WINTER-15 EXAMINATION

Subject Code:0805 **Model Answer** Page No: 1/ 34

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.

WINTER-15 EXAMINATION

Q.1. Attempt any EIGHT of the following. 16

a) Enlist four methods for size reduction. (0.5 mark each)

Ans: Methods for size reduction:

i) Cutting ii) Compression iii) Impact iv) Attrition iv) Combined impact and attrition.

b) Define 'drug' and 'dosage form'. (1 mark each definition)

Ans: i. **Drug:** A chemical agent intended for use in the diagnosis, mitigation, treatment, cure or prevention of disease in man or in other animals.

ii. **Dosage Form:** Dosage form is a transformation of a pure chemical compound into a predetermined form by admixing drug components with non drug components.

c) Write the main objectives of mixing.(0.5 mark each)

Ans: Objectives of mixing:

i. To form uniform mixture.

ii. To promote chemical reaction.

iii. Dispersion of solid particles in liquid.

iv. Dispersion of two immiscible liquids.

d) Name any four materials used for packaging.(0.5 mark each)

Ans: Types of materials used for packaging are:

i) Glass ii) Plastic iii) Metal iv) Paper and board

e) Define 'slurry' and 'filter cake'.(1 mark each definition)

Ans: i) Slurry: Mixture of insoluble substances suspended in a liquid and intended to filter before use.

ii) Filter cake: The solid which gets collected on the filter is called as filter cake.

f)Why are tablets coated ?(0.5 mark each, any 4 points)

Ans: Reasons for coating of tablets:

i. To mask the unpleasant taste and odour.

ii. To improve the appearance of tablets.

iii. To prevent the medicament from atmospheric effects.

iv. To control the site of action of drugs.

v. To produce the sustained release product.

vi. To prevent the drug degradation in stomach pH.

g)Differentiate between active and passive immunity.(0.5 mark each)

Ans:

Active Immunity	Passive Immunity
1. Antigens are injected in human body as a result antibodies are formed.	1. Readymade antibodies are injected in human body.
2. Onset of action is slow.	2. Onset of action is quicker.
3. Immunity produced is for longer period.	3. Immunity produced last for shorter period.
4. Treatment is prophylactic or preventive.	4. Treatment is therapeutic or curative.
5. Preparations: vaccines , toxoids	5. Preparation: sera

h)Define 'menstruum' and state three ideal qualities of a menstruum. (0.5 mark definition, 0.5 mark each properties 3 points)

Ans: **Menstruum :-** Solvent used to extract the drug.

Ideal properties of menstruum:

i) Cheap.

ii) Non-toxic.

iii) Stable chemically and physically.

iv) Selective i.e. remove the desired active constituents with minimum amount of inert materials.

i)Why injectables should not be stored in soda lime glass containers? (0.5 mark each)

Ans: Soda lime glass container is not used for the storage of parenterals because:

i. It yields an appreciable quantity of alkali to water.

ii. Flakes separate comparatively easily.

iii. On repeated use its surface loses some of its brilliance.

iv. It's relatively high coefficient of expansion makes it liable to fracture with sudden changes of temperature.

j) List any four equipment used in drying.(0.5 mark each)

Ans: Equipment used for drying:

i) Tray dryer ii) Tunnel dryer iii) Rotary dryer

iv) Fluidized Bed Dryer v)Vacuum dryer vi) Freeze dryer.

k) Give steps involved in moist granulation. (2 marks)

Ans: - Steps:

i. Moisten of Medicament with excipients with granulating agent.

ii. Sieving of moist mass through sieve number 8 or 10.

iii. Drying of wet granules in hot air oven at 60^{O} C.

iv. Sieving of dried granules through sieve number 20 to collect granules of uniform size

v. Lubrication of sifted granules with lubricating agent

l)Define Pharmacopoeia. List official books used in India.

(1 mark definition, 1mark list of books)

Ans:

Defination: Pharmakon means "a drug" and poeia 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.

List official books used in India:

i) Indian Pharmacopoeia (I.P)

ii) British Pharmacopoeia (B.P.)

iii) United States Pharmacopoeia (U.S.P.)

iv) European Pharmacopoeia (E.P.)

v) International Pharmacopeia

vi) Japanese Pharmacopoeia (J.P.)

vii) Martindale Extra Pharmacopoeia

Q.2. Attempt any FOUR of the following. **12**

a) Define sterilisation and classify methods of sterilisation.

(1mark definition, 2 marks classification)

Ans: Definition: Sterilizations is the process of complete destruction of all microorganisms along with their spores present in the system.

Methods of sterilization:

I. Physical methods:

1. Dry heat sterilization
2. Moist heat sterilization
3. Radiation sterilizations i) Use of u.v. rays ii) Ionizing radiation

II. Chemical methods:

1. sterilization by heating with bactericide
2. Gaseous sterilisation

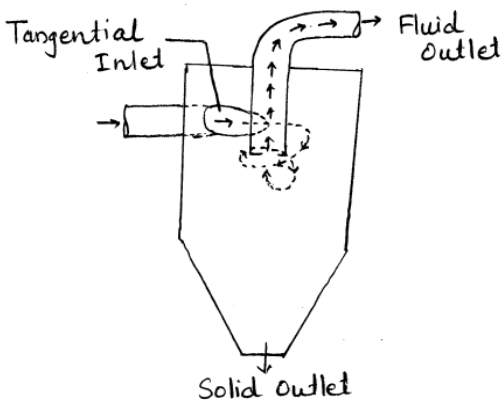
III. Mechanical methods:

1. Ceramic filters
2. Seitz filters
3. Sintered glass filters

4. Sintered metal filters
5. Membrane filters

b) Describe construction and working of a cyclone separator with a neat diagram. (1mark construction, 1 mark working, 1 mark diagram)

Ans: Diagram:



Cyclone Separator

Construction:

i) It consists of cylindrical vessel with a conical base.
ii) In upper part of vessel is fitted with a tangential inlet and fluid outlet.
iii) At the base it is fitted with solid outlet.

Working:

i) The suspension of solid in gas is introduced tangentially at a very high velocity.
ii) The rotary movement takes place within the vessels.
iii) The fluid is removed from the outlet at the top.
iv) The rotatory flow within the cyclone separator causes the particle to be acted on by centrifugal force.
v) The solids are thrown out to the wall and fall to the conical base for discharge.

c) How many parts of 60%, 45% and 75% alcohol should be mixed to get 50% alcohol?

Ans:

75		5 parts of 75 %
60	50	5 parts of 60 %
45		25 + 10 = 35 parts of 45 %

d) Explain the factors which affect size reduction of drugs. (0.5 mark each any 6 pts)

Ans:

1. Hardness:
2. Toughness:
3. Stickiness:
4. Material Structure:
5. Moisture content
6. Temperature.
7. Purity.
8. Physiological effect.
9. Ratio of feed size to product size.
10. Bulk density

1. **Hardness:** Soft material easy break than hard.
2. **Toughness:** Drug with fibrous nature or those having high moisture content are tough and hard to reduce in size.
3. **Stickiness:** Material adheres to the grinding surface or sieve surface of the mill. It is very difficult to powder a drug of having gummy or resinous material.
4. **Material structure:** Material with some special structure cause problem during size reduction e.g. Vegetable drug with cellular structure produce long fibrous particle on size reduction, similarly a mineral substance having lines of weakness, produce flake like particle on its size reduction.

5. **Moisture content:** The presence of moisture in the material influences a number of its properties such as hardness, toughness or stickiness. The material having 5% moisture in case of dry grinding and 50% in case of wet grinding is permissible.
6. **Temperature**: Waxy material such as stearic acid or drug containing oils or fat, become softened during the size reduction, due to heat. This can be avoided by cooling the mill.
7. **Purity**: In some mills during size reduction there is chances of addition of impurities. If high degree of purity is required avoid such mills or Mills should be cleaned thoroughly.
8. **Physiological effect:** Some drugs are very potent. During their size reduction in mill, dust is produced which may have effect on operator.
9. **Ratio of feed size to product size:** To get a fine powder in a mill, it is required that a fairly small feed size should be used. Hence to carry out size reduction in various stages e.g. preliminary crushing followed by coarse powder and then fine grinding.
10. **Bulk density:** The output of the size reduction of the material in a machine depends upon the bulk density of the substance.

e) Differentiate between hard gelatin and soft gelatin capsules. (0.5 mark each any 6 points)

Ans:

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

f) Describe in brief the procedure for preparation of B.C.G. vaccine along with it's dose, storage and uses.

(1.5 marks procedure, 0.5 mark dose, 0.5 storage, 0.5 mark uses)

Ans:

Method of preparation of BCG vaccine:

It is freeze- dried preparation containing live culture of the bacillus Calmette and Guerin strain of Mycobacterium tuberculosis.

Preparation: The bacilli are grown on a suitable culture media until 1 mg when plated out on a suitable solid culture media shows not less than 20 million colonies. The growth period should not be more than 14 days in any case.

After a suitable growth, they are separated by filtration in the form of a cake. The cake is homogenized in a grinding flask and suspended in a suitable sterile liquid medium designed to preserve the antigenicity and viability of the vaccine. The suspension is transferred into the final sterile containers and freeze-dried. Then containers are sealed so as to prevent contamination or deterioration of the vaccine. The vaccine contains no antimicrobial agent.

Storage: Store in hermetically sealed light resistant glass containers at a temperature between 2^0 C and 8^0 C.

The reconstituted vaccine should be used immediately after its preparation.

Uses: Immunising agent which provides protection against tuberculosis.

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

Q.3 attempt any FOUR of the following: 12

a) Draw a well-labelled diagram of soxhlet apparatus, what are the limitation of soxhletion method?

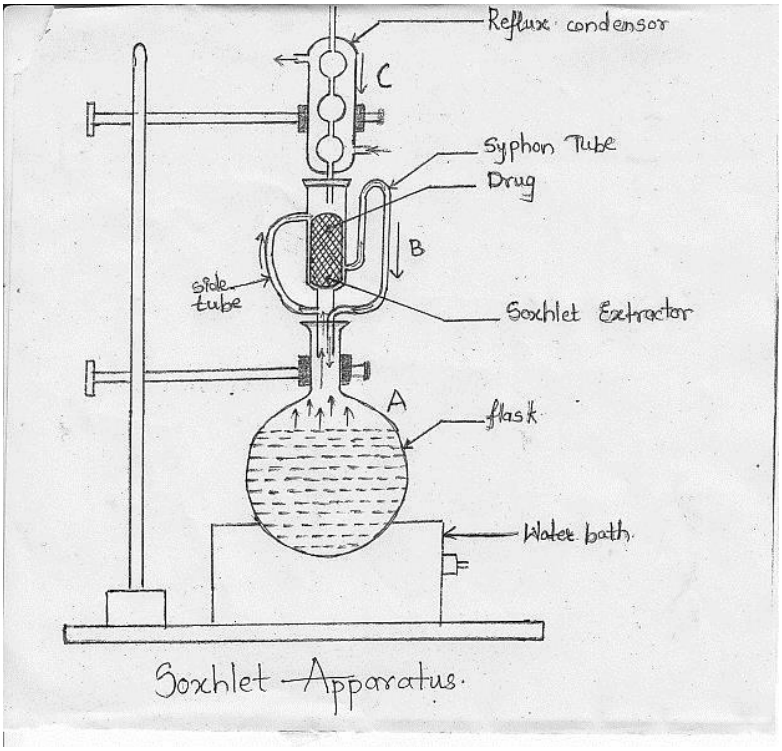
Ans: **Limitation (0.5 X2 = 1M):**

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 thermolabile active constituents such as enzymes, alkaloids, anthraquinone derivatives, esters, etc.

Diagram (2M)



b) Enlist different manufacturing defect that may appears in tablets, and explain in brief any two defects.

Enlist: (0.5 X 2 = 01M) and Describing defect 1 mark each

1. Capping.
2. Picking and sticking.
3. Mottling.
4. Weight variation.
5. Hardness variation.
6. Double impression.

1.C**apping:**

In this there is partial or complete removal of top or bottom portion of tablet.

Reasons:

- Excessive fine.
- Defective punch die.
- High speed of machine.
- Granules too dried.

Defect can be removed:

- Setting the die and punch properly.
- Reduce % of fine.
- Punches should be polished.
- Maintain the desire moisture in granules.
- Maintain the speed at optimum.
- Regulate the pressure of punches.

2. Picking and sticking:

The material is removed or picked up by upper punch from the upper surface of the tablet.In the sticking he material stick to the wall of the die cavity.

Reasons:

- Use of worn out die and punch.
- Use of small quantity of lubricants.
- Presence of excess moisture in the granules.
- Scratches on the surface of the face of the punches.
- Defect in formulation.

Defect can be removed:

- Using new set of die.
- Adding proper quantity of lubricants in granules.
- Dry granules.

3.Mottling:

An unequal distribution of colour on the surface of a coloured tablet.

Reasons:

- Migration of dye in the granules during drying.
- Use of different coloration of medicaments and Excipients.

Defect can be avoided:

- Drying the granules at low temperature.
- Using the dye which can mask the colour of all medicaments.

4. Weight variation:

Weight variation occur during the compression of granules in a tablet machine.

The tablet do not have the uniform weight.

Reasons for this defect:

- Granules are not in uniform size.
- Presence of excess amount of powder in the granules.
- No proper mixing of lubricants.
- No uniform flow of granules.
- During compression change in capacity of die.
- Variation in the speed of the tablet machine.

5.Hardness variation.

The tablet do not have a uniform hardness.

It depends on the weight of the material and space between the upper and lower punch during the stage of compression.

If volume of the material varies and distance varies between punches, the hardness also varies.

6.Double impression.

This effect occur when the lower punch has a monogram or some other engraving on it.

During compression, tablet receive an imprint of the punch.

Due to some defect in he machine lower punch move slightly upward before ejection of tablet and give second impression.
This can be controlled by managing the movement of punch.

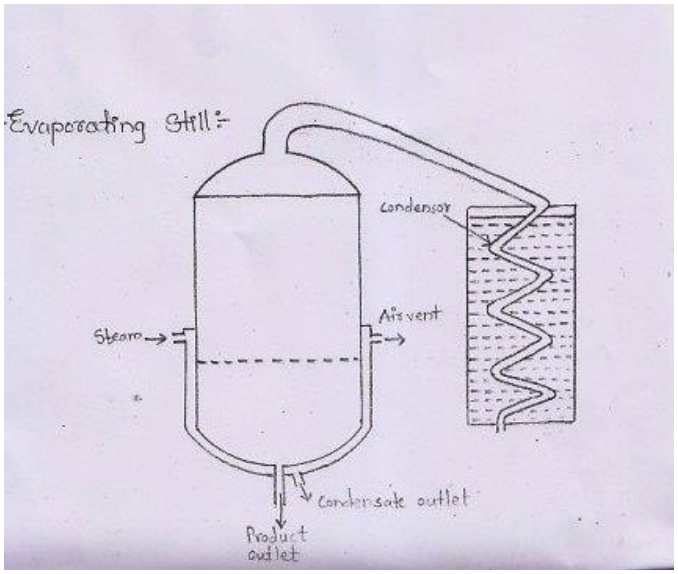
c) **Give the importance of dosage form.(0.5 X 6 = 3M)**

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.

d) Explain in detail evaporating still with its advantage and disadvantages.
Diagram = 0.5M, Explain = 1M, Adv = 0.5 X 2= 1, Dis adv 0.5 X 1 = 0.5M)



- It consist of a hemispherical pan made from copper or stainless steel.
- It is surrounded by a steam jacket.
- Still is covered from top and connected to condenser.
- Hemispherical shape provide large surface area for evaporation.
- It consist of product outlet at bottom.
- **Advantages:**
  - Simplest equipment.
  - Economical.
  - Easy to clean, use and maintain.
  - Condenser is provided to increase the speed of evaporation.
  - Vacuum can be attached.

Disadvantages:

- Co-efficient of heat transfer is poor.
- Heating surface is limited.
- Not suitable for thermolabile material.

e) **Differentiate between purified water and water for injection.(0.5x6=3marks)**

Sr.no.	Purified water	Sr.no.	Water for injection
1	Water which is free from volatile and non volatile impurities is called as purified water	1	Water which is free from volatile and non volatile impurities , microorganism and pyrogens is called as purified water
2	It may contain pyrogens	2	It is free from pyrogens
3	Cannot be used in parenteral preparation	3	Can beused in parenteral preparation
4	pH 4.5 to 7.0	4	pH 5.0 to 7.0
5	These are supplied in large volume.	5	These are supplied in small volumes.
6	Use it for longer duration	6	Must be Used within 24 hrs for parenteral preparation.

f) Write the working of filter press with well labelled diagram.

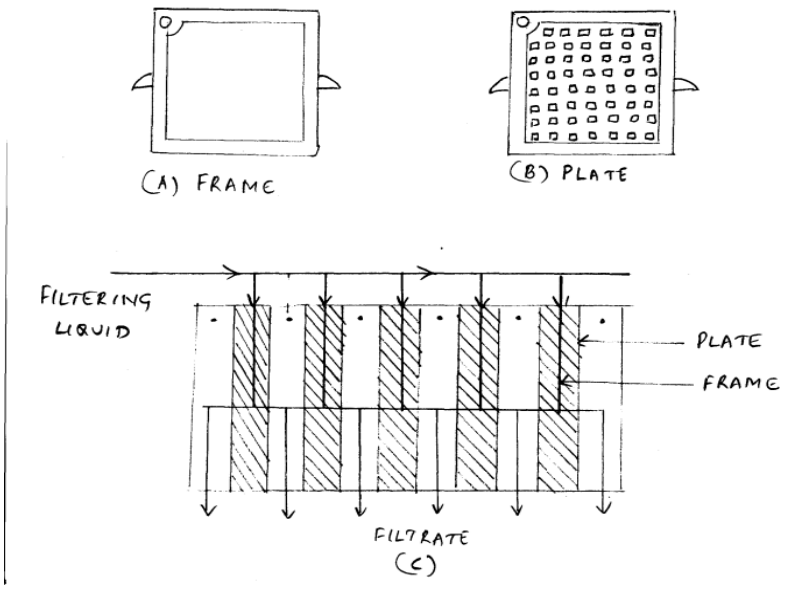
Working: (2 marks)

1. The slurry is pumped in under positive pressure up to 20 bar and fill each frame.
2. The filtrate passes through the cloths on opposite sides of the frame and runs down between the studs on the plate surface.
3. There is an outlet cock in the bottom right hand corner of the frame

allowing the filtrate to discharge in to channel.

4. The solid in the slurry build up to form cake in each frame which will eventually meet in the centre of the frame.
5. When the process is stopped, the frame is emptied and cycle is restarted.
6. Thickness of cake can be varied by using frame of different thickness.

Diagram: (1 mark)



Q.4 Attempt any FOUR of the following: **12**

a) Explain the factors affecting evaporation of a liquid.

Factor affecting evaporation (0.5 X 6 = 3M)

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).

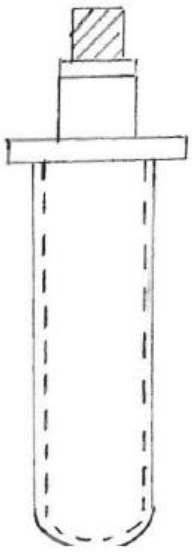
5. **Effect of concentration:** During evaporation the upper layer tends to form a film and there is formation of precipitate in the product which results in lowering down the rate of evaporation. Therefore, efficient stirring is required which will prevent degradation of the product at the bottom due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

b) Draw a well labelled diagram of filter candle. Give its working and disadvantages.

Diagram (1M):



Working (1M):

- The filter candle is placed in a vessel containing the liquid to be filtered.
- When vacuum is applied, the pressure inside the candle is decreased.
- Due to the difference in external pressure & pressure inside the candle, the liquid move inside through thick wall of the candle and get collected inside the candle.
- The filter candle can be blocked with continuous use. This can be cleaned by scratching the external surface with nail brush and passing water through it in the reserve direction.

Disadvantages (0.5X2 =1M)

1. Chance of clogging/blocking.
2. Traces of material may come in the solution.

c) **Write the advantages and disadvantages of glass as a material for packaging. Merits of Glass container: (0.5 X 3 = 1.5M)**

- Economical.
- Available in variety of sizes and shapes.

- Chemically inert, impermeable, strong and rigid.
- Does not deteriorate with age.
- Easy to label.
- Excellent barrier against light.

Demerits of Glass Containers: (0.5 X 3 = 1.5M)

- Fragile, easy to break.
- Heavy, Bulky to carry.
- Leaching and absorption of alkalis.
- Flak formation

d) Define drying. Give application of drying in pharmacy.

Definition: (1M)

- **Drying:** It is defined as final removal of liquid from solid by vaporization with aid of heat.

Application: (0.5 X 4 = 2M)

1) In pharmaceutical industry it is used as a unit process in the **manufacture of granules** which can be dispensed in bulk or converted into tablets or capsules.

2) Drying can also be used to **reduce the bulk** and weight of the material, thereby lowering the cost of transportation and storage.

3) It helps in the **preservation** of crude drugs of plant from mould growth, which occurs due to presence of moisture.

4) It helps in the **size reduction** of crude drugs. The presence of moisture in the crude drug does not allow it to get powdered easily.

5) Drying is also used in the processing of materials eg. the preparation of dried aluminium hydroxide, the spray drying of lactose and in the preparation of solid extract.

6) **Improves solubility** of product, when powder is dried it gets solublised fast.

7) Drying ensures free flowing of powders.

e)Describe in brief history of Indian pharmacopoeia.

Ans) 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 Pharmacopoeal 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 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-DS

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.

f) Give principal and working of silverson homogenizer with labelled diagram.

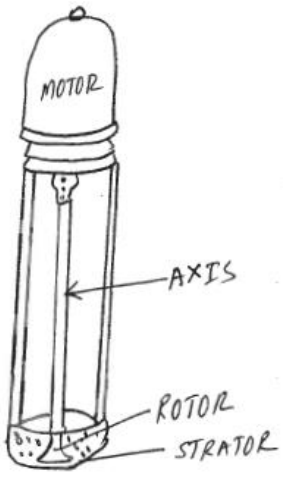
Principal: (1M)

These work on the principal of braking large globules in to small globules by passing them under pressure through a narrow orifice.

Working: (1M)

- The emulsified head is placed in the vessel containing immiscible liquid, in such a way that it should get dipped into it.
- When the motor is started, the liquid is sucked through the fine holes and the oil is reduced into fine globules due to the rotation of blades.
- So a fine emulsion is produced which is then expelled out.

Diagram (1M):



SILVERSON MIXER HOMOGENISER.

WINTER-15 EXAMINATION

Q.5. Solve any FOUR of the following. 12 Marks

a. Define aseptic techniques. What are the various sources of contamination?

Definition: Aseptic technique (1 Mark)

The method which is used to prevent the access of microorganism during the preparation of parenteral product and their testing are called "Aseptic Technique"

Sources of contamination: (0.5 X 4 = 2 Mark)

1. Atmosphere, which is contaminated with dust, droplet and droplet nuclei becomes the breeding ground of microorganism.
2. The hair
3. Unsterile equipment.
4. Working surface.
5. The hands are a major means of transmitting infection.
6. Coughing, sneezing and spitting can cause contamination considerable distance.
7. The clothes which absorb dust particles are also a source of contamination. A handkerchief is the richest source of contamination.

b. Give the principle and working of Fluidised bed dryer.

Principle: (0.5 Mark)

In FBD, good contact between hot air and particles to be dried is obtained which cause rapid drying.

Working of Fluidised bed dryer: (1M for diagram and 1.5 M for working)

Two types of FBD are used in pharmaceutical industry. There are:

1. Vertical FBD

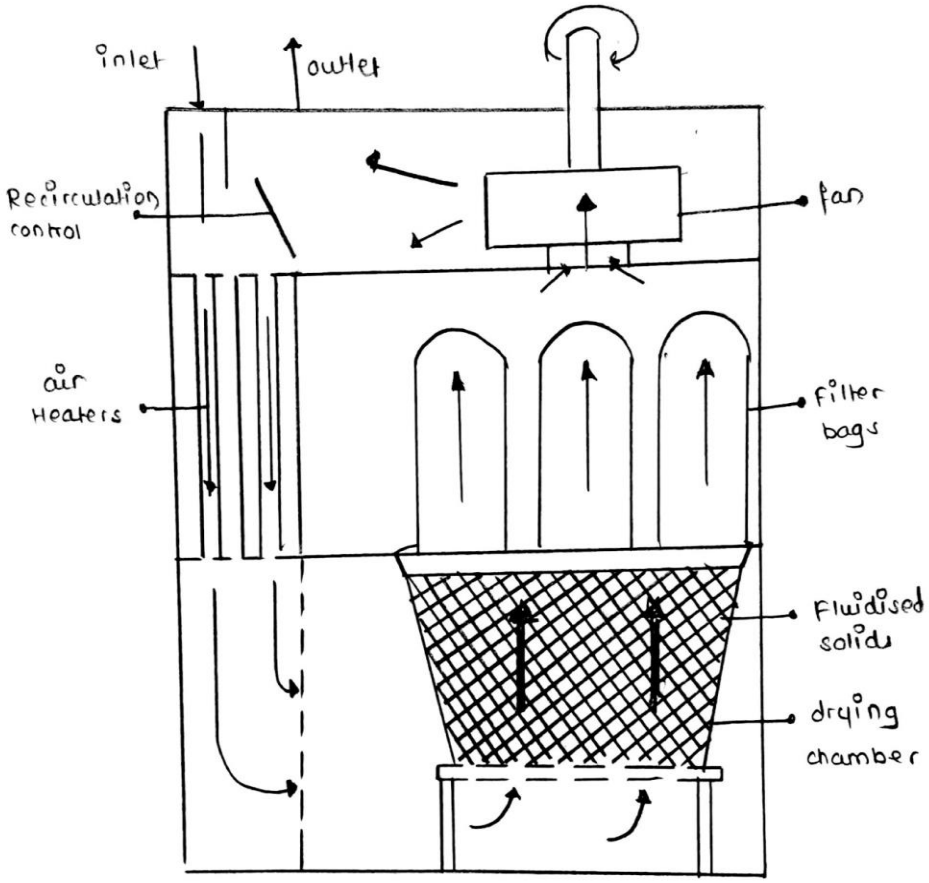
2. Horizontal FBD

The fluidising air stream is induced by a fan which is mounted in the upper part of dryer.

The air is heated to the required temperature in air heaters and passed through the wet material contained in a drying chamber fitted with a wire mesh support at bottom. The air flow rate is adjusted by means of recirculation control and fabric filter bags are provided to prevent the passage of fine particles.

This type of FBD is a batch type dryer and the drying chamber is removed from the unit for charging ad dumping.

The FBD available in different capacities ranging from 5 kg to 200 kg with an average drying time of about 20-40 min.



Fluidised energy bed dryer

c. Write special application of capsule. (Any 3 applications 3 Marks)

Applications of capsule:

1. **Enteric coated capsule:** These capsules do not disintegrate in stomach (Acidic Medium) but break up in intestine (Alkaline medium). On commercial scale, a coating of cellacephate (cellulose acetate phosphate) and mixture of waxes with fatty acids and esters are given.

   Categories of drug needed coatings:

   - Irritation to GIT
   - Destroyed in GIT
   - Specially intended to intestine
   - Required to produce delayed action

2. **Sustained release capsule:**
   - In order to maintain a proper blood concentration.
   - Preparation of coated pellets according to different release rate.
   - E.g. a capsule may be filled with mixture containing 30 % uncoated pellets for immediate release of the drug, 30 % each of the coated pellet, that release the drug 4 hour and 8 hour intervals and 10 % of neutral pellets are mainly used to fill capsule.
3. **Rectal Capsule:**
   - Soft gelatine capsule may be used as substitutes for rectal and vaginal suppositories.
   - Soft gelatine capsule of various shapes and sizes available but pear shape commonly used.
   - Both solid and liquid medicament can be filled in to soft gelatine capsule.
   - Also base used for incorporating medicament is non toxic, non-irritant and compatible with capsule shell.
4. **Capsule containing ophthalmic ointments**
   - It must be sterile
   - It required to fill in single dose container

- Soft gelatine commonly used
- Capsule punctured by using sterile needle and then instilled into the eye.

d. Write the official standards of powder. (1 x 3 = 3 Marks)

i. Coarse powder:

A powder of which all particles pass through sieve no 10 with nominal aperture size 1.7mm and not more than 40% pass through sieve no 44 with nominal aperture size 355um.

ii. Moderately Coarse powder:

A powder of which all particles pass through sieve no 22 with nominal aperture size 710um and not more than 40% pass through sieve no 60 with nominal aperture size 250um.

iii. Moderately fine powder:

A powder of which all particles pass through sieve no 44 with nominal aperture size 355um and not more than 40% pass through sieve no 85 with nominal aperture size 180um.

iv. Fine powder:

A powder of which all particles pass through sieve no 85 with nominal aperture size 180 um.

v. Very fine powder:

A powder of which all particles pass through sieve no 120 with nominal aperture size 125 um.

e. Define pharmaceutical container. Give qualities of an ideal container.

Definition: Pharmaceutical container (1 Mark)

A device that holds the drug and it may or may not be in direct contact with the pharmaceutical dosage form or preparations.

Qualities of an ideal container: (0.5 X 4 = 2 Mark)

1. Neutral
2. No interaction.
3. Stability against environmental factor.
4. Withstand wear and tear during handling.
5. Easy to remove dose.
6. Withstand changes in pressure and temperature.
7. Labelled easily
8. Non-toxic.
9. Closure easily removable/replaceable.

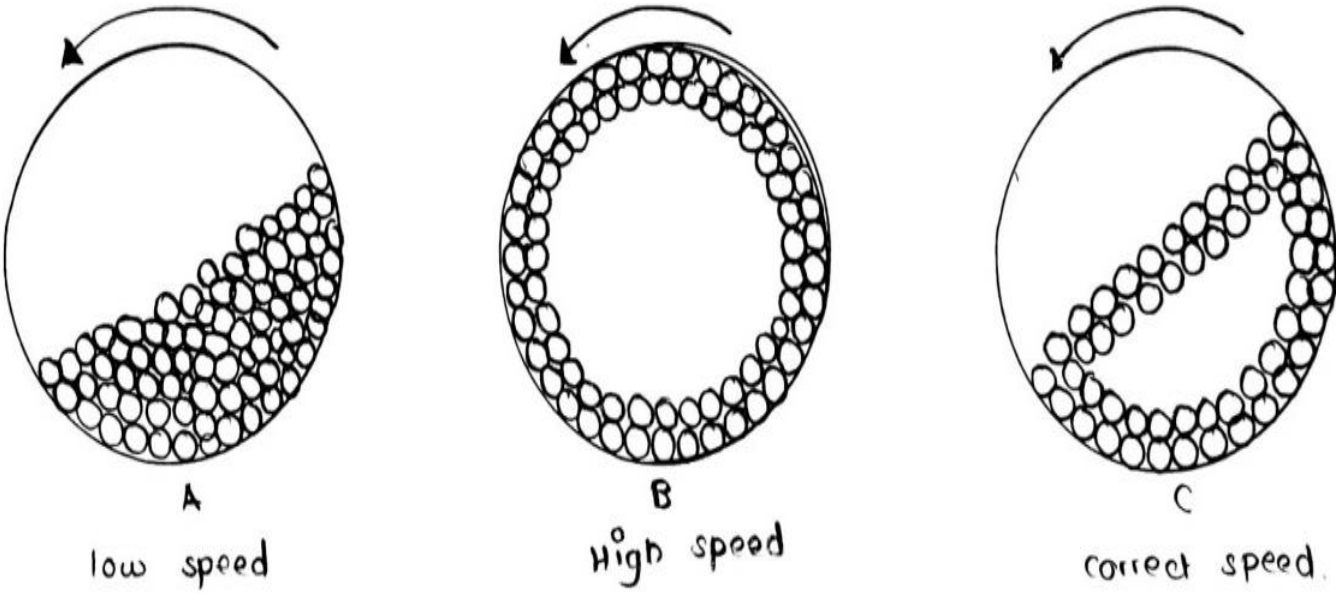
f. Discuss working of ball mill with neat diagram.

(Working 1.5 marks, 1.5 marks for diagram)

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 $2/3^{rd}$ 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.

Ball mill diagram:

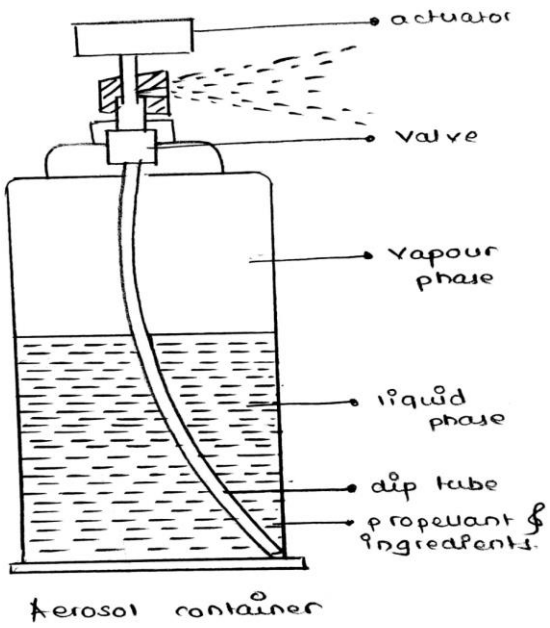


Q.6. Solve any FOUR of the following. 16 Marks

a. Draw a well labelled diagram of aerosol container and give its advantages and disadvantages.

Diagram of aerosol container (2 Marks)

WINTER-15 EXAMINATION



Advantages: (0.5 x 2 = 1)

1. Medicament can be delivered directly to affected areas.
2. Absence of air prevents oxidation.
3. Hydrolysis of medicament prevented.
4. Drugs can be given oral inhalation.
5. Sterility maintained.
6. Application of medicament is easier.
7. A fine mist easily formed for inhalation.
8. Manual contact avoided.
9. Drug does not pass from GIT. Hence chances of decomposition are less.

Disadvantages: (0.5 x 2 = 1)

1. Costly.
2. Sometimes propellants are toxic.
3. Cooling effect from propellant causes discomfort on injured skin.
4. Difficulties occurred during formulation when drug not soluble in propellants.

b. Mention official and unofficial evaluation test for tablets. Describe weight variation test. (List 0.5 X 4 =2 marks, explanation 2 marks).

Official test list:

1. Size and shape of tablet.
2. Appearance.
3. Content of active ingredient.
4. Uniformity of weight/weight variation test
5. Uniformity of content
6. Disintegration.
7. Dissolution.

Unofficial test list:

1. Hardness test.
2. Friability

Weight variation test:

Uniformity of weight: Weigh 20 tablets selected at random and determine their average weight. Not more than 2 of the individual weights may deviate from the average weight by more than the percentage deviation given in the table and none should deviate by more than twice that percentage.

Sr. No.	Average Wt. of a tablet deviation	Percentage (%)
1.	80 mg or less	10
2.	More than 80 mg and less than 250 mg	7.5
3.	250 mg or More	05

c. Give application of simple distillation. What is the principle of fractional distillation?

Applications of simple distillation: (0.5 x 4 = 2)

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 and aromatic spirit of ammonia.

v. To separate volatile and non volatile solvents.

Principle of fractional distillation: (2 Marks)

- When substance dissolved in liquid, the vapour pressure of liquid is lowered.
- The pressure exerted by each liquid in the mixture is known as partial pressure.
- Since complete separation is not obtained in simple distillation, fractional distillation is used.
- In fractional distillation, fractionating column is used which is fitted between distillation flask and condenser. Fractionating column is used for continuous separation of two miscible liquids.
- The vapours formed are allowed to pass through fractionating column where a part of the vapour is condensed and while returning to still comes into an intimate contact with rising vapour resulting in further fractionation of the liquid being distilled.
- The liquid with higher boiling point is condensed first and vapour becomes richer with the liquid having the lower boiling point which gets condensed in a condenser.

d. Explain principle and working of fluid energy mill with a diagram.

Principle (1 Mark)

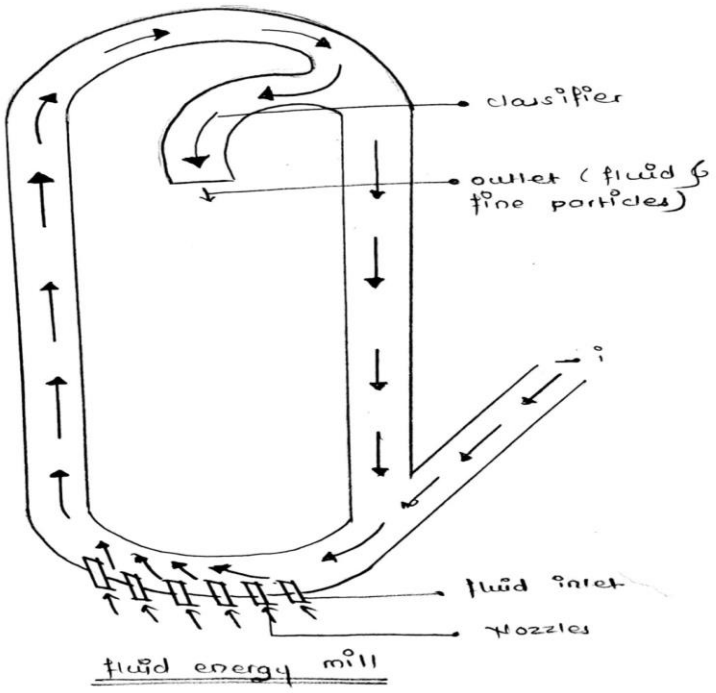
It works on the principle of impact and attrition.

Working (1 Mark)

The air or inert gas is introduced with a very high pressure through nozzles. Solids are introduced into air stream through inlet. Due to high degree of turbulence, impact and attrition forces occur between the particles. The fine particles are collected through a classifier. Fluid energy mill reduces the particles to 1 to 20 micron.

To get a very fine powder, even up to five micron, the material is pre-treated to reduce the particle size to the order of 100 mesh and then passed through fluid energy mill.

Diagram of fluid energy mill (2 Mark)

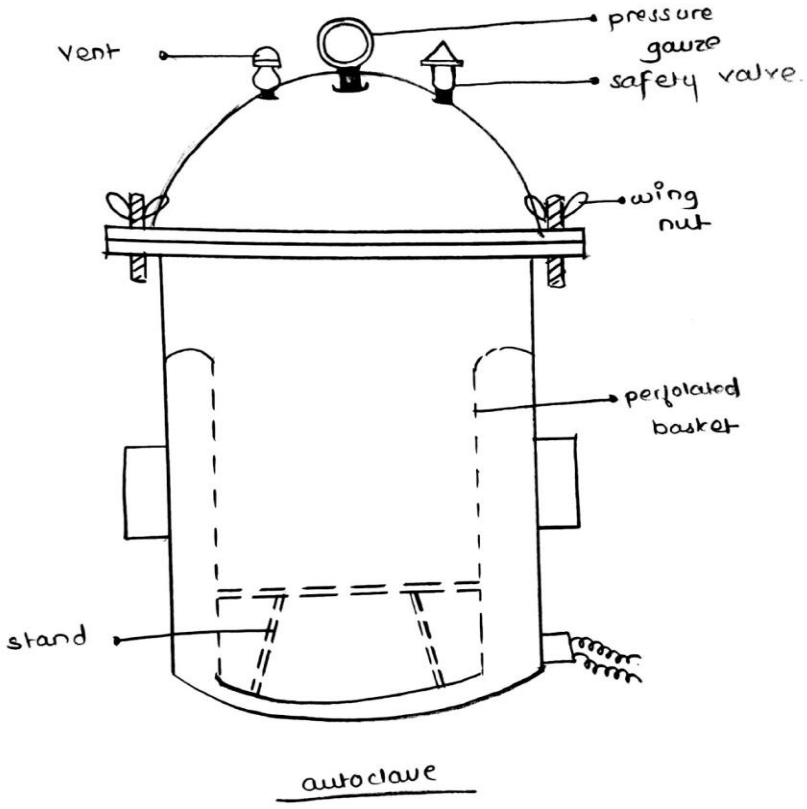


fluid energy mill

WINTER-15 EXAMINATION

e. Describe with diagram working of autoclave.

Diagram of autoclave: (2 Mark)



Working of autoclave: (2 Mark)

- A sufficient quantity of water is poured in to the chamber after removing the perforated chamber.
- The water level is adjusted in such a way that it does not touch the bottom of the chamber.
- The material is packed in the perforated chamber.
- The lid is then closed.
- The autoclave is switched on to heat the water.
- The vent is opened & safety valve is set at the required pressure.

- When a steam start coming out from the vent & it continues for 5 minutes, it is then closed.
- It indicates that air has been removed The steam pressure starts raising & it comes to 10 lbs/square inch with corresponding temperature 121^0c.
- After the stated period switch off the autoclave. Allow it to cool to about 40^0c before opening the vent.
- When all the steam inside the autoclave is removed, the lid is opened & the material is taken out.

f. Find out the proportion of procaine HCL which will yield solution iso-osmotic with blood plasma. (2 Marks Formula and 2 Marks Answer)

Given: F. P. Of 1% procaine HCl = - 0.122^0c

By applying formula;

$$= \frac{0.52 - a}{b}$$

Where,

a = F.P of 1%w/v solution of Unadjusted substance

b = F. P. of 1%w/v solution of adjusted substance

$$\% \text{ w/v of procaine HCL required } = \frac{0.52 - 0.00}{0.122}$$

$$\% \text{ w/v of procaine HCL required } = \mathbf{4.2\ w/v}$$