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.
Q. No. | Subject Title: PHARMACEUTICS-I
---|---
(a) | **Define Pharmacopoeia. Give example.**
   **Pharmacopoeia:** Pharmakon means “a drug” and poein means “to make”.
   Pharmacopoeia is defined as a compressive book which is issued under the authority of
government and contains a list of drugs and formulae used for medicinal preparation with
description and the tests for those substances and the standards to which they must confirm.
   **Example:**
   I.P., B.P., USP, European Pharmacopoeia, etc.

(b) | **Define container and closure.**
   **Container** is a device that holds the drug and it may or may not be in direct contact with the
   pharmaceutical preparations.
   **Closure** is the device by means of which container can be opened and closed.

(c) | **What are qualities of good container?** The container should be:
   i. Neutral
   ii. No interaction.
   iii. Stability against environmental factor.
   iv. Withstand wear and tear during handling.
   v. Easy to remove dose.
   vi. Withstand changes in pressure and temperature.
   vii. Labeled easily
   viii. Non-toxic.
   ix. Closure easily removable/replaceable.

(d) | **What is difference between filtration and clarification**
---|---
| Marking Scheme |
| 12| Marks |
| (2M) |
| (1M) |
| (0.5 X 2= 1M) |
| (2M) |
| (1+ 1) |
| (2M) |
| 0.5x4=2 |
| 2M |
Filtration may be defined or separation of a solid from fluid by means of porous medium that retain the solid but allows fluid to pass.

Filter paper is used
Different filter media are used
Intention of filtration may be the collection of filter cake.

Clarification
When solids are in small amount (less than 1%), the process is usually spoken as clarification.
Talcum is used.
No filter media is used
Intention of Clarification may be the collection of filtrate.

(e) Give application of freeze drying.
   (i) The process is mainly used for drying of biological products such as antibiotics, blood products, vaccines, enzymes preparation, microbiological cultures etc.
   (ii) The heat sensitive material can be dried.

(f) What are advantages of water as menstruum for extraction?
   • It is cheap & easily available.
   • Non-toxic
   • Non inflammable.
   • It has wide solvent action.

(g) What are advantages of evaporating still?
   • It is simple to construct.
   • Easy to clean and maintain.
   • The vapors are condensed in it. It increases the speed of evaporation and the costly solvent can be recovered. E.g. ethyl alcohol.
   • As vapors are condensed there is no chance of discomfort to the operator.
   • A vacuum pump can be fitted to the condenser for operation under reduced pressure.

(h) Calculate the quality of dextrose required to prepare one quart of 5% solution.
   \[
   \begin{align*}
   \text{Mass of dextrose} &= \text{Volume of solution} \times \text{Concentration} \\
   &= 1 \text{ quart} \times 5\% \\
   &= 0.5 \times 4 = 2 \text{ M}
   \end{align*}
   \]
Q.2 (i) 4.375 gr. in 1 fl ounce = 1% w/v solution
   4.375x5(21.874 gr.) in 1 fl ounce = 5% w/v solution
   21.874 gr. in 1 fl ounce = 5% w/v solution

   ? gr. in 40 fl ounce = 5% w/v solution  [As 1 quart = 40 fl ounce]

   21.874x40/1 = 875 gr in 40 fl ounce = 5% w/v solution

   Solution: Dextrose required is 875 gr in 40 fl ounce (1 quart) is required

   Or

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

   Therefore, 4.375 x 40 x 5 = 875 grain [As 1 quart = 40 fl ounce]

   Draw a labelled diagram of double cone blender

   [Diagram of double cone blender]

Q.2 (a) Attempt any FOUR of the following

   2M
### Define the following terms:

**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 forms*- Dosage form is a transformation of a pure chemical compound into a predetermined form by admixing drug components with non drug components.

**iii)** *Excipients*: The excipients are used to give a particular shape to the formulation & to increase stability & also to increase its palatability as well as to give more elegance to the preparation OR

These are the ingredients which along with Active Pharmaceutical Ingredients make up the dosage forms. Eg. suspending agent, emulsifying agent etc.

### Define Aerosols. What are advantages and disadvantages of Aerosols?

Aerosols may be defined as disperse phase system in which very fine solid particles or liquid droplet gets dispersed in the gases which act as continuous phase.

These are pressured packages.

#### Advantages:

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

#### Disadvantages:

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

**Working (1M)**
1. The material which is to be size reduced is fed in the grinding chamber from the bottom through the feed inlet.
2. The air or inert gas is introduced with a very high pressure through nozzles.
3. Due to high degree of turbulence, impact and attritional forces between the particles there is size reduction.
4. The air moves at a very high speed in elliptical part carrying with it fine particles that pass through the outlet in a classifier and are collected.
5. The large particles are carried by centrifugal force to the end whereby they are further exposed to the moving air.
6. The design of the mill provides for the internal classification of the particles whereby lighter, finer particles are discharged and heavier particles are retained due to effect of centrifugal force to be reduced to smaller size.
7. Feed should be of 20 to 200 # size & mill produces particles of 1 to 30 micron range to get a very fine powder even upto 5µ, the material is pre-treated to reduce the particle size to the order of 100# and then passed through fluid energy mill.

**Advantages (0.5x2=1mark)**
1. No contamination of the product.
2. An arrangement is made for classification in mill.
3. Suitable for heat sensitive material such as vitamins & antibiotics.
4. It is used to grind the material to fine powder.
5. Up to 6000 kg of feed can be milled per hour.

**Disadvantages (0.5x2=1mark)**
1. Not suitable for soft, tacky and fibrous materials.
2. The equipment is expensive, because it needs additional accessories.
3) Pre-milling of material is necessary

**BALL MILL**

**Working:** (1 marks)

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

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

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

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

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

**Advantages** (0.5x2=1mark)

- It can produce very fine particle.
- It can be used continuous operation, if sieve or classifier is attached.
- It is capable of grinding a large variety of material of different character and of different degree of hardness.
• Suitable for wet and dry grinding.
• Used to grind toxic material.

**Disadvantages: (0.5x2=1 mark)**

1) It is a very noisy machine
2) Not suitable for soft and sticky materials.
3) Contamination of product may occur due to particles generated due to wear from balls as well as casing.

---

**Define size reduction. What are different factors affecting to the rate of size reduction?**

Size reduction is the process of reducing drugs into smaller pieces, coarse particles or fine powder.

**Factors affecting size reduction:**

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) **How many tablets, each containing 8.75 grains of mercuric chloride will be required to make one pint of 0.2% solution?**

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

   4.375 gr \times 0.2 = 0.875 gr required to get 1 fl.oz 0.2%

   0.875 gr \times 20 = 17.5 gr required to get 20 fl.oz 0.2%

   17.5 gr \div 8.75 gr = 2 tablets

(f) **Write short note on (any one):**

   (i) **Classification of liquid dosage forms**

   ![Diagram of liquid dosage forms]

   - **Monophasic**
     - External: Gargles, Throat paints, Mouth washes, Throat Sprays, Eye lotions, ear drops, Nasal drops, Douches, Enemas, Liniments, Lotions
     - Internal: Syrup, Elixir, Linctuses, Drop draught

   - **Biphasic Emulsions Suspension**
OR

(ii) Materials used in pharmaceutical closures.

Following are materials used in pharmaceutical closures:

1) Rubber
   - Cork is obtained from the bark of oak tree.
   - Cork is chemically inert and it does not impart any odour or flavour to the product.
   - Not used for liquid preparations because of danger of mould growth.
   - Cork closures are rarely used nowadays & replaced by plastic or rubber closures.

2) Glass
   - Glass closures are ideal but they mostly slip during transportation and handling.
   - Mainly used for reagent bottles in laboratories.

3) Plastic
   - Plastic closures are nowadays commonly used.
   - They are available in various shapes and sizes.
   - They are light in weight and are unbreakable.
   - Plastic closures must be tested for any extractable matter, physiochemical & biological testing.

4) Metal
   - Made from tin plate and aluminum.
   - Aluminum closures are preferred because of their durability and ease of conversion into desired shape.
   - Metal closures can be made pilfer-proof by using a liner.

5) Rubber
   - Rubber is used mainly for the construction of closure meant for vials, transfusion fluid bottles.
   - Rubber, two types natural or synthetic,
Q3  a) Attempt any FOUR of followings:

Differentiate between simple and modified maceration with example. (3.5M)

<table>
<thead>
<tr>
<th>Simple maceration</th>
<th>Modified maceration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Drug along with whole menstruum is used in maceration process</td>
<td>1. Drug along with 4/5th of menstruum is used in maceration process</td>
</tr>
<tr>
<td>2. The period of maceration is 7 days</td>
<td>2. The period of maceration is 2-7 days</td>
</tr>
<tr>
<td>3. Strain off the liquid and press the marc</td>
<td>3. Decant the liquid. Marc is not pressed.</td>
</tr>
<tr>
<td>4. Mix the pressed liquid with the macerate and clarify by subsidence or filtration.</td>
<td>4. Filter the liquid and pass the remaining 1/5th of menstruum.</td>
</tr>
<tr>
<td>5. Final volume is not adjusted</td>
<td>5. Final volume is adjusted</td>
</tr>
</tbody>
</table>

Examples of tincture made by this process are:

6. a. Tincture of Orange
    b. Tincture of Lemon
    c. Tincture of Capsicum

Examples of tincture made by this process are:

6. a. Tincture of Tolu
    b. Tincture of Myrrh
    c. Tincture of Benzoin

b) Define capsule as a dosage form along with its advantages and disadvantages.

**Definition:** (1M)

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

**Advantages of capsules: (0.5 X 3=1.5M)**

1. Drugs having unpleasant odor 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.
c) Disadvantages: (0.5 X 2 = 1M)
1. Hygroscopic drugs cannot be filled in capsule as they make the shell very brittle.
2. Concentrated preparation which needs dilution before administration cannot be given in form of capsule.

What do you mean by enteric coated tablet? Give reasons for enteric coating.

Enteric Coated tablet: (1M)
1. These tablets are coated with the material which does not disintegrate in stomach but passes through as it is i.e. enteric polymer e.g.: Hydroxypropyl methyl cellulose phthalate etc.
2. These tablets dissolve in intestine.
3. These are site specific.

Enteric coating is given to the tablets when: (0.5 X 5 = 2.5M)
1. Medicaments produce severe irritation in stomach.
2. Action required in intestine.
3. Medicament may decompose or destroyed by stomach pH.
4. Drug absorption is better in intestine.
5. Delayed action is needed.

Differentiate filtration and clarification. Enlist the different factors affecting the rate of filtration.

Difference: (0.5 X 2 = 1M)

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Filtration</th>
<th>Clarification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>It is the separation of an insoluble solid from a fluid or gas by means of a porous medium that retain the solid but allow the fluid to pass.</td>
<td>When the solid are present in very small proportion i.e. not exceeding 1.0% the process of its separation is known as clarification.</td>
</tr>
<tr>
<td>2</td>
<td>Different filter media are used</td>
<td>No filter media is used</td>
</tr>
<tr>
<td>3</td>
<td>Intention of filtration may be the collection of filter cake.</td>
<td>Intention of Clarification may be the collection of filtrate.</td>
</tr>
<tr>
<td>4</td>
<td>Filter paper is used</td>
<td>Talcum is used.</td>
</tr>
</tbody>
</table>
### Factors affecting the rate of filtration: \((0.5 \times 5 = 2.5M)\)

1. Area:
2. Pressure:
3. Viscosity:
4. Thickness of cake:
5. Temperature of liquid to be filtered.
6. Particle size:
7. Pore size of filter medium:
8. Nature of solid material:

### How will you prepare 330g of dilute acetic acid from acetic acid IP. \((3.5M)\)

**Given:**

i. Acetic acid IP = 33\% wtr of Acetic acid.

ii. Dilute Acetic acid = 6 \% wtr Acetic acid.

**Solution:**

\[
\text{Volume of dilute solution} \times \frac{\text{percentage of dilute solution}}{100} = \text{Weight of stronger acid to be used}
\]

Percentage used

\[
= 330 \times \frac{6}{33} = 60 \text{ g}
\]

Thus 60g of Acetic acid IP can be diluted with 270g of water to produce 6\% w/w Acetic acid \((60g+270g=330g)\)

### Write short note on (any one)

i. Metafilter.

ii. Additives used in tablet formulation.

**Metafilter:**

**Construction:** \((1.5M)\)

- It consists of grooved, drainage rod on which a number of metallic ring are packed.
- The rings are usually of stainless steel and have 0.8 mm outer thickness, 15 mm inside diameter & 22 mm outer diameter.
- The rings have a number of semicircular projections on one surface and when they are
packed on the rod, the opening between the rings about 0.2 mm.

**Working:** (1M)
- The entire assembly is placed inside a pressure vessel, containing the liquid to be filtered.
- When vacuum is applied liquid will flow from outside to inside.
- In this form a metafilter can only be used as strainer for coarse particle, but for separation of fine particle a bed of suitable material kieselguhr is used.
- In this way pack of ring act as a base on which the fine filtration medium is supported.

**Diagram:** (1M)

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**OR**

**Additives in tablet formulation:** (3.5M)

1. Diluents: To increase the bulk e.g. Lactose, sucrose etc.
2. Disintegrates: To break the tablet e.g. Potato, maize, wheat starch etc.
3. Granulating agents: To make a cohesive mass e.g Starch paste, IPA etc.
4. Glidants: To improve the flow property e.g magnesium stearate & Talc
5. Lubricants: To reduce the friction e.g. Talc & magnesium stearate.
6. Binding agents: Keep tablet intact e.g. gum tragacanth, methyl cellulose etc.
7. Adsorbing agents: Prevent sticking e.g. Mg stearate, stearic acid etc.
8. Colors, flavors and sweetening agents:

Attempt any FOUR of followings:

Differentiate between hard and soft gelatin capsule with example. (0.5 X 7 = 3.5M)

<table>
<thead>
<tr>
<th>SR. NO</th>
<th>HARD GELATIN CAPSULES</th>
<th>SOFT GELATIN CAPSULES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The hard gelatin capsule shell consists of two parts: Body and cap</td>
<td>The soft gelatin capsule shell becomes a single unit.</td>
</tr>
<tr>
<td>2.</td>
<td>They are cylindrical in shape</td>
<td>They are available in round, oval and tube-like shapes.</td>
</tr>
<tr>
<td>3.</td>
<td>The contents usually consist of medicaments in the form of powder, beads or granules.</td>
<td>The contents usually consist of liquids or semisolids.</td>
</tr>
<tr>
<td>4.</td>
<td>These are prepared from gelatin, titanium dioxide, coloring agent and plasticizer.</td>
<td>These are prepared from gelatin, more amount of plasticizer (sorbitol or glycerin) and preservative.</td>
</tr>
<tr>
<td>5.</td>
<td>Filling and sealing takes place in different steps</td>
<td>Filling and sealing are done in a combined operation of machines.</td>
</tr>
<tr>
<td>6.</td>
<td>Shell is perfectly dry.</td>
<td>Shell is not perfectly dry.</td>
</tr>
<tr>
<td>7.</td>
<td>These capsules can be adulterated.</td>
<td>These capsules cannot be adulterated.</td>
</tr>
<tr>
<td>8.</td>
<td>Ex. Amoxicillin capsule</td>
<td>Ex. Pudin Hara capsule</td>
</tr>
</tbody>
</table>

Define tablet as a dosage form along with advantages and disadvantages.

Definition: (0.5M)
Tablets are solid unit dosage form containing medicament or medicaments usually circular in shape and may be flat or biconvex.

Advantages: (0.5 X 4 = 2M)
1. Easy to administered.
2. Easy to dispense.
4. Accuracy in dose.
5. Bitter and nauseous substance can be easily dispensed after coating.
6. Light and compact.
7. Economical.

Disadvantages: \(0.5 \times 2 = 1M\)
- 1. Amorphous drugs or low density drugs resist compression.
- 2. Coating increases the cost.
- 3. Slow dissolution thus not suitable in emergency.
- 4. Bioavailability is low.
- 5. Bitter-tasting drugs, moisture sensitive drugs requires coating.

c) What do you mean by reserved percolation? Enlist different steps involved in it.

Reserve percolation: \(2M\)
- In this process a part of percolate, generally \(\frac{3}{4}\)th volume of the finished preparation is reserved (contains high solute concentration).
- Then the percolation process is continued till the drug is completely exhausted.
- The percolate is subjected to evaporation or distillation to convert it to soft extract.
- Distillation will help to recover the costly solvent.
- Hence the major portion of active constituents of the drugs are saved from deterioration.
- This soft extract is dissolved in reserve portion of percolate and sufficient menstruum is added to make up the volume.
- **Stages involved in reserved percolation: \(0.5 \times 3 = 1.5\)**
  - a. Imbibition,
  - b. Maceration,
  - c. Percolation,
  - d. Distillation or evaporation.

3.5M

D) Explain the different steps involved in sugar coating of tablet.

Steps of sugar coating of tablet:- \(3.5M\)
- Sieving
- Sealing

\(3.5M\)
- Sub-coating
- Syrup coating
- Finishing
- Polishing

i) **Sieving** :- The tablets to be coated are shaken in a suitable sieve to remove the fine powder or broken pieces of tablets

ii) **Sealing** :-
- Sealing is done to ensure that a thin layer of water proof material, such as, shellac or cellulose acid phthalate is deposited on the surface of the tablets.
- The shellac or cellulose acid phthalate is dissolved in alcohol or acetone & its several coats are given in coating pan.
- A coating pan is made up of copper or stainless steel.
- The pan is rotated with the help of an electric motor.

iii) **Sub coating** :-
- In sub coating several coats of sugar & other material such as Gelatin, Acacia etc. are given to round of tablet and to help in building up to tablet size.
- Several coats of concentrated syrup containing acacia or gelatine are given.
- After each addition of the syrup, dusting powder is sprinkled.
- The dusting powder is a mixture of starch, talc & powdered acacia.

iv) **Syrup coating** :-
- This is done to give sugar coats, opacity & color to tablets
- Several coats of the syrup are applied
- Coloring materials & opacity agent are also added to the syrup
- The process of coating is repeated until uniform colored tablets are obtained

v) **Finishing** :-
- Three to four coats of sugar are applied in rapid succession without dusting powder and cold air is circulated to dry each coat. Thus forms a hard smooth coat

vi) **Polishing** :-
- Beeswax is dissolved in volatile organic solvent & a few coats of it are given,
The finished tablets are transferred to a polishing pan and rotated at a suitable speed so the wax coated tablets are rubbed on the canvas cloth.

This gives a proper shining to the tablets.

**How will you prepare 180g of cmehona powder containing 6% alkaloid from the three lot of powder containing 10%, 8% and 3% alkaloid? (3.5M)**

1. For 10%:
   12 : 3
   180 : ?
   \[180 \times \frac{3}{12} = 45 \text{ ml.}\]
2. For 8%:
   12 : 3
   180 : ?
   \[180 \times \frac{3}{12} = 45 \text{ ml.}\]
3. For 3%:
   12 : 6
   180 : ?
   \[180 \times \frac{6}{12} = 90 \text{ ml.}\]

**ANS:**

180 g of powder containing 6% alkaloid can be obtained by mixing 45g of 10%, 45g of 8% and 90g of 3% of alkaloids.
f) Write short note (any one)
   i. Filter aid.
   ii. Ayurvedic dosage form.

Filter aid
Definition: (1M)
These are the substance which reduces the resistance of filtrate to flow.

Objective: prevent the blocking of filter medium by forming open porous cake.

It is used mainly for clarification in the concentration of 0.1 to 0.5% before filtration.

Ideal qualities of filter aid: (0.5 X 3 = 1.5M)
1. It should be remain suspended in the liquid.
2. It should be free from impurities.
3. It should be inert.
4. It should have a particle size distribution suitable for retention of solid.
5. It should have structure that permits formation of porous cake.

Filter aid Material: (0.5 X 2 = 1M)
1. Cellulose.
2. Asbestos.
3. Carbon.
4. Diatomaceous earth.
5. Perlite

OR

Ayurvedic dosage form:
Classification: (1.5M)

**LIQUID DOSAGE FORMS** – Examples: Swarasa, arka etc

**SEMISOLID DOSAGE FORMS** - Examples: Avaleha, lepa etc

**SOLID DOSAGE FORMS** - Examples: Churna, vati etc

Description: (1 X 2 = 2 M)
1. Anjan: These are medicated fine powder intended to be used in eye for their local effect. To relieve pain especially in the head.
2. Arakas: These are distilled essences or liquors made by soaking drug in water for 24 to
48 hours and then distilling the same. Distilled collected is called Arakas.

3. Aristas: These are weak alcoholic preparations prepared by making a decoction of the drugs and then allowing them to undergo fermentation by the help of raw sugar or honey. The fermentation is done for a period of 7-10 days in hot weather and for 15-30 days in cold weather.

4. Asavas: These are medicated alcoholic liquors prepared by the fermentation of raw vegetables juices with honey or jiggery or treacle. The various parts of the plants such as root, leaves and bars etc. are cut into pieces and infusion is prepared in water in airtight or earthen jars. Honey or treacle is mixed in it. The fermentation is done for at least six months.

5. Avalehas: These are thick extracts of the drugs. The decoction of the drug is prepared and after straining it is again boiled down to a thick soft consistency with sugar or honey. In case sugar is used in the preparation, the quantity used should be four times that of the drugs, whereas in case of jiggery, its quantity should be twice that of the drugs. Avalehas are used for digestive troubles, respiratory problems and as a general tonic.

6. Bhasmas: These are ashes which are prepared from vegetables and mineral substances. The vegetable drugs are cut into a coarse powder or pieces and then burnt till they are completely reduced to ashes. The mineral ashes are prepared from metals. The metals are first subjected to purification by treatment with oil, fat free curd and cow’s urine. The purified mass is oxidized and then subjected to a process of roasting. The roasted mass is reduced to a fine powder. Ashes are also prepared from various animal products such as hart’s horn, pearls and cowries etc.

7. Churnas: These are powdered mixtures prepared by mixing dry mineral, animal or vegetables substances in a pestle mortar. The powdered mixture is then passed through cloth, linen or fine sieve. In case jiggery is to be mixed with powder, it should be equal to the quantity of churan and in case of sugar, it should be double the quantity of churan. Churnas are usually taken with milk, hot water and cow’s urine. Churnas are usually given in bulk. Its action is quick but its effect is only temporary.

8. Ghan: It is a semi-solid preparation, prepared by evaporation of the quaths to
semisolid consistency. Ghans are meant for converting quaths to tablets or pills.

9. Ghritas: These are medicated ghees or clarified butter. The ghrita or clarified butter is heated on a fire to remove water. A little turmeric juice is then added to purify it. The purified ghrita is melted with a gentle heat in earthen pot, copper or iron pan and then mixed with the medicinal paste and decoctions of medicines to be used. It is then boiled with gritas till the water content gets evaporated and it is free from the froth. It is then strained through cloth and preserved for use. It is meant for internal use.

10. Gutikas: These are large pill. These are prepared from the pill mass. The pill mass is prepared by reducing a decoction of vegetable substances to a thick consistency and then mixed with powdered medicines, raw sugar, honey, gum, guggal etc. The pill mass is then converted into pill pipes and finally converted into gutikas.

11. Kalkas: It is a paste which is prepared by grinding dry or fresh whole vegetable substances, moistened with water on a flat stone or slab with a muller. It is then mixed with honey, ghee or oil which should be double the quantity of the drug. In case sugar or jiggery is to be mixed, its proportion should be the same as that of the drug.

12. Kanjika: It is a sour liquid produced from the fermentation of powdered paddy (Brassica juncea) and other grains. It is a clear transparent fluid with an acid taste and vinous smell. It is cooling, useful as a drink in fever and burning of the body etc.

13. Ksharas: Medicinal plants or herbs or specified parts of them are wholly or completely burnt and their ashes are allowed to dissolve or mix in the water. It is filtered and then evaporated to a fine white residue, which is called Kshar. This is very effective preparation used in liver and spleen ailments.

14. Kshirpaka: It is a decoction in milk which is prepared by boiling one part of drug in 8 parts of milk and 32 parts of water till the milk alone remains. The decoction is then strained.

Q5 a) Attempt any FOUR of the following:

Differentiate between Active and Passive Immunity along with examples.

14M

0.5 X 7 = 3.5M
## Active Immunity

1) Antigens are injected in the human body as result antibodies are formed.  
2) it develops slowly  
3) it remains for longer time  
4) the treatment is preventive  
5) Immunological memory is present  
6) Not useful in Immune-deficient hosts  
7) Ex : Vaccines, toxoids

## Passive Immunity

1) Readymade antibodies are injected in the human body  
2) it develops quickly  
3) it remains for the short period  
4) the treatment is therapeutic  
5) immunological memory is absent  
6) Useful for immune-deficient host  
7) Ex: Sera

### b) Define microencapsulation. What are its advantages and different techniques involved in it?

**Microencapsulation** : it is the technique in which a thin coating is applied on the particles of solids, liquids, resulting in the formation of micro-capsules ranging from micron to 5000 micron

**Advantages:**

1) It is useful to mask the taste of bitter drugs.  
2) used in the formation of sustained release dosage form  
3) used in the separation of incompatible materials  
4) Used for the protection of drugs against moisture, oxygen etc.  
5) used in the conversion of liquid to Solid

**Techniques:**

Microencapsulation is generally carried out by Coacervation/ Phase inversion technique. Commonly used techniques are as mentioned below:


### c) Define Drying. What are different factors affecting to the rate of drying?

**Definition:** Final removal of liquid from the solid with the help of heat is called drying.
Factor affecting the rate of drying:

Following factor can affect the rate of drying:

1) Surface area of material: increase in surface area leads to increase in rate of drying.
2) Rate of heat transfer by increasing airflow, temperature gradient.
3) Moisture content of the material: time taken for drying will be more if the moisture content is more.
4) Time and temperature: High temperature with less time drying will takes place without degrading the material.
5) Difference in humidity (Hs-Hg) between surface layer and atmospheric: if difference is more rate of drying will be fast.

Differentiate between Evaporation and Distillation and explain the working and application of simple distillation.

<table>
<thead>
<tr>
<th>Evaporation</th>
<th>Distillation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Free escape of vapors from the surface of liquid below its boiling point.</td>
<td>1) Process of converting liquid into vapors by heating and reconverting again into liquid by condensing the vapors.</td>
</tr>
<tr>
<td>Evaporation takes place even at room temperature</td>
<td></td>
</tr>
<tr>
<td>2) liquid is heated below its boiling point</td>
<td>2) Liquid its heated at its boiling point</td>
</tr>
<tr>
<td>3) Vapors are formed at the surface of the liquid</td>
<td>3) Vapours are formed throughout liquid</td>
</tr>
<tr>
<td>4) Vapors formed are not usually collected</td>
<td>4) Vapours formed are condensed and collected</td>
</tr>
<tr>
<td>5) Recovery of solvent is possible in few methods</td>
<td>5) Recovery of solvent is always done</td>
</tr>
<tr>
<td>6) used for the preparation of Conc. Liquid, Soft and dry extract.</td>
<td>6) Used for separation of volatile oil</td>
</tr>
</tbody>
</table>

Working of Simple Distillation:

It involves simple equipment like an evaporating still, for vaporization of liquid, and condenser. Usually a glass assembly is used for this purpose. The distillation flask has a side
### Applications of Simple Distillation:

1. It is used for the preparation of Distilled water and Water for Injection.
2. Many Volatile oils and aromatic water are prepared by simple distillation.
3. Organic solvents are purified by distillation.
4. Many official Compounds are prepared by distillation. E.g.: spirit of nitrous ether and aromatic spirit of ammonia.
5. Concentration of liquid and to separate non volatile solid from the volatile liquid such as alcohol and ether.

**Find the concentration of sodium chloride required to make 1% w/v/solution of cocaine HCl iso osmotic with blood plasma.** *(Given: F.P. of 1% w/v Cocaine HCl = -0.09 °C, F.P. of 1% w/v NaCl Solution = -0.576 °C)*

**Ans:**

\[
\text{F.P. of 1% w/v Cocaine HCl} = -0.09 \, ^\circ \text{C} \\
\text{F.P. of 1% w/v NaCl Solution} = -0.576 \, ^\circ \text{C} \\
\text{Freezing point of 1% NaCl} = 0.576 \\
0.52 = \text{Constant to prepare the isotonic solution}
\]

**Formula:** \(\%\text{w/v of adjusting sub needed}=0.52-a/b\)

**Calculation:**

\[
\text{% w/v Nacl required} = 0.52 - (0.09 \times 1)/0.576 \\
= 0.746 \, \% \text{w/v}
\]

### Write short note on any one

1. **BCG Vaccine:**
   - It is freeze-dried preparation containing live culture of the bacillus Calmette and Guerin strain of *Mycobacterium tuberculosis*.

2. **Silverson mixer homogenizer:**
Method of 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°C and 8°C. The reconstituted vaccine should be used immediately after its preparation.

Uses: Immunizing agent which provides protection against tuberculosis.

Silverson Mixer Homogenizer

Construction:
1) It consists of emulsified head which is covered with fine meshed stainless steel sieves.
2) Emulsifier head consist of number of blades which rotate at very high speed to produce powerful sharing action.
3) Blades are rotate by using an electric motor fitted at the top.

Working:
1) Emulsifier head is placed in the vessel containing immiscible liquid in such a way that it should get dipped into it.
2) When the motor is started liquid is sucked through fine holes and oil is reduced into fine globules due to the rotation of blades.
3) So fine emulsion is produce which is then expelled out.

Use:
Useful for the preparation of fine emulsion and suspension.

Diagram:
Attempt any four of the following

Differentiate between sterilization and Disinfection. Enlist the different methods of sterilization.

<table>
<thead>
<tr>
<th>Sterilization</th>
<th>Disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is the process of complete destruction of microorganisms present in the system</td>
<td>It is process that removes infection potential by microorganisms</td>
</tr>
<tr>
<td>In case of sterilization spores are destroyed</td>
<td>Spores are not destroyed</td>
</tr>
<tr>
<td>Sterilization done by using any physical or chemical or mechanical method</td>
<td>Disinfection is done by using disinfectants</td>
</tr>
<tr>
<td>Ex : Ethylene dioxide</td>
<td>Ex : Phenol cresol</td>
</tr>
</tbody>
</table>

Different methods of Sterilization:

I. Physical methods

1. Dry heat sterilization
2. Moist heat sterilization
3. Radiation sterilization

i) Use of U.V rays ii) Ionizing radiation
II. Chemical methods
1. Sterilization by heating with bactericide
2. Gaseous sterilization

III. Mechanical methods
1. Ceramic filters
2. Seitz filters
3. Sintered glass filters
4. Sintered metal filters
5. Membrane filters

b) Define immunity. What are the different types of immunity?

**Definition:** Immunity is the power of body to resist effect of invasion of microorganisms.

Types of immunity

- Natural Immunity
- acquired Immunity

1) age
   - Active
   - Passive
2) Race
   - Natural
   - Artificial
3) Species
4) Individual

**Active Immunity** - Antigens are injected in human body; as a result antibodies are formed.
- It develops slowly
- Remains for longer time
- Treatment is preventive

**Passive Immunity** - Readymade antibodies are injected in human body.
- It develops quickly, it remains for short period treatment is therapeutic

c) Define size separation. How will you grade the powder according to IP 1985.

**Definition:**
- It is technique used to separate particles of specified size.
- Different grades of power according to IP 1985.
MODEL ANSWER
SUMMER– 17 EXAMINATION

Subject Title: PHARMACEUTICS-I

1) Coarse powder—it is the powder of which all the practices pass through sieve no.10 and not more than 40% pass through sieve no.44
2) Moderately coarse powder—it is powder of which all particles pass through sieve no.22 and not more than 40% pass through sieve no.60
3) Moderately fine powder—it is powder of which all the particles pass through sieve no.44 and not more than 40% pass through sieve no.85
4) Fine Powder—it is powder of which all particles pass through sieve no.85
5) Very fine powder—it is powder of which all particles pass through sieve no.120

Explain the objectives of mixing. Explain the different types of mixtures.

Objective of mixing:
1) To form a uniform mixture.
2) To promote chemical reaction to get uniform product
3) Help in formation of suspension/paste
4) Help in mixing of water and oil e.g. emulsion.

Different types of mixtures:
1) Positive Mixture—When two/more miscible liquids are mixed or soluble solid is dissolved in water, the mixtures are called as positive mixture e.g. Solution. It is irreversible.
2) Negative Mixture—Two immiscible liquids are mixed or insoluble solids are mixed with water it forms negative mixture. E.g. emulsion, suspension, mixtures. It is reversible.
3) Neutral Mixture—The substances do not have tendency to mix but once mix, don’t separate after mixing. E.g. ointment, paste, cream.

Find the concentration of NaCl required to produce a solution iso-osmotic with blood plasma (Given Mol.wt of NaCl=58.5, NaCl is ionizing substance and get dissociates into 2 ions)

Data Given:
Mol.wt of NaCl=58.5
NaCl is ionizing substance and get dissociates into 2 ions,
So,
Formula=W=0.3/N
<table>
<thead>
<tr>
<th>f) Write short note on (any one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. Cyclone separator.</td>
</tr>
<tr>
<td>ii. Fluidized bed dryer.</td>
</tr>
</tbody>
</table>

**Cyclone Separator**

**Principle:** Centrifugal force

**Construction:**
1) Cyclone separator is a size separation device
2) It consists of a cylindrical vessel with a conical base.
3) The upper part of the vessel is fitted with a tangential inlet and a fluid outlet.
4) At the base it is fitted with a solid outlet

**Working:**
The suspension of a solid gas (Usually air) is introduced tangentially at a very high velocity so that rotary movement takes place within the vessel. The fluid is removed from a central outlet at the top. The rotator flow within the cyclone separator causes the practices to be acted on by centrifugal force. The solid are thrown out to the walls. There after it falls to the conical base and discharge through the solid outlet.

**Diagram:**

---

Solution = 0.3 × 58.5/2

= 8.8 gm per/lit.

\[ W = \frac{8.8}{100} \text{ g/100 ml.} \]
**Fluidized bed dryer**

**Construction** –
1) Dryer consists of conical vessel with perforated bottom into which material is placed.
2) Filter bags are fitted to conical vessel above which fan is fixed.
3) There is an inlet for air and outlet for air.
4) Fluidizing air stream is created by means of fan which is placed at upper part of dryer.
5) Filtered and heated air then pass through powder bed.
6) Filter bags are provided to trap the fines producing during drying.

**Advantages**-
1) High rate of drying.
2) Suitable for heat sensitive material.
3) Economic.
4) Efficient for free flowing.
5) Use for drying of granules.

**Disadvantages**:
1) High air velocity causes friction of particles.
2) Due to turbulences fines are produced.
3) High friction between practices generate electrostatic charges.

**Diagram:**

![Diagram of Fluidised Bed Dryer](image)