It can be moulded any shape.
4. Chemically inert.
5. Strong and Rigid
6. Transparent
7. Can be sterilized by any method.

Disadvantages:

1. Easily breakable.
2. More weight.
3. Some times containers impart alkalinity.

Q.4 Write a note on plastic as container.

Ans: plastics are synthetic polymers of high molecular weight. In addition to the polymer plastics contain lubricants, stabilizers, plasticizers, antioxidants, dyes and pigments.
There are two types of plastics **(i)** Thermosetting Type **(ii)** Thermoplastic Type
(i)Thermosetting Type: plastics are usually hard and brittle at room temperature but become flexible on heating. They are used for making the closures for bottles and jars.
Ex: shampoos and creams dispensed in flexible type.
(ii) Thermoplastic Type: Thermoplastic Type of plastic is used for manufacture of plastic containers used for packing mixture, tablet, capsules, ointment etc. this type of plastic gets softened to viscous fluid on heating and hardness again on cooling.

Various thermoplastic polymers used for the manufacture of containers are:

a) Low density polythene
b) High density polythene
c) Polyvinyl chloride (PVC)
d) Polystyrene
e) Polypropylene
f) Poly methylmethacrylate (PMMA)
g) Polytetrafluoroethylene (PTFE)
h) Polyamides (nylons)

Advantages:

1. They are cheaper as compare to other containers.
2. They are unbreakable tough and flexible.
3. They are light in weight and can be easily transported.
4. They can be moulded into various size and shapes.

Disadvantages:

1. They cannot with stand heat.
2. They can interact with certain chemicals acids, oils etc.
3. They may change with age.
4. They are permeable to water vapour and atmospheric gases.

Q.5 Describe briefly the rubber as a closure.

Ans: Rubber consists of a long chain polymers of isoprene units linked together. Types of rubbers are 1) Natural rubberand 2) Synthetic rubber.

1) Natural rubber: it consists of latex from heavea brazileinsis and is an isoprim polymer.

2) Synthetic rubber: synthetic rubber are silicon, neoprene, nitrite or butyl rubber. They are expensive.

Advantages:

1. It should provide air tight closing tom the container.
2. It should compatible with the preparation in the container.
3. Withstand sterilization temperature.
4. Soft and elastic in nature.
5. Doesnot detoriate with age.
6. Unbreakable tough and can be easily transported.
7. It gives sealing for the containers.

Disadvantsges:

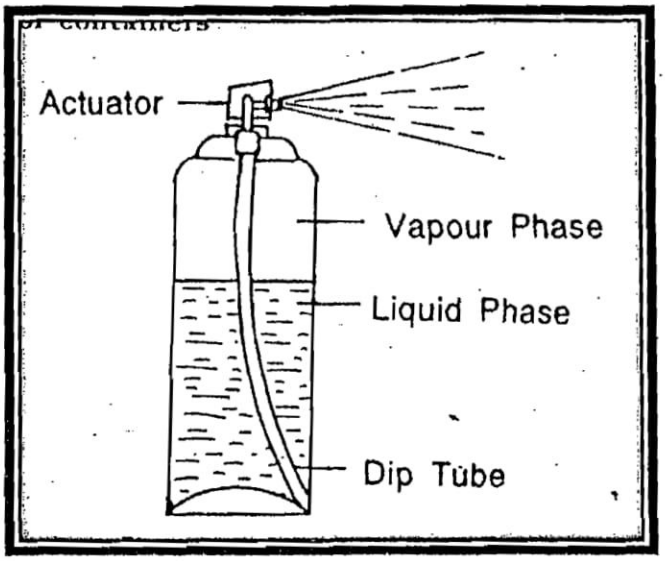
1. The composition of rubber is complex and manufacture process is complicate.
2. It may absorb the active medicament, preservatives or other material when it comes in contact with parenteral solution.
3. The additives contain may impart to the preparation.

Q.6 Define aerosol. Explain construction &working of aerosol.

Ans: A pharmaceutical aerosol may be defined as the preparation containing the active medicaments dissolved, suspended or emulsified in a propellant or a mixture of solvent and propellant and packaged in a pressurized aerosol container.

Construction of aerosol:

Aerosol is packed in metal containers and glass containers. Aerosol containers can be divided into four parts namely:- 1. Container 2. Dip tube 3. Valve 4. Actuator



1. Container: Aerosol containers are made from glass, synthetic resins, plastics and metals such as aluminum tin plated steel etc. these containers provide a good mechanical strength and can withstand a high pressure.

2. Dip tube: It is a tube which is attached to the bottom of the valve and leading down to the bottom of the container .whenever the actuator is pressed, the product enter into the dip tube and sprayed.

3. Valve: various types of valves are used in aerosols. In continuous spray valve, the product is expelled until the pressure is completely released .Only a definite quantity is expelled when the actuator is pressed.

4. Actuator: various types of actuator are available and used in aerosol. It is fitted on the valve system. The actuator helps to open and close the valve when required. A fine spray of the product is expelled through the valve orifice and actuator nozzle into the atmosphere.

Working of aerosol:

1. Aerosol is prepared by dissolving the active medicament and other additives such as solvent antioxidant, surface active Agent, flavoring agent are dissolved in propellant. This final product is known as aerosol.

2. The propellants used in liquefied gas or mixture of gases.

3. Aerosols are packed in aerosol containers. The propellants are low boiling substances so that a pressure is excreted within the container even at room temperature.

4. Whenever the actuator is pressed, the valve opens and a fine spray of the contents is expelled through the valve orifice and actuator nozzle into the atmosphere until the pressure is completely released.

Advantage:

1. Aerosol packaging protects the medicaments from light, dust, atmospheric moisture.
2. They protect the medicaments from atmospheric oxidation.
3. They maintain the sterility of the product.
4. Measured doses applied directly into the affected part.
5. It is easier and convenient.

Disadvantages:

1. The cost of the packaging is high.
2. When the container is stored at high temperature, the internal pressure may develop inside the container.

Containers used for aerosols: Various materials have been used in the manufacture of aerosol, A container includes:

a) **Metal**:
   1) Tin plated steel: side seam (3 pieces) two piece or drawn tin free steel.
   2) Aluminium: two piece, one piece (extruded or drawn)

b) **Glass**: un-coated glass, plastic coated glass.

c) **Plastics**: 1) Its adaptability to production methods.
   2) Compatibility with formulation components
   3) Ability to sustain the pressure intended for the product.
   4) Aesthetic appeal on the part of the manufacturer.

CHAPTER.5
SIZE REDUCTION

Q.1 Define size reduction and write the different mechanisms of size reduction.

Ans: Size reduction means to reduce the size of the material. It is defined as the mechanical process by which the drug or any other material is reduced to smaller pieces or coarse powder or fine powder.

Mechanisms of size reduction:

Cutting: The material is cut on small pieces by means of a sharp blade or any other sharp instrument. **Eg.** Cutter mill.

Compression: The material is crushed by the application of pressure on the small scale; size reduction is carried out by using pestle or mortar. **Eg.** Roller mill.

Impact: It occur when the material is more or less stationary and is hit by an object moving at high speed and material breaks into small pieces. **Eg.** Hammer mill and Disintegrator.

Attrition: In attrition pressure is applied on the material as in the case of compression, but the surfaces are in motion relation to each other, resulting in shear forces which break the particles into still smaller sizes. **E.g.** Roller mill or motor pestle.

Combined Impact and Attrition: The mechanism of impact and attrition can be combined in the mill to get better result. **Eg.** Ball Mill, Fluid-energy Mill.

Q.2 Write the application of size reduction in pharmacy.(or) objective of size reduction.(or) advantages and disadvantages of size reduction.

Ans:

Advantages of size reduction:

1. Size reduction is essential to prepare various pharmaceutical dosages forms such as tablets, capsules, injection, etc.
2. It is useful to increase surface area which ultimately increases the rate of solution and absorption.
3. It is useful for exposing tissues for easy penetration in extraction.
4. It helps the processes of drying and mixing.
5. It is useful for easier and economical.
6. On reducing the particle size the bulkiness of certain drugs can be increased.

Disadvantages of size reduction:

1. On grinding, the aromatic and volatile constituents of crude drug may be lost due to increased temperature during grinding.
2. Due to increased surface area & if exposed to atmospheric conditions, it may result in oxidation and hydrolysis.

Q.3 Which are the factors affects size reduction.

Ans: The following factors affect the process of size reduction:

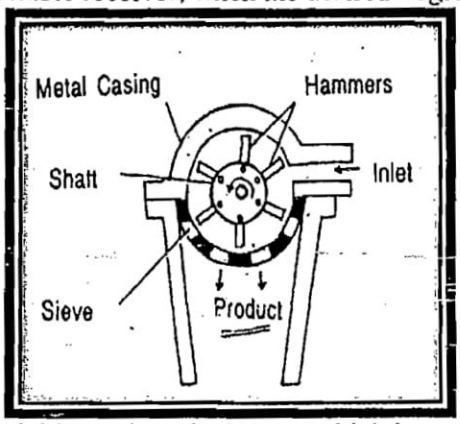
1. **Hardness:** If the material is very hard, it is difficult to reduce into smaller particles.
2. **Toughness:** a soft and tough materjal cause more problems in size reduction than a hard brittle substances.

3. **Stickness:** some substances may stick to the sides of the instrument and making the process of size reduction difficult.
4. **Temperature:** size reduction process produces heat. Drugs containing oils or fats or waxy substances like stearic acid may melt during the sizer reduction process. So such substances cannot be processed.
5. **Mouisture content:** the presence of moisture in the material influences a number of its properties such as hardness, toughness or stickiness which in its turn affects the particle size reduction.
6. **Physiological effect:** some drugs are very potent. During their particle size reduction in a mill, dust is produced which may have an effect on the operator. In such cases enclosed mills are used to avoid dust.

Q.4 Describe the construction and working of hammer mill (or) what is impact mill? discuss in detail the construction and working of any one of the impact mill?

Ans: Impact Mill: In these methods, material is more or less stationary and is hit by an object moving at high speed, or moving takes place by both the ways. **Eg.** Hammer Mill.

Principle: It works on the principle of impact i.e. material is more or less stationary and is hit by an object moving at a high speed.
Construction: It consist of a steel casing ,enclosing a central shaft ,to which four or more swinging hammers are attached .The lower part of the casing consists of a screen, through which material can pass and collected in a suitable receiver, when the desired degree of size reduction is attached.



Working: The material is put into the hopper which is connected with the drum. The material is powdered to the desired size, due to fast rotation of hammers and is collected under the screen. This mill has the advantage of continuous operation because the chance of jamming is less as the hammers are not fixed. It can produce coarse to moderately fine powder.
Due to high speed of operation, heat is generated which may affect thermoliable drugs or materials. Moreover, high speed of operation also causes damage to the mill if foreign objects such as stone or metal is present in the feed.
Uses: The hammer is used for producing intermediate grades of powder from almost all types of substances except sticky materials that choke the screen.

Q.5 Principle, construction and working of ball mill.

Ans: Principle: It works on the principal of Impact and attrition.

Construction: It consists of a hallow cylinder which is mounted on a metallic frame in such a way, that it can be rotated on its longitudinal axis. The cylinder contains balls that occupy 30 - 50% of the mill volume. The weight of the balls is kept constant. The ball size depends on the size of the feed and the diameter of the mill. The cylinder and the balls are made of metal.

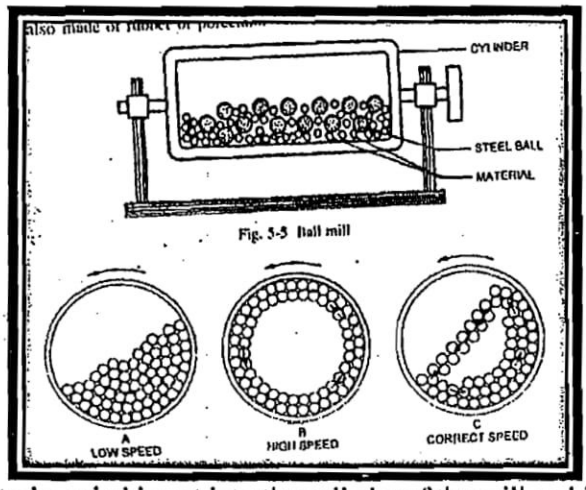


Fig. 5-5 Ball mill

Working: The drug to be grind is put into the cylinder of the mill and is rotated. The speed of rotation is very important. At a low speed, the mass of balls will slide or roll over each other and only a negligible amount of size reduction will occur. At a high speed, the balls will be thrown out to the walls by centrifugal force and no grinding will occur. But at about 2/3rd of the speed, the centrifugal force just occurs with the result that the balls are carried almost to the top of the mill and then fall in. By this way the maximum size reduction is effected by the impact of particles between the balls and by attrition between the balls.

After a suitable time, the material is taken out and passed through a sieve to get powder of the required size.

Uses: The mill is used to grind brittle drugs to fine powder.

Advantages:

1.It can produce very fine powders.
2. It can be used for continuous operation, if sieve or classifier is attached to the mill.
3. It is capable of grinding a large variety of materials of different character and of different degree of hardness.
4. It is suitable for both wet and dry grinding processes.
5. It can be used to grind toxic materials as it can be used in a completely enclosed form.

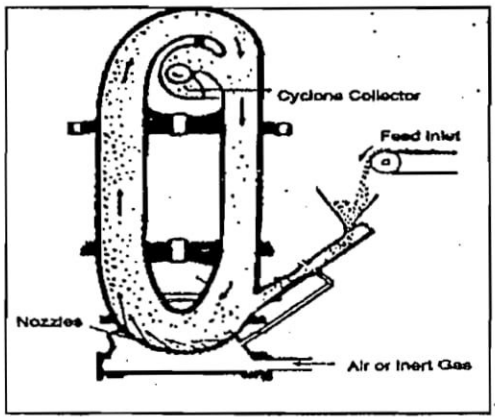
Disadvantages:

1. Ball mill is very noisy machine.
2. Wear occurs from the balls as well as from the casing, which may result in contamination of the product.

Q.6 Construction and working of the fluid energy mill.

Ans: Principle: It works on the principle of impact and attrition.

Construction: It consist of a loop of pipe, which has a diameter of 20 to 200 mm, depending on the overall height of the loop, which may be upto about 2m.There is an inlet for the fee and a series of nozzles for the inlet of air or an inert gas. It also has an outlet with a classifier which allows the air to escape but prevent the particles to pass until they become sufficiently fine.



Working: The air or inert gas is introduced with a very high pressure through the nozzles. Solids are introduced into air stream through inlet .Due to high degree of turbulence ,impact and attritional forces occurs between the particles .The fine particles are collected through a classifier .Fluid energy mill reduces the particles to 1 to 20 micron. To get a very fine powder, even up to five micron, the material is pretreated to reduce the particle size to the order of 100 mesh and then passed through fluid energy mill.

Uses: The mill is to grind heat sensitive materials to fine powder. The mil is used to grind those drugs in which degree of purity is required.

Advantages:

1. The mill is used to grind the material to fine powder.
2. The particle size of the powder can be controlled due to the use of a classifier.
3. There is no wear of the mill and hence there is no contamination of the product.
4. It is useful for grinding heat sensitive substances such as sulphoamides, vitamins.

Q.7 Construction and working of the disintegrator.

Ans:

Principle: The size reduction in disintegrator is done by impact.

Construction: It consists of a steel drum having a shaft in the centre. The shaft contains a disc, on which four beaters are fixed .The shaft rotates with a speed of 5000-7000 rpm. The side and upper inner surface of the drum is rough and undulating. The lower part of the drum has a detachable screen or sieve. The sieve has a definite pore size.

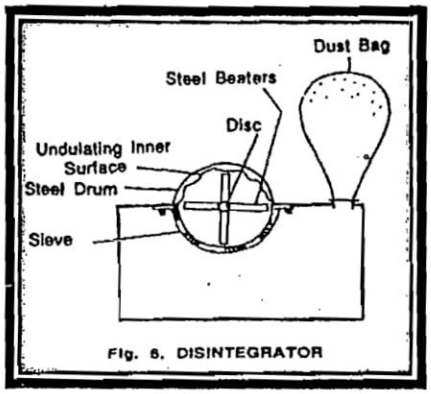


Fig. 6. DISINTEGRATOR

Working: The beaters are mainly responsible for grinding but are helped by the undulation of the inner surface and roughness of drum. The materials are feed to beaters, through hopper which is fitted to the drum. The material is broken into small particles by impact of the beaters. Due to high velocity of beaters the air velocity inside the chamber is increased. The air is allowed to pass through an outlet on which dust bag is tied, which retains the fine particles of powder.

Uses: The mill is used to powder all types of drugs including very hard drugs. The drugs should be dried before feeding into the disintegrator to get fine powder. To avoid the jamming of the beaters of the disintegrator, use moderately small pieces.

CHAPTER.6
SIZE SEPARATION

Q.1 Define size separation and give its importance.

Ans: Size separation process may be applied to the measurement of particle size, in which the portion of each size of particle in a sample is determined and data is utilized to control raw or to maintain the quality of manufacture product.

Importance of size separation:

1. It is applied to the measurement of particle size, in which the proportion of each size of particle in a sample is determined and the data is utilized to control raw material or to maintain the quality of manufactured product.
2. During the process of size reduction it is not possible to obtain the particles of uniform size hence separation gave the standard for particle size. The degree of coarsens or fineness of a powder can be achieved by size separation process.
3. Size separation increases the rate of absorption of drug and improves the stability of pharmaceutical dosage form such as suspensions.
4. Size separation helps in uniform mixing of drugs, required for preparing different formulations for administration.

Q.2 Write a note on official grades of powders or grading of powder.

Ans: Grading of powder: In pharmacopoeia the powders are given with different grades based on their sieve numbers and these grades are called as official grades of powders.

The sieve number can be defined as number of meshes or openings included in the length of 2.54 cm in each transverse direction parallel to the wires. Thus sieve no.40 has 40 openings in 2.54 cm in each transverse direction.

The various grades of powders which are official in I.P. are as follows:

Coarse powder(10/44): Coarse powder is defined as ,when the powder is passed through sieve number 10,all particles passes through sieve number 10 but not more than 40 percent of particles passes through sieve number 44.

Moderately coarse powder (22/60): A powder of which all particles passes through 22 mesh sieve and not more than 40% through 60 mesh sieve.

Moderately fine powder (44/85): Moderately fine powder is defined as, when the powder is passed through sieve number 44, all particles passes through sieve number 44 but not more than 40 percent of particles pass through sieve number 85.

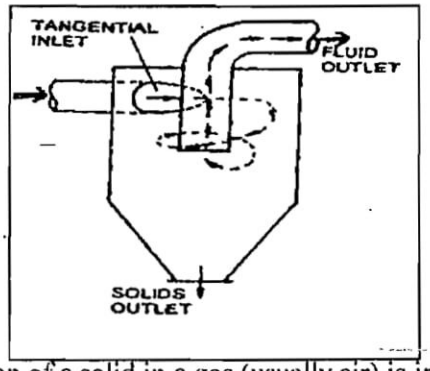
Fine powder (85): A fine powder of which all the particles passes through 85 mesh sieve.

Very fine powder (120): A powder of which all the particles passes through 120 mesh sieve.

Q.3 Write a note on cyclone separator.

Ans: Principle: In cyclone separator, the centrifugal force is used to separate solids from fluids .The separation depends not only on the particle size but also on density of particles. Hence depending on the fluid velocity, the cyclone separator can be used to separate all types of particles or remove only coarse particles and allow fine particles to be carried through with the fluid.

Construction: It consists of a cylindrical vessel with a conical base .In the upper part of the vessel is fitted with a tangential inlet and a fluid outlet and at the base it is fitted with solid outlet.



Working: The suspension of a solid in a gas (usually air) is introduced tangentially at a very high velocity, so that rotary movement take place within the vessel .The fluid is removed from a central outlet at the top .The rotary flow within the cyclone separator causes the particles to be acted on by centrifugal force .The solids are thrown out to the walls, thereafter it falls to the conical base and discharged out through solids outlet.

Uses: Cyclone separators are used to separator the suspension of a solid in a gas (air) .It can be used with liquid suspensions of solids.

Q.4 Explain the process of size separation by elutriation tank. (or) Mechanical air classifier.

Ans: Elutration is a process of size separation of the particles depending on the particle size and density .The process is exclusively applicable to separation of coarse and fine particles on non-hydrating inorganic powders, after the process of levitation. The elutriation is to be carried out in elutriation.

Elutriation method: The apparatus consists of a vertical column with an inlet at the bottom and an outlet at the bottom. The suspension is passed through the inlet. Depends upon the movement of the fluid, the particle size is separated. Usually two fractions are separated in single vertical column. The coarse particles are collected through the outlet at the bottom .The fine particles are carried along with the fluid which are collected through the outlet at the top.

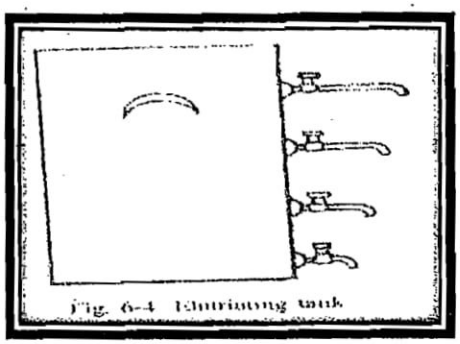


Fig. 6-4 Elutriating tank

Advantage:

1. The process is continuous.
2. The apparatus is more compact.
3. The separation is quicker than the sedimentation.

Application of sedimentation and elutriation methods:

1. Both methods are used to separate over size particles and particles of different sizes.
2. These two techniques are applicable to the size separation of insoluble solids such as kaolin or chalk.

CHAPTER.7
MIXING AND HOMOGENIZATION

Q.1 Define mixing and homogenization.

Ans: Mixing: Mixing may be defined as the process in which two or more components are mixed so that each particle of one component is in contact with each particle of other component.

Homogenization: Homogenization is the process by which the large globules or particles in a coarse emulsion or suspension or semisolid preparations are broken into smaller globules or particles by passing the sample under pressure through a narrow orifice. As the result, the final product is more stable and uniform.

Q. 2 Equipment used for mixing liquids (or)Write the note on silverson mixer?

Ans: Construction and working: Silverson mixer emulsifier consists of an emulsion head with sharp blades. The head is covered with stainless steel mesh having small holes. Within the emulsor head, numbers of sharp blades are present. The emulsor head is fixed on long rods. There is one central rod which is directly attached to the sharp blades. Motor is fitted at the top.

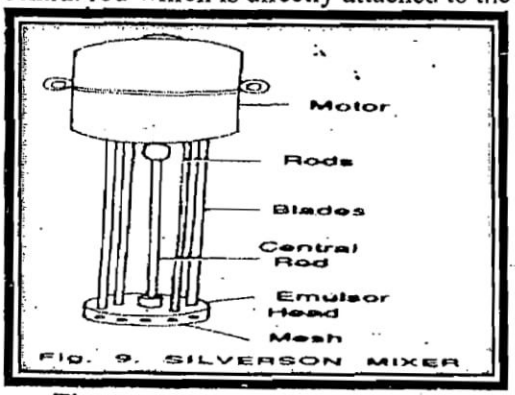


FIG. 9. SILVERSON MIXER

The coarse emulsion (handmade emulsion)is taken in a suitable vessel. The emulsion head is immersed in the emulsion. The motor is switched on. The long rods along with sharp blades rotate at very high speed. As the result the liquids are sucked and expelled with great force

through the small holes and the oil phase is reduced into fine globules by powerful shearing action of rotating blades. Homogeneous fine emulsion is produced.

Applications: Silverson mixer emulsifier is used to produce stable emulsion of having oil globules 1.5 to 2 microns.

Q.3 Write a note on homogenizer.

Ans: Construction and working: It consists of high pressure pump, a spring scatted valve and an orifice. The homogenizing valve is held in position on the valve sheet by means of springs. Hand – Made emulsion is passed through the inlet under high pressure. When the high pressure is applied, the springs are compressed. At this point the energy that has been stored in the liquid is released. So the valve sheet rotates at high speed. As a result of shearing action and turbulence motion of the valve sheet, the oily globules are broken into very small globules and stable emulsion is formed. After this first homogenization, the globules may agglomerate. So the homogenization process may be repeated second and third time. In homogenizer, the globule size may be 0.02 micron.

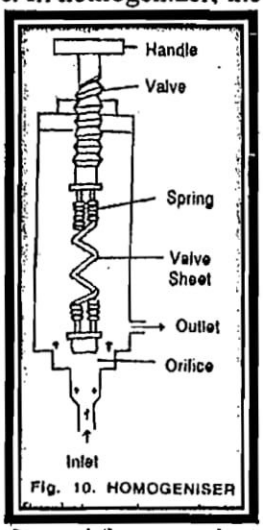
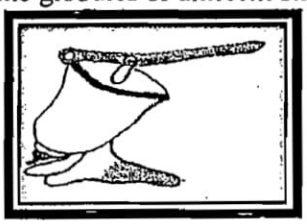


Fig. 10. HOMOGENISER

Applications: Homogenizer is used for preparing stable emulsions and suspensions. It is also used in the manufacture of cosmetic creams and ointments.

Q.4 Write a note on hand homogenizer.

Ans: Construction and working: It consists of a hopper and a fine orifice. The hand-made emulsion is taken in the hopper. This homogenizer operates with hand. The handle is moved up and down .By this way, the emulsion is forced to pass through the fine orifice continuously and thereby the oil globules are broken into fine globules of uniform size.



Q.5 Write a note on propeller mixer.

Ans: Construction and working: It consists of a number of blades, fixed in a long shaft. The liquids to be mixed are taken in a vessel. The shaft is allowed to rotate at high speed. As the blades