Subject Title: PHARMACEUTICS-I Subject Code: 0805

Important Instructions to examiners:

1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for anyequivalent figure drawn.
5) Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.
6) In case of some questions credit may be given by judgement on part of examiner of relevant answer based on candidate's understanding.
7) For programming language papers, credit may be given to any other program based on equivalent concept.

Subject Title: PHARMACEUTICS-I Subject Code: 0805

Q. No.	Sub Q. N.	Answer	Marking Scheme
1		**Answer any *Eight* of the followings:**	16M
1	**a)**	**Name some of the modern dosage forms.** 1. Implants 2. Liposome drug carriers 3. Nanoparticles 4. Prodrugs 5. Films and strips 6. Erythrocytes 7.Controlled drug delivery system 8.Sustained release system	**2M (0.5x4)**
1	**b)**	**In which year various editions of pharmacopoeia of India came out?** 1. First Edition in 1955 2. Second Edition in 1966 3. Third Edition in 1985 4. Fourth Edition in 1996 5. Fifth Edition in 2007 6. Sixth Edition in 2010 7. Seventh Edition 2014	**2M (0.5x4)**
1	**c)**	**Define 'Containers'. What are the basic materials used in making of container?** **Containers:** A device that holds the drug and it may or may not be in direct contact with the pharmaceutical dosage form or preparations. **Basic materials used in making of container:** i)Glass ii) Plastic iii) Metal iv) Paper and board	**2M (1M Def.) (0.5×2=1 M)**
1	**d)**	**What are the various factors which affect the size reduction of the drugs?** **1. Hardness:** Soft material easy break than hard. **2. Toughness:** Drug with fibrous nature or those having high moisture content are tough and hard to reduce in size. **3. Stickiness:** Material adheres to the grinding surface or sieve surface of the mill. It is very difficult to powder a drug of having gummy or resinous material. **4. Material structure:** Material with some special structure cause problem during size reduction e.g. Vegetable drug with cellular structure produce long fibrous particle on size reduction, similarly a mineral substance having lines of weakness, produce flake like particle on its size reduction.	**2M (0.5 X 4)**

		5. Moisture content: The presence of moisture in the material influence a number of its properties such as hardness, toughness or stickiness. The material having 5% moisture in case of dry grinding and 50% in case of wet grinding is permissible. **6. Temperature:** Waxy material such as stearic acid or drug containing oils or fat, become softened during the size reduction, due to heat. This can be avoided by cooling the mill. **7. Purity:** In some mills during size reduction there is chances of addition of impurities. If high degree of purity is required avoid such mills or Mills should be cleaned thoroughly. **8. Physiological effect:** Some drugs are very potent. During there size reduction in mill, dust is produced which may have effect on operator. **9. Ration of feed size to product size:** To get a fine powder in a mill, it is required that a fairly small feed size should be used. Hence to carry out size reduction in various stages e.g. preliminary crushing followed by coarse powder and then fine grinding. **10. Bulk density:** The output of the size reduction of the material in a machine depends upon the bulk density of the substance.	
1	**e)**	**Name the various standards of sieves.** **According to I.P. standards for sieves are as follows** I .Approximate sieve number ii. Nominal mesh aperture size iii. Approximate percentage of sieving area iv. Tolerance average aperture size According to I.P. sieves must confirm the above mentioned specifications for the given sieve number.	**2M (0.5×4)**
1	**f)**	**Give the list of equipments used for mixing of semi-solids.** **Equipment's used for mixing of semi solids:** i. Triple roller mill. ii. Agitator mixer. iii. Planetary mixer. iv .Sigma Mixer	**2M (0.5 X 4)**
1	**g)**	**Name the factors which affects the rate of filtration.** 1**.** Area 2. Pressure 3. Viscosity 4. Thickness of cake	**2M (0.5x4)**

		5. Temperature of liquid to be filtered 6. Particle size 7. Pore size of filter medium 8. Nature of solid material	
1	**h)**	**What is 'Water for Injection'?** Water which is free from volatile and non-volatile impurities, micro-organisms and pyrogens which is prepared by distillation and reverse osmosis called as water for injection. It is used for preparation of parenteral preparation.	**2M**
1	**i)**	**What are the two main steps in drying of materials?** Drying process involves both heat transfer and mass transfer. The steps needed for drying are; i.Heat must be supplied to provide latent heat of vaporization. ii.The liberated vapour must be removed by moving an air stream.	**2M (1×2)**
1	**j)**	**Give the list of chemicals which are used as bactericide?** **List of Bactericides** i. Chlorocresol . 0. 2% ii. Phenyl mercuric nitrate or acetate 0.002% iii. Benzalkonium chloride 0.01% iv. Thiomersal 0.01% v. Chlorohexidine acetate 0.01%	**2M (0.5×4)**
1	**k)**	**What does the term 'Desiccation'' mean?** **Definition:** Desiccation is the process of complete removal of mechanically admixed water from substances. **Examples of desiccants:** i. Dried Silica gel, ii. Phosphorous pentoxide iii. calcium sulfate, iv. Anhydrous calcium chloride, v. Conc. Sulphuric acid vi. Phosphorous trioxide	**2M (def.1M And 0.5 ×2)**
1	**l)**	**Difference between fine powders and granules.**	**2M (0.5×4)**

		<table><tr><th>Fine powder</th><th>Granules</th></tr><tr><td>1. Fine powder does not have free flowing property, hence weight variation in tablet is produced.</td><td>1.Granules flow easily and do not give weight variation in the tablet produced</td></tr><tr><td>2. In mixed powder, segregation of different components is possible.</td><td>2. Granules are of uniform composition and segregation is not a problem. But granules should contain 5-15%of fine</td></tr><tr><td>3. Tablets formed are brittle.</td><td>3. Granules packed down easily and produced hard tablets.</td></tr><tr><td>4. Fine particles tend to blow out of die cavity during compression.</td><td>4. Granules being heavier do not blow out of die cavity.</td></tr></table>	
2		**Attempt any FOUR of the followings**	**12M**
2	**a)**	**Define 'Viscosity'. Write the applications in Pharmacy.** **Defination of Viscosity:** It is the property of liquid to resistance to flow**.** **Applications of Viscosity in Pharmacy:** i.Viscosity plays an important role in the stability of emulsions and suspensions. ii. Ophthalmic preparations are made viscous to prolong the contact time of the drugs. E.g. methyl cellulose. iii. Paints are made more viscous so that they remain in contact with the skin for long time. E.g. glycerine in included in paint formulations to increase the viscosity. iv. Fats, waxes and other viscous substances are filtered at high temperature as at high temperature there is decrease in viscosity and hence rate of filtration is increased. v. Certain pharmaceutical formulations are standardized on the basis of its viscosity. E.g. liquid extract of liquorice. vi. The viscosity of certain liquid preparations is increased in order to improve pourability or to make preparation more palatable.	**3M** **1M** **(0.5 X 4)**
2	**b)**	**What are the equipments used for mixing of liquids? Give in detail about 'Propeller Mixer'.** **Equipments used for mixing of Liquids** i .Propeller mixer ii .Turbine mixer iii .Paddle mixer **Propeller Mixers** **Construction:** • .It consists of vessel and propeller, • Propeller usually operates at high speed which is upto 8000 rpm which gives lot of turbulence. • Propeller produced flow pattern parallel to their axis of rotation. • It is used when little shear is needed.	**3M** **(0.5M)** **(2.5M)**

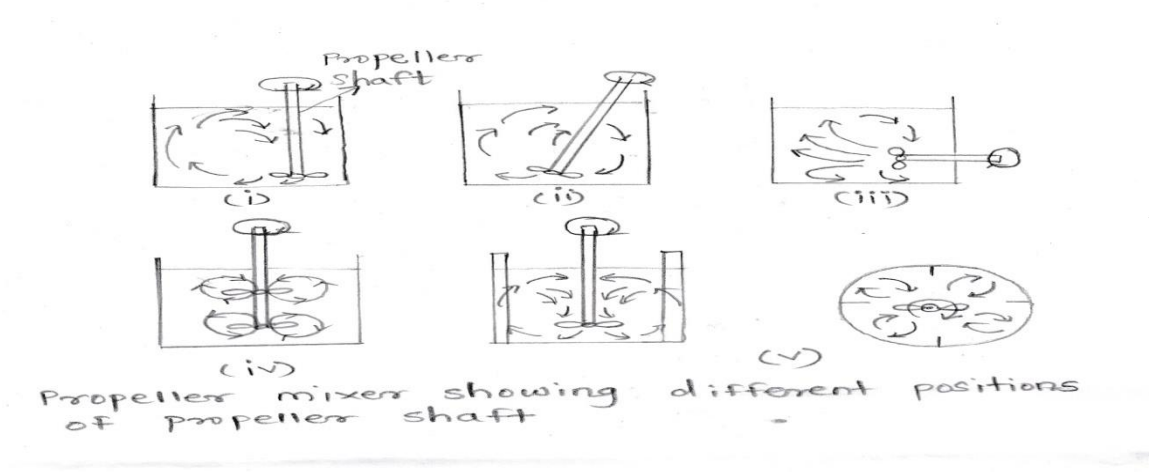
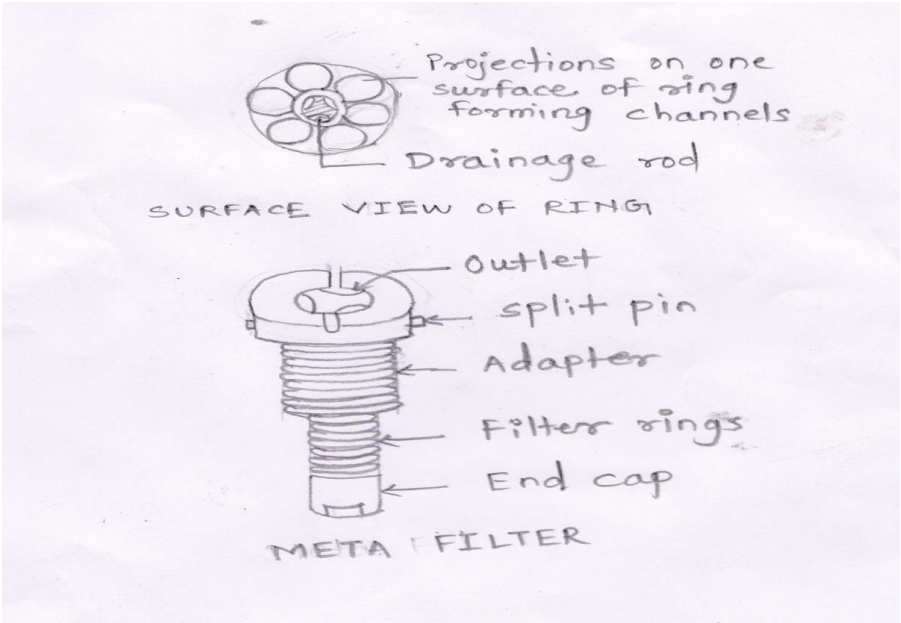
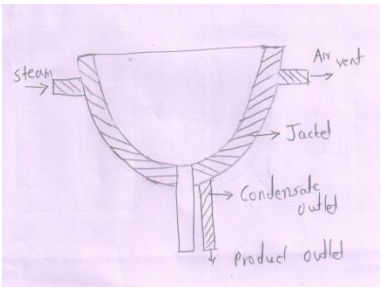
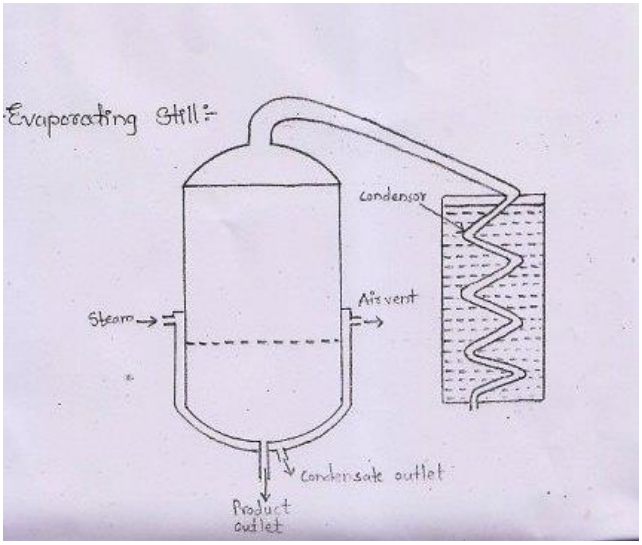
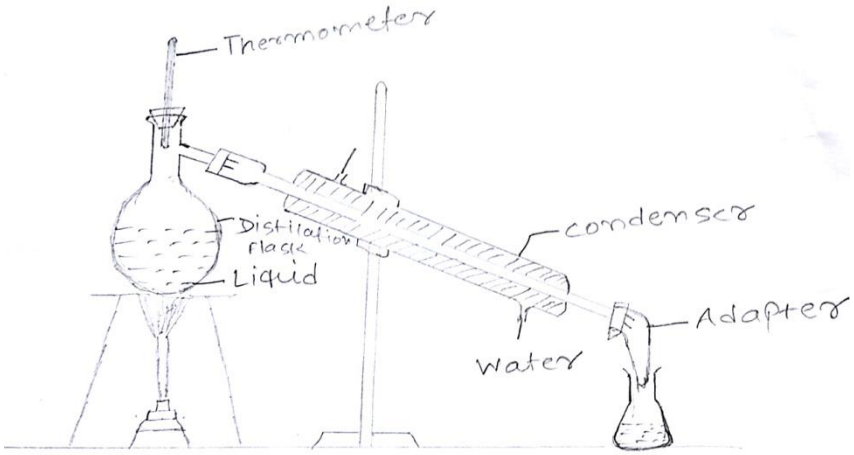
		Working: • Liquids to be mixed are placed in a vessel. • During the mixing of liquids, air gets entrapped in liquid or there is formation of vortex. • To avoid air entrapment and vortex formation ,position of propeller shaft can be changed as follows: i. Offset from centre. ii. Mounted at angle. iii. Enter the side of the vessel. iv. Using push-pull propeller: In which two opposite pitch is mounted on the same shaft so that rotator effect is in opposite direction and cancels each other. v. By the use of baffles: Install baffles along the sides of the tank **Diagram:**  Propeller mixer showing different positions of propeller shaft **Application:** It is used for mixing of liquids having low viscosity.	
2	**c)**	**Explain the construction and working of 'Meta Filter'.** **Construction:** i. It consists of grooved, drainage rod on which a number of metallic ring are packed. ii. The rings are usually of stainless steel and have 0.8 mm outer thickness, 15 mm inside diameter & 22 mm outer diameter. iii. The rings have a number of semicircular projections on one surface and when they are packed on the rod, the opening between the rings about 0.2 mm. **Working:** i. The entire assembly is placed inside a pressure vessel, containing the liquid to be filtered. ii. When vacuum is applied liquid will flow from outside to inside. iii. In this form a metafilter can only be used as strainer for coarse particle, but for separation of fine particle a bed of suitable material kieselguhr is used. iv. In this way pack of ring act as a base on which the fine filtration medium is supported	**3M** **1M** **1M**

		Diagram:  	**1M**
2	**d)**	**Write the qualities of an ideal filter aids. Give examples of filter aid.** **Ideal qualities of filter aid:** i.It should be remain suspended in the liquid. ii. It should be free from impurities. iii. It should be inert. iv. It should have a particle size distribution suitable for retention of solid. v. It should have structure that permits formation of porous cake **Examples of filter aid :** i. Asbestos. ii. Cellulose. iii. Carbon. iv. Diatomaceous earth (silica). v.Perlite. vi.Activated Charcoal	**3M (0.5 X 4=2M)** **(0.5X2=1 M)**
2	**e)**	**Why imbibition is necessary before packing of the drug into the percolator?** . Imbibition is done in order to: i. It allow the swelling of tissue of drug before packing. ii .It is imbibed for uniform packing in percolator. iii. It allows the entrapped air to escape. iv. Quantity of menstrum required can be reduced.	**3M**
2	**f)**	**Write in detail about modified percolation process.** **Modified Percolation:** In percolation process for tinctures drug\ percolate (d/p) ratio is 1:4.The drug/percolate ratio is reduced to 1:3 by modifying percolation process. Thus saves lot of heat, time and menstrum. It is proved that the menstrum remaining in contact with the drug dissolves more active constituents than the flowing menstrum. Hence simple percolation process requires more menstrum to exhaust the drug. But if continuous percolation stage has suitable	**3M**

		breaks by short maceration stages, the d/p ratio can be reduced to 1:3 e.g .In Simple Percolation process: Drug→ Imbibition → Maceration → Percolation (**200gm) (4hrs.) (for 24 hrs.)** collect the Percolate, i.e.3/4th of the volume of finished product. In modified percolation process: Drug → Imbibition → Maceration → Percolation- **(1000gm) (for 24 hrs.)** collect 1000ml of percolate → Maceration → Percolation- **(for 12 hrs.)** collect 1000ml of percolate → Maceration → Percolation- **(for 12 hrs.)** collect 1000ml of Percolate □ Drug : Percolate 1000gm : 3000ml d/p = 1:3 After exhaustion of the drug, the percolate is evaporated and then mixed with main percolate. Final volume is made by adding more menstrum.	
3		**Attempt any FOUR of the followings**	**12M**
3	**a)**	**Explain how heat is transferred from the source of the article.** Heat is Transferred from the source of the article by following Methods: 1. **Conduction:** The heat transfer takes place by transmission of momentum of individual molecule. Ex. Heat transfer in solid and liquid. 2. **Convection:** Heat transfer is takes place by the actual motion of the particle i.e. during mixing, heat transfer takes place in liquid. 3. **Radiation:** Energy transfer takes place through space i.e without using any medium.	**1X3=3M**
3	**b)**	**Explain with the help of a neat sketch one of the evaporators covered under the group of natural circulation evaporators.** **Natural circulation evaporators:** The movement of liquid takes place as a result of convection current set up by heating process. Ex. evaporating pan, evaporating still, and short tube evaporator.	**(Any one 3M, 2m explanation and 1 for**

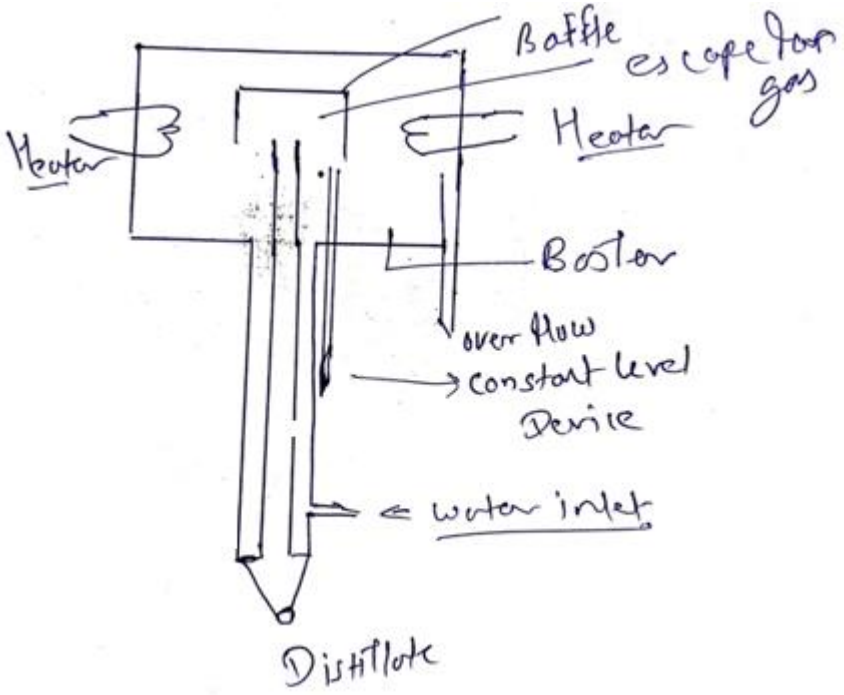
		1. **Evaporating pan:** • It consist of a hemispherical pan made from copper or stainless steel and surrounded by a steam jacket. • Hemispherical shape provide large surface area for evaporation. • It consist of product outlet for fixed evaporating pan. • In other type evaporator is mounted in such a way that they can be tilted. **Diagram**:  2. **Evaporating still:** • It consist of a hemispherical pan made from copper or stainless steel. • It is surrounded by a steam jacket. • Still is covered from top and connected to condenser. • Hemispherical shape provide large surface area for evaporation. • It consist of product outlet at bottom. **Diagram**:  	**diagram)**
3	**c)**	**Explain with a neat sketch the working of the apparatus used for distillation on laboratory scale.** There are two apparatus used for distillation on laboratory scale. 1. Simple apparatus. 2. Still apparatus. **Simple apparatus:**	**Any one apparatus: 2M for working and 1M for diagram**



Working:

1. Water is filled in the round bottom flask.
2. Flask connected to condenser and condenser to receiver though adaptor. (as shown in diagram).
3. Liquid in flask is boiled and vapours are formed which are condensed by condenser and collected in the receiver.

Still apparatus:

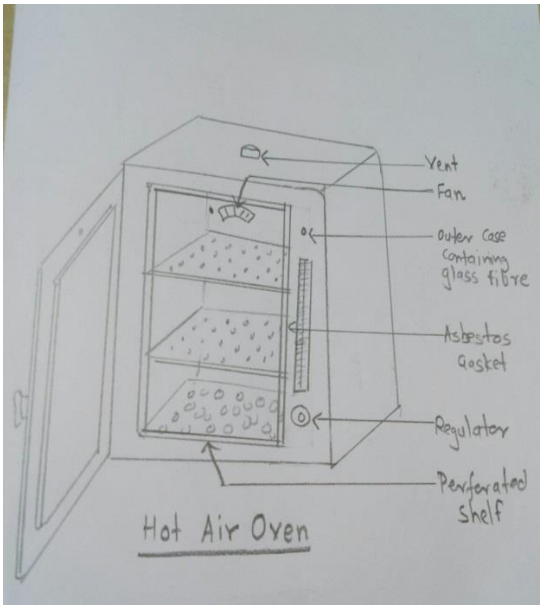


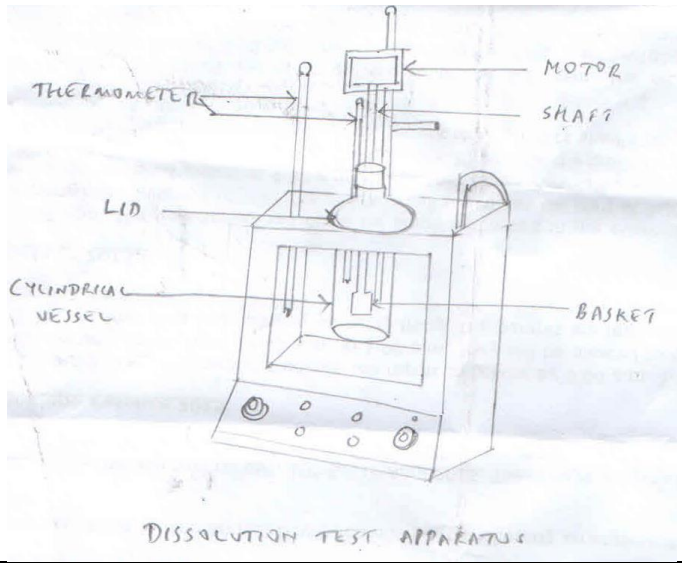
Working:

1. It consists of boiler which is made of cast iron.

		2. It is connected to the condenser tubes through the baffles. 3. The condenser tubes and baffles are made of stainless still. 4. Baffles are provided over the top of the condenser tubes to avoid water drops getting mixed with the vapours. 5. It is done to avoid carry-over of pyrogen and other water soluble material in the droplet. 6. The cooling water enters at the bottom of the condenser and heated by condensing vapours. 7. The flow rate is adjusted such a way that water gets heated at 900-950 C before it enters the boiler. 8. The top of condenser jacket is open, so that gases from the water can escape into atmosphere. 9. A constant level device is fitted in such a way that only heated water free from gases enters the boiler.	
3	**d)**	**Explain the theory of fractional distillation.** **Theory:** • When the substance dissolved in a liquid, the vapour pressure of the liquid is lowered. • When two miscible liquid are mixed together, each will act as solute or solvent for the other. So, when mixture of such two liquid is heated, vapour pressure of each is lowered. • The pressure exerted by each liquid is known as "partial pressure". • The liquid boils when the sum of partial pressure equals the atmospheric pressure. • It differs from simple distillation in that Partial condensation of vapour is allowed to occur in a fractionating column through which the vapour must pass before reaching the condenser. • This column enables ascending vapour from the still to come in contact with the condensing vapour returning to still. This results in enrichment of the vapour in the more volatile component.	**3M**
3	**e)**	**Write the applications of drying.** i. It is used in manufacturing of granules. ii. It reduces the bulk and weight of the material. iii. It helps in preservation of crude drug. iv. It helps in size reduction of crude drug. v. It is used in the drying of aluminium hydroxide. vi. It controls the moisture level in solids.	**03M.** **0.5 X 6**
3	**f)**	**Write the advantages and disadvantages of fluidised bed dryer.** **Advantages:** i. It give high drying rate. ii. Suitable for thermolabile material. iii. Drying takes place of individual particles. iv. Temperature can be controlled. v. Prevent the risk of migration of soluble material.	**Adv: 0.5 X 4 = 2M and disadv: 0.5 X 2=1M**

		vi. It can mostly used for drying of granules. **Disadvantages:** i. Turbulence produces cause attrition of particles. ii. Movement can generate electrical charges.	
4		**Attempt any FOUR of the followings**	**12M**
4	**a)**	**Classify the different methods of sterilizations.** A. Physical Method: 1. Dry heat sterilization. 2. Moist heat sterilization. 3. Radiation sterilization. B. Chemical method: 1. Sterilization by heating with bactericidal. 2. Gaseous sterilization. C. Mechanical Method: 1. Ceramic filter. 2. Seitz filter. 3. Sintered glass filter. 4. Membrane filter.	**1 X 3 = 3M**
4	**b)**	**Describe dry heat method of sterilization in detail.** **Principle:** • All the microorganism including spores are destroyed. • Principle of killing is by dehydration and oxidation of essential metabolites. • In hot air oven heating is done at 160^0 C for 2 hours. **Construction:** • It consists of double walled chamber made of steel. • Insulation is given of asbestos or other material for preventing heat loss. • The door is also double walled having insulation. • Two perforated shells provided to keep the material. • An electric fan is provided for uniform circulation of hot air. • A heater is fitted at the bottom for heating. • A thermometer for maintaining the temperature. **Working:** • Wrap the material with paper. • Keep the Wrapped material in perforated shelves. • Material should not be kept at floor of the oven. • Close the door. • Switch on the oven and set the temperature and time as required. • After time is over. • Switch off the oven. • Allow to cool. • Take out the material.	**3M** **0.5 + 1+1+0.5= 3M**

		Diagram:  	
4	**c)**	**Name the various manufacturing defects in tablets.** 1. Capping. 2. Picking and sticking. 3. Mottling. 4. Weight variation. 5. Hardness variation. **6.** Double impression.	**0.5 X 6 = 3M.**
4	**d)**	**Describe in brief about dissolution test for tablets.** **Dissolution test**: The test is done for measuring the amount of time required for a given percentage of drug substance in a tablet to go into solution under specified condition in vitro. The apparatus consists a cylindrical covered vessel made of glass or other transparent material having 1000 ml capacity. The vessel is fitted with a lid having 4 holes, one for shaft of stirrer, second for placing thermometer and remaining two for removing the sample. An electric motor which is capable of rotating the basket (woven wire cloth having aperture size 425 micrometer) in the vessel at varied speed between 25 and 150 revolutions per minute. 1000 ml of water at 37 o + 0.5 o C in placed and specified number of tablets are placed in the dry basket. The motor is started and the rotation speed is adjusted to 100 rpm or as directed in the monograph. Withdraw the stated volume of solution from the vessel after 45 minutes or after the time specified in the monograph. Filter and determine the amount	**3M** **2M for test and 1M for diagram**

		of active ingredient present in it. The tablets pass the test if for each of the five replicates; the amount of active ingredient in solution is not less than 70% of the stated amount. **Diagram.**  	
4	**e)**	**Write the approximate capacity in mg of a capsule having number 000, 0, 1, 2, 3, 4 and 5.** **Capsule no. / Capacity** **000 – 950** **00 – 650** **0 – 450** **1 – 300** **2 – 250** **3 – 200** **4 – 150** **5 – 100**	**0.5 X 6 = 3M.**
4	**f)**	**Differentiate between hard gelatin capsule and soft gelatin capsule.**	**0.5 X 6 = 3M.**

		<table><tr><th>SR. NO</th><th>HARD GELATIN CAPSULES</th><th>SOFT GELATIN CAPSULES</th></tr><tr><td>1.</td><td>The hard gelatine capsule shell consists of two parts: Body and cap</td><td>The soft gelatine capsule shell becomes a single unit.</td></tr><tr><td>2.</td><td>They are cylindrical in shape</td><td>They are available in round, oval and tube-like shapes.</td></tr><tr><td>3.</td><td>The contents usually consist of medicaments in the form of powder, beads or granules.</td><td>The contents usually consist of liquids or semisolids.</td></tr><tr><td>4.</td><td>These are prepared from gelatine, titanium dioxide, coloring agent and plasticizer.</td><td>These are prepared from gelatine, more amount of plasticizer (sorbitol or glycerine) and preservative.</td></tr><tr><td>5.</td><td>Filling and sealing takes place in different steps</td><td>Filling and sealing are done in a combined operation of machines.</td></tr><tr><td>6.</td><td>Shell is perfectly dry,</td><td>Shell is not perfectly dry.</td></tr><tr><td>7.</td><td>These capsules can be adulterated.</td><td>These capsules cannot be adulterated.</td></tr><tr><td>8</td><td>Ex. Amoxicillin capsule</td><td>Ex. Pudin Hara capsule</td></tr></table>	
5		**Attempt any FOUR of the followings**	**12M**
5	**a)**	**What are different types of vaccines? Write method of preparation of small pox vaccine.** There are 4 main types of vaccines: • Live-attenuated vaccines • Inactivated vaccines • Subunit, recombinant, polysaccharide, and conjugate vaccines • Toxoid vaccines **Small pox vaccine is prepared by two methods** 1) By using animals 2) By using Eggs **By using Animals** : it is done in following steps Selection of Animals: Healthy Sheep or calves selected and kept in an isolated area for 10-14 days under observation, it should be free from diseases. ↓ Preparation of animal for scarification (Abdomen and flanks are scrubbed, washed and disinfected). ↓ Inoculation (Light incisions are made on clear skin by scarifier, seed vaccine is inoculated in that area) ↓ Incubation	**3M** **0.5M** **Any one method 2.5M**

		(Incubate for 7-9 days, kept clean and aseptic, pustules are formed on line of Scarification). ↓ Collection of viruses (Abdomen and flanks are washed with sterile water. The Pustules are withdrawn aseptically) ↓ Purification(mixed with equal volume of glycerin, cool and finely ground and store at -10°C ↓ Filling and sealing (filled in final container and sealed aseptically) **By using eggs**: Hen egg is used (Which is incubated after 12 days) ↓ Small cut on the shell (exposed chorio-allantoic membrane) ↓ In this membrane, viruses are inoculated (by seed of known potency) ↓ Cut was sealed by flap or paraffin wax ↓ Again incubate for 72 hours ↓ Using aseptic condition, shell is removed and chorio-allantoic membrane is separated ↓ Contents are added in normal saline solution at 0° C ↓ Add 50 % glycerin ↓ Material is ground to produce homogenized suspension. ↓ Transfer to suitable sterile container and freeze dried	
5	**b)**	**Discuss natural immunity in brief.** **Natural immunity to diseases is possessed by an individual due to following factors:** **Age:** majority of children in the age between 2-5 years are susceptible to diphtheria, where as adults are immune to it **Race:** Negroes have a high resistance to yellow fever, the white races are very susceptible to it	**3M**

		Species: Men are susceptible to typhoid fever, whereas mice are immune to it. Fowls are immune to plague, where as men are susceptible**.** **Individual:** Some persons have more resistance against cold and skin diseases than others.	
5	**c)**	**Differentiate:** Maceration for organized drug vs Maceration for unorganized drug 1. Drug along with whole of menstrum is used in maceration process / Drug along with $4/5^{th}$ of the menstrum is used in the maceration process. 2. The period of Maceration is 7 days / The period of Maceration is 2 to 7 days 3. Strain off the liquid and press the marc / Decant the liquid and marc is not pressed 4. Mix the pressed liquid with the macerate and clarify by filtration. Filtrate is not adjusted to volume. / Filter the liquid and pass the remaining $1/5^{th}$ of menstrum through filter to make up the volume. 5. Example of tincture: Tincture of orange, Tincture of capsicum, tincture of lemon. / Example of tincture: Tincture of tolu, Tincture of catechu, compound tincture of benzoin.	**(0.5 X 6 =3M)**
5	**d)**	**Write importance of dosage form.** Transformation of drug into dosage forms is done for the following reasons: 1. To protect the drug substance from oxidation, hydrolysis and reduction. Eg. Coated tablets and sealed ampoules. 2. To protect drugs from destructive effect of gastric juice (HCl) of the stomach after oral administration eg. Enteric coated tablets. 3. To provide a safe and convenient delivery of accurate dosage. 4. To conceal the bitter, salty and obnoxious taste or odour of drugs. Eg. Capsules, coated tablets and flavoured syrups. 5. To provide for the optimum drug action through inhalation therapy. Eg. Inhalation aerosols and inhalants. 6. To provide for the insertion of drug into one of the body cavities e.g. rectal and vaginal suppositories. 7. To provide the maximum drug action from topical administration sites. E.g. creams, ointments, ophthalmic preparation. 8. To provide sustained release action through controlled release mechanism. E.g. sustained release tablets, capsules.	**(0.5 X 6 =3M)**

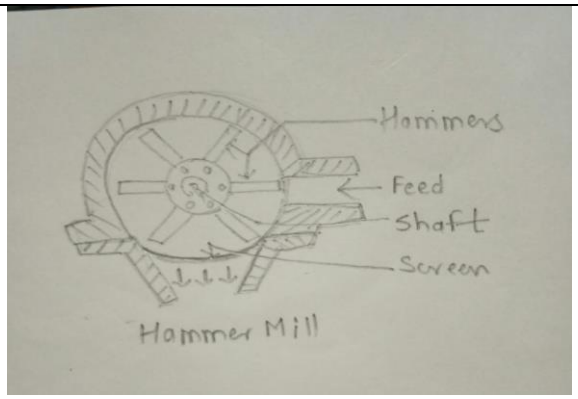
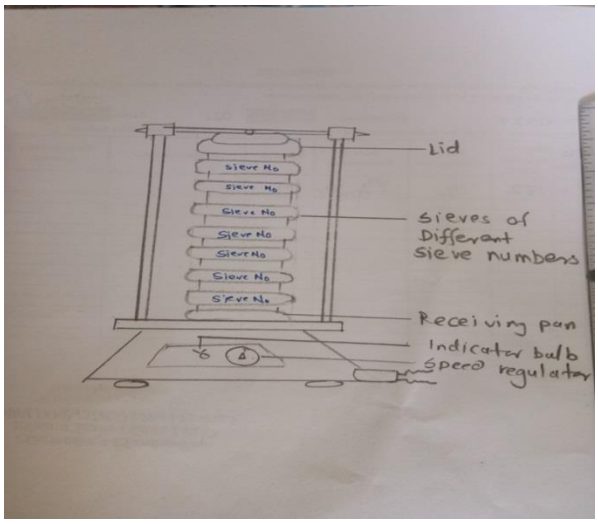
		9. To provide liquid dosage form of the drugs in a suitable vehicle. Eg. Solutions. 10. To provide liquid preparation of the drugs which are unstable or insoluble in different vehicles. E.g. suspensions. 11. Many dosage forms can be easily identified from their distinct colour, shape or identifying markings.	
5	**e)**	**Write the salient features of third edition of Indian Pharmacopoeia** **Salient Features III Edition 1985:** i. New analytical techniques such as flame photometry, Flurometry, have been introduced as official method for certain chemical analysis. ii. Dissolution test has introduced in the case of certain tablets. iii. Disintegration Test has been amended by modifying the design of apparatus and method of testing. iv. A microbial limit test has been prescribed for certain pharmaceutical aid & oral liquid preparation. v. Pyrogen test has been revised to make the test less time consuming than the previous method. vi. Gas liquid chromatography has been recognized as an alternative method for the determination of alcohol concentration in various preparations. vii. Test for determination of viscosity has been modified by introduction to other method involves. viii. The new appendix on water for pharmaceutical use" has been introduced to clearly indicate the different official standard in respect of purified water. ix. Some of the drugs have been renamed in this edition. x. Many drugs have been omitted from the third edition and many new drugs have been included in the third edition. xi. It provides the official standard to the new drug which came into use after the publication of first addendum to third edition.	**(0.5 X 6 =3M)**
5	**f)**	**By applying formula;** % of NaCl for adjustment to isotonicity = 0.9- (% of medicament solution× NaCl equivalent of medicament) = 0.9 - (1×0.12) = 0.78 0.78 of NaCl is needed for adjustment of isotonicity.	**3M**
6		**Attempt any FOUR of the followings**	**16M**
6	**a)**	**Give the full form of BCG. Discuss in brief about BCG vaccine.**	**4M**

		Full form of B.C.G. **is Baccillus Calmettee Guerin** **Method of preparation of BCG vaccine** It is freeze- dried preparation containing live culture of the bacillus Calmette and Guerin strain of Mycobacterium tuberculosis. **Preparation**: The bacilli are grown on a suitable culture media until 1 mg when plated out on a suitable solid culture media shows not less than 20 million colonies. The growth period should not be more than 14 days in any case. After a suitable growth, they are separated by filtration in the form of a cake. The cake is homogenized in a grinding flask and suspended in a suitable sterile liquid medium designed to preserve the antigenicity and viability of the vaccine. The suspension is transferred into the final sterile containers and freeze-dried. Then containers are sealed so as to prevent contamination or deterioration of the vaccine. The vaccine contains no antimicrobial agent. **Storage**: Store in hermetically sealed light resistant glass containers at a temperature between 2^0 C and 8^0 C. The reconstituted vaccine should be used immediately after its preparation. **Uses**: Immunising agent which provides protection against tuberculosis. **Dose**: Prophylactic, 0.1 ml as a single dose by intra-cutaneous injection	**1M** **1.5M** **0.5M** **0.5M** **0.5M**
6	**b)**	**Explain different types of excipients used in formulation of tablets with suitable examples.** **The following are some of the excipients which are generally required in the formulation of tablets:** • **Diluents** • **Granulating agents** • **Binding agents** • **Disintegrating agents** • **Lubricants ,Glidant , Anti adherents** • **Absorbents** • **Colouring agents , flavouring agents and sweetening agents** 1 Diluent: Diluent is added when medicament is small quantity and to improve flow property and cohesiveness. Eg. lactose, sucrose, sodium chloride, dextrose and starch, mannitol , sorbitol ,dibasic calcium phosphate dihydrate and calcium sulphate dihydrate . 2.Granulating agents A granulating agent provided proper moisture to convert the fine powder into a damp mass which after passing through a sieve of suitable number forms of granules. Eg.water , alcohol , mucilage of starch , mucilage of acacia , mucilage of tragacanth ,	**4M** **0.5×6**

		gelatin solution , iso-propyl alcohol , acetone etc. 3 Binding agents: Used in granulation to provide proper binding to granules. E.g. Gum acacia, gum tragacanth, gelatin, sucrose MC etc. 4 Disintigrating agents: Disintegrants are added to the formulation as it breaks the dosage form into smaller particles when it comes in contact with the liquid, these smaller fragments have greater surface area which will increase the dissolution of the drug They act by i. Swelling: potato ,maize starch, Methyl cellulose etc ii. By producing effervescence: Sodium bicarbonate, citric and tartaric acid. iii. By melting at body temperature: cocabutter 5 **Lubricants ,Glidant , Anti adherents** : **Lubricants** It will reduce interparticular friction during ejection of tablet. E.g. Lubrcants: talc, Mg stearate, Ca stearate etc **Glidants**: It will improve flow property of granules from hopper to die. Eg.Na Cl, Mg stearate. Boric acid etc **Anti adherents**: They prevent sticking of the material eg .liquid paraffin, stearic acid etc. **6Adsorbing agents**: These substances are used to adsorb volatile oils, liquid extracts and tinctures etc. which are included in the formulations. E.g. Mg carbonate, kaolin and starch. 7 Colour flavour and sweetening agents are added to improve patient compliance. E.g. approved FD and C dyes, volatile oils and saccharin respectively.	
6	**c)**	**Discuss in brief Freeze drying.** **Principle:** • The material is frozen in a suitable container connected to a high vacuum system, so that the vapour pressure of water is reduced to less than that of material being	**4M** **1 M**

		dried. • Thus, it reduces the temperature and pressure to values bellow the triple point. • Under these conditions, any heat transfer is used as latent heat and the ice sublimes directly to the vapour state. • The water vapour is removed from the system by condensation in a condenser maintained at a temperature lower than a frozen material.	
		Components of Freeze dryer: 1 A chamber for vacuum drying **2 A vacuum source** **3A heat source** **4 A vapour removal system**	**0.5 M** **1.5 M**
		Working: **Pre-treatment**: It is done to reduce volume of solution. The solution is pre-concentrated under normal vacuum tray drying. This reduces drying time by 8-10 times. **Pre-freezing:** This is done to solidify water. Sample is frozen at a temp. below -50 °C. **Primary drying:** Material is spread on the surface to increase surface area. Temp. & pressure is kept below the triple point of water. Heat is supplied & ice sublimes directly into vapour form. **Secondary drying:** Moisture remained after primary drying is removed by an ordinary vacuum drying. Vacuum drying is done at a temp. 50-60 °C. **Packing:** Packaging of product is performed carefully to protect it from moisture. The containers should be closed under aseptic conditions. Containers are labeled and packed in card-board boxes.	
		Advantages: • The product obtained is light and porous having excellent solubility. • The chances of hydrolysis are minimized as drying takes place at a very low temperature. • Drying takes place under vacuum; hence oxidation is minimized as there is no contact with air. • The heat-sensitive materials can be dried. • The loss of volatile material is minimum. • The freeze-dried material can be stored at room temperature if it is properly sealed in an inert atmosphere. • The sterility of the product can be maintained.	**0.5M** **Any 1**
		Disadvantages: 1. The process is very expensive because a complicated plant is used.	**0.5M** **Any 1**

		2. The product obtained is very hygroscopic, so packaging requires special precautions. **3.** The period of drying is quite long.(usually not less than 10 hours)	
6	**d)**	**Define the term 'Closures'. Write in detail about different types of closures commonly used in pharmaceutical industry.** **CLOSURES** are devices by means of which containers can be opened and closed. **TYPES OF CLOSURES WITH EXAMPLES**: 1. **Plug type** – It is a push-fit into the neck of the container. **E.g. cork or glass stopper.** Nowadays plastic stoppers being flexible and unbreakable are used to ensure a good fit into the container. 2. **Crown cap** – The cap is commonly used as crimped closure for beverage bottles. E.g.Cap of glass beverage bottle. 3. **Push-fit cap** – These are simple slide fit over the neck of the container. These are made of plastic and are shaped in such a way that these must be stretched over the neck to fit on the container. It provides tight fit. 4. **Screw closures** – It consists of three components – i) Cap: It is made of tin plate of aluminium. The container is simply closed by screwing the cap on the container. Ii) Wad: it is a seal which prevents contamination of the product. Made of rubber or silicone rubber, however cork or cardboard wads are also used. Iii) Liner: It is made of metal foils, rubber, plastic films, and paper impregnated with a suitable resin, wax or plastic. **E.g. Caps of pharmaceutical liquid dosage forms.**	**4M** **1M** **(1X3=3M)**
6	**e)**	**Give principle construction and working of hammer mill with neat diagram.** **PRINCIPLE:** Impact **CONSTRUCTION:** It consists of a stout metal casing enclosing to which four or more swinging hammer 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 reached **WORKING:** The material is put in to the hopper which is connected with the drum. The material is powdered to the desired size , due to fast rotation of hammer and is collected under the screen . This mill has the advantage of continuous operation because of change of jamming is less as the hammers are not fixed . The mill can produce coarse to moderately fine powder. **DIAGRAM:**	**4M** **1M** **1M** **1M** **1M**

			
6	**f)**	**Name different methods of size separation. Explain any one with labelled diagram.** **Different methods of size separation are**: 1 Sieving 2 Cyclone separator 3 Air separator 4 Elutriation **SIEVING:** Diagram:  **Construction:** • In this method fine powder is separated from coarse by using sieve of desired number. • In sieve separator sieves are arranged in descending order of size. • The bottom sieve is attached to receiving pan. **Working** :Different methods used: 1 Agitation 2 Brushing 3 Centrifugation **CYCLONE SEPARATOR:**	**4M** **(0.5X2=1 M)** Description of any one method **3Marks**

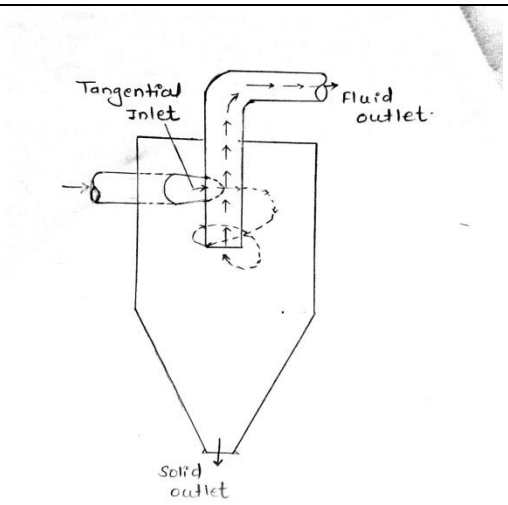


Fig- Cyclone separator

Construction-

- Cyclone separator is size separation device
- It consists of a cylindrical vessel with a conical base.
- The upper part of the vessel is fitted with a tangential inlet and a fluid outlet.
- At the base it is fitted with solid outlet

Working of cyclone separator

- The suspension of a solid gas (Usually air) is introduced tangentially at a very high velocity so that rotary movement takes place within the vessel.
- The fluid is removed from a central outlet at the top. The rotator flow within the cyclone separator causes the practices to be acted on by centrifugal force.
- The solid are thrown out to the walls. There after it falls to the conical base and discharge through the solid outlet.

AIR SEPARATOR:

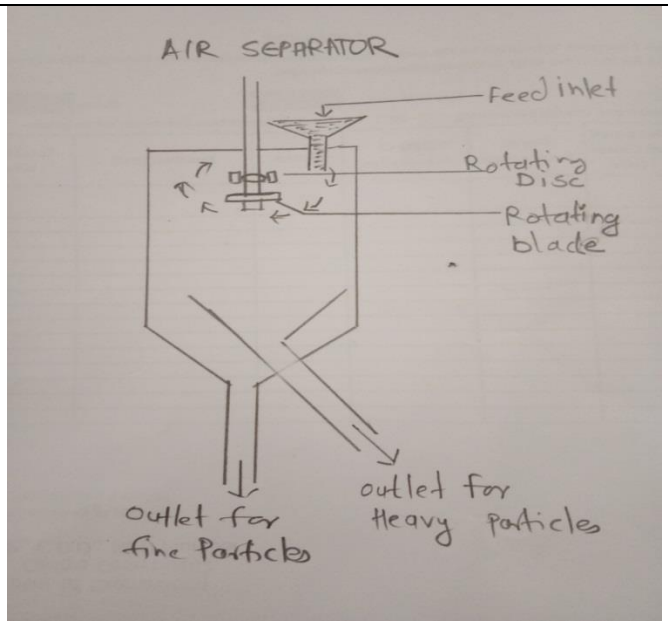
Construction:

- It consist of a cylindrical vessel with conical base
- The upper part of the vessel is fitted with a feed inlet and at base there are two outlets. One for fine and other for heavy particles.
- Rotating disc and blades are attached to the central shaft to produce air movement.

Working:

The sample of powder is passed through the feed inlet, which falls on the rotating disc. The rotating blades are attached to same shaft. The fine particles are picked up and are carried to the space, where air velocity is sufficiently reduced. The fine particles were dropped and collected at outlet. The heavy particles are removed at outlet for heavy particles.

Diagram:



ELUTRIATION:

Construction

- The size separation of powder is based on the low density of fine particles and high density of coarse particles.
- . The dry powder or paste is kept in an elutriating tank and mixed with large quantity of water.
- The solid particles are uniformly distributed in the liquid by stirring and then it is allowed to settle down.
- Depending on the density of the solid particles, it will either settle down or remain suspended in water.
- The sample is withdrawn at different heights through the outlets. These are dried and thus the powder with various size fractions is collected.

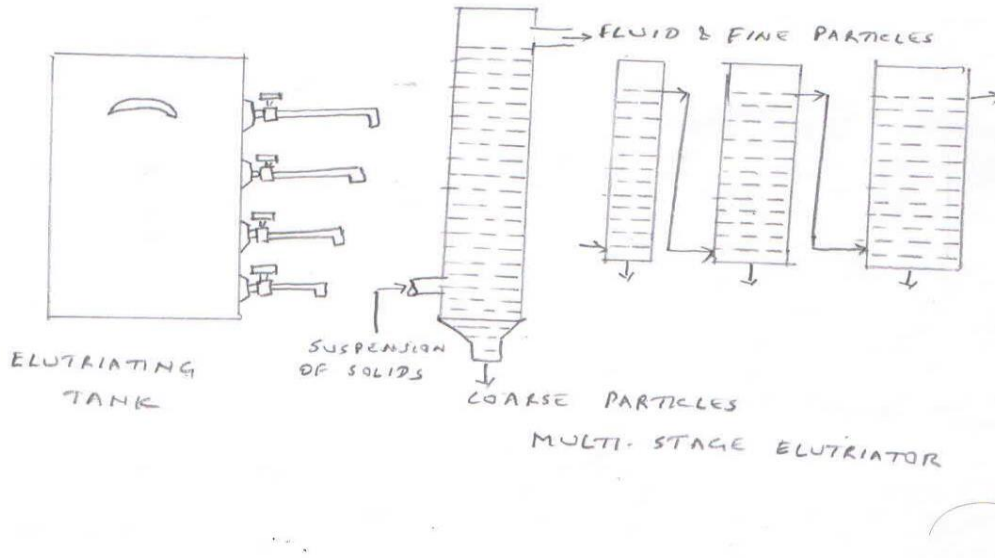
Working:

- The particles are suspended in a moving fluid, generally water or air.
- The apparatus consists of a vertical column with an inlet near the bottom for suspension, an outlet at the base for coarse particles and an overflow near the top for fluid and fine particles.
- One column will give a single separation into two fractions.
- If more than one fraction is required, a number of tubes of increasing area of cross-section can be connected in series.
- The velocity of fluid decreases in succeeding tubes as the area of cross-section increases, thus giving a number of fractions. These fractions are separated and dried.

Application:

Elutriating tank is used to separate the coarse and fine particles of powder after levigation

Diagram:


FLUID & FINE PARTICLES
ELUTRIATING TANK
SUSPENSION OF SOLIDS
COARSE PARTICLES
MULTI- STAGE ELUTRIATOR