SUMMER – 13 EXAMINATION

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 any equivalent 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.

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Q.I Answer any FIVE: (2 marks for each question)

a) Define (1 mark each)

i) Drug- A Drug may be defined as an agent intended for use in the diagnosis, mitigation, treatment, cure or prevention of diseases in human beings or in other animals.

ii) Dosage forms- Any form in which the drug is administered in prescribed quantity is called as Dosage forms.

OR

Dosage form is a transformation of a pure chemical compound by processing into a predetermined form by admixing drug component with different kinds of inert non drug components as additives.

b) (1/2 mark each editon, any 4)

Different six editions of Indian Pharmacopoeia in chronological order are as follows:

First Edition in 1955

Second Edition in 1966

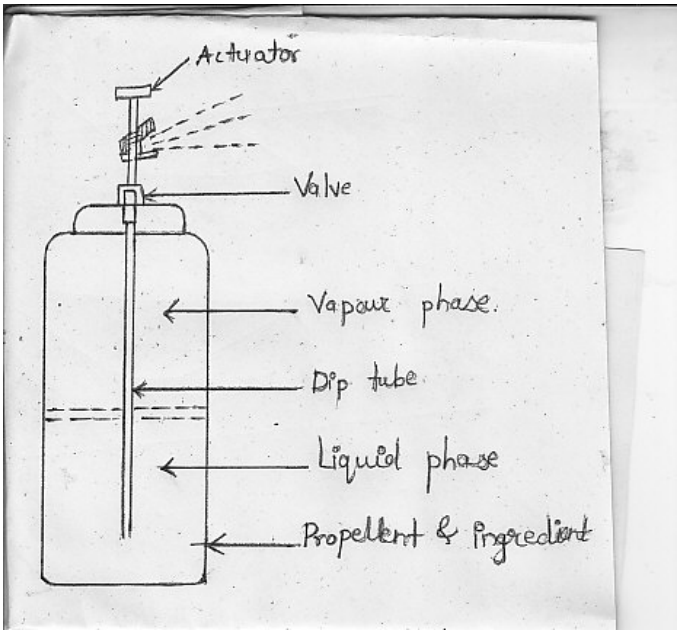
Third Edition in 1985

Fourth Edition in 1996

Fifth Edition in 2007

Sixth Edition in 2010

e)Aerosol container (1 mark for diagram and 1 mark for labeling)



d)Difference between Hard Gelatin Capsule and Soft Gelatin Capsule(1/2 mark each point, any 4 points)

	HARD GELATIN CAPSULES	SOFT GELATIN CAPSULES
1.	The hard gelatin capsule shell consists of two parts: Body and cap	The soft gelatin capsule shell becomes a single unit.
2.	They are cylindrical in shape	They are available in round, oval and tube-like shapes.
3.	The contents usually consist of medicaments in the form of powder, beads or granules.	The contents usually consist of liquids or semisolids.
4.	These are prepared from gelatin, titanium dioxide, colouring agent and plasticizer.	These are prepared from gelatin, more amount of plasticizer (sorbitol or glycerin) and preservative.
5.	Filling and sealing takes place in different steps	Filling and sealing are done in a combined operation of machines.
6.	Shell is perfectly dry,	Shell is not perfectly dry.

e) (1 mark each)

i) 1 fliud ounce

1 ounce (avoirdupois) in 100 fl ounces = 1% w/v solution

437.5 gr. in 100 fl ounce = 1% w/v solution [As 1 ounce (avoirdupois) = 437.5 grains]

4.375 gr. in 1 fl ounce = 1% w/v solution

So 4.375 gr. are required to obtain 1% solution measuring 1 fliud ounce

ii) 1 pint

4.375 gr. in 1 fl ounce = 1% w/v solution

70 gr. in 16 fl ounce = 1% w/v solution

70 gr. in 1 pint = 1% w/v solution [As 1 pint=16 fl ounce]

f) Applications of Viscosity (1/2 mark each point)

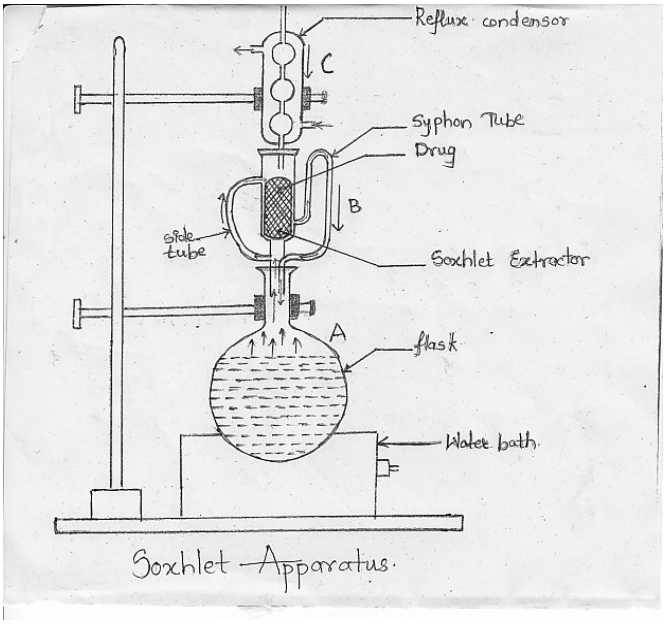
i) Viscosity affects rate of Filtration. Rate of filtration can be increased or decreased by decreasing or increasing viscosity.

ii) When we change viscosity there is change in concentration of material.

iii) For making liquid dosage forms which are required to be taken for throat infection, should be viscous as they have to remain at the site of action for longer time eg. Throat paints, linctus, syrups etc.

iv) Viscosity of material influences heat transfer through it.

g) Soxhlet extractor (1 mark for diagram and 1 mark for labeling)

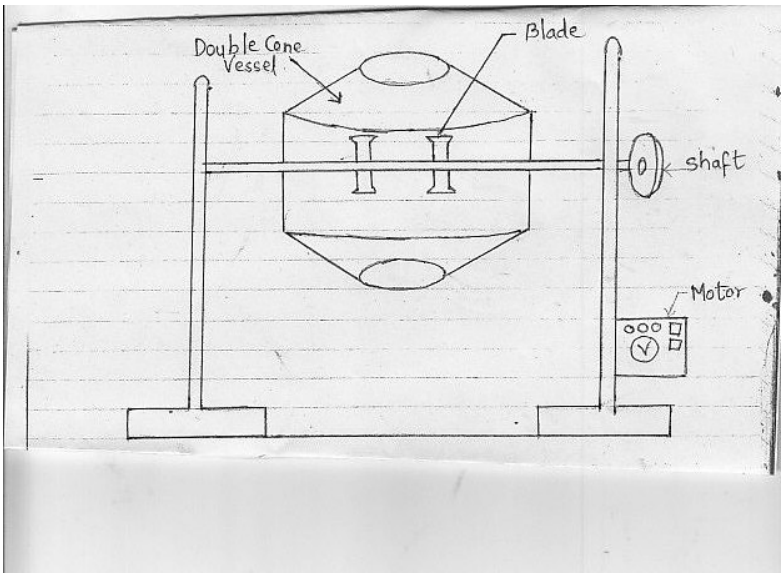


Q. II **Answer any FOUR** (3 $^{1}/_{2}$ marks)

a) Double Cone Blender ($1^{1}/_{2}$ marks)

Working: The material to be blended is loaded in approximately 50-60% capacity of conical shaped vessel. As the blender rotates, the material undergoes tumbling motion and mixes the material thoroughly. Agitator blade can also be used in order to produce shearing action and design is useful for mixing powders of different densities in small quantities.

Diagram (1 marks)



Application ($1^{1}/_{2}$ marks)

Mixing of powders for preparation of granules, for mixing of powders of tablets and capsules.
For mixing of powders of different densities.
For mixing of powders of small quantities.

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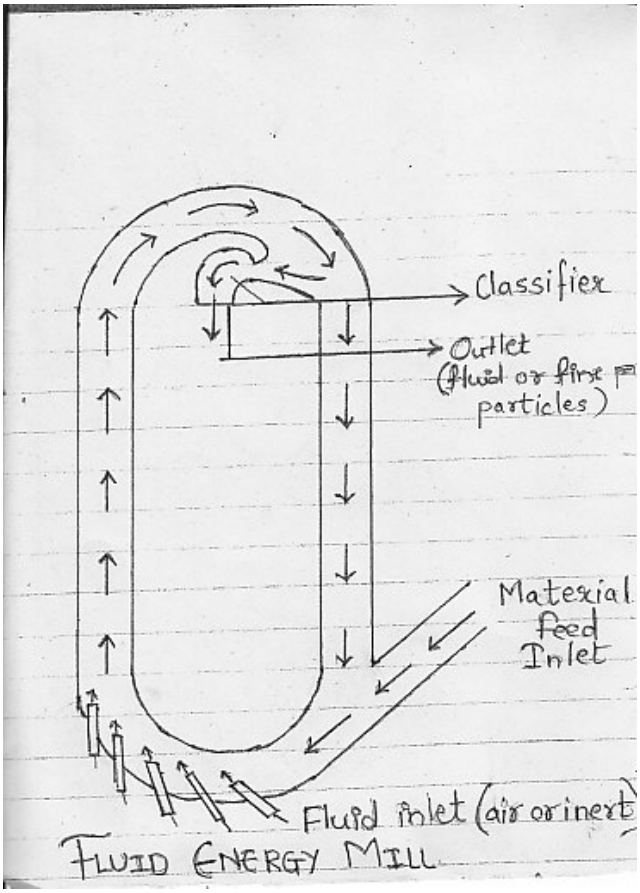
b) Fluid Energy mill OR Ball mill works on the principle of combined impact and attrition.

Fluid Energy mill

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

Construction: ($1^1/_2$ marks):



Working (2 marks)

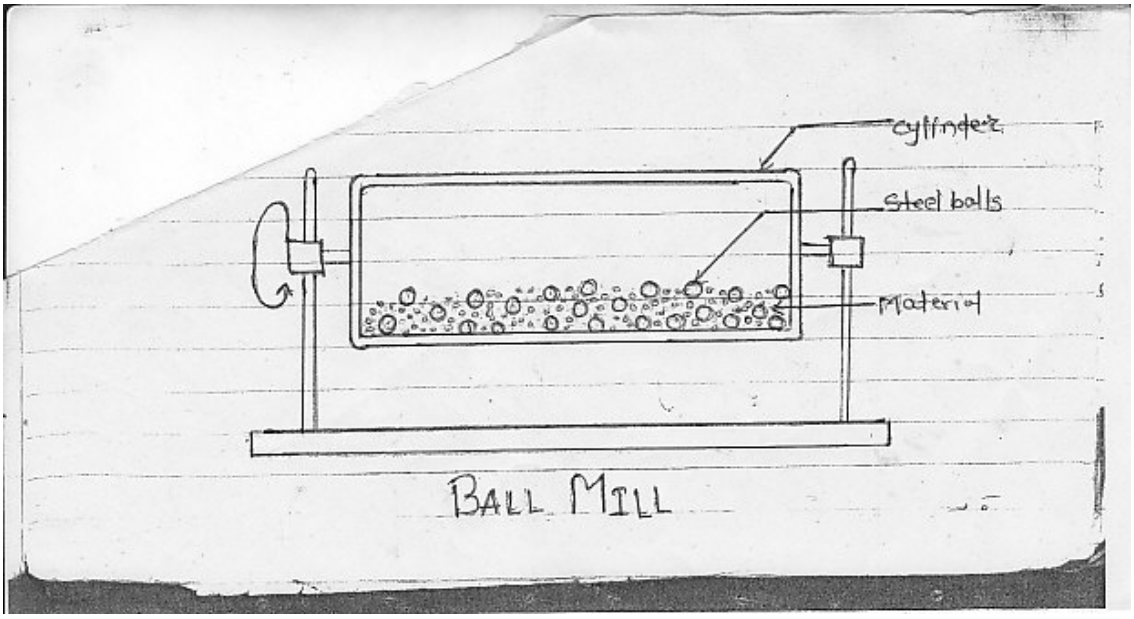
1. The material which is to be size reduced is fed in the grinding chamber from the bottom through the feed inlet.
2. The air or inert gas is introduced with a very high pressure through nozzles.
3. Due to high degree of turbulence, impact and attritional forces between the particles there is size reduction.
4. The air moves at a very high speed in elliptical part carrying with it fine particles that pass through the outlet in a classifier and are collected.
5. The large particles are carried by centrifugal force to the end whereby they are further exposed to the moving air.

6. The design of the mill provides for the internal classification of the particles whereby lighter, finer particles are discharged and heavier particles are retained due to effect of centrifugal force to be reduced to smaller size.
7 .Feed should be of 20 to 200 # size &mill produces particles of 1 to30 micron range to get a very fine powder even upto 5µ,the material is pre-treated to reduce the particle size to the order of 100# and then passed through fluid energy mill.

.Ball mill

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

Construction: ($1^1/_2$ marks)



It consists of a hollow cylinder mounted on a metallic frame in such a way that it rotates on its longitudinal axis. The cylinder contains 30-50% balls. The cylinder and balls are made of metal and are usually lined with chrome or rubber or porcelain.

Working:(2 marks)

Ball mill works on the principle of impact and attrition. There are three types of patterns as shown in figure:-

1) Cascading at a low speed the balls tumble, roll and jump down on the material. Negligible amount of size reduction will occur in this case.

2) Cataracting at an increased speed,the ball reaches the top of the mill and falls on the material.No size reduction will occur in this case.

3) Centrifuging about 2/3rd of the speed, the centrifugal force occurs with the result that the balls are carried just to the top of the mill and then fall in, by this way size reduction occurs at maximum rate by impact of material between the balls and by attrition between the balls and the surface.

After the required time the material is taken out & is passed through the sieve to get powder of required size.

c) Official grades of powders ($3\ ^1/_2$ marks)

The I.P.85 specifies five grades of powder which are as under

Coarse powder : A powder of which all the particles pass through a sieve with nominal mesh aperture of 1.70 mm (**No. 10 sieve**) and not more than 40.0 per cent through a sieve with nominal mesh aperture of 355 um (**No.44 sieve)** is called coarse powder.

Moderately coarse powder : A powder of which all the particles pass through a sieve with nominal mesh aperture of 710 urn **(NO. 22 sieve**) and not more than 40.0 per cent through a sieve with nominal mesh aperture of 250 um **(No.60 sieve)** is called moderately coarse powder.

Moderately fine powder : If all the particles of a powder pass through a sieve with nominal mesh aperture of 355 um (**No. 44 sieve**) and not more than 40.0 per cent through a sieve with nominal mesh aperture of 180 um (**No.85 sieve),** it falls in this group.

Fine powder : In case all the particles pass through a sieve with a nominal mesh aperture of 180 um (**No.85 sieve**), it is called fine powder.

Very fine powder : If all the particles of the powder pass through a sieve with a nominal mesh aperture of 125 um (**No. 120 sieve**), it is said to be very fine powder

d) **Darcy law** with respect to rate of filtration ($3\ ^1/_2$ marks)

This is also called as theory of filtration which gives idea about factors affecting rate of filtration through the filter medium.

Any fluid while passing through porous medium offers resistance, the rate of filtration through the filter media is expressed in the form of an equation which is known as Darcy's law

The equation is,

$$V = \frac{KA \Delta P}{\mu l}$$

where , V = Volume of filtrate

K = permeability coefficient & is dependent on filter medium & filter cake.

A = Area of filter bed.

ΔP = Pressure drop across filter medium & filter cake.

l = Thickness of filter cake

μ = Viscosity of filtrate

From the above equation, it is clear that the rate of filtration depends not only on nature of liquid undergoing filtration but also on other different factors. Increase in pressure difference,temperature,surface area of filter medium, pore size increases rate of filtration, while increase the rate of filtration while increase in viscosity of fluid & thickness of filter cake decreases the rate of filtration.

e) **Galenicals** are the medicinal preparations composed mainly of herbal or vegetable matter prepared by one of the extraction methods. Eg. Tinctures, extracts (1/2 mark)

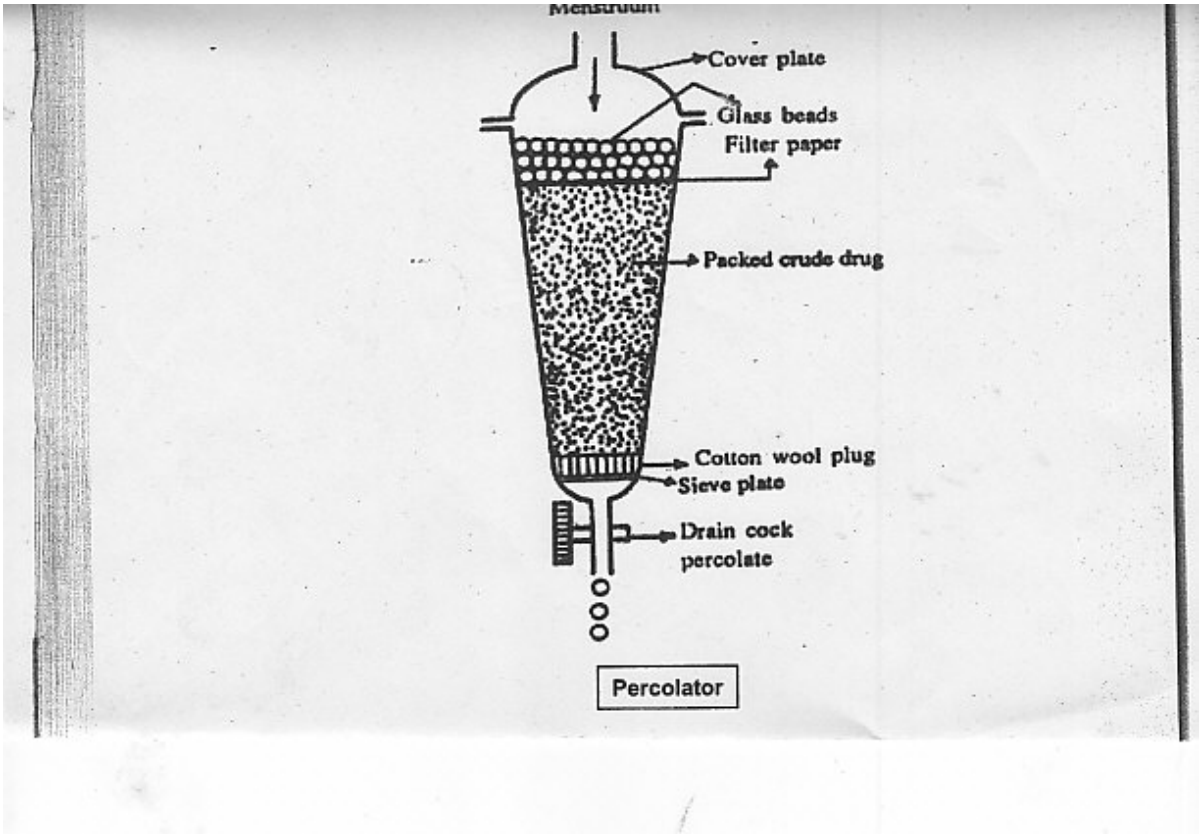
Percolation process for Vasaka extract I.P.(3 marks)

Percolation process involves following stages:

1) Size reduction
2) Imbibition
3) Packing
4) Maceration
5) Percolation
6) Pressing the marc
7) Adjustment to volume
8) Clarification

Vasaka consists of the fresh and dried leaves of Adhatoda vasica family Acanthaceae. The first portion which is alcoholic contains most of the active ingredients is reserved. The percolate is collected till all the drug is exhausted, and the percolate is distilled to syrupy consistency to which the reserved portion is added.

1. Exhaust the drug by percolation process, reserving the first 75 ml of the percolate.
2. Recover the alcohol from the remainder percolate by distillation process.
3. Evaporate the residue to consistency of soft extract.
4. Dissolve the soft extract in the reserved portion.
5. Add sufficient 40% alcohol to produce 100ml.



Percolator

f) Classification of Dosage forms with eg.(3½ marks)

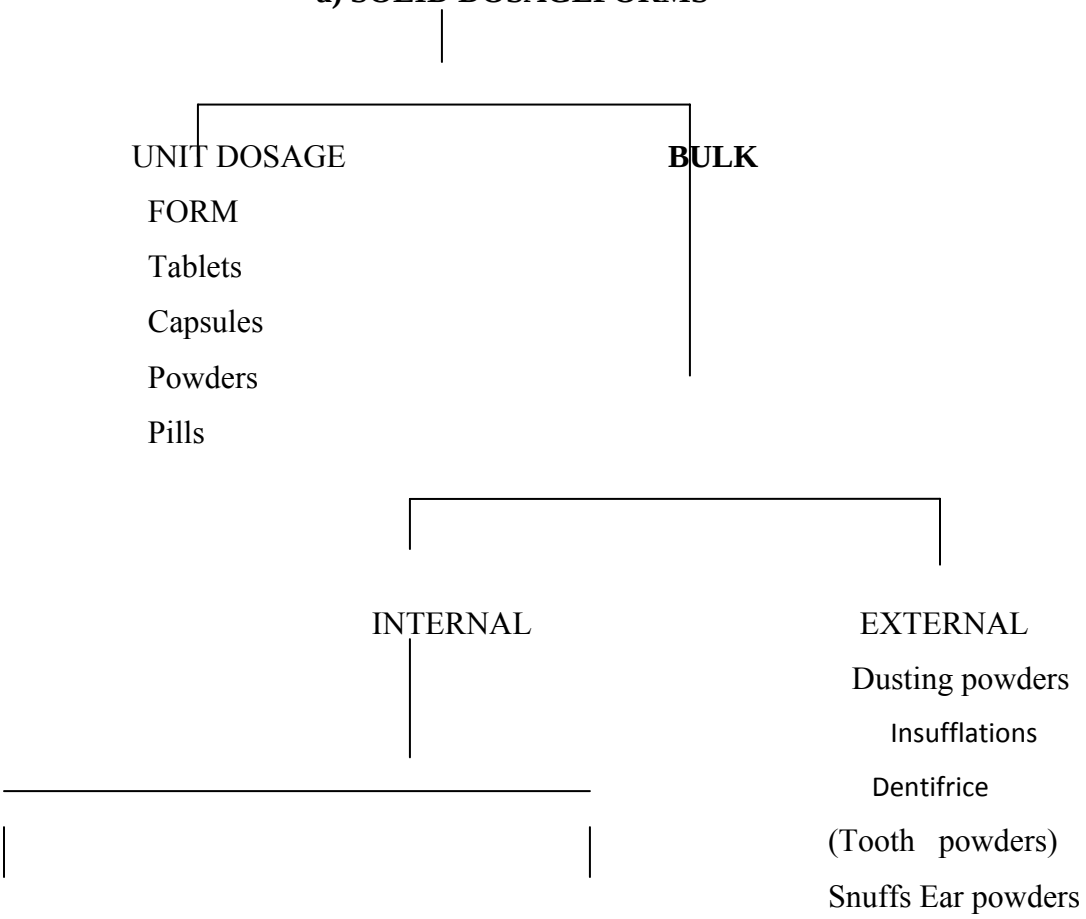
Dosage form is classified into three types

a)Solid dosage forms

b)Liquid dosage forms

c)Semisolid dosage forms

a) SOLID DOSAGEFORMS



b) LIQUID DOSAGE FORMS

- MONOPHASIC
  - EXTERNAL
    - Liniments
    - Lotions
    - Gargles
    - Throat paints
    - Mouth washes
    - Sprays
    - Eye lotions
    - Eye drop
    - Nasal drop
  - INTERNAL
    - Syrups
    - Elixirs
    - Linctus
    - Drops
- BIPHASIC
  - Emulsions
  - Suspensions

c) SEMI-SOLID DOSAGE FORMS

- EXTERNAL
  - Ointments
  - Creams
  - Pastes
  - Jellies
- INTERNAL
  - Suppositories
  - Pessaries

Q. III Answer any FOUR of the following: (3 ½ marks for each question)

a) Define tablets and classify different types of tablets

Tablets are solid unit dosage forms containing medicament or medicaments along with additives, usually circular in shape and may be flat or biconvex. Prepared by compression method.(01 mark)

Classification of tablets

1. Tablets ingested orally

a)compressed tablet b)multiple compressed tablets c)multilayered tabs d)sustained release tabs d)enteric coated tabs e)sugar coated tabs f)film coated tabs g)chewable tabs

2. Tablet used in oral cavity

a) Buccal tabs b) Sublingual tabs c) Lozenge tabs and touches d)Dental cones

3. Tablets administered by other routes

a) Implantation tabs b) Vaginal tabs

4. Tablets used to prepare solutions

a) Effervescence tabs b) Dispensing tabs c) Hypodermic tabs d) Tablet triturates (2½ marks)

b) Define immunity and differentiate between active and passive immunity

The capacity or power of the body to resist and overcome infection is called as **immunity** (01mark)

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.Preparations vaccines , toxoids	Preparation, sera (21/2) marks

c) Define capsule, state composition of capsule shell, give merit and demerit of capsule as dosage form.

Capsules are solid unit dosage forms in which drug or drugs along with additives are enclosed in water soluble shell. (01 mark)

Capsule shell is made from gelatin, colour and titanium dioxide (01 mark)

Merits

1. drug with unpleasant odour and taste can be administered by enclosing in capsule.
2. They become slippery when moist so easy to swallow.

Demerits:

1. Hydroscopic drugs cannot be filled in capsule as they make the shell very brittle.
2. Concentrated preparation which needs dilution before administration canot be given in form of capsule

(Beside above merits and demerits other can be given) (1 ½ marks)

d) Explain the term sterilization, classify different methods of sterilization.

Sterilisation is the process of complete destruction of all microorganisms along with their spores present in the system. (01 mark)

Methods of sterilization:

I. Physical methods

1. Dry heat sterilisation

2. Moist heat sterilisation

3. Radiation sterilisation i) Use of u.v. rays ii) Ionising radiation

II. Chemical methods

1. Sterilisation by heating with bactericide

2. Gaseous sterilisation

III. Mechanical methods

1. Ceramic filters

2. Seitz filters

3. Sintered glass filters

4. Sintered metal filters

5. Membrane filters (2 ½ marks)

e) Explain in brief about fractional distillation.

Fractional distillation is used for separation of two miscible liquids

When two miscible liquid are mixed and the mixture when heated , the vapour pressure of each liquid is lowered ,pressure exerted on each liquid is known as partial pressure , liquid boil when sum of partial pressure is equal to atmospheric pressure (01 mark)

Construction: The apparatus consist of distillation flask having fractionating column connected to condenser and condenser to receiver. The length of column depends on difference in boiling point of two liquids.

Working: When mixture of two liquids is heated the vapours of liquid having higher boiling point are formed first and are condensed in the condenser, whereas liquid having lower boiling points returns to the still. (1 ½ marks)

Application:

1. Purification of alcohol.
2. Separation of miscible liquids like alcohol and water,benzene and chloroform.
3. Used for separation of enzyme preparation derived from oils and fats (01) mark

f) State salient features of fourth edition of Indian pharmacopoeia.

1. It contains 1149 monographs and 123 appendices and available in two volumes.

2. Introduction of computer generated formula

3. Some titles have been changed to include more commonly accepted names in India e.g.Hyoscine Hydrobromide for Scopolamine hydrobromide.

4. I.R and U.V absorption spectrophotometric tests for identification of drug substance have been introduced.

5. HPLC has been widely used as method of analysis in many formulations.

6. Test for bacterial endotoxins as a more suitable substitute for test for pyrogens.

7. Number of general monographs e.g. eye drops ,eye ointments pessaries have been included.

8. A quantitative method for determining particulate matter in injectable preparation has been replaced by qualitative test.

9. Biological assays provided for vaccines, hormones, blood products.

10. Monograph for (ORS) Bicarbonate dropped due to stability problem

(1\2 mark for each point)

Q. IV Answer any FOUR of the following: (3 ½ marks for each question)

a) How many parts of 90%, 80%,60%& 40% alcohol should be mixed so as to obtain 70 % alcohol

% alcohol		Parts
90		30
80	70%	10
60		10
40		20

90% 30 parts, 80% 10 Parts, 60% 10 Parts and 40% 20 parts should be mixed to get 70 % Alcohol

b) Define Closure, Container, state various types of closures, state various materials to be used for making closures.

Closures are the devices by means of which containers can be opened and closed.

Types of closures plug type, crown cap, push-fit cap and screw closures. (1 ½ marks)

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Containers-The containers are device that holds the drug. The immediate container is that which is in direct contact with the drug. The secondary container holds primary container and is not in immediate contact with the drug. (01 mark)

Materials used for making closures: Cork, glass, plastic, metal and rubber. (01 mark)

c) Explain various factors affecting rate of evaporation.

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. (1\2 mark for each point)

d) Suggest one instrument/ equipment for the following operations:

i) For sterilization of oily injections Ans Hot air oven

ii) For sterilization of apron Ans Autoclave

iii) For sterilization of Hand gloves Ans Autoclave

iv) For sterilization of operation theatre Ans Gaseous sterilization using formaldehyde or by radiation (01 mark for right ans)

e) Explain the term Micro encapsulation. Enlist various techniques of micro-encapsulation state its advantages.

Micro encapsulation is a process by which thin coating can be applied to small particles of solids, droplets of liquids or dispersion, thus forming microcapsules. This process is used to coat the particles having a particle size range from several tenths of a micro to 5000 micometer. (01 mark)

Techniques

1. Pan coating
2. Fluidised bed coating
3. Coacervation
4. Electrostatic deposition
5. Vaccum deposition
6. Polymerisation
7. Multi orifice centrifuge process (1 ½ marks)

Advantages:

1. Helps in formulating sustained release dosage form.
2. Separation of incompatible materials
3. Conversion of liquid to solid
4. Protection of drug against moisture, oxygen etc. (01 mark)

f) Define the following:

i) **Filtration:** 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.

ii) Clarification: It is process of removal of solid in very less concentration from liquid, conc of solid is less than1%

iii) Filter media: The porous medium which retains solids known as filter media.

iv) Filter cake: It is the solid cake formed on the surface of filter media.

v) Filter aid: These are substances which increase the rate of filtration by reducing the resistance. They are added in concentration of0.1% to 0.5% w/v before filtration.

(1/2 mark for each definition)

Q.V. Answer any FOUR of the following: (3 ½ marks for each question)

a) Marc:-The drug residue which remains behind after extraction.(1 mark)

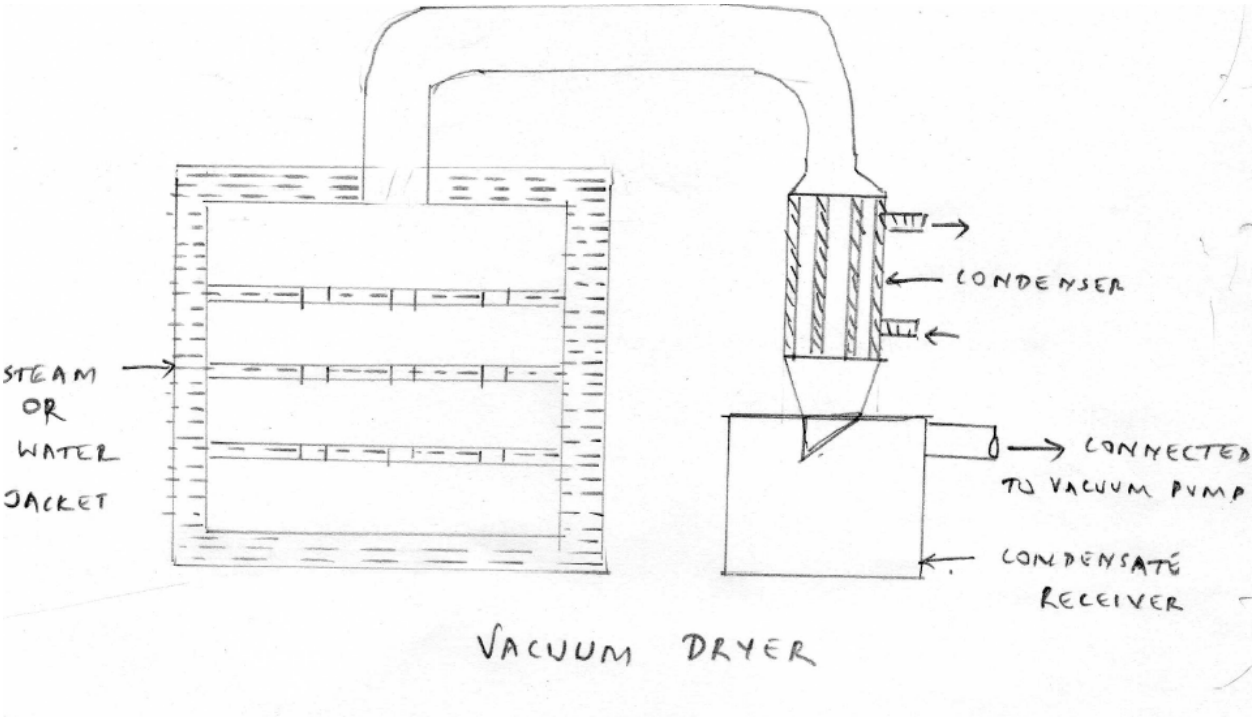
Menstrum :- Solvent used to extract the drug.(1 mark)

Ideal properties of menstrum:(1½ marks)

1. Cheap.
2. Non-toxic.
3. Stable chemically and physically.
4. Selective i.e. remove the desired active constituents with minimum amount of inert materials.

b) Construction and working of vacuum dryer: It consists of a jacketed vessel made of a material which can withstand within the oven and steam pressure in the jacket. The oven can be closed by a door that can be locked tightly to rovide an airtight seal. The oven is connected to a vacuum pump through a condenser and a receiver. Generally, vacuum oven is operated at the pressure of about 0.03 to 0.06 bar. At this pressure water boils at 25-35 ^{0} C. In the pharmaceutical industry, an oven of the size of about 1.5 cubes having 20 shelves is commonly used. (2 marks)

Diagram: (1½ mark)

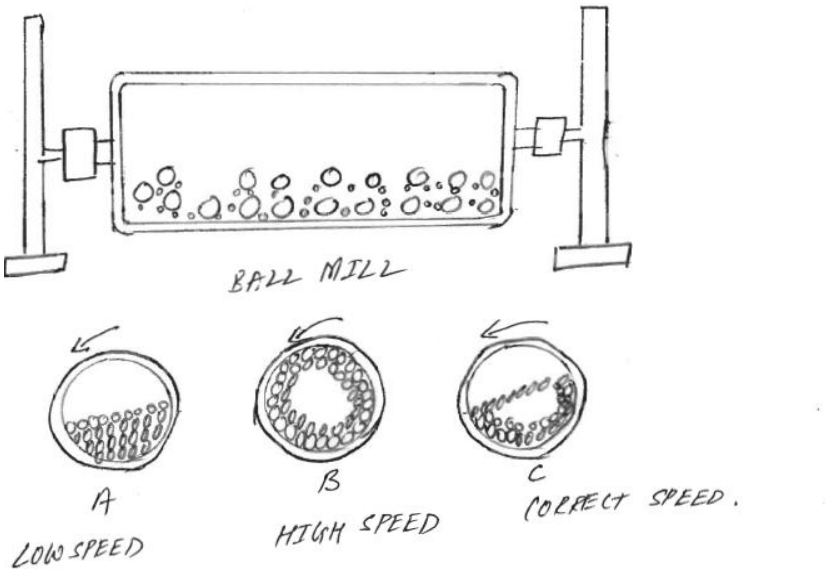


c) Ball mill:

Principle: Impact and attrition. (1/2 mark)

Construction: It consists of a hollow 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 ball size depends on the size of the feed and the diameter of the mill. The cylinder and balls are made of metal (also of rubber or porcelain) (1 mark)

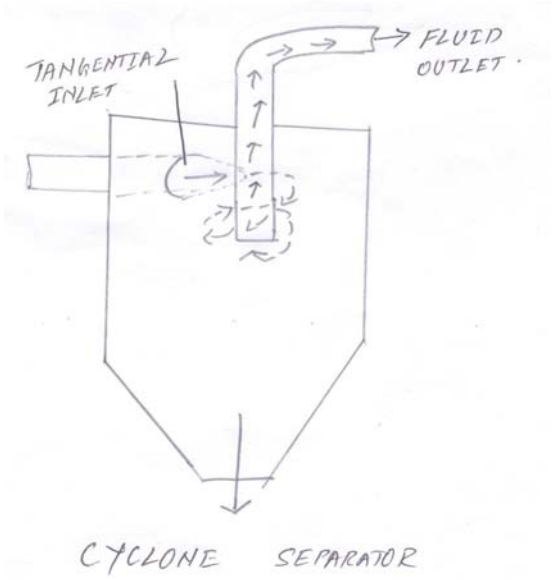
Working: The drug to be ground is put into the cylinder of the mill and is rotated. The speed of the rotation is very different. At low speed, the mass of balls will slide or roll over each other and only a negligible amount of size reduction will occur. At a high speed, the balls will be thrown out to the walls by centrifugal force and no grinding will occur. But at about 2/3rd of the speed, the centrifugal force just occurs, the balls are carried almost to the top of the mill and cascading occurs. 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. (2 marks)



d) Working of cyclone separator: The suspension of a solid in 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 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 through the solids outlet.(1½ marks)

Application: Cyclone separators are used to separate suspension of a solid in a gas (air). It can be used with liquid suspensions of solids. (1 mark)

Diagram: (1 mark)



e) Special applications of capsules:(4 points, each carries 1 mark)

1. Enteric-coated capsules: These capsules do not disintegrate in the stomach but break up in the intestine. On a commercial scale, a coating of cellulose acetate phthalate and mixtures of fatty acids or their esters is given.
   The following categories need enteric coating:
   i) Drugs which cause irritation to gastric mucosa and lead to nausea and vomiting.
   ii) Drugs destroyed by gastric juice.
   iii) Drugs intended to act in the intestine. E.g. amoebicides and anthelmintics.
   iv) Drugs required to produce a delayed action.
2. Sustained release capsules: In order to maintain a proper concentration of the medicament and reducing the number of doses per day, a capsule containing numerous coated pellets is administered that release the drug successively over a long period.
3. Rectal capsules: Soft gelatin capsules may be used as substitutes for rectal and vaginal suppositories. Various shapes and sizes are used, but the pear-shaped form is commonly used.
4. Capsules containing ophthalmic ointments: Soft gelatin capsules are used for filling ophthalmic ointments. These are intended for a single application to the eye.

f) Mechanisms of heat transfer: (3 points, each 1 mark)

Heat may be transferred by any one of the following methods:

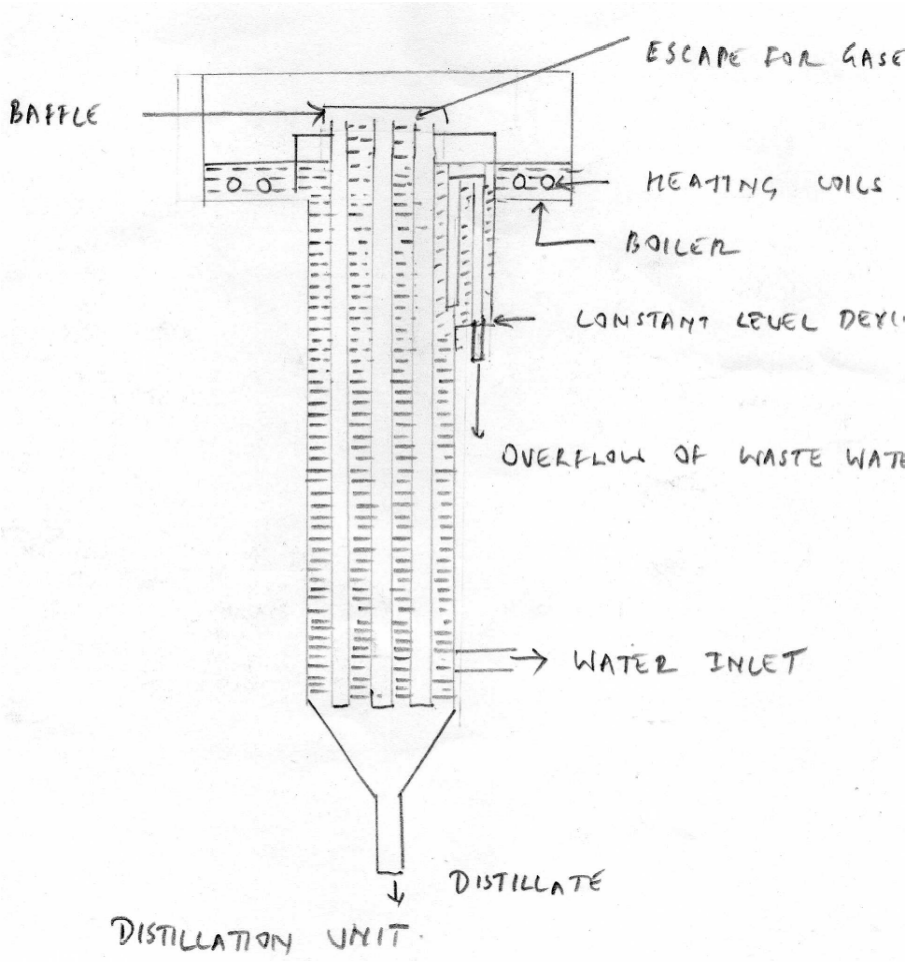
1. Conduction: In this method, the heat energy transfer takes place by transmission of momentum of individual particles. Heat transfer in solids and liquids takes place by this method.
2. Convection: In this method, the heat transfer takes place by the actual motion of the particles i.e. during the process of mixing. Heat transfer in liquids takes place by this method.
3. Radiation: In this method, the energy transfer takes place through space i.e. without using any medium. The heat of the sun reaches the earth by this method.

Q. VI. Answer any FOUR of the following: (3 ½ marks for each question)

a) Preparation of water for injection I.P.:(2 marks)

Water for injection is prepared in a distillation unit. It consists of a boiler made of cast iron. It is connected to condenser tubes through the baffles. The condenser tubes and baffles are made of stainless steel. Baffles are provided over the top of the condenser tubes to avoid water drops getting mixed with the vapours. It is done to avoid carry-over of pyrogen and other water-soluble materials in the droplets. The cooling water enters at the bottom of the condenser and is heated by the condensing vapours. The flow rate is adjusted in such a way that water gets heated at 90-95 ^{0} C before it enters the boiler. The top of the condenser jacket is open so that gases from the water can escape into the atmosphere. A constant level device is fitted in such a way that only the heated water free from gases enters the boiler.

Diagram:(1 ½ marks)



b) Moist heat sterilizer or Autoclave:

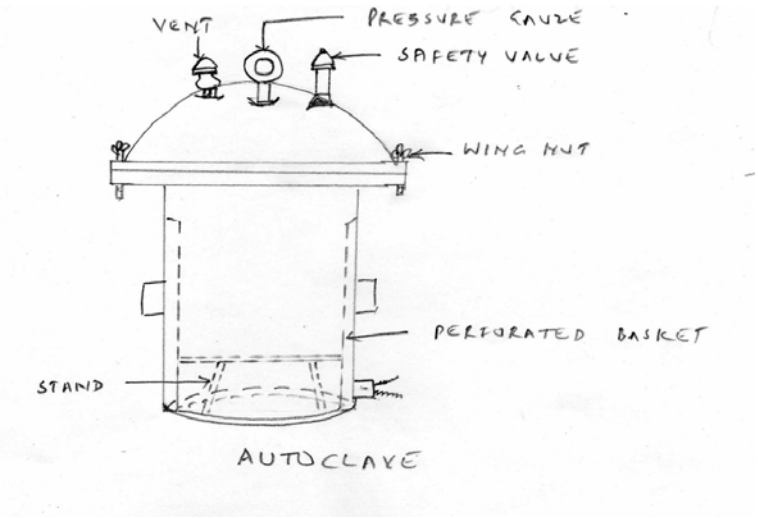
Construction: It consists of a string metallic chamber usually made of stainless steel. It has a cover fitted with a steam vent, pressure gauze and a safety valve. Rubber gasket is fitted on the inner side of the lid in order to make autoclave airtight. The cover is closed with wing nuts and bolts. The electrically heated element is fitted at the bottom to heat the water to convert into steam. The perforated inner chamber is place on the stand. The material to be sterilized is loosely packed into it.(1 mark)

Working: A sufficient quantity of water is poured into the chamber after removing the perforated chamber. The level of the water is adjusted in such a way that it does not touch the bottom of the perforated chamber. The lid is then closed with wing nuts and bolts. The autoclave is switched on to heat the water. The vent is opened and safety valve is set at the required pressure. When steam starts coming out from the vent and it continues for 5 minutes, it is then closed. The steam pressure starts raising and it comes to the desired pressure i.e. 10 lbs/sq inch with corresponding temp 115 ^{0} C or 15 lbs/sq inch with corresponding temp 121 ^{0} C. After the stated period, switch off the autoclave. Allow it to cool to about 40 ^{0} C before opening the vent. When whole of the steam is removed, the lid is opened and the sterilized material is taken out.(1½ marks)

Application: (1 mark)

1. Sterilisation of surgical dressings and surgical instruments.
2. Sterilisation of containers and closures.
3. Sterilisation of official injections.

Diagram:



c) **Reasons for coating**:(1½ marks)

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.

Stages in sugar coating:(2 marks)

1. Sieving: The tablets to be coated are shaken in a suitable sieve to remove fine powder or broken pieces of tablets.
2. Sealing: Sealing is done to ensure that a thin layer of water-proof materials such as shellac or CAP is deposited on the surface of the tablets.
3. Subcoating: Several coats of sugar and other materials such as gelatin, acacia, etc. are given to round off tablets and to help in building up the tablet size. Several coats of conc. Syrup containing acacia or gelatin are given. After each addition of the syrup, dusting powder is sprinkled and hot air is blown.
4. Syrup coating: This is done to give sugar coats, opacity and colour to the tablets. Several coats of syrup are applied. Colouring materials and opacifying agents are also added to the syrup. The process is repeated till uniform coloured tablets are obtained.
5. Finishing: 3 to 4 coats of syrup are applied in rapid succession without dusting powder and cold air is circulated to dry each coat. This forms a hard smooth coat.
6. Polishing: Beeswax is dissolved in volatile organic solvents and a few coats are given. The finished tablets are transferred to a polishing pan which is made of canvas cloth which gives a proper shining to the tablets.

d) **Immunological products**: These are the preparations which are meant for prevention of diseases, such as vaccines or for the treatment of diseases, such as antitoxin and antiserum or for diagnostic purposes e.g. bacterial toxin. These are biological products and are proteinous in nature except poliomyelitis vaccine.(1 mark)

Method of preparation of BCG vaccine(2 ½ marks)

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.

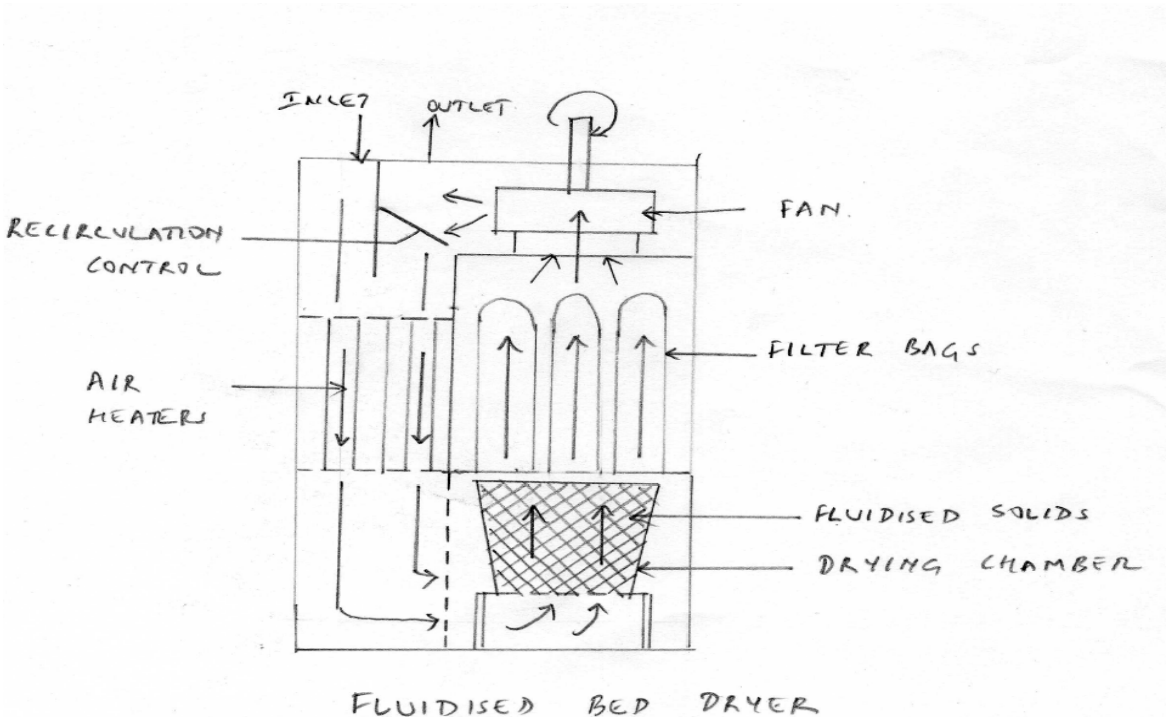
Dose: Prophylactic, 0.1 ml as a single dose by intracutaneous injection.

e) Construction and working of fluidized bed dryer:(2 marks)

In fluidised bed dryer air is introduced by fan situated in the upper part of dryer.

Air is heated by heater to required temp and air flow is adjusted by recirculation control and air is filtered by filter bags to prevent the passage of fine particles to dryers, then air is passed to the bottom to flow through the bed of material to be dried. They are available in different capacity ranging from 5 kg to 200 kg and drying time is 20 to 40 mins.

Diagram: (1½ marks)



f) **New drug delivery system**(any 3, each 1 mark)

1. Implants: The hypodermic tablets are placed under the skin by a minor surgery in order to release drugs over a prolonged period of time. These implants are useful in hormone therapy.
2. Liposome drug carriers: Liposomes are phospholipids which can transport both hydrophilic and hydrophobic drugs. The small drug molecules get trapped in liposomes whereas large drug molecules can also make hydrophobic or electrostatic bonding with it. They are used in cancer therapy, immunological products. Liposome entrapped insulin is active orally.
3. Nanoparticles: The particle size is in nanometer range i.e. 200 to 500 mm. The system consists of a drug and a carrier to deposit drug at the target site. The carriers used are naturally occurring macromolecules like human serum albumin, bovine serum albumin and other substances such as gelatin, casein and ethylcellulose. Nanoparticles are used to incorporate cytotoxic agents into tumour cells in cancer chemotherapy. They are also used to study morphology, blood flow and functions of various organs of the body.

4. Prodrugs: The compounds which undergo biotransformation before showing desired pharmacological activity are called prodrugs. They are generally esters or amides of parent drugs. They are useful in improving the solubility, stability, bioavailability, masking the unpleasant taste or odour of the parent drug and reducing the drug toxicity.
5. Films and strips: These are meant for topical application for slow release of drug over predetermined period of time. The films and strips which are becoming popular these days are zero order release films, buccal strips and spray bandages.
6. Erythrocytes: Resealed erythrocytes are prepared by putting them into hypotonic medium so that they can be swollen. The aqueous solution of the drug is added to the medium so that the drug gets into the erythrocytes through the open pores. When the isotonicity is adjusted the erythrocytes shrink thus encapsulating the drug within them. These erythrocytes may be suspended in normal saline solution for preparing injections.