WINTER – 12 EXAMINATION

Subject Code: **0805** **Model Answer** Page No: 01/ N

Q.1 Answer **any Ten**; (2 marks for each question)

a) A substance having slight or no value therapeutically, but used in the preparation of various pharmaceuticals, to give particular shape, to formulation, to increase stability to increase palatability. called also *pharmaceutical aid*

Eg. Preservatives (methyl parabene, propyl parabene), diluting agents (glycerin), emulsifying agents (spans, gum acacia) , and suspending agents(tragacanth);

b) Difference between **Exotoxin** and **Endotoxin** (1/2 mark for each difference)

Exotoxin	**Endotoxin**
1) These are toxins which can diffuse freely through the bacterial cell wall into the blood or the medium in which the micro organisms are growing	1)These toxins cannot diffuse through
2) These toxins are carried to all parts of the body	2) Endotoxins are liberated only when the bacteria are disintegrated.
3) In its response the human body produces antibodies to neutralize its effect which is called as antitoxin	3) The antibodies are named according to their mode of action
4) Diphtheria Antitoxin	4) Diphtheria Toxoid

C) (2 marks)

Ayurvedic dosage forms are classified into four types depending upon their physical forms

1) solid dosage form:

e.g. Pills, gutika ,vatika

2) Semisolid dosage form:

e.g. Avaleha paka, lepa

3) Liquid dosage form:

e.g. Arista,asava,Taila,dravaka.

4) Powder dosage form:

Eg. Bhasma,satva,lavan

d) (1 mark for each definition)
Menstrum :- Solvent used to extract the drug.

Marc:-The drug residue which remains behind after extraction

e) (2 marks)

1 g of potassium permanganate in 100 ml gives 1% solution

1 in 1000 is $\frac{1 \times 100}{1000}$ = 0.1% w/v

OR 0.1 g in 100 ml gives 0.1% solution.

Therefore, 0.5 g in 500 ml will give 1 in 1000 solution.

f) (1 mark for each definition)

Slurry: It is defined as the mixture of insoluble substances suspended in a vehicle & is intended to be filtered

Filter cake: Solid cake formed on the surface of filter medium is known as filter cake.

g) (1 mark for definition 1 mark for advantages)

A **SUSTAINED RELEASE DOSAGE** form provides a therapeutic blood level of the drug which is attained rapidly & maintained over extended period of time during treatment by releasing medicament at definite interval of time.

Advantage

- Prolonged therapeutic effect by continuously releasing medicament
- to prevent frequency of dosage administration.

h) Limitation of Continuous Hot Percolation

- **Physical character of the drug**:

The physical character of the drug block the soxhlet apparatus

e.g. opium, gum, resin, orange peel *etc.*

- **Solvent**: Only pure solvents or constant boiling mixtures.
- **Chemical constituents of the drug** *:*
- unsuitable for drugs having thermolabile active constituents such as enzymes, alkaloids, anthraquinone derivatives, esters etc.

i) Imbibition is soaking process & is necessary to give turgidity to cellwall & thus facilitate diffusion of **Menstrum** inside cell

j) Galenicals medicinal preparation composed mainly of herbal or vegetable matter.
Eg tinctures, extracts

k) Prodrugs (Definition 1 mark & any 2 example written 1mark)

- The compounds which undergo biotransformation before showing desired pharmacological activity are called prodrugs

Applications:

1. Chloramphenicol palmitate, the prodrug of chloramphenicol is used in the preparation of paediatric suspension because it has no bitter taste Chloramphenicol palmitate, the prodrug of chloramphenicol is used in the preparation of paediatric suspension because it has no bitter taste.
2. Procaine-penicillin G and Benzathine-penicillin G are prodrugs of penicillin G which shows resistance to hydrolysis as compared to the parent drug.
3. Testosterone cypionate the prodrug of testosterone is long-acting in comparison to the parent drugs when injected in an oil.

l) (1/2 mark for each difference)

Injectables are not stored in soda lime glass

1. It liberates alkali in aqueous preparations.
2. On repeated use its surface loses some of its brilliance.
3. It is not resistant to sudden changes in temperature.
4. Flakes separate more easily as compared to other types of glass.

m) Unit dose packing: These containers are used to supply only one dose of medicament.

e.g. ampoules and strip packing.

Q.2 (3 marks for each question)

a) 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.

b) (definition of container 1 mark & qualities 2 marks)[any 4 question can be given]

Pharmaceutical container has been defined as a device that holds the drug and it may or may not be in direct contact with the pharmaceutical preparation.

Qualities of good container:

- The container must not interact physically or chemically with the substance which it holds, so as to change the strength, quality or purity of the substance.

- It should help in maintaining the stability of product against the environmental factors like temp , humidity, oxygen, light.

- It should be made of materials which can withstand wear and tear during normal handling.

- Compatible with product & its ingredients.

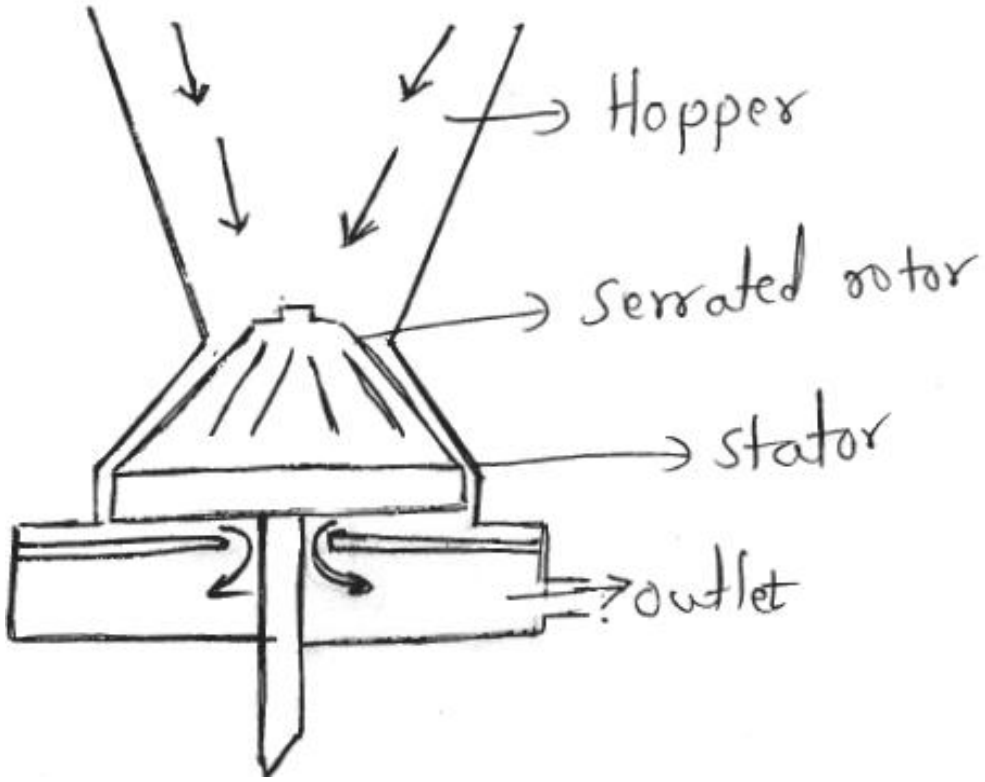
- designed that a dose can be drawn from it conveniently.

- material of the container must be non-toxic.

- It-should be able to withstand changes in pressure and temperature. (sterilization of parenteral products).

- The container must be such that it can be labelled easily.
- Pharmaceutically-elegant appearance.
- The closure of the container must be easily removable and replaceable.

c) Colloidal mill (1 mark for principle,1mark for construction, 1 mark for working)



- Principle: It is based on homogenisation
- Homogenisation is a process which renders the material to uniform quality, consistency & structure. & is defined as the process of preparing fine emulsion from coarse emulsion by passing through small orifice (by applying shear force) .
- 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.
- 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 of the rotor .

d) FACTORS AFFECTING RATE OF FILTRATION (½ Marks for each point)

- The factors affecting rate of filtration were studied by Darcy & he expressed in 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

1. **Area of filter surface.**

- Pressure drop across the filter medium & cake
- Viscosity of filtrate
- Thickness of filter cake
- Filtration rate is directly proportional to the surface area of the filter. i.e. As surface area increases , filtration rate increases .

1) **The surface area of the filter can be increased by**

1. Using a larger filters.
2. By using no. of small units in parallel as in filter press

3. By continuous removal of filter cake, as in rotary filter.

2. Pressure drop across the filer medium & cake:

- The rate of filtration of liquid is directly proportional to the pressure difference between the filter medium & filter cake.
- Thus rate of filtration may be increased by applying pressure on the liquid being filtered or decreasing pressure beneath the filter.
- The pressure can be decreased by applying vacuum.

3.Viscosity of filtrate:

- The rate of filtration is inversely proportional to the viscosity .
- As viscosity increases ,It will increase the resistance to flow. Hence rate of filtration decreases .It must be emphasized that it is the viscosity of liquid & not of slurry is imp. Since the resistance to flow occurs as the filtrate flows through the filter cake.

  The rate of filtration may be increased by
- Increasing solution temp.(However temp. of volatile or thermolabile liquids cannot be increased .
- Diluting the solutions – Since syrups are viscous when cold , it gets more quickly filtered when hot than cold.

4.Thickness of filter cake:

- The rate of filtration is inversely proportional to the thickness of filer cake that is formed during filtration
- As filtration process proceeds , the solid particles starts depositing on the filter medium & thus increases thickness of the cake & decreases the rate of filtration .
- The thickness of cake can be decreased by,

1. Increasing the surface area of filter media.
2. Continuous removal of cake i.e .rotary filter

e) Principle & working of UV Radiation Method (2 Marks)

- The germicidal light produced by Hg vapour lamp is emmited at wavelength 250 µm.
- It subjects to law of visible light & travels in straight line. It's intensity is reduced in proportion to square of distance its travels. Therefore its penetrates the material poorly & selectively.
- When U.V. Light passes through matter, energy is liberated to orbital electron within constituent atom.
- The absorbed energy causes highly energy state of the atom & their reactivity is altered,
- When such excitation & alteration of activity of essential metabolites [cellular nucleic acids], the organisms are unable to reproduce

Applications UV Radiation Method (one application 1 Mark)

- 1) Sterilization & maintenance of aseptic area in pharmaceutical industry. It is installed in ceiling of sterile area provided the eyes of workers shd be protected from harmful effect of uv radiation.
- 2) sterilization of water

f) TABLETS are solid Flat or biconvex discs, prepared by compressing a drug or a mixture of drugs with or without diluents. (1 Mark)

ADVATAGES OF TABLETS (Any two Advantage – 1 mark)

- Essentially tamper proof dosage form.
- Accuracy of dosage. Unit dosage form which offers greatest dose precision & least content variability.
- Low cost ,easiest & cheapest to pack & ship.
- Light & most compact
- Product identification easy.
- Ease of swallowing & great ease of administration.
- Suitable for large scale production.
- Enteric coating & S.R.D. is possible.

DISADVANTAGES OF TABLETS (Any 2 Disadvantage – 1 Mark)

- Some drugs cannot be compressed into dense, compacts because of amorphous nature.
- Drugs with poor wetting property, low dissolution & large dosage may be difficult to formulate.
- Some drugs may require encapsulation.

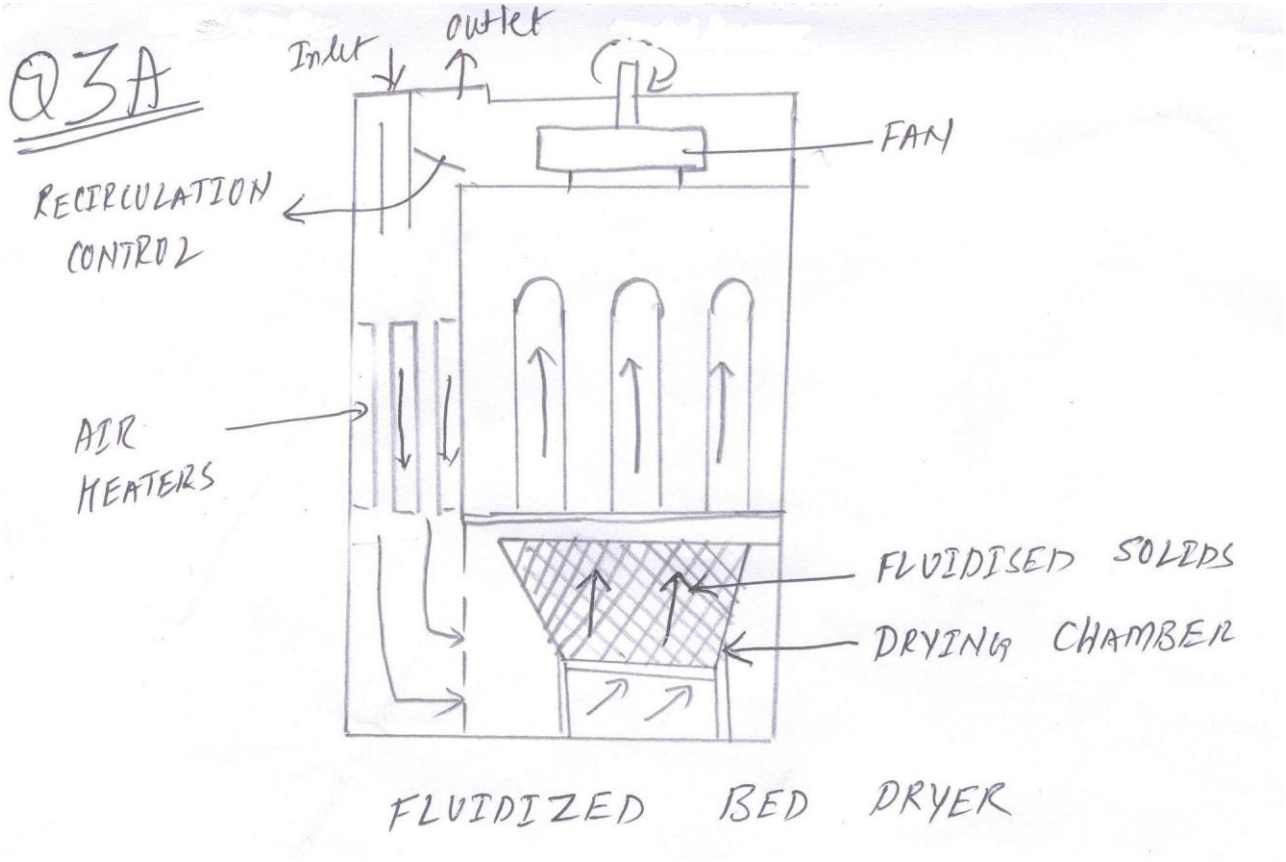
WINTER – 12 EXAMINATION

Subject Code: **0805** **Model Answer** Page No: 10/ N

Q.3 a) (diagram 1 mark, construction 1 mark ,application 1 mark)

There are two types of fluidised bed dryer 1) vertical FLD 2) horizontal FLD

Diagram:



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.(1marks)

Applications: 1.Used in granulation process for tablet preparation

2. It is used in coating.

3. used for drying of filter cake.

Q.3 b) These are substances which reduces the resistance of filtrate to flow. They are added in the preparation in conc. of 0.1 to 0.5 % (1 marks)

Ideal qualities of filter aids

1. It should be able to remain suspended in the liquid.

2. It should be free from impurities

3. It should be inert to the liquid being filtered

4. Particles size distribution should be suitable for retention of particles

5. It should have structure suitable for formation of porous cake (2 mks 1\2 mks for each points.)

Q.3 c) Precaution required for safe and effective handling of **Autoclave**

1. The pressure release valve and safety valve should be working properly

2. Lid should be fixed properly to withstand high pressure.

3. Allow complete removal of air before closing air vent.

4. Checking pressure gauze and thermometer for their efficiency

5. Autoclave should not be disturbed during its operation

6. Arrangement for emergency venting of steam.(1 1/2mks for any 3 points)

Hot air oven

1. It should be filled to its capacity only

2. Glass apparatus and equipment should be wrapped individually.

3. Articles should be placed in such away that they should not interfere with air flow

4. Once in operation oven should not be open

5. Proper biological indicators should be used

6. Thermolabile substance should not be sterilized in hot air oven (1 1\2 mks for any 3 points)

Q.3 d) Manufacturing defects that appear in tablets

1. Binding

2. Capping and lamination

3. Chipping and cracking

4. Mottling

5. Weight variation

6. Sticking and picking

7. Hardness variation

8. Double impression (2 mks)

Binding- adherence of the tablet to the die wall is called binding in the die.

Capping and lamination – capping is partial or complete removal of top or bottom portion of the tablet.(1 mark can be given to explanation on any 2 defects)

Q.3 e) The power of the body to resist the effect of the invasion of micro organisms is called immunity. (1mark)

Factors responsible for producing immunity are

1) Phagocytosis: means injestion of bacteria by certain cells of body, which make them harmless .Phagocytosis means the ingestion of bacteria by certain cells of the body, which make them harmless. Phagocytosis is caused by two types of body cells :

   Cells of reticulo-endothelial system

   White blood corpuscles (W.B.C.)

2) Antibody formation

The nature has given further protection from micro-organisms by forming substances known as antibodies. Antibodies may is defined as substances formed in the body in response to the presence of foreign proteins and certain other materials in the tissues. Production of antibodies in the body is stimulated by the invasion of pathogenic microorganisms. (2 marks)

Q.3 f) Ointments are semi solid preparation meant for application to the skin or mucous membrane in which the medicaments are either dissolved, suspended or emulsified in the ointment base (1 mark)

White soft paraffin may contain traces of the bleaching agent which are left over after bleaching yellow soft paraffin and these traces of bleaching agent causes irritation to eyes. (1 mks)

1. It should be inert odourless smooth

2. It should be physically and chemically stable

3. It should be compatible with skin and medicament

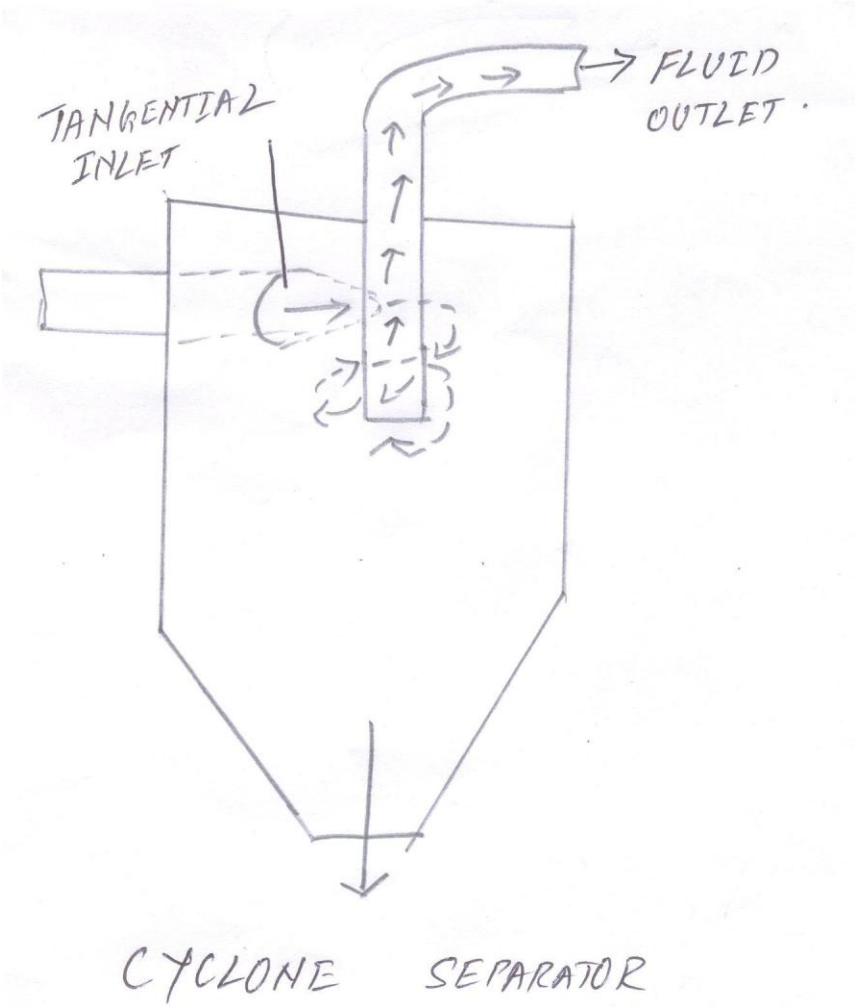
4. Consistency should be such that it can easily spread on skin surface

5. It should not retard healing of wound

6. It should not produce irritation to the skin (1 Mark for 2 Points)

Q.4 a)

Diagram:



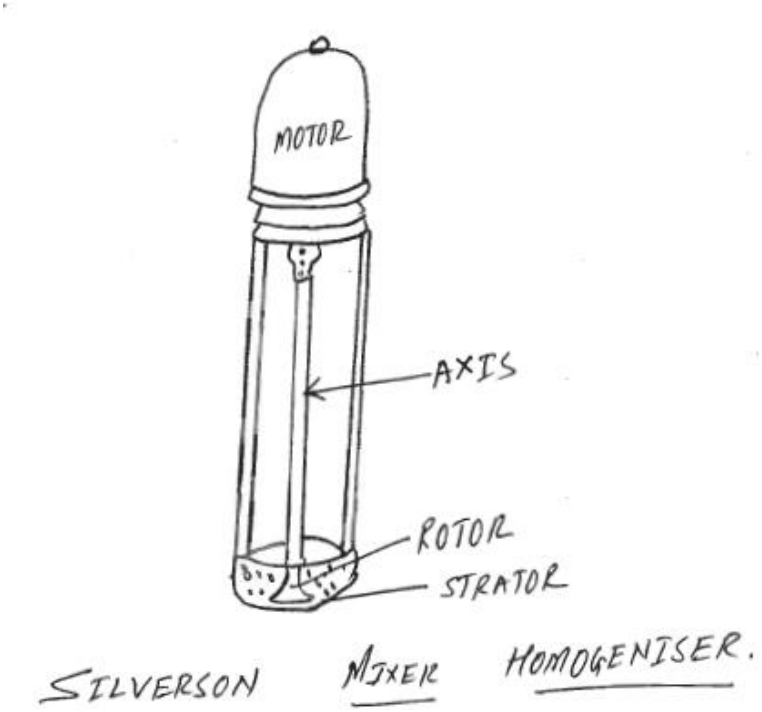
In cyclone separator the centrifugal force is used to separate solids from fluids separation depends on particle size and density of particles.

Working: The suspension is fed through tangentially inlet at a very high velocity so that rotatory movement takes place in the vessel. The rotatory flow causes the particles to be acted by centrifugal force. The solids are thrown to the walls and fall to conical base and collected through solid outlet. Fluid is removed from central outlet at the top.(1 mks)

Application –They are used to separate the suspension of the solid in the gas or liquid. (1 mks)

Q.4 b)

Diagram: (1 mark)



Silverson homogenizer works on principle of mixing and homogenization large gobules in a coarse emulsion are broken into small globules by passing them under pressure through a narrow orifice (1mark)

Working –The emulsifier head is kept in a vessel containing immiscible liquid. When the motor is started, the liquids are sucked through the fine holes, and oil is reduced to fine globules due to the rotation of blades. (1 mark)

(1 mark for diagram)

Q.4 c) Capsules are solid dosage form in which the drug substance is enclosed in a water soluble shell or an envelope, the capsule shell is made from gelatin , the capsule are both hard gelatin or soft. (1mark)

Merits –

1. The drug having unpleasant odour and taste can be administer in form of capsule

2. They become slippery on moistening and can be easily swallowed

3. They are economical

4. They are easy to handle and carry

5. They release the medicament when desired in GI tract

6. Shell is therapeutically inert

7. They are attractive in appearance

8. They are available in various shape and size

9. Micro encapsulation provide sustained released

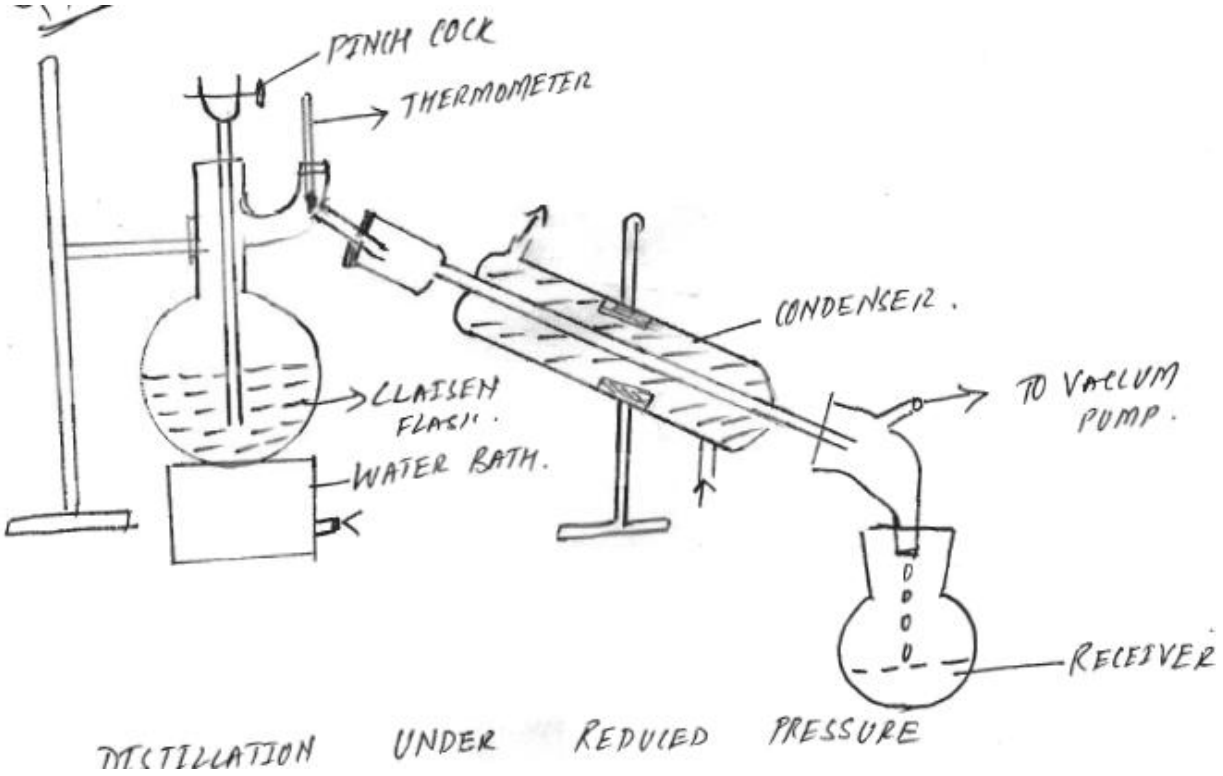
Demerits –

1. Hydroscopic drugs cannot be filled as they will make the shell brittle

2. Concentrated preparation which needs dilution cannot be administered in capsule form (1\2 mks for each points)

Q.4 d)

Diagram: 1 mark



Liquid boils when its vapour pressure is equal to the atmospheric pressure the boiling point of the liquid may be lowered to the desired temperature by reducing the pressure on its surface (1 mark)

Working –

1. Heating of claisen flask is started when the desired vaccum has been attained

2. The liquid starts boiling – below its boiling point

3. The vapours are condensed in the condenser and distillate is collected (1 mark)

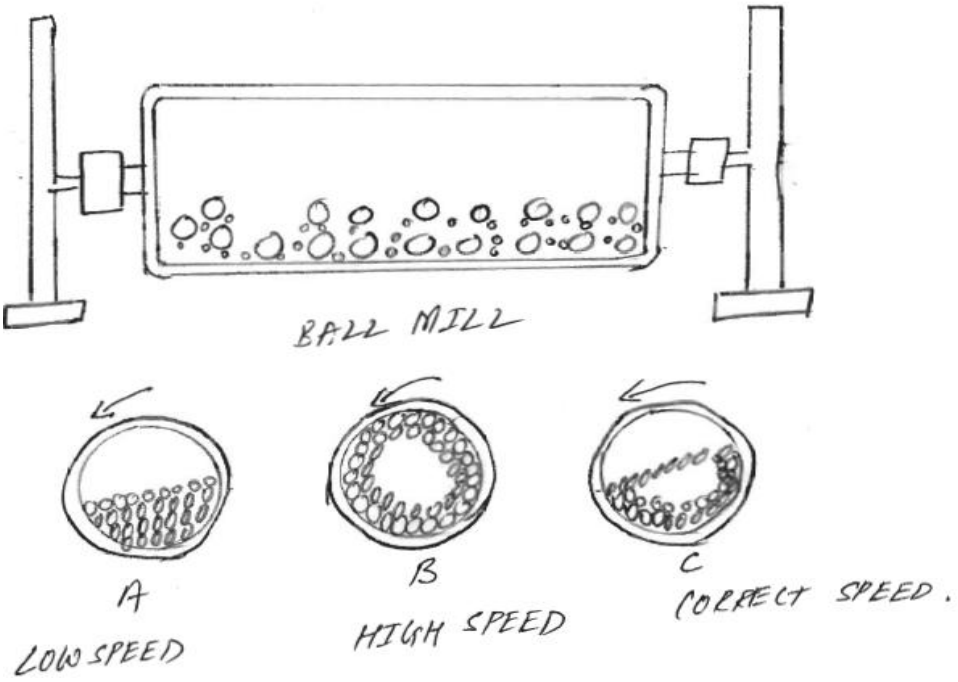
Q.4 e) Levigation is the process of wet grinding (1 mark)

Elutriation is the process of separation of fine particles and coarse particles from a paste obtained after levigation (1 mark)

Advantages: (1 mark for 2 pts.)

1. The process is continuous.
2. Depending on no. of fractions, the same no. of tubes of different area of cross section can be connected.
3. Separation is quick.
4. Apparatus is more compact.

Q.4 f) Diagram of ball mill: (1mark)



Advantages: (1 mark for any 2)

1. Produces fine powders.
2. Can be used for continuous operation if sieve or classifier is used.
3. Capable of grinding large variety of materials.
4. Suitable for wet or dry grinding processes.
5. Can be used for grinding toxic materials in an enclosed form.

Disadvantages: (1 mark for any 2)

1. Noisy machine.
2. Wear occurs from balls as well as casing

Q.5. Answer any FOUR of the following:

(a) (1 ½ mark for preparation and 1 ½ mark each for storage, uses and dose)

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.

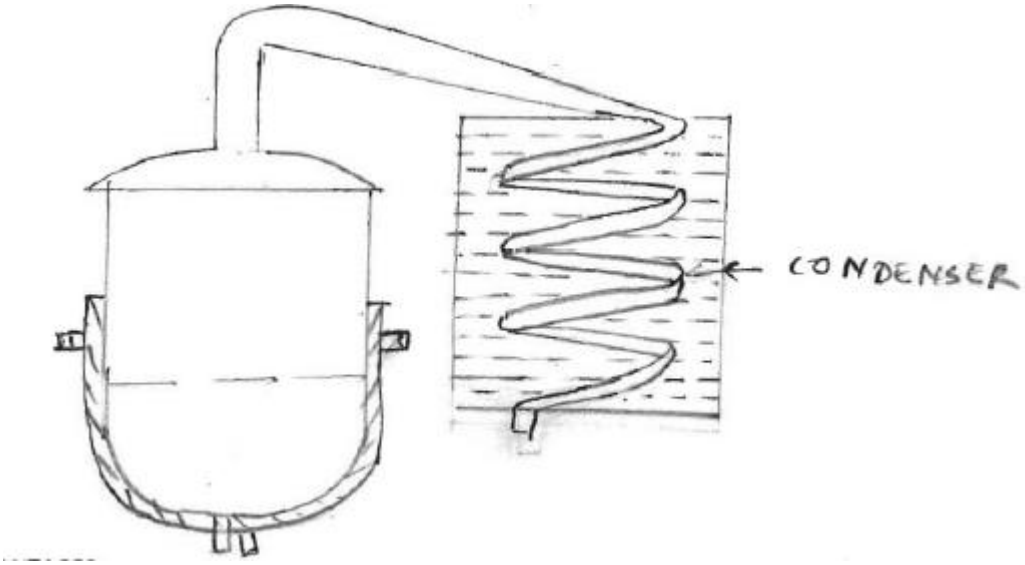
STORAGE: Store in hermetically sealed light resistant glass containers at a temperature between $2^{o}C$ and $8^{o}C$. The reconstituted vaccine should be used immediately after its preparation.

USES: Immunising agent which provides protection against tuberculosis.

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

(b) (1 mark for description with diagram, 1 mark for advantages and 1 mark for disadvantages)

EVAPORATING STILL: It is a vessel similar to evaporating pan with a cover that connects it to a condenser so that the liquid is distilled off and hence named still. The cover can be removed for cleaning or removal of the product.



ADVANTAGES:

1. It is simple to construct.
2. Easy to clean and maintain.
3. The vapours are condensed in it. It increases the speed of evaporation and the costly solvent can be recovered. E.g. ethyl alcohol.
4. A vacuum pump can be fitted to the condenser for operation under reduced pressure.

DISADVANTAGES:

1. Heating surface is limited.
2. Evaporating still is not suitable for thermolabile materials as the liquor is heated all the time.
3. Due to natural circulation, coefficient of heat transfer is poor.

(c) (1 mark for definition and 2 marks for properties)

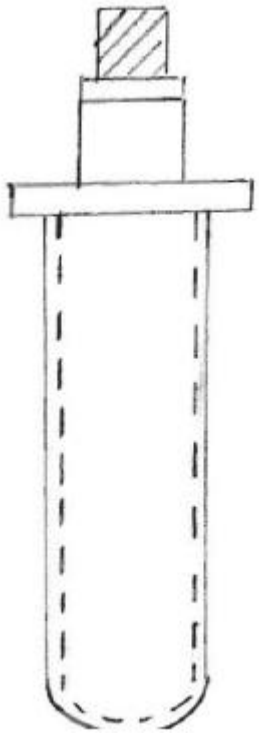
SUSPENSIONS are the biphasic liquid dosage forms of medicament in which finely divided solid particles (dispersed phase) are dispersed in a liquid or semisolid medium (continuous phase).

An ideal suspension must possess the following properties:

1. It should settle slowly and should be readily redispersed on shaking.
2. The particle size should remain fairly constant throughout its long period of undisturbed standing.
3. The suspension should pour readily and evenly from its container.
4. It should be free from large particles which spoil its appearance, gives gritty taste to oral preparations and also cause irritation when applied externally.

(d) (1 mark for diagram, 1 mark for working and 1 mark for disadvantages)

DIAGRAM OF FILER CANDLE



WORKING: The candle is placed in the solution to be filtered. When vacuum is applied, the liquid will pass through the thick wall of candle and gets collected inside the candle from where it is removed.

The filter candle gets blocked with continuous use. This can be cleaned by scratching the external surface with a nail brush and passing water through it in reverse direction.

DISADVANTAGES:

1. It has tendency to absorb materials from aqueous solutions so it is not used commonly.
2. The pores become clogged with organisms and debris and a thorough cleaning is required.

(e) (½ mark for each point, any 6 points)

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.

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.

(f) (3 marks)

MOIST GRANULATION PROCESS: This method consists of the following steps:

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. Coarse screening of the wet mass using 6-12 mesh screen.

6. Drying the moist granules at 60^0C in a hot air oven by spreading in trays.

7. Screening of dry granules with lubricant, glidant and disintegrating agent.

Q.6. Answer any FOUR of the following:

(a) (1/2 mark for each point, at least 6 points)

SR. NO	ACTIVE IMMUNITY	PASSIVE IMMUNITY
1.	Body takes an active part in formation of antibodies.	Body does not take an active part in formation of antibodies.
2.	Antigens are injected and hence antibodies are produced	Readymade antibodies are given.
3.	Onset of action is slow.	Onset of action is fast.
4.	Immunity is long lasting	Immunity is short lived.
5.	Prophylactic or preventive.	Therapeutic or curative.
6.	Immunological memory is present.	Immunological memory is absent.
7.	Not useful in immunodeficient hosts.	Useful in immunodeficient hosts.
8.	e.g. vaccines, toxoids	e.g. anti-toxins, anti-sera.

(b) (1 mark for definition and 2 marks for types)

CLOSURES: 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.

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.

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.

(c) (1/2 mark for each point and at least 6 points)

SR. NO	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.
7.	These capsules can be adulterated.	These capsules cannot be adulterated.

(d) (1/2 mark for each point and at least 6 points)

FACTORS AFFECTING SIZE REDUCTION:

1. Hardness: The harder the material the more difficult it is to reduce in size although this is linked with toughness. Hardness of some materials is characterised by Moh's scale. Hardness numbers of upto 3 signify soft and above 7 signify hard materials while those in between are considered intermediate.

2. Toughness: Toughness is encountered in many pharmaceutical materials, particularly in fibrous drugs, and is often related to moisture content. A soft but tough material (e.g.rubber) may present more problems in size reduction than a hard but brittle substances (e.g.chalk).

3. Abrasiveness: It is a property of hard materials, particularly those of mineral origin and may limit the type of machinery that can be used.

4. Stickiness: It causes difficulty in size reduction as the material may adhere to the grinding surfaces of the meshes of screens may become choked. Pharmaceutical substances that are gummy or resinous may be troublesome particularly if the methods used for size reduction generate heat. Complete dryness may help and the addition of inert substances may sometimes help.

5. Softening temperature: Many of the size reduction processes result in the generation of heat which may cause some substances to soften. E.g waxy substances such as stearic acid, or drugs containing oils or fats. The use of water jacket or liquid nitrogen may be helpful to cool the mil.

6. Material structure: Majority of the substances show some special structure. E.g. mineral substances may have lines of weakness along which the material splits to form flake-like particles, while vegetable drugs have a cellular structure often leading to long fibrous particles.

7. Moisture content: It has an important influence on a number of properties that affect size reduction e.g. hardness, toughness or stickiness. Usually less than 5% of moisture is suitable for dry grinding and more than 50% in case of wet grinding.

8. Physiological effect: Some substances are very potent and small amounts of dust may have an effect on the operators. In such cases, wet grinding if possible or enclosed mills must be used to avoid dust.

9. Purity required: Certain types of size reduction apparatus cause the grinding surfaces to wear and such methods must be avoided in a high degree of purity of product is needed.

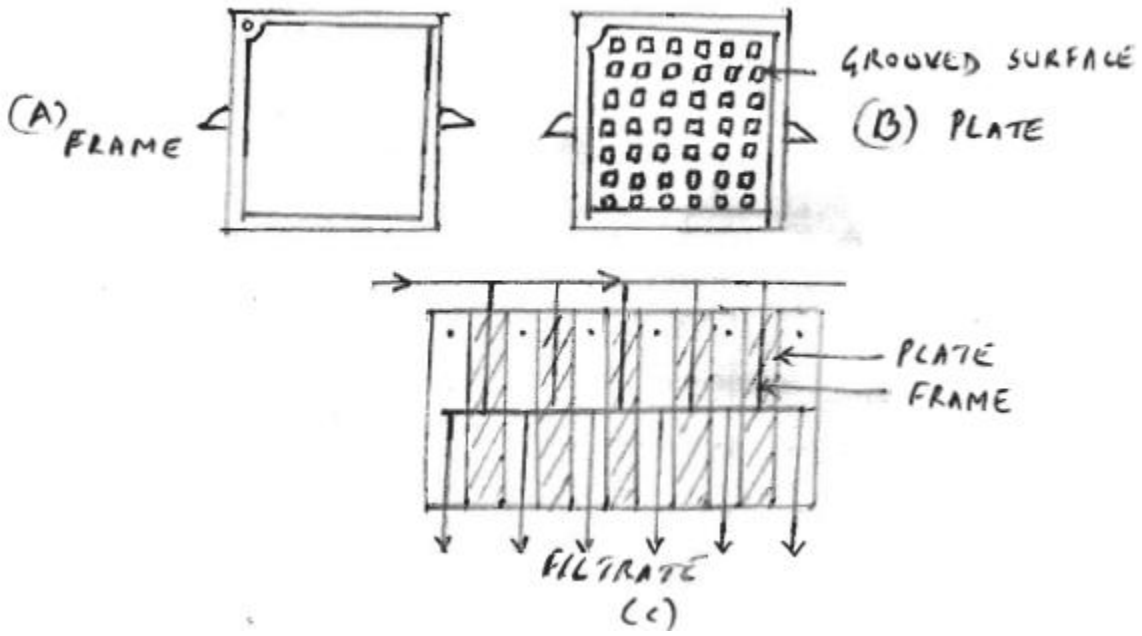
10. Ratio of feed size to product size: Machines that produce a fine product required a fairly small feed size. Thus, it may be necessary to carry out size reduction process in several stages with different equipment e.g. preliminary crushing followed by coarse grinding and then fine grinding.

11. Bulk density: The output of size reduction in a machine depends upon the bulk density of the substance.

(e) (1 mark for definition, 1 mark for diagram and 1 mark for working)

FILTRATION is the process whereby solid particles are separated from the liquid or gas by passing it through a porous medium which retains the solid but allows the fluid to pass.

WORKING OF FILTER PRESS:



As shown in the diagram (C), the filtering liquid enters the frame under pressure from the feed channel. The filtrate passes through the filter medium onto the surface of the plate.

The filtrate is collected in the plates from where it is collected through common outlet pipe. The cake is deposited in the frames. The process of filtration is continued until the frame is filled with filter cake. When the process is stopped, the frame is emptied and the cycle is restarted.

The thickness of the cake can be varied by using frames of different thickness. The thickness of filter cake depends mainly on the solid content present in the filtering liquid and the resistance of filter cake.

(f) (1 mark for definition and ½ mark each for at least 4 points)

EVAPORATION means a free escape of vapour from the surface of a liquid below its boiling point i.e. evaporation can take place even at room temperature.

FACTORS AFFECTING EVAPORATION:

1. Temperature: The rate of evaporation is directly proportional to the temperature of the liquid. The evaporation can be accelerated by increasing the temperature but it will cause decomposition of heat sensitive principles of many drugs. Many glycosides and alkaloids are decomposed at a temperature below $100^{o}C$. Hormones, vitamins, enzymes, antibiotics, malt extract need special treatment to avoid decomposition.

2. Temperature and time of evaporation: It has been observed that exposure to a relatively high temperature for a short period of time (as in film evaporators) may be less harmful than exposure to a lower temperature for a longer period.

3. Temperature and moisture content: Some drug constituents decompose more readily in the presence of moisture if heated at a high temperature due to hydrolysis. To avoid this, the evaporation is done at a low temperature and then the final drying is done at a high temperature when only little moisture remains in it.

4. Types of product required: The selection of the method and equipment required for evaporation depends upon the type of product required (liquid, semisolid or solid).

5. Effect of concentration: During evaporation the upper layer tends to form a film and there is formation of precipitate in the product which results in lowering down the rate of evaporation. Therefore, efficient stirring is required which will prevent degradation of the product at the bottom due to excessive heat and also prevent deposition of solids.

6. Surface area: The rate of evaporation is directly proportional to the surface area of the evaporator.

7. Vapour pressure of the liquid to be evaporated: The rate of evaporation is directly proportional to the vapour pressure of the evaporating liquid. The rate of evaporation is maximum at its boiling point when the liquid has maximum vapour pressure.