Subject Title: PHARMACEUTICS-I

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.

Q. No.	Sub Q. N.	Answer	Marking Scheme
1		**Answer any *Eight* of the followings:**	**16M**
1	**a)**	**Why glycerine is added as a base in throat paint?** **Ans:** Glycerine is added in throat paint because: It has mild sweet taste and viscous in nature, it adhere to inflamed mucous membrane, this **increases the contact time** of drug with inflamed mucous membrane giving maximum therapeutic benefit.	**2M**
1	**b)**	**Define the term "Pharmacopoeia."** **Pharmacopoeia:** Pharmakon means "a drug" and poein means "to make". Pharmacopoeia is defined as a compressive book which is issued under the authority of government and contains a list of drug and formulae used for medicinal preparation with description and the tests for those substances and the standards to which they must confirm.	**2M**
1	**c)**	**Why glass containers are not used these days?** **Ans:** Due to following disadvantages glass containers are not used these days: 1) Glass is fragile, 2) Glass is heavy, that can increase transportation charges, 3) Glass containers may release alkali to aqueous preparations, 4) Flaking and weathering of glass are two serious issues related to glass.	**2M** **(0.5x4)**
1	**d)**	**Write the importance of particle size reduction in pharmacy.** Can be listed as follows: i) Increase the rate of solution. ii) Increase the rate of penetration of solvent. iii) It helps in uniform mixing of drugs. iv) It increases the rate of absorption. v) Smaller the particles slower the rate of sedimentation. Thus stable the suspension.	**2M** **(0.5 X 4)**
1	**e)**	**Define the terms size separation and sieves** **Size separation:** Is a process to separate particles according specified size. **Sieve no:** Sieve number indicates the number of meshes in a length of 2.54cm in each	**2M** **(1+1)**

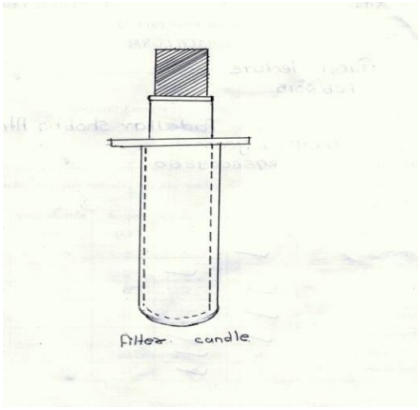
		transverse direction parallel to the wires.	
1	**f)**	**Name the different mechanisms which are applicable in mixing of powders.** The mixing mechanisms are as follows: 1)Convective mixing 2) Shear mixing 3) Diffusion mixing	**2M (any two)**
1	**g)**	**Name the commonly used filter aids.** Commonly used filter aids are as follows: 1) Cellulose 2) Asbestos 3) Carbon 4) Diatomaceous earth 5) Perlite	**2M (0.5x4)**
1	**h)**	**What are the different types of distillation?** Following are the different types of distillation: 1) Simple distillation 2) Distillation under reduced pressure 3) Fractional distillation 4) Steam distillation 5) Destructive distillation	**2M (0.5x4)**
1	**i)**	**Write the applications of spray drier.** Spray drier can be used for drying of: 1) Any substance in solution or suspension 2) Thermolabile substances, 3) Extracts, gelatin citric acid, 4) Soaps and detergents also can be dried using spray drier.	**2M (0.5x4)**
1	**j)**	**Pasteurization** It is a partial sterilization method used to make milk safe and to improve its keeping properties. **Different methods are as follows:** **Holder method:** Here the milk is heated at 62.8^0C for 30 minutes in a steam jacketed stainless steel tank. **Flash method:** The milk is heated to 71.6^0C for 15 sec. and then cooled quickly.	**2M (Def-1+any one method 1)**
1	**k)**	**Discuss in brief about BCG vaccine.** **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	**2M**

		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.	
1	**l)**	**Describe in brief about " churnas"** **Churna:** These are powdered mixture prepared by mixing dry mineral, animal or vegetable substance in a pestle and mortar in known as churna. The powdered mixture is then passed through cloth, linen or fine sieve. If jaggery is to be mixed it should be equal and in case of sugar it should be double the quantity of churna. They are generally taken with milk, hot water or cow urine.	**2M**
2		**Attempt any FOUR of the followings**	**12M**
2	**a)**	**Differentiate between Active and passive immunity.**	**3M (0.5 X 6)**

Sr. no	Active immunity	Passive immunity
1	Antigens are injected in human body as a result, antibodies are formed	Readymade antibodies are injected in human body
2	Onset of action is slow.	Onset of action is quicker
3	Immunity produced is for longer period.	Immunity produced last for shorter period
4	Treatment is prophylactic or preventive.	Treatment is therapeutic or curative
5	Side effects are very few	Sometimes body react to antisera. It is termed as serum sickness
6	Preparations : Vaccines , Toxoid	Preparation: sera

2	**b)**	**What are main objectives of mixing? Give the list of equipment's used for mixing of semi solids.** **Objectives of mixing are as follows:** i) Simple physical mixing of materials to form a uniform mixture. ii) To promote the chemical reaction to get uniform product. iii) Dispersion of solid in liquid to form suspension or paste. iv) Dispersion of two immiscible liquids to form an emulsion.	**3M Any four objectives 2M& 0.5X2=**

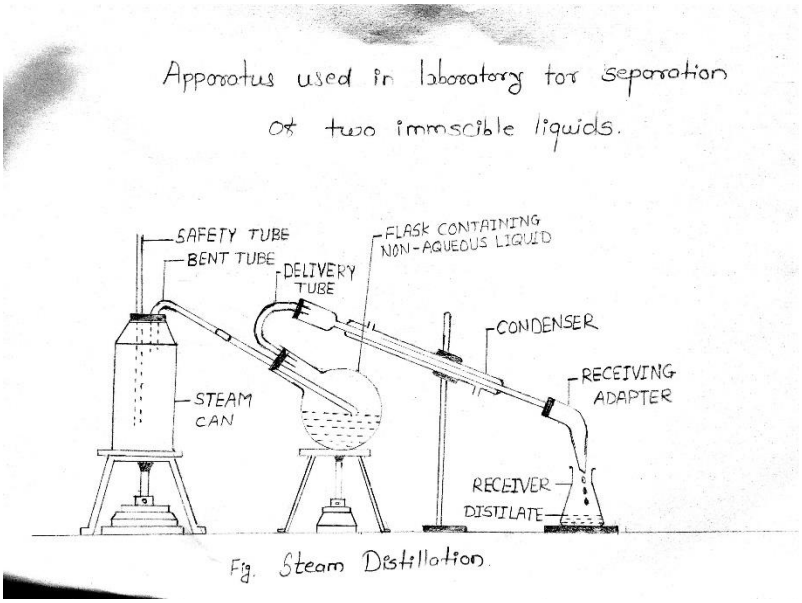
		Equipment's used for mixing of semi solids: • Triple roller mill • Agitator mixer. • Planetary mixer	**1 for equipment's)**
2	**c)**	**Differentiate between filtration and clarification. Enlist various filter media used in Pharmacy.** **Sr. no. / Filtration / Clarification** **1** / It is process of removal of solids or suspended matter in a liquid or gas by passing through a porous medium in which solids are retained. / It is process of removal of solid in very less concentration from liquid, concentration of solid is less than1% **2** / Can be achieved by using different filter medias / Can be achieved by doing filtration or centrifugation **3** / Filter leaf, candle, press etc can be used / Meta filter is used in clarification of syrups and elixirs. **List of different filter media:** i) Filter paper ii) Cotton wool iii)Glass wool iv) Asbestos v) Fine muslin vi) Filter cloth vii) Membrane filters viii) Sintered glass filters.	**3M (0.5 x 2=1M for difference and 0.5 x 4=2m for differed medias)**
2	**d)**	**Explain construction and working of filter candle.** **Construction:** • These are cylindrical candles with an opening, • The opening is connected to vacuum pump for reducing pressure under it, during filtration process. • The candles are made up of porcelain or Kieselguhr.	**3M (1+1+1)**

		Diagram:  **Working :-** 1) The candle is placed in the solution be filtered. 2) When vacuum is applied, the liquid will pass through the thick wall of the candle & gets collected inside the candle from where it is removed.	
2	**e)**	**Write advantages and disadvantages of tablets.** **Advantages of tablets:** 1. Easy to administered. 2. Easy to dispense. 3. More stable. 4. Accuracy in dose. 5. Bitter and nauseous substance can be easily dispensed. 6. Light and compact. 7. Economical. **Disadvantages of tablets:** i) Problem with compression to crystalline drug. ii) Hygroscopic drugs are not suitable for compressed tablets. iii) Drugs with low or poor water solubility, slow dissolution, may be difficult to formulate. iv) Cost of production may be increase because of coating and encapsulation to remove bitter and unpleasant taste. v) Swallowing is difficult especially for children and ill (unconscious) patients.	**3M (0.5 X3=1.5 for advantages &(0.5 X3=1.5 for disadvantages)**

2	**f)**	**Explain in detail about maceration with adjustment. How does it differ from simple maceration process?** **Maceration with adjustment:** This process is carried out for unorganized drug. **Method:** i) Place unorganized drug with $4/5^{th}$ of the menstruum in a close vessel for 2-7 days. ii) Shake the vessel occasionally. iii) After stipulated period filter the liquid and make up the final volume with the remaining i.e. $1/5^{th}$ of the menstruum. (Do not press the marc) **Justification:** **i)** The period of maceration can be reduced from 7 to 2 days in few cases. As unorganized drugs behave like simple chemicals which dissolves in the solvent very easily and quickly ii)The marc left is gummy, it does not retain the menstruum thus not pressed. iii) The final volume is made up with $1/5^{th}$ of menstruum. As marc is not pressed there is no change in concentration of the preparation.	**3M (1.5 for method & 1.5 for three difference)**

Sr No	**Simple Maceration process**	**Maceration with adjustment**
1	Drug along with the whole of the menstruum is used in maceration process.	Drug along with 4/5th of the menstruum is used in the maceration process.
2	The period of maceration is 7days	The period of maceration is 2 -7 days as specified
3	Strain off the liquid and press the marc.	Decant the liquid. Marc is not pressed.
4	Mix the pressed liquid with the macerate and clarify by subsidence or filtration. Filtrate is not adjusted to volume.	Filter the liquid and pass the remaining 1/5th of menstruum through filter to make up the final volume.

		5	Examples of tinctures: Tincture of Orange, Tincture of Lemon, Tincture of Capsicum	Examples of tinctures: Compound Tincture of Benzoin, Tincture of Tolu, Tincture of Myrrh	
3		**Attempt any FOUR of the followings**			**12M**
3	**a)**	**Write the advantages & disadvantages of an evaporating pan** **Advantages**: • It is simple and cheap to construction. • Easy to clean and maintain. • Economical. **Disadvantages**: • Poor coefficient of heat transfer. • Heating surface is limited. • Not suitable for concentration of thermolabile material. • Evaporating pan is open so vapour cause discomfort to the worker.			**3M 0.5X3= 1.5 for advantages & 0.5X3 = 1.5M disadvantages)**
3	**b)**	**Define the terms-1) sublimation ii) evaporation** **i) Sublimation**: It is the process in which solid gets converted into vapour without formation of liquid and on cooling; the vapours get converted into solids. **ii) Evaporation:** Evaporation may be defined as free escape of vapours from the surface of the liquid below its boiling point.			**3M (1.5 each)**
3	**c)**	**Write the applications of simple distillation in pharmacy.** i. It is used for the preparation of distilled water and water for injection. ii. Preparation of many volatile oils and aromatic water. iii. Purification of organic solvent. iv. Preparation official compound like spirit of nitrous ether. v. Preparation official compound like spirit of aromatic spirit of ammonia. vi. To separate volatile and non-volatile solvents.			**3M (0.5X6 =3M)**
3	**d)**	**How will you separate two immiscible liquids in pharmacy? Draw a libelled sketch of the apparatus used in laboratory.** **:Steam Distillation(immiscible liquids):**			**3M (1.5 each for**

		• In pair of immiscible liquids , each liquid exerts its own vapour pressure & neither liquid has any appreciable effect on the vapour pressure of the other. • The vapour pressure of the mixture at given temperature is equal to the sum of the vapour pressure of two pure components at that temp. • A mixture of immiscible liquids begins to boil, when sum of their vapour pressure is equal to atmospheric Pressure. • Thus in case of water & liquid which boils at much higher temp. than water, the mixture boils below the boiling point of pure water  Fig. Steam Distillation. • For eg. Boiling point of turpentine is about 160 ºc, but when mixed with water & heated, the mixture boils at about95.5 °c. • At this temp. 95.5 ° c, the vapour pressure of water is 647mm & that of turpentine is 113mm of mercury, the sum is 647 + 113 = 760 mm which is equal to normal atmospheric pressure • From this, it will be seen that a high boiling substance may be distilled with water at temp. much below its boiling point. • For substances which are insoluble in water & are not decomposed by water , this provides an alternative to distillation under reduced pressure	**expiation and diagram)**
3	**e)**	**Discuss the theory, construction, and working of freeze drying apparatus**	**3M**

		Theory: Freeze drying or sublimation drying consists of simply reducing the temperature & pressure to values below the triple point .(4.579mm of Hg& temp. of 0.0099 c) • Under these conditions, any heat transferred is used as latent heat & the ice sublimes directly to the vapour state. • Many pharmaceutical products lose their viability in liquid state & readily deteriorate if dried in air at normal atmospheric pressure. • These pharmaceutical products may be heat sensitive or they may react readily with oxygen • Such materials are blood serum, plasma, antibiotics, hormones, bacterial cultures, vaccines, & many foodstuffs. **Construction**: Freeze dryer is composed of four basic components: **A chamber for vacuum drying**: Having shelves for keep the material **A vacuum source**: vacuum pump is connected to the chamber. **A heat source**: heat is provided by conduction or radiation. **A vapour removal system as vacuum pump**: The condenser consists of large cooled surface by solid carbon dioxide mixed with acetone or ethanol. **Working: steps involved in freeze drying are** 1. **Pre-treatment:** Solution is concentrated in normal vacuum tray dryer before introducing in the chamber this reduces drying by 8-10 times. 2. **Pre-freezing**: Ampoules, vials and bottles having aqueous solution are packed and frozen in cold shelves at a temp. below - 50^0C. 3. **Primary drying:** The material to be dried is spread to increase the surface area for sublimation.98-99% moisture removed. 4. **Secondary drying:** Remaining moisture is removed by vacuum drying done at 50-60^0C.It takes 10-20 hrs. 5. **Packing:** Biological products are dried packed in aseptic condition immediately after drying.	**(1+1+1)**
3	**f)**	**Discuss in brief about gaseous sterilization.** **Ans: Gaseous sterilization using Ethylene oxide:**	**3M** **(1.5**

		Ethylene oxide:
		• It is colourless gas at room temperature.
		• It can be liquefied easily and boil at 10.8^0C.
		• It is highly inflammable so it us used in mixture form:
		  • Ethylene oxide 1 part + carbon dioxide 9 part.
		  • Ethylene oxide 11% w/v part + Trichlofluromethane 79% w/w + dichlorodiflurometane 10%w/w
		  • Ethylene oxide 12%w/w + dichlorodifluromethane 88%w/w.
		• Sterilization is done in a chamber which can be heated to the desired degree of temperature.
		• The material is to be sterilized is packed in chamber and treated with Ethylene oxide gas.
		• Sterilization in absence if air:
		• It is carried out in a evacuated sterilizer at sub atmospheric pressure with Ethylene oxide 90% + carbon dioxide 10%.
		Advantages:
		1. High penetration.
		2. Can maintained high conc.
		3. Very reactive.
		4. Non Irritant to respiratory tract.
		5. Used for heat sensitive material.
		6. Used for sterilization of moist –sensitive material.
		Disadvantages:
		• Method very slow.
		• Cost is high.
		• Apparatus very expensive.
		• It is highly inflammable.
		• Certain toxic substance produced such as ethylene chlorohydrins.
		Mechanism of action:
		Ethylene oxide exerts its lethal effect on microorganisms by alkylation essential
			method 0.5 Advantage, 0.5 for disadvantages, 0.5 mechanism)

		metabolites. The alkylation probably occurs by replacing an active hydrogen on sulphahydral, amino, carboxyl, hydroxy group in enzymes ,proteins & nucleic acids **Method:** • The sterilization is done in pressure chamber which is designed in such a way to give controlled temp., humidity, gas conc. & exposure time. • The material to be sterilized is first exposed to high humidity of about 98% leading to humidification of organism. • Then it is exposed to sterilizing gas. (fuming ethylene oxide) under pressure till desired concentration is obtained. • Exposure period may range from 6-24 hrs depending upon degree of contamination & penetrability of material . • Others gases used are formaldehyde and Beta-propiolactone.	
4		**Attempt any FOUR of the followings**	**12M**
4	**a)**	**Write in detail about moist heat method of sterilization** **Principle:** • The steam has more penetration power than dry heat and thermal capacity of steam is more than thermal capacity of dry heat. • The method is useful for killing of bacterial spores. • The moist steam penetrate the spores and capsules of bacteria, rupture it and escaping protoplasma it coagulated. • The temperature conditions for autoclaving: 1 115^0C to 118^0C 30 min. 2 121^0C to 124^0C 15 min. 3 126^0C to 129^0C 10 min. 4 134^0C to 138^0C 5 min. **Construction:** • It consists of a strong metallic chamber usually made of stainless steel. • It has cover fitted with steam vent, pressure gauze, and a safety valve. • Rubber gasket is fitted in inner wall of lid in order to make it air tight.	**3M** **(**1+1+1 **0r** 1 for principle 1 for working 0.5 advantage or 0.5 disadvantages**)**

		• The cover is closed with wing nut and bolts. • An electric heater is fitted at the bottom to heat the liquid. • A perforated basket is provided to keep the material in the autoclave. **Working:** • A sufficient quantity of water is poured into the chamber after removing the perforated basket. • The level of water adjusted in such a way that it should not touch the bottom of perforated basket. • The material is placed in the basket and it placed in the autoclave. • Close the lid with wing nuts and bolts. • Switch on the heater. • Vent is opened and safety valve is set to required pressure. • When steam comes out for 5 min, then close the vent, the steam pressure stats rising and it should be maintained to required level. • After the stated time, switch off the autoclave. • Allow to cool to about $40^{o}C$. • Open the vent and allow the complete steam to pass from autoclave. • Lid is opened and sterilized material is taken out **Advantages:** 1. It destroy microorganism more efficiently than dry heat. 2. It is used for sterilization of s large number of official injection. 3. Rubber, plastic can be sterilized. 4. A large quantity of material can be sterilized in one batch. **Disadvantages:** • It not suitable for powder or oils. • It is not suitable for sterilization of plastic which melt at $115^{0}C$.	
4	**b)**	**Explain the term aseptic techniques. What are the various points to be considered while designing an aseptic room?** **Definition:** The method which is used to prevent the access of microorganism during the preparation of parenteral product and their testing are called "aseptic Technique".	**3M (Definition1M and 2M**

		Design of aseptic room: 1. Site: • Away from stairs, lift and corridor. • Best site is one where is no disturb. 2. Size: • Depend on maximum no of people work. 2. Window: • Glass panes should be used. • Ventilation is provided by laminar air flow. 3. Door: • Air lock with double door system. 4. Surface material: • The floor, wall and bench tops of an aseptic room must be smooth, resistant to chemical and easily cleanable. • The floor should be built with terrazzo, linoleum and plastics. • Wall should be provided with tiles or coated with hard glass paint or smooth plaster or covered with plastic laminates board. 5. Services: • Ventilation. • Electricity. • Gas connection. • Vacuum. • Disposable waste. 6. Furniture: • Shack type. • Fume –cupboard.	**for design)**
4	**c)**	**Discuss in brief about moist granulation method.** • Drug + Excipients → Blending → Formation of cohesive mass → Screening → Drying → Screening → Blending → Compression. **This method consists of the following steps:**	**3M**

		1. Milling of drugs and excipients such as diluents, disintegrating agent. 2. Mixing of milled powders. 3. Preparation of binder solution. 4. Mixing of binder solution with powder mixture to form a cohesive mass. 5. Course screening of the wet mass using 8-12 mesh screen. 6. Drying the moist granules at 60^0C in a hot air oven by spreading in trays. 7. Screening of dry granules through sieve no 20. 8) lubricating agent , glidant and disintegrating agent added/mixed. 8) Granules ready for compression	
4	**d)**	**Why coating of tablet is done? What are the different methods of coating?** **Reasons for coating:** 1. To mask unpleasant taste and odour. 2. To improve the appearance of tablets. 3. To prevent the medicament from atmospheric effects. 4. To control the site of action of drugs. 5. To produce the sustained release product. **Methods of tablet coating :** 1. Sugar coating: 2. Film coating 3. Enteric coating.	**3M (0.5X4 =2Mfor reasons + 0.5X2= 1M for method s)**
4	**e)**	**Why ophthalmic ointments are now days packed in capsules?** 1. Sterility can be maintained. 2. Contamination can be avoided. 3. No wastage. 4. Easy to handle. 5. Easy for transportation. 6. Economical. 7. Easy to use or good patient compliance.	**3M (0.5X6 =3M)**
4	**f)**	**What should be the properties of powder to be filled in hard gelatine capsule?** **Properties of powder:**	**3M**

		Flow property of powders depends upon followings: 1. Particle size.: Uniform 2. Particle shape.: Spherical 3. Density: same density 4. Surface texture: smooth 5. Angle of repose. • Maximum angle which is formed between the surface of a pile of powder and horizontal surface is called the "angle of repose". • This is determined for flow properties of powder. • **It is Tan Ø = 2h/D or h/r.** • The powder flow smoothly, if angle of repose is 25^0 . • The powder does not flow smoothly, if angle of repose is more than 50^0.	
5		**Attempt any FOUR of the followings**	**12M**
5	**a)**	**Write in brief about Mantous test.** A dose of 5 tuberculin units of old tuberculin or an equivalent dose of PPD is injected intradermally. After 48 to 72 hours the reaction of the test is observed at the site of the injection. A positive reaction consists of a raised indurated area. induration measuring 10 mm or more is interpreted as positive for past or present infection with *Mycobacterium tuberculosis.* Induration of 5 to 9 mm is regarded as of doubtful significance. The induration of less than 5 mm is interpreted as a negative. The presence of erythema without induration is not significant**.**	**3M**
5	**b)**	**Explain the term 'Immunological products'. Discuss any one vaccine in brief.** **Immunological Product:** These are the preparations which are meant for the prevention of diseases, such as vaccines or for treatment of diseases. **Immunological Products:**	**3M (1M definition and 2m for**

A. Active immunization:
   1. Bacterial vaccine.
   2. Viral rickettsial vaccine.
   3. Toxoids.

B. Passive immunization:
   1. Antitoxins.
   2. Antiviral serum.
   3. Antibacterial serum.
   4. Immune blood derivatives.

any one vaccine)

(i)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

OR.

(ii)Small pox vaccine is prepared by two methods :

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

(iii)General method of preparation of toxoids:

A suitable strain of bacteria is grown on liquid medium. Incubation is carried out under optimum conditions until toxin productions has reached a satisfactory level. Filter the media and the filtrate containing toxins are converted by chemical treatment to toxoid in which toxicity has been reduced, but antigenic effect is maintained.

The conversion of toxin to toxoid is done by the treatment with formaldehyde solution at 37^0 C. The product obtained is known as formal toxoid (FT).

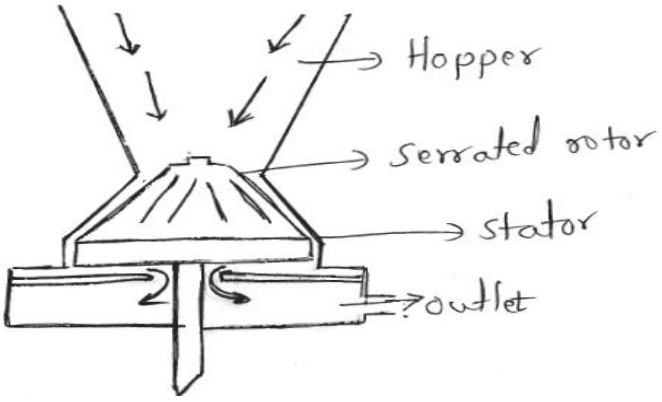
The formal toxoid obtained may be further purified by:

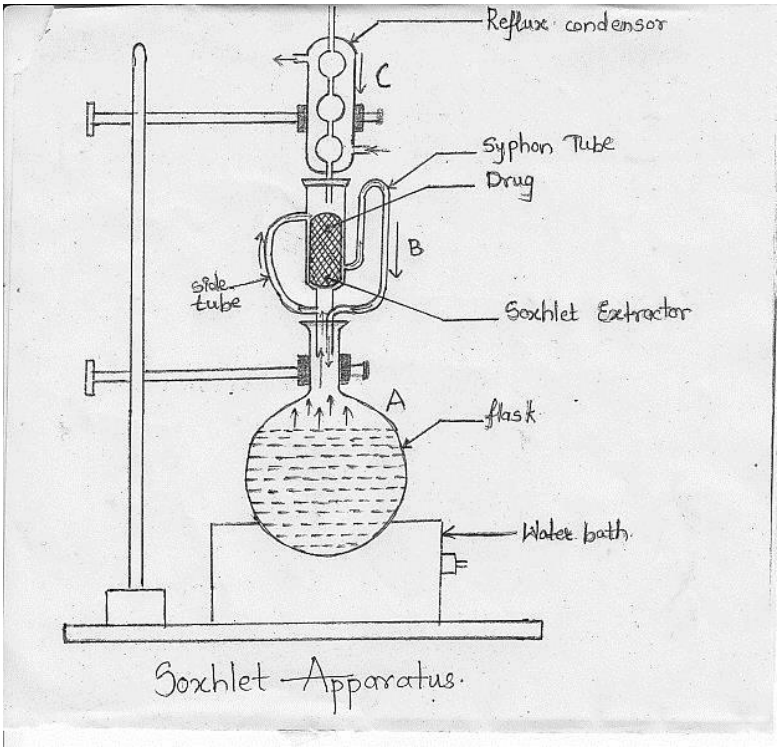
i. Precipitating with alum (APT)
ii. Flocculating it with the corresponding antitoxin (TAF)
iii. Adsorbing an aluminium hydroxide (PTAH) or hydrate aluminium phosphate (PTAP).

5	c)	**Discuss in brief about 'Multiple Maceration'.** • This is done to achieve maximum extraction of active constituents as well as complete exhaustion of drugs. **Double maceration:** ▪ It is carried in the same way as simple maceration. ▪ The menstruum is divided in two parts. ▪ The quantity of menstruum required for two macerations are calculated as. Volume of menstruum req. for first maceration = Total Vol. of menstruum – Vol. to be retained by drug / 2 + Vol to be retained by drug. Volume of menstruum req. for second maceration = Total Vol. of menstruum – Vol. of menstruum used for first maceration. ▪ In Double maceration drug is macerated for 48 hr for first maceration and 24 hr for second maceration. ▪ Strain the liquid and press the marc. ▪ Mix the liquid obtain from two maceration and keep it for 14 days and then filter. ▪ Ex. Concentrated infusion of orange and gentian infusion. **Triple Maceration Process** In this maceration process, the drug is macerated **thrice** by using the menstruum which is divided into three parts in such a manner that the same volume is used for each maceration. The quantity of menstruum required for three macerations is calculated as follows: **Volume of menstruum required for first maceration =** Total vol. of menstruum / 3 - Vol. to be retained by the drug + Vol. to be retained by the drug **Volume of menstruum used for 2nd and 3rd maceration =** Total vol. of menstruum - Vol. of menstruum used in first maceration	**3M (1.5 + 1.5=3M)**

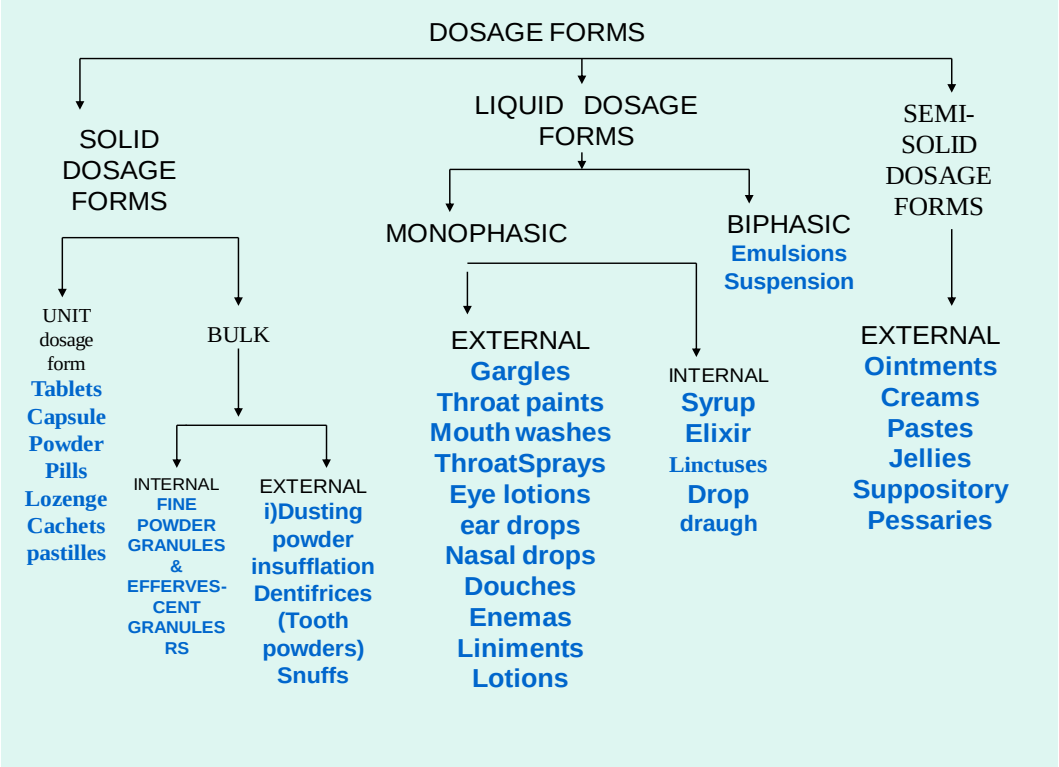
		2 **PROCEDURE FOR TRIPLE MACERATION** • The whole of the drug is macerated for one hour with part of menstruum required for first maceration and strained. • Macerate again for one hour with a part of menstruum required for second maceration and strained. • Macerate again for one hour with a part of menstruum required for third maceration and strained. • Press the marc lightly. Then combine the liquids obtained from second and third maceration and evaporate it to a specified extent. • Mix it with the liquid obtained from first maceration. Add alcohol 90% equal to l/4th of the volume of the finished product. Adjust volume with water. Allow it to stand for 14 days and filter.	
5	**d)**	**Why plastic containers are more commonly used now a days? Write its demerits.** **Plastic containers are more commonly used now a days for following advantages**: 1.They are light in weight and can be handled easily 2.They are poor conductor of heat . 3.They have sufficient mechanical strength. 4.They can be transported easily. 5.Unbreakable 6.Available in various shape and sizes. 7.They are resistant to inorganic chemicals. 8.They have good protection power. 9. There are no formation of flakes as it comes in glass containers. **Demerits of Plastic:** 1.They are permeable to water vapour and atmospheric gases 2.They cannot withstand heat without softening or distorting. 3,they may interact with certain chemicals to cause softening or distortion	**3M** **0.5** **X3=1.5** **and** **0.5** **X3=1.5** **M)**

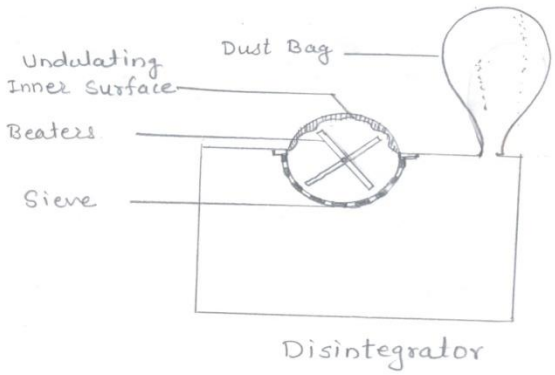
		4.They may absorb chemical substances such as preservatives for solution. 5.They are relatively expensive. 6.Special type of gum or adhesive required for labelling.	
5	**e)**	**Explain the factors which affect the rate of evaporation of a liquid.** **Factors affecting rate of evaporation:** **1. Temperature:** The rate of evaporation is directly proportional to the temperature of liquid. The evaporation can be accelerated by increasing the temp but it will cause decomposition of thermolabile substances. **2. Temperature and time of evaporation:** Exposure to relatively high temp for short period of time may be less harmful to the active principles of a drug than a lower temp with exposure for longer time. **3. Temperature and moisture content:** Some drug constituents decompose more readily in presence of moisture if heated at high temp. **4. Type of product required:** On evaporation of the liquid, conc. liquid, semisolid, and solid are formed. **5. Effect of concentration:** There is tendency of forming film on the upper layer of liquid which reduces the rate of evaporation. **6. Surface area:** The rate of evaporation is directly proportional to surface area of evaporating surface. **7. Vapour pressure of the liquid to be evaporated:** The rate of evaporation is directly proportional to the vapour pressure of evaporating liquid.	**3M (any six 3 M)**
5	**f)**	**Calculate the quantity of 60% alcohol required to make 500ml of 20% alcohol.** 60% — 20 parts of water 20% 0% (water) — 40 parts 60% Total parts — 60 parts	**3M**

		For 500 ml of 20 % alcohol **Water used is 20 parts** 500x20 = 166.66 60 **60% alcohol used is 40 parts** 500x40 = 333.33 60	
6		**Attempt any FOUR of the followings**	**16M**
6	**a)**	**Define 'Homogenisation'. Write the principle of homogenisation. Write in detail about 'Colloidal Mill'.** • Homogenization is the process of preparing fine emulsion from a coarse emulsion by converting the large globules in to small globules. • **Principle**: These work on the principal of braking large globules in to small globules by passing them under pressure through a narrow orifice.  **CONSTRUCTION:** • Colloid mill consists of rotor & stator. The milling surfaces are conical in shape & gap between them is about 0.002- 0.03 inch & is adjustable.	**0.5 + 0.5 + 1+1+1= 4M)**

		• The rotor rotates at about 3000 - 20000 rpm speed. **Working of colloidal mill** • The emulsion or suspension is placed in hopper of mill. • It is then passed through the narrow gap between rotor & stator & thus reduced to fine particle size • The material is thrown outward due to centrifugal action	
6	**b)**	**Draw a well labelled diagram of 'Soxhlet apparatus.' Mention the various limitations of continuous hot percolation process.**  **Limitation:** 1. Physical character of the drug: If the drug would block the soxhlet apparatus then this process cannot be used for extraction. Eg opium. Gum, resin, orange peel, etc. 2. Solvent: Only pure solvents or constant boiling mixtures can be used. 3. Chemical constituents of the drug: The process is unsuitable for drugs having	**4M 2M for diagram & 2M for Limitation)**

		thermolabile active constituents such as enzymes, alkaloids, anthraquinone derivatives, esters, etc.	
6	**c)**	**Give in brief the history of the 'Pharmacopoeia of India'.** The government of India directed the Drugs Technical Advisory Board to list the drugs that are used in India, which are not mentioned in British Pharmacopoeia and also recommend the standards to be prescribed to maintain uniformity and the chemical tests to be used to establish identity and purity. The Government of India published the Indian Pharmacopoeial List in 1946 as a supplement to British Pharmacopoeia. The term list in the title was 'misleading' in that, the book not only contained a list of drugs which were of substantial medicinal value but also laid down standards. The Indian Pharmacopoeial List contained about 180 monographs and a number of appendices prepared on the lines of the British Pharmacopoeia. Approximately 100 monographs were on vegetable drugs growing in India and on their galenicals. `The drugs of plant origin such as artemesia, bael, berberis, cannabis, ispaghula, kaladana, kurchi, myrobalan,picrorhiza, punarnava, rauwalfia, vasaka etc.were included in it. Similarly several oils such as ajowan,cassia, chaulmoogra, neem and pudina were included it. The appendices gave detail for a number of determinations referred to in the monographs. The Pharmaceuticals and Drugs Research Committee of the Council of Scientific and Industrial Research decided in February 1947to compile a 'Brochure' to highlight the information and clinical users of the important indigenous drugs of India. Later on it was decided to prepare a 'Codex' instead of Brochure on the lines of the British Pharmaceutical Codex. The first Indian Pharmaceutical Codex published in 1953.The Codex consisted of two parts. The part carried about 190 general monographs on natural product and drugs of vegetable and animal origin, and a few chemicals. The second part consisted of formulary of galenicals and other preparations. After the publications of the Indian Pharmacopoeial List the Government of India, constituted an eleven member Indian Pharmacopoeial Committee in 1948, in their notification No. F.1-1/48-DS dated 23rd November, 1948, for preparing the	**4M**

		Pharmacopoeia of India. The tenure of the office of the members of the Committee was five years. It was extended by one year vide Government notification no F.6-10/53-DS34 dated 21st November 1953. In compiling the monographs of the first Pharmacopoeia of India, help was taken from all available established scientific data in the modern Pharmacopoeia, such as British Pharmacopoeia, the United States Pharmacopoeia, and the international Pharmacopoeia and from scientific institutions interested in drugs and Pharmaceuticals products. The first edition of Pharmacopoeia of India was compiled and then published in 1955.	
6	**d)**	**How will you classify different dosage forms?**  	**4M**
6	**e)**	**Write the principle, construction, working and uses of the disintegrator.** **Principle:** The Disintegrator works on the principle of impact.**(0.5M)** **Construction: (1 mark)** The Disintegrator consists of steel drum having a shaft in the centre. The shaft contains a disc, on which four beaters are fixed. The shaft rotates with a	**4M (0.5+1+1+1+0.5=4M)**

		speed of 5000 to 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. **Working:(1Mark)** The beaters are mainly responsible for grinding but are helped by the undulation of the inner surface and roughness of drum. The material is fed 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. **Diagram(1 mark)**  **Use: (1/2Mark)** This mill is used to powder all types of drugs including very hard drugs.	
6	**f)**	**Describe the principle, construction, working and uses of cyclone separator.** **Principle**: Centrifugal force **(0.5M)** **Construction-(1M)** 1) Cyclone separator is size separation device 2) It consists of a cylindrical vessel with a conical base. 3) The upper part of the vessel is fitted with a tangential inlet and a fluid outlet. 4) At the base it is fitted with solid outlet **Working**: **(1M)** The suspension of a solid gas (Usually air) is introduced tangentially at a very high velocity	**4M (0.5+1+1+1+0.5)**

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.

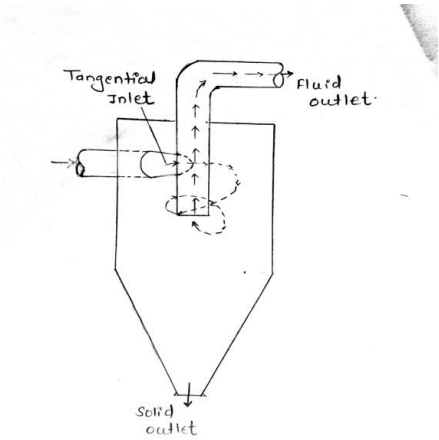


Fig - Cyclone separator

Uses of cyclone separator: (0.5M)

1. Cyclone separator is used to separate the suspension of a solid in gas
2. It can be used with liquid suspension of solid