



SUMMER– 14 EXAMINATION

Subject Code: **0805**

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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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1. Solve any ten of the following: (2 marks for each question) 20M

a) Define 'Drug' and 'Dose'.

Ans: A **drug** may be defined as an agent intended for use in the diagnosis, mitigation, treatment, cure or prevention of disease in man or in other animals. (1 mark)

Dose: The specified quantity of a drug or medicine prescribed to be taken at one time or stated intervals. (1 mark)

b) What is levigation?

Ans: Levigation is the process of wet grinding. **(1Mark)**

The material is converted into paste with water and then grinding of paste is done in a mortar using a pestle. In case of large scale grinding, it is done by using colloidal mill or a mill resembling edge-runner mill. The process is used for preparation of light kaolin, chalk, red and yellow mercuric oxide, calamine and camphor, etc. **(1 mark)**

c) Define container and closure.

Ans: Container is a device that holds the drug and it may or may not be in direct contact with the pharmaceutical preparations. **(1 mark)**

Closure is the device by means of which container can be opened and closed. **(1Mark)**

d) Define 'Pharmacopoeia'. Name the editions of I.P. published so far with the year of publication.

Ans: Pharmakon means "a drug" and poiein means "to Make".

"Pharmacopoeia is defined as a compressive book which is issued under the authority of government and contains a list of drugs and formulae used for medicinal preparations with description and the tests for those substances and the standards to which they must conform. e.g. I.P., B.P., U.S.P". (1 mark)



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Different six editions of Indian Pharmacopoeia in chronological order are as follows: **(1 mark)**

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) Name the principles of size reduction with example of mill based on that principle. (1 mark for 4 principles and 1 mark for examples)

Ans: 1. Cutting eg. Cutter mill

2. Compression e.g. Roller mill

3. Impact e.g. Hammer mill, disintegrator

4. Attrition e.g. Roller mill

5. Combined impact and attrition e.g. Ball mill, fluid energy mill

f) Define mixing. Give objectives of mixing.

Ans: Mixing is an operation in which two or more than two substances are combined together so that each particle of one material lies as nearly adjacent as possible to a particle of other material. **(1/2 mark)**

Objectives of mixing: **(½ mark for each, any 3 objectives)**

1. Simple physical mixing of materials to form a uniform mixture.
2. To promote the chemical reaction to get uniform product.
3. Dispersion of solid in liquid to form suspension or paste.
4. Dispersion of two immiscible liquids to form an emulsion.



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g) State the difference between Infusion and Decoction. (any 4 points, 2 marks)

| Sr. No | Infusion | Decoction |
|--------|---|---|
| 1. | Cold or boiling water is used as menstruum. | Drug is boiled in water. |
| 2. | Drug having soft tissue is used. | Drug of a hard tissue is used. |
| 3. | Drug constituents may be volatile. | Drug constituents should not be volatile. |
| 4. | Final volume is not adjusted. | Adjustment to volume is done. |
| 5. | When boiling water is used as menstruum, precautions are taken to prevent escape of heat by covering the vessel with cloth. | No such precaution is required because final volume is adjusted at the end. |

h) What is sieve number? Name the equipments used for size separation.

Ans: Sieve number indicates the number of meshes in a length of 2.54 cm (1 inch) in each transverse direction parallel to the wires. (**1mark**)

Equipments used for size separation: Sieves, Cyclone separator, air separator, Elutriator (**1 mark**)

i) What are galenicals? (2 Marks)

Ans: a standard medicinal preparations (as an extract or tincture) containing usually one or more active constituents of a plant and made by a process of infusion, decoction, maceration, percolation and digestion are called galenicals.



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j) What is percolation?

Ans: Percolation may be defined as downward displacement of saturated menstrum through column of drug. 'Short successive maceration' or 'extraction by method of displacement'. (0.5 Marks)

In percolation, the powdered drug is placed in a cylindrical or conical vessel called percolator. The menstruum is allowed to pass through a column of drug under influence of gravity at a regulated rate which allows the menstruum to dissolve the active constituents. (1 Marks)

Steps involved: Imbibition, Maceration and percolation. (Students may write classification as extra part marks should be granted) (0.5 Marks)

The various percolation processes used for extraction of drugs are:

1. Simple percolation or percolation process for tinctures.
2. Percolation process for concentrated preparations such as reserve percolation or modified percolation.
3. Continuous hot percolation or soxhlation.

k) Define immunity. Name two preparations used for active immunity.

Ans: The power of body to resist the effects of invasion of micro-organisms is called immunity. (1 mark)

Preparations for active immunity: (any 2 preparations 1 mark)

1. Bacterial vaccines e.g. BCG vaccine, typhoid vaccine
2. Viral and rickettsial vaccines e.g. poliomyelitis vaccine, rabies vaccine
3. Preparations containing toxoids e.g. Diphtheria toxoid, Tetanus toxoid



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l) What tablets are enteric coated?

Ans: Enteric coating is done due to following reasons: (**any 4 reasons 2 marks**)

1. Medicaments produce severe irritation in the stomach.
2. The action of medicament is required in the stomach. E.g. anthelmintics and amoebicides.
3. Medicaments get destroyed by acidic medium of the stomach or gastric juice.
4. Drug absorption is better in the intestine.
5. Delayed action is needed.

m) Give any four advantages of capsules.

Ans: Advantages of capsules: (**any 4 adv 2 marks**)

1. Drugs having unpleasant odour and taste can be administered by enclosing them in a shell.
2. They are smooth, become slippery when moist and can be easily swallowed.
3. Economical.
4. Easy to handle and carry.
5. Capsules are made from gelatin and hence they are therapeutically inert.
6. Attractive.
7. Microencapsulation provides sustained release dosage form.



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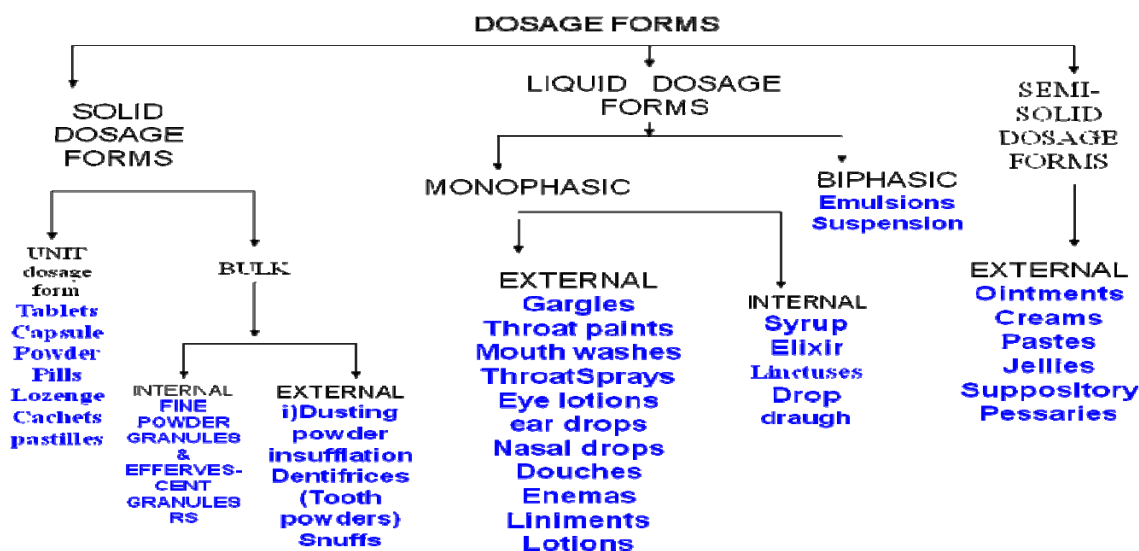
2. Answer any four of the following: (3 marks for each question) 12

a. Define dosage form. Classify dosage forms with examples.

Ans: Dosage forms- Any form in which the drug is administered in prescribed quantity is called as dosage form. 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. (1 mark)

Dosage form is classified into three types (2 marks)

- a)Solid dosage forms
- b)Liquid dosage forms
- c)Semisolid dosage forms





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b) Give the gradation of powder according to I.P.

Ans: The I.P.85 specifies five grades of powder which are as under: **(3 marks)**

- 1. 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.
- 2. 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.
- 3. 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.
- 4. 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.
- 5. 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.

c) Describe in short the construction and working of ball mill.

Ans: **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)**

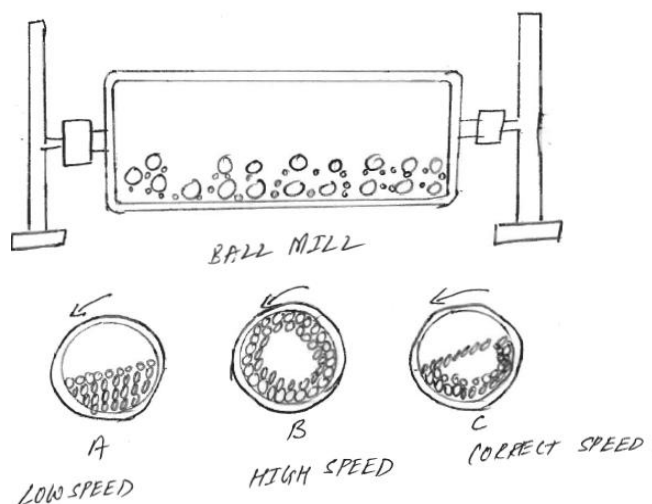
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Working: The drug to be ground is put into the cylinder of the mill and is rotated. The speed of the rotation is very different. At low speed, the mass of balls will slide or roll over each other and only a negligible amount of size reduction will 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 $2/3^{\text{rd}}$ 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. (1 mark for dia., 1mark for working)



d) **Define drying. Name the equipments used for drying.**

Ans: Drying is defined as the final removal of liquid from solids by vapourisation with the aid of heat. (1mark)

Equipments used for drying: Tray dryer, tunnel dryer, rotary dryer, fluidized bed dryer, vacuum dryer, freeze dryer. (2 marks)



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e) Write advantages and disadvantages of plastic as a material for packing.

Ans: Advantages: (any 4, 2 marks)

1. Light in weight and can be handled easily.
2. Poor conductor of heat.
3. Sufficient mechanical strength.
4. Transported easily.
5. Unbreakable.
6. Available in various shapes and sizes.
7. Good protection power.
8. No formation of flakes.

Disadvantages: (any 2, 1 mark)

1. Permeable to water vapour and atmospheric gases.
2. Cannot withstand heat without softening or distortion.
3. May interact with certain chemical to cause softening or distortion.
4. May absorb chemicals such as preservatives.
5. Relatively expensive.
6. Special type of gum or adhesive required for labeling.

f) What is lyophilisation? Give its pharmaceutical applications.

Ans: Lyophilisation is a process in which there is removal of water vapours from a frozen solution by sublimation. This consists of reducing the temperature and pressure to values below the triple point. Under these conditions, any heat transferred is used as latent heat and the ice sublimates directly to vapour state. **(1.5 marks)**



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Applications: (any three 1.5 Marks)

1. It is mainly used for the drying of biological products such as antibiotics, blood products, vaccines, enzyme preparations, microbiological cultures and other thermolabile pharmaceutical substances.
2. Product obtained is light & porous having excellent solubility.
3. Drying takes place at very low temp & under vacuum, thus decomposition & oxidation of product is minimized.
4. It helps in preservation of material.

3. Answer any four of the following.

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a) Plate and frame filter press.

Construction: (1mark)

- It consists of alternative plate and frame mounted on two parallel support bars.
- The pressure can be applied through screw thread so that the plate and frame are rigidly fixed between two end plates.
- The frame is open and is used as an inlet for material to be filtered.
- Plates has grooved surface which give support to the filter cloth.
- The plate and frame are made of non corrosive material.
- Filter cloth is placed at each side of the plate.
- Each plates acts as single filtration unit and outlet is connected to common outlet for plate.



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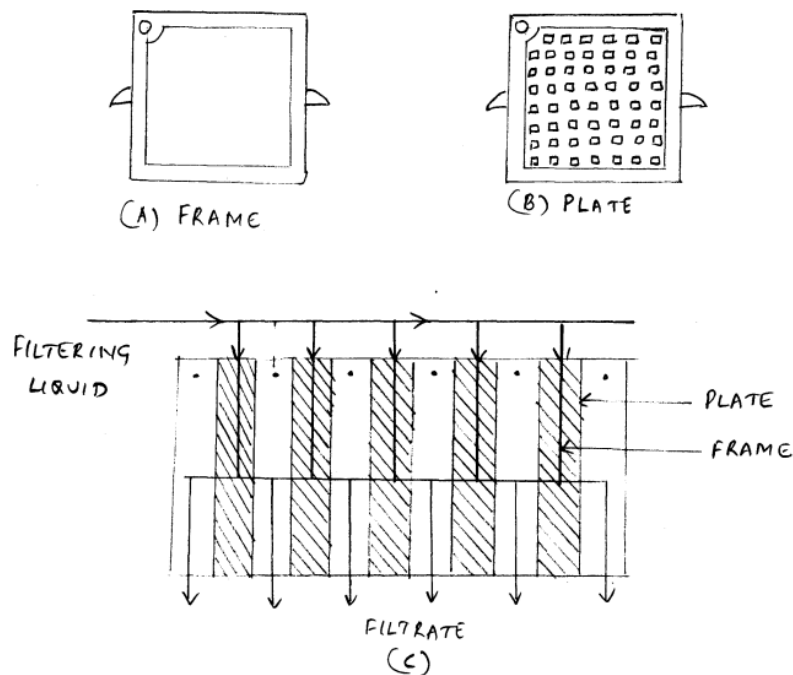
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Working: (1mark)

- The slurry is pumped in under positive pressure up to 20 bar and fill each frame.
- The filtrate passes through the cloths on opposite sides of the frame and runs down between the studs on the plate surface.
- There is an outlet cock in the bottom right hand corner of the frame allowing the filtrate to discharge in to channel.
- The solid in the slurry build up to form cake in each frame which will eventually meet in the centre of the frame.
- When the process is stopped, the frame is emptied and cycle is restarted.
- Thickness of cake can be varied by using frame of different thickness.

Diagrams: (1 m)





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b) **Solvent used for extraction:** any two names ; **(0.5 X 2 = 1Marks)**

Water, ethyl alcohol, methyl alcohol, Petroleum ether, diethyl ether etc.

Water: - (1M)

Advantages:

- It is cheap.
- It has wide solvent action.
- Non-toxic.
- Non inflammable.

Disadvantages:

- It dissolves wide range of substances which might be undesirable.
- It helps in mould and bacterial growth.
- It may cause hydrolysis of many substances.
- Large amount of heat is required to concentrate the aqueous preparation than the non-aqueous preparation.

Alcohol: - (1M)

Advantages:

- Mould growth not takes place.
- It is neutral.
- Non-toxic.
- A small amount of heat required to concentrate the preparation.
- It dissolves selective active constituents.

Disadvantages:

- Costly.
- Inflammable.



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c) Definition: (1M)

Extraction is the process removal active constituents from plant or animals tissue by the treatment with solvent.

Differentiate: (any four points 0.5 X 4 =2M)

| | Tincture made from organized drug | Tincture made from unorganized drug |
|---|---|--|
| 1 | Drug along with whole of menstrum is used in maceration process | Drug along with 4/5 th of the menstrum is used in the maceration process. |
| 2 | The period of Maceration is 7 days | The period of Maceration is 2 to 7 days |
| 3 | Strain off the liquid and press the marc | Decant the liquid and marc is not pressed |
| 4 | Mix the pressed liquid with the macerate and clarify by filtration. Filtrate is not adjusted to volume. | Filter the liquid and pass the remaining 1/5 th of menstrum through filter to make up the volume. |
| 5 | Example of tincture: Tincture of orange, Tincture of capsicum, tincture of lemon. | Example of tincture: Tincture of tolu, Tincture of catechu, compound tincture of benzoin. |

d) Evaporating Pan: -

Construction: (1M)

- It consists of a hemispherical pan made from copper or stainless steel and surrounded by a steam jacket.
- Hemispherical shape provides large surface area for evaporation.
- It consists of product outlet for fixed evaporating pan.
- In other type evaporator is mounted in such a way that they can be tilted.

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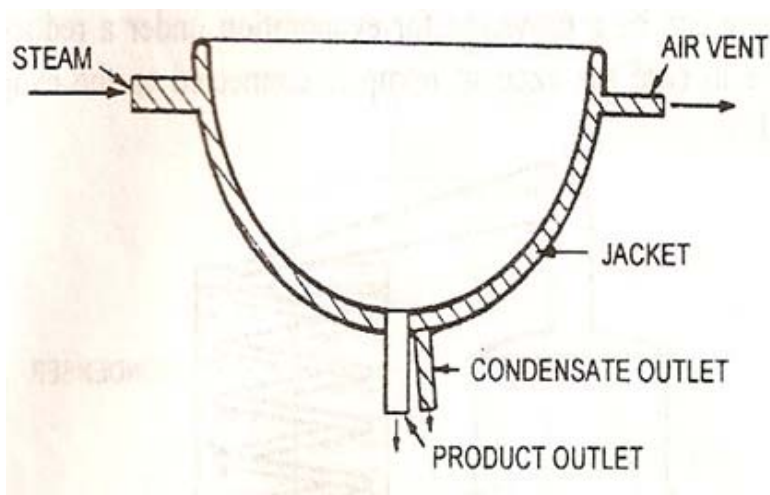
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Working: (1M)

- Material to be evaporated is filled in the pan.
- Pass the steam through the steam inlet.
- Liquid start boiling and vapours are escaped from the top.
- Liquid gets concentrated and removed from bottom product outlet.

Diagram: - (1M)



e) Merits of liquid dosage form: (0.5 X 3 = 1.5M)

1. Easy for swallowing.
2. Faster absorption than solids
3. More flexibility in achieving the proper dosage of the medication.
4. Palatable.
5. Best choice for children and old patients.

Demerits of liquid dosage form: (0.5 X 3 = 1.5M)

1. Shorter life before expiration than other dosage forms
2. Harder to measure accurately
3. May have special storage requirements.
4. Less stable.
5. Bulky to carry.



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f) Factor affecting size reduction: (Names 0.25 X 6 =1.5 M)

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

Discuss any three (0.5 X 3 =1.5 M)

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.



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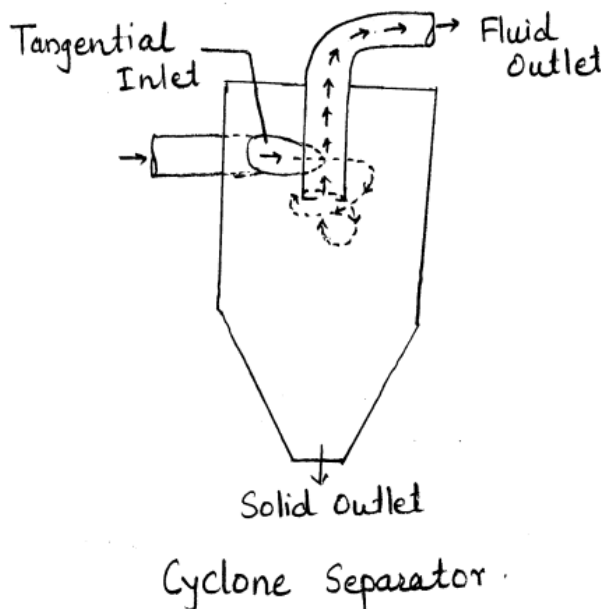
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6. **Temperature:** Waxy material such as stearic acid or drug containing oils or fat, become softened during the size reduction, due to heat. This can be avoided by cooling the mill.
7. **Purity:** In some mills during size reduction there is chances 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.

4. Answer any four of the following.

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a. Diagram (1M)





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Construction: (1M)

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

Working: (1M)

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

b. Definition: (1M)

Tablets are the solid dosage form containing medicament, usually circular flat or biconcave in shape and are prepared by compression.

Types of tablet: (0.5 X 4 = 2M)

A. Tablet ingested orally:

- Compressed, multiple compressed tablet, Multilayer tablet.
- SR tablet.
- Enteric coated tablet and Sugar coated tablet.
- Film coated tablet.
- Chewable Tablet.

B. Tablet used in oral cavity:

- Buccal tablet.
- Sublingual tablet.
- Dental cone.



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C. Tablet administered by other rout:

- Implantation tablet.
- Vaginal tablet.

D. Tablet used for preparation of solution:

- Effervescent tablet.
- Dispensing tablet.
- Hypodermic tablet.
- Tablet triturate.

c. Microencapsulation: (1.5 M)

- **Micro-encapsulation** is a process in which tiny particles or droplets are surrounded by a coating to give small capsules of many useful properties.
- In a relatively simple form, a **microcapsule** is a small sphere with a uniform wall around it.
- The material inside the microcapsule is referred to as the core, internal phase, or fill, whereas the wall is sometimes called a shell, coating, or membrane.
- Most microcapsules have diameters between a few micrometers and a few millimeters.

Applications: (any three 0.5 X 3= 1.5M)

1. To mask the bitter taste of drugs like Paracetamol, Nitrofurantoin etc.
2. To reduce gastric and other gastro intestinal (G.I) tract irritations, For eg., sustained release.
3. A liquid can be converted to a solid for easy handling and storage,
4. Hygroscopic properties of core materials may be reduced by microencapsulation.
5. Protection against external environment.



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6. Microencapsulation has been employed to provide protection to the core materials
7. Separation of incompatible substance has been achieved by encapsulation.

d. Definition: (1M)

- Capsules are a solid dosage form in which the drug substances are enclosed in a water soluble shell or an envelope.

Excipients: any four (0.5 x 4 = 2M)

i. Diluents:

- To increase bulk, e.g. lactose, sorbitol, starch etc.

ii. Absorbents:

- Eutectic or hygroscopic drug need absorbent for, e.g. oxides and carbonates of magnesium and calcium.

iii. Glidants:

- To ensure a regular flow of powder, e.g. talc and magnesium stearate.

iv. Antidusting agents:

- During filling of capsule in automatic filling machine a lot of dust comes out to avoid this Antidusting agent added e.g. inert oils.

e. Reserved percolation: (2M)

- Liquid extract are more concentrated preparation as compared to tinctures hence are produced by this method.
- In this process a part of percolate, generally $\frac{3}{4}$ th volume of the finished preparation is reserved.
- Then the percolation process is continued till the drug is completely exhausted.



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- The percolate is subjected to evaporation or distillation to convert in to soft extract.
- This soft extract is dissolved in reserve portion of percolate and sufficient menstruum is added to make up the volume.
- First reserve percolate is more concentrated.
- Other portion of percolate is evaporated is which contains traces of active constituents.
- The product of evaporation is concentrated form of the percolate mixed with earlier reserved.

Advantages: (any two 0.5 X 2 = 1M)

- i. More concentrated product is produced.
- ii. Complete exhaustion of crude drug is done.
- iii. Process is economical.
- iv. Quantity of menstruum required is less than it required for simple percolation.

f. Definitions: (3X1= 3M)

2. **Purified water I.P.:** water free from volatile & non volatile impurities is called purified water.
3. **Water for Injection I.P.:** Water which is free from volatile and non volatile impurities, micro-organisms & pyrogen is called as water for injection I.P.
4. **Sterile Water for Injection I.P.:** Sterile water for injection is a clear, colourless, odourless, tasteless liquid, which is sterilized & suitable packed, it is free from dust, dirt, dissolved, undissolved impurities, microorganism & pyrogen.



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Q. 5 Answer any four of the following:

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a. Give the metric equivalents for the following : (1/2 mark each)

- i. 30 grain = 1.8 gm. or 1.95 gm
- ii. half ounce = 15 gm / 14.2 gm/15 ml
- iii. one tablespoonful = 15 ml.
- iv. 480 minims = 28.8 ml or 30 ml.
- v. two fluid drachm = 8 ml.
- vi. one teaspoonful = 4 ml

b. What are salient features of II edition of I.P. (Any 6 points, 1/2 mark each).

1. The titles of monographs have been changed from Latin to English.
2. The words of the title have been transposed to give the name of the drug first.
e.g. Injection of Aminophylline has been changed to Aminophylline Injection.
3. Doses are expressed in the metric system only.
4. Solubility is expressed in parts of solvent per unit part of solute.
5. The preparations of a drug have been given immediately after the monograph on the parent drug.
6. The test for sterility has been modified to provide for detection of fungi in addition to aerobic and anaerobic bacteria.
7. New analytical techniques such as non-aqueous titrimetry, column chromatography have been included.
8. In the monographs of "Tablets" and "Injections", a new sub-heading "Usual Strength" has been given to represent the strength of the tablet or injection in which it should be generally marketed.



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c. Describe in short the stages of sugar coating of tablets. (1/2 mark each)

Ans: Sugar coating is done by pan coating method. Sugar coating makes the tablet smooth, elegant and also helps in masking the unpleasant taste and odour of medicament. It consists of following steps:

1. Sieving.
2. Sealing.
3. Sub-coating.
4. Syrup coating.
5. Finishing.
6. Polishing.

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. Sub-coating: 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.



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d. Definitions:(1 mark each)

- i. Sterilization** Sterilization is a process of complete destruction of all micro-organisms & their spores present in a system.
- ii. Tyndallisation:** This is a fractional sterilization method. This method is used for sterilization of medicaments unstable at 115°C but able to withstand low temperature heating. This method consist of heating the material at 80°C or 100°C for 1 hour on three successive days presuming that on the first day all vegetative bacterial cells will be destroyed and the spores may germinate in the days to follow and will be killed subsequently.
- iii. Pasteurization:** It is a partial sterilization method which is used to make milk safe and also to improve its keeping properties. The process kills only 97 to 99 percent micro-organisms, but it does not kill bacterial spores.

e. Enumerate Evaluation tests for tablets. Explain friability test.

Evaluation tests: (any four tests $0.25 \times 4 = 1$ Marks))

- 1) Shape and size of tablets.
- 2) Appearance
- 3) Content uniformity
- 4) Weight variation
- 5) Disintegration test
- 6) Dissolution test
- 7) Hardness (Mechanical Strength)
- 8) Friability test.

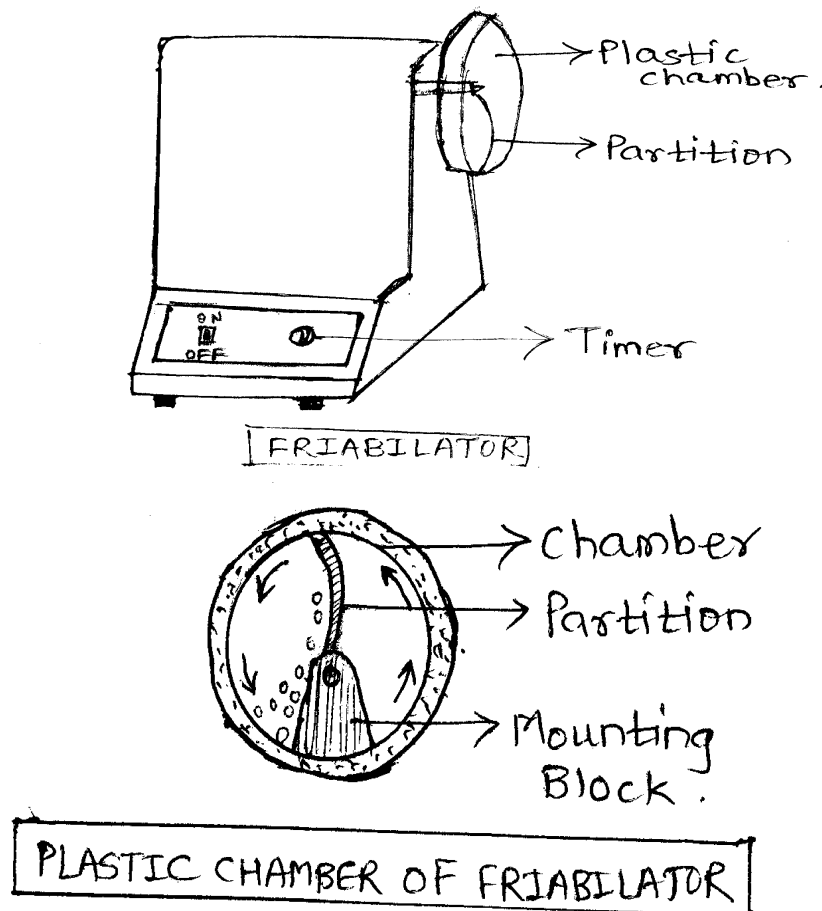
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Friability test: (1mark diagram and 1 mark for explanation)



Friability test is performed to evaluate ability of the tablet to withstand wear and tear in packing, handling, and transporting. The apparatus used to perform this test is known as "Friabilator".

The apparatus consists of a plastic chamber, which is divided into two parts and it revolves at a speed of 25 rpm. Twenty tablets are weighed and placed in a plastic chamber. The chamber is rotated for 4 minutes or 100 revolutions. During each revolution the tablet falls from a distance of 6 inch. The tablets are removed from the chamber after 100 revolutions and weighed. Loss in weight indicates the friability. The tablets are considered to be of good quality if the loss in weight is less than 0.8%.



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f. Differentiate between hard and soft gelatin capsules. (1/2 marks each point).

| 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 available in round, oval and tube-like shapes. |
| 3. The contents usually consist of medicaments in the form of powder, beads or granules. | 3. The contents usually consist of liquids or semisolids. |
| 4. These are prepared from gelatin, titanium dioxide, colouring 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. |



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Q. 6. Answer any four of the following:

12.

a. Define vaccine. Give the method of preparation of BCG vaccine.

Vaccine: Vaccines are the mostly antigenic preparations which stimulate antibody formation there by producing immunity. **(1 mark)**

Method of preparation of BCG vaccine: (2 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.

b. Enumerate the factors affecting rate of evaporation and discuss any three.

Factors: (any three $0.25 \times 6 = 1.5$ marks).

1. Temperature
2. Temperature and time of evaporation
3. Temperature and moisture content
4. Type of product required
5. Effect of concentration
6. Surface area
7. Vapour pressure of the liquid to be evaporated



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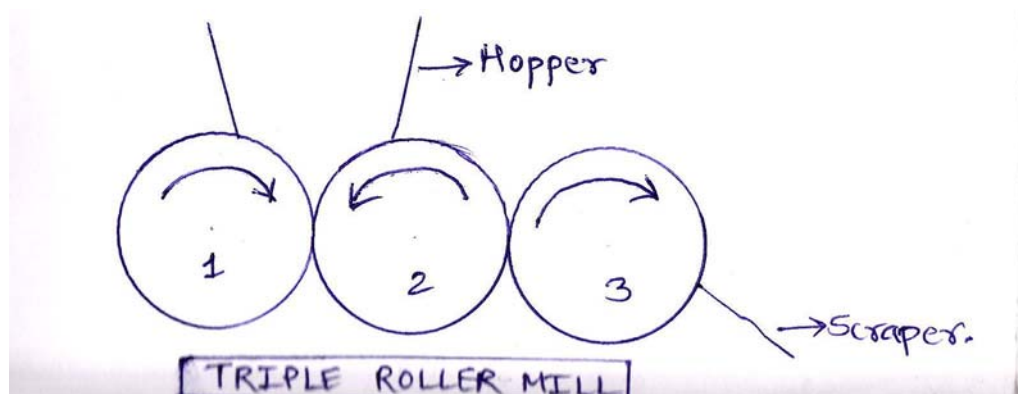
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Factors affecting rate of evaporation: (any three 1.5 Marks)

- 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.

- c. Describe the construction and working of Triple Roller Mill. (1 mark dia, 1 mark con. and 1 mark working).



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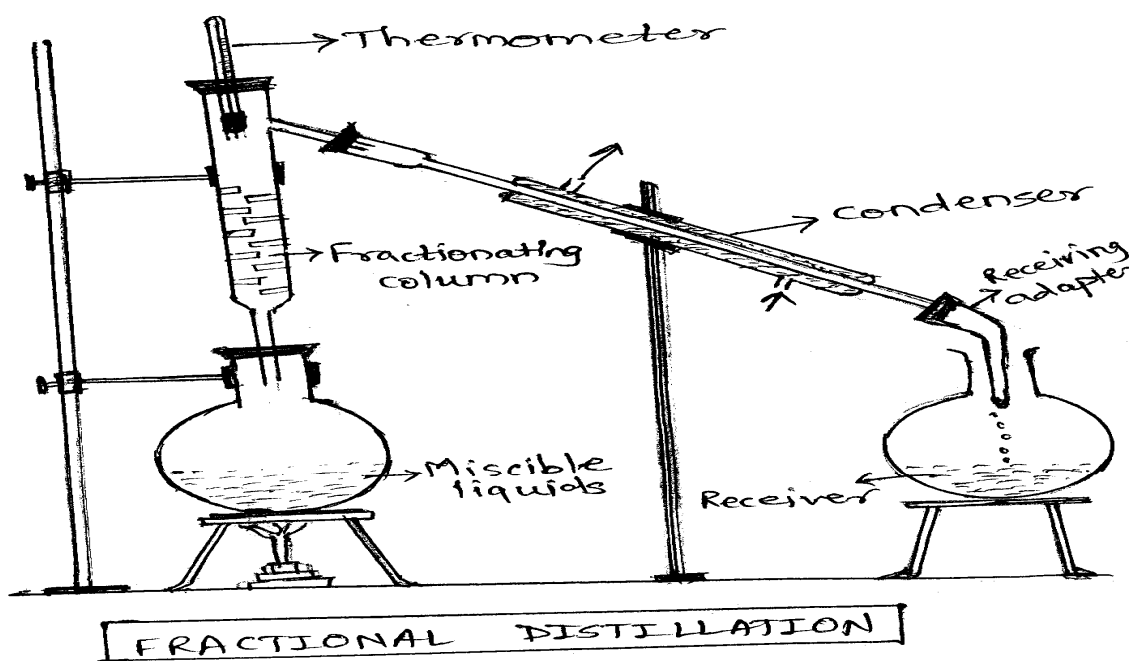
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Construction: The mill consists of three rollers which are made of a hard abrasion - resistant material. These rollers are arranged in such a way, that they come very close to each other. These rollers are rotated at different rates of speed. The material coming between the rollers is crushed depending on the gap between them and the difference in rates of movement of two surfaces.

Working: As shown in figure, the material after passing through hopper comes between roller 1 and 2 and is reduced in size in the process. The gap between roller 2 and 3 is usually less than that between 1 and 2, further crushes and smoothes the mixture which adheres to roller 2. A scraper is arranged in such a way, that it can remove mixed material from the roller 3 and does not allow the material which has not passed between both sets of the rollers to reach the scraper.

d. Draw a neat labelled diagram of fractional distillation method. (3 marks)



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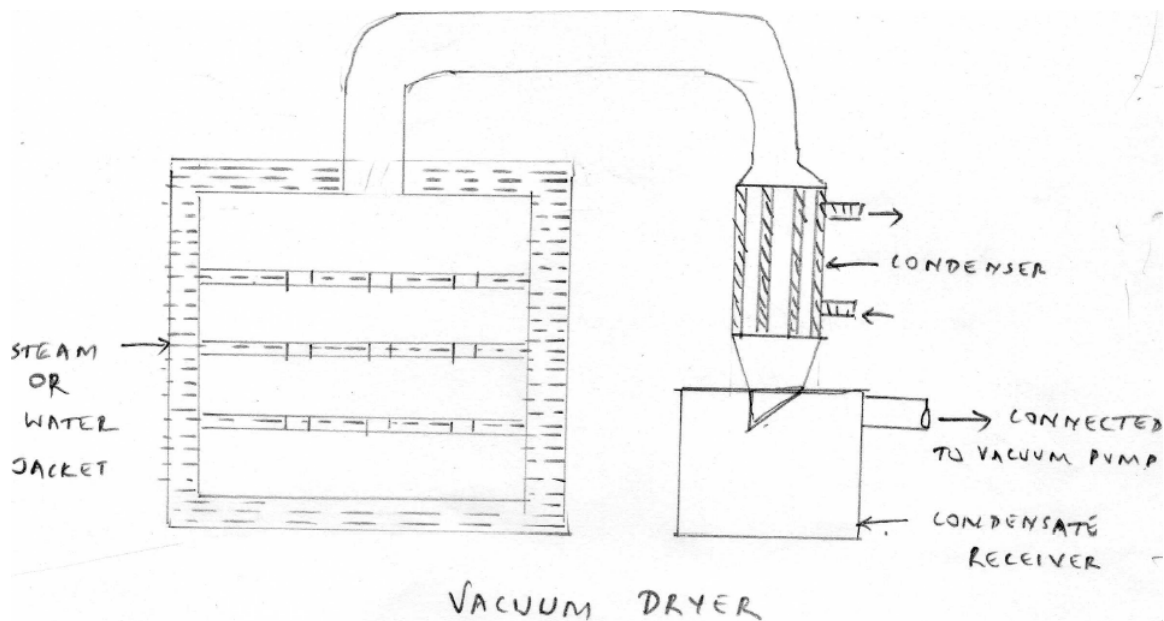
- e. In what proportion 30%, 45%, and 60% alcohols should be mixed to obtain 35% alcohol. (3 marks).

60 5 parts of 60 %

45 35 5 parts of 45 %

30 25 + 10 = 35 parts of 30 %

- f. Explain construction and working of vacuum dryer. (1 mark dia, 1mark con. and 1 mark working)





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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 provide 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 °C. In the pharmaceutical industry, an oven of the size of about 1.5 cubes having 20 shelves is commonly used.