

# Pharma Unit



## Pharmaceutics Top 15 IMP Questions with Answers

### According To PCI New Syllabus ER -2020

#### 1) Define pharmacopoeia? write about Indian pharmacopoeia in detail?

**Ans.** Pharmacopoeia is the standard book which helps in formulating the drugs. The book is published in almost every country under the authority of its own government.

Pharmacopoeia is derived from Greek word Pharmakon – Drugs, Copoeia - Means to make

##### **Indian Pharmacopoeia (IP)**

The Indian Pharmacopoeia is published by the Indian Pharmacopoeia commission (IPC) on behalf of the ministry of health and family welfare Government of India. Indian Pharmacopoeia Headquarter is in Ghaziabad (Uttar Pradesh). Indian Pharmacopoeia commission (IPC) is regulated by Ministry of Health and Family Welfare. Indian Pharmacopoeia is written in English and official title of monographs given in Latin.

**1st Edition :-** The first attempt to publish in India's own book of standard was made in 1946. The Indian pharmacopoeia list contain a list of drugs which were of medicinal value. For the preparation of pharmacopoeia of India, the pharmacopoeia of other countries like British, Europe United States, Japan, national formulary, and Merck index were also used. The first edition of Indian pharmacopoeia was published in 1955 by the controller of publications Delhi on the behalf of government of India and ministry of health and family welfare. It was written in English and official titles of monographs were in Latin. It covered 986 monographs.

**2nd edition :-** The second edition of Indian pharmacopoeia was published in 1966 under the chairmanship of Dr. Nityanand. The official titles of monographs were in English. In all 274 monographs from IP 1955 and their supplements were deleted and 93 new monographs were added.

**3rd edition :-** The third edition of Indian pharmacopoeia was published in 1985 under the chairmanship of Dr. Nityanand. This edition of Indian pharmacopoeia published in two volumes as volume one and volume two which included total of 261 new monographs were added and 450 monographs were deleted.

**4th edition :-** 4th edition of IP was published in 1996 which contain 1149 monographs including 291 new monographs and 110 monographs were deleted and the titles of 142 monographs was changed. 4th edition of IP was also presented in two volumes:- Volume 1 and volume 2. Volume one contains the monographs from alphabet A to O and volume 2 contain the monograph from alphabet P to Z.

**5th edition :-** The 5th edition of IP was published in 2007 by Indian pharmacopoeia Commission in Ghaziabad. The 5th edition of pharmacopoeia was presented in 3 volumes. 5th edition of pharmacopoeia included those herbal drugs which had supporting quality control standards. Monographs on vaccines Sera for human use, blood and blood related product, biotechnological product were also added.

**6th edition :-** The 6th edition of IP was published in 2010 by IPC Ghaziabad. This IP was also presented in three volumes volume 1 contain notices, acknowledgments, introduction, and general chapters. Volume 2 contain the monographs on dosage form, drug substance, pharmaceutical aids from A to M whereas the volume 3 contain the monographs on drug substance dosage form and pharmaceutical aids from N to Z.

**7th edition :-** The 7th edition of IP was published in 2014 and was presented in 4 volumes with DVD. It was released by Ghulam Nabi Azad under the chairmanship of PK Pradhan. In this edition 2548 monographs of drugs were added, 19 new radiopharmaceutical monographs were also added. Separate volume of veterinary product with 143 monographs were also added.

**8th edition :-** The 8th edition of IP was published in 2017 but made effective from 1st January 2018. This IP was also presented in four volumes, 220 new monographs were also added, and 7 monographs were omitted.

#### 2) Write about salient features of Indian pharmacopoeia?

**Ans.**

##### **Salient features of Indian pharmacopoeia**

###### **1st edition**

1. The titles of monographs have been given in Latin language
2. The weights and measure have been given in metric system
3. Doses of the drugs are expressed both in metric system as well as in English system
4. A list of preparation has been given at the end of some of the monographs

### 2nd edition

1. Doses of the drugs are expressed only in metric system
2. The title of the monographs have been changed from Latin to English
3. The title of the monographs were also modified for example Injection of aminophylline have been changed to aminophylline injection
4. In Sterility testing the testing of aerobic and anaerobic bacteria was also added

### 3rd edition

1. The analytical method Such as flame photometry was also included
2. Dissolution test has been included for certain tablets
3. Modified disintegration test has been included
4. Microbial limit test has been prescribed for certain preparation
5. Pyrogen test was also revised to make it less time consuming
6. Name of some drug was renamed

### 4th edition

1. It contains 1149 monographs
2. It was presented in two volumes
3. The computer-generated structural formula was also introduced
4. Some title of the drugs was renamed
5. Infrared and ultra-red absorption spectrophotometric test was also included for some drugs

### 5th edition

1. This addition was presented in three volumes
2. The use of chromatographic method has been extended
3. The test for pyrogens involving the use of animal was eliminated

### 6th edition

1. The number of monographs of excipients, anti-cancer drugs herbal products and anti-retroviral drugs has been increased
2. Monographs of vaccines immune sera are upgraded

### 7th edition

1. This edition was presented in four volumes
2. The drugs which were not in used were omitted option
3. It included 2548 monographs of drugs

### 8th edition

1. This edition was presented in four volumes
2. The use of chromatographic method was extended

## 3) Define packaging materials with examples and explain different types of packages?

**Ans.** Packaging is a process in which the pharmaceutical products are suitably and safely placed so that they can retain their therapeutic effectiveness until they are consumed by patients. Pharmaceutical package is an important part of pharmaceutical product, it is defined as a device which contains the pharmaceutical product, and the container may or may not be in direct contact with the product

Examples :- Aluminium, Tin, Lead, Natural rubbers, Silicone rubber, Butyl rubber, Chlorobutyl rubber, Neoprene rubber, Nitrile rubber, etc.

Types of packages

### 1. Primary package 2. Secondary package 3. Tertiary package

**1) Primary package:-** The primary packaging material consist of those packaging components Which have direct contact with the pharmaceutical formulations. The main function of the primary package is to protect the pharmaceutical formulation from any chemical, climatic, biological or any mechanical damage.

Example:- Aerosol cans, Plastic bottles, Glass bottles, Wrappers, Blister and Strip packed medicines, Envelopes, etc.

**2) Secondary package :-** The packaging external to the primary package is called as secondary package. This package provides additional physical protection which is necessary during storage. Secondary package also includes the information about the drugs which is present in primary package.

Examples:- Boxes, cartons, Leaflets, Shrink wraps, etc.

**3) Tertiary package :-** Tertiary packaging is used for the transportation of pharmaceutical products in bulk form. Tertiary packaging also used for the storage of pharmaceutical products in large amount. Tertiary package not only use for the transportation of drug in bulk amount, but it also provides protection to secondary as well as primary packaging of drugs

Examples :- Barrels, Large cardboard boxes, large containers, etc



#### 4) Give advantages and disadvantages of glass, plastics, metals, and rubbers?

**Ans.**

##### **Advantages of glass**

- 1) Glass protects pharmaceutical product from environmental conditions such as temperature, light, etc.
- 2) They are transparent in nature so we can easily identify the product by the looking at the color.
- 3) They are available in various shapes and sizes.
- 4) Glass can be available easily.
- 5) They are impermeable to water, gases, and vapors.
- 6) They can be labelled easily.
- 7) They do not deteriorate with age.
- 8) They are strong enough to handle any pharmaceutical product.
- 9) They can be easily sealed to provide hermetic protection.
- 10) During sterilization the glass can withstand with high temperature and pressure.

##### **Disadvantages of glass**

- 1) Glass is expensive to manufacture.
- 2) Glass has tendency of shedding some part of the silica into pharmaceutical formulations.
- 3) Glass is heavy thus it increases the transportation cost.
- 4) Glass is fragile, so it has tendency of breaking or cracking.
- 5) Glass container may release some chemical to aqueous pharmaceutical product if it is not treated properly before manufacturing.

##### **Advantages of plastics**

- 1) Plastics are easy to manufacture
- 2) Plastics are easy to recycle
- 3) Plastics are available in different qualities
- 4) Plastics are economical in nature
- 5) Plastics have sufficient mechanical strength
- 6) Plastics are unbreakable in nature
- 7) Plastic is preferred over other packaging materials
- 8) Plastics are non-fragile and light in weight
- 9) Plastics have good sealing properties

##### **Disadvantages of plastics**

- 1) Sometimes the properties of plastic may change with ages.
- 2) Plastic cannot withstand high heat
- 3) Disposable plastics which are used for packaging of pharmaceutical products are harmful with environment.
- 4) Sometimes plastic may change the color of pharmaceutical products

##### **Advantages of metals**

1. Metals are strong to handle any pharmaceutical product
2. Metals are suitable for pressurized packaging
3. Metals have excellent temper resistance container
4. Some metals are light in weight so the transportation cost will low
5. They are unbreakable
6. They are impermeable to light moisture and gases
7. Metals are easy for labelling

##### **Disadvantages of metals**

1. Metals are expensive
2. Some metals are heavy so transportation cost will be high
3. Metals may show some chances of toxicity
4. Metals are reactive to certain chemicals
5. Some metals have shedding properties

##### **Advantages of rubber**

1. Rubber is easy to use
2. Rubber is inexpensive
3. Rubber have good elastic property
4. Rubber have ability to be removed easily from a material
5. Rubber is very soft and stretchable
6. Rubber can with stand high temperature and pressure during sterilization

##### **Disadvantage of rubber**

1. Most of the rubbers have bad odor
2. Materials of rubber have tendency to migrate in the pharmaceutical product
3. Rubbers are incompatible with some of the chemical during storage
4. They are bad conductor of heat

## 5) Write a note on preservatives?

**Ans. Preservatives** :- A preservative is a natural or synthetic substance that is added to pharmaceutical products to prevent decomposition by microbial growth or by undesirable chemical changes. Preservatives inhibit the growth of bacteria, yeast and molds that can cause disease.

### Ideal properties of preservatives

1. It should be non-toxic.
2. It should protect the pharmaceutical product from microbial growth.
3. It should be chemically stable.
4. It should produce the desired effect.
5. It should not change the chemical nature of the drug.
6. It should give its effect in small quantities i.e., potent.

### Types of preservatives with examples and uses :-

#### 1) Based on mechanism of action :-

**A) Antioxidant** :- The agents that prevent oxidation of drugs are called as antioxidants

Examples :- Vitamin E, Vitamin C, Butylated hydroxytoluene, Butylated hydroxyanisole, etc.

Uses :- antioxidants such as vitamin E are used as preservatives in pharmaceutical products to protect the drug from oxidation and deterioration. They are used in concentration of 0.001-0.05%.

**B) Antimicrobial Agents** :- The agents that prevent or kill the microbes are called antimicrobial agents

Examples :- sodium benzoate, methyl paraben, propylparaben, etc.

Uses :- Antimicrobial agents such as Methylparaben is used in almost all types of pharmaceutical formulation, it may be used either alone or in combination with other parabens. Methylparaben is most effective against yeast and molds.

Propyl paraben as a preservative is used in cosmetics such as creams, lotions, shampoos, and soaps. It is also used in food as preservatives.

Sodium Benzoic is used as preservative in concentration of 0.02 to 0.5% in oral medicines, 0.5%

In parenteral products and 0.1 to 0.5% in cosmetics

**C) Chelating Agents** :- These are the agents which form the complex with the pharmaceutical ingredients and prevent degradation of pharmaceutical products.

Examples :- Disodium ethylenediamine tetra acetic acid(EDTA), Poly phosphates, citric acids, etc.

Uses:- EDTA is used as a preservative for pharmaceutical products.

#### 2) Based on source :-

**A) Natural Preservatives** :- These are the substances obtained from natural sources such as plant minerals and animals.

Examples :- neem oil, sodium chloride, lemon, honey, etc

Uses :- Natural preservatives are used to protect the drug from microbes.

**B) Artificial Preservatives** :- These are the preservatives prepared by chemicals that are effective in small concentrations.

Examples :- benzoates, sorbates, nitrites, etc.

Uses :- Artificial preservatives are used in almost all the drugs to prevent deterioration of drugs from microorganisms during storage.

## 6) Describe construction working and application of hammer mill and ball mill?

**Ans.**

### Hammer mill

A hammer mill is an essential machine in pharmaceutical industries, it is used to reduce the size of material.

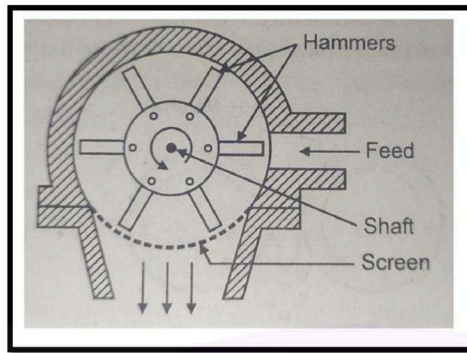
#### Principle

It operates on the principle of impact i.e.; the size of material is reduced when the material is hit by a moving object at high speed.

#### Construction

1. It consists of metal casing enclosing a central shaft to which four or more swinging hammers are attached the hammers are sharp and very hard.
2. The lower part of casing consists of screen through which material is passed and collected out when a desirable degree of size reduction is achieved.
3. The shaft is rotated with electric motor.
4. In hammer mill one opening is also present which is called as feed through which the material is added for size reduction.
5. The speed of motor is 1000 to 5000 rpm.





#### Working

1. Whole hammer mill is started by using electricity
2. The material is put into the hopper which is passed into hammer mill through feed
3. The material is reduced to small size due to fast rotation of hammers
4. When material achieves the desired size passes through the screen

#### Applications

1. Hammer mill can be used to crush play large fibrous materials into small
2. Hammer mill is also used to reduce the size of large brittle material
3. Hammer mill is also used to produce different grades of powders
4. Hammer mill is also used for powdering of leaves, barks, roots

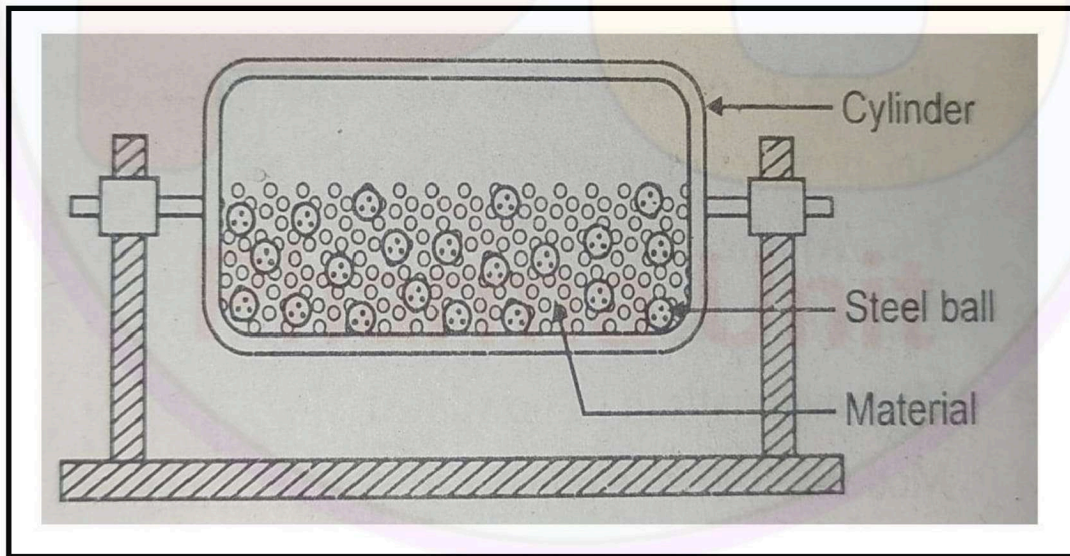
### Ball mill

#### Principle

Ball mill works on the principle of combine impact and attrition. If material is hitted by continuously moving ball then impact mechanism occur, and if material is present in between the two balls the attrition mechanism will occur.

#### Construction

1. It consists of hollow metallic cylinder mounted on a metallic frame rotated on its longitudinal axis
2. The cylinder contains ball made up of steel or rubber which occupy 30 to 50% volume of the cylinder
3. The ball size depends upon the size of mill and diameter of mill, if the size of cylinder is small then the size of ball will also be small and if size of cylinder is big than the size of ball will also be big.
4. The cylinder has diameter of about 1 to 3 meters



#### Working

1. The material or the drugs whose size to be reduced are put into the cylinder of ball mill with the metallic balls.
2. The speed of the rotation is very important in case of ball mill.
3. After putting drugs and balls in the cylinder we must close the cylinder tightly and set the speed of rotation.
4. The speed of rotation is very critical, if the speed is low then the ball will slide over each other and if this speed is very high then the ball is thrown to the wall of cylinder and hence no size reduction will take place. But at optimum and correct speed balls are carried to the top of cylinder and then the ball falls on the material which results in the size reduction.
5. After suitable time when the desired size reduction take place, we stop the machine and the material with balls are taken out from the cylinder and the materials are separated from the balls

### Applications

1. Ball mill are used for grinding of hard solid material
2. Ball mill are also used for grinding of wet pharmaceutical material
3. Ball mills are also used to grind brittle drugs into small and fine particles
4. Ball mill are also used for grinding of ores
5. Ball mills are also used for reducing the size of sticky pharmaceutical material

## 7) Write about principle construction and working of cyclone separator?

**Ans.**

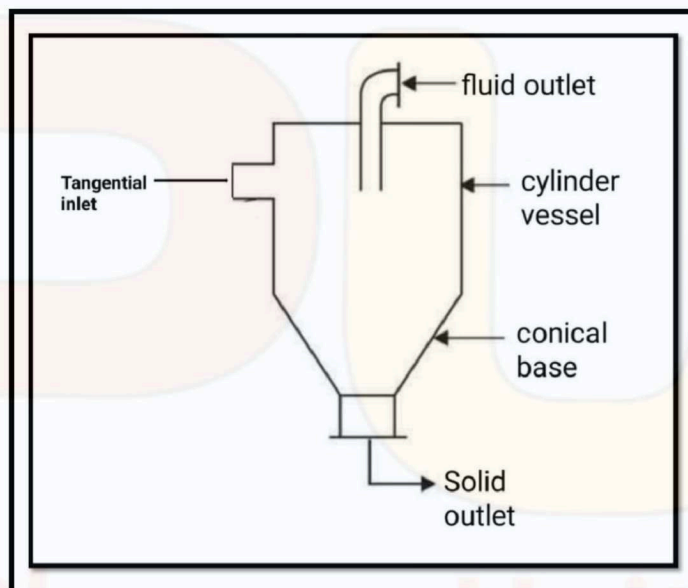
### Cyclone separator

#### Principle

In cyclone separator centrifugal force is used to separate solids from fluid, the separation depends upon particle size and density of particles. Cyclone separator is used to separate all types of particles depending on the fluid velocity, otherwise it can be also used to separate only coarse particles while fine particles are carried out with the fluid.

#### Construction

- 1) It consists of cylindrical vessel with a conical base
- 2) Upper part of vessel consists of tangential inlet
- 3) A fluid outlet is present at the top most position in center of the cylindrical vessel
- 4) Solid outlet is fitted at the base of cylindrical vessel
- 5) Cyclone separator are available in different shapes and sizes



#### Working

The suspension of a solid in gas (usually air) is introduced tangentially through tangential inlet at very high velocity so that Rotary moments take place within the vessel. The fluid is removed from the central fluid outlet present at the top position of the cylindrical vessel; if any fine particle is present then this fine particle is also removed with fluid from the fluid outlet. The Solid particles are thrown to the walls and fall to the conical base of the cylinder and collected through solid outlets.

#### Application

- 1) Separation of suspension of solid in gas or liquid
- 2) It is also used for separation of fine particle from coarse granules

## 8) Describe principle construction and working of double cone blender and triple roller mill?

**Ans.**

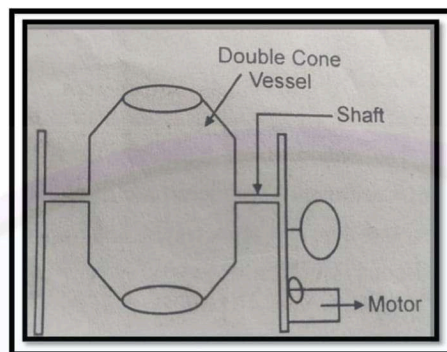
### Double cone blender

**Principle :-** Double cone blender works on the principle of tumbling and shear action i.e., the mixing of powder take place due to tumbling action (Due to rotation of vessel) and shear action with the blades



### Construction

1. Double cone blender is also called as twin shell blender
2. It consists of two cone shaped vessel mounted on a shaft
3. Inside the vessel agitator blades are also present
4. Double cone blender is made up of stainless steel and available in different capacities ranging from 5Kg to 200Kg or more
5. The speed of rotation of double cone blender is about 30 to 100 rpm



### Working

The solid to be mixed is taken in the conical shape vessel. Due to rotation the powder starts to mix. When the vessel starts to rotate the powdered material moves along the side of the vessel and it reaches to the top position then from the top position the powder falls at the bottom of the vessel and thus mixing takes place. As the vessel rotates the material undergoes tumbling motion and agitator blades provide shearing action to the material and mixing takes place thoroughly.

### Application

1. Double cone mixer is used for mixing the powder of different densities
2. It is also used for mixing of granules
3. It is also used for dry powder to wet mixing
4. It is also used for mixing of chemicals which are used in cosmetic products

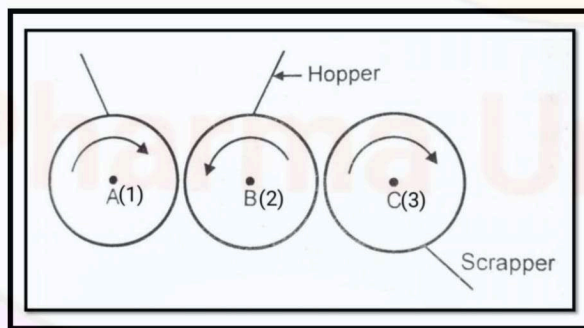
## Triple Roller Mill

### Principle

Triple roller mill works on the principle of compression and shear action

### Construction

1. It consists of three rollers which are made up of hard abrasion resistance material
2. The rollers are arranged in such a way that they can come very close to each other
3. These rollers are rotating at different rate of speed
4. Hopper is attached between 1st & 2nd roller
5. The scraper is attached at 3rd roller
6. The gap between roller 2nd and 3rd is usually less than the gap between 1st and 2nd roller



### Working

The materials to be mixed are put into the hopper. From the hopper the material comes between roller number 1 and 2 and the size of material is reduced in this process. After this the material comes in between roller number 2 and 3, in this step the material becomes more mixed and becomes smoother. After mixing the material is removed with the help of scraper which is present at the roller number 3

### Application

1. Triple roller mill is used for the mixing of solid powder in the ointment base
2. It is also used in the process of ointment, cream and paste making
3. It is also used for mixing of pharmaceutical materials, herbal and chemicals

## 9) Define Tablet write advantages and disadvantages of tablet?

**Ans.**

Tablet is defined as a compressed unit solid dosage form containing medicaments with or without excipients

### Advantages of tablets

1. Accuracy of dose of drug can be maintained
2. Tablet is stable dosage form as compared to other dosage forms
3. The cost of tablets are lower as compared to other dosage form
4. Tablets are easy for transportation
5. Tablets have elegant appearance
6. Tablets have greatest physical chemical and microbial stability
7. Any person can identify tablet easily

### Disadvantages of tablets

1. Tablets are difficult to swallow by small children and unconscious patients
2. Drugs with poor wetting properties are difficult to manufacture as a tablet
3. The drugs which are bitter in taste and have bad odor require special type of coating
4. Tablets requires more time to show their action as compared to other dosage forms

## 10) Discuss different defects in tablet?

**Ans.**

### Defects in tablet

**1. Capping and lamination** :- capping is the partial or complete removal of top or bottom portion of the tablets lamination is the breakdown of tablets in two or more layers

Reasons	Remedies
Excessive fines in granules	By reducing the percentage of fines
Defective punches and dies	Replace defective punches
Excessive drying of granules	Do not dry the granules too much

**2. Chipping and cracking** :- chipping is the defect in which small pieces are broken off from the tablet cracking is the defect in which the tablet is cracked from anywhere

Reasons	Remedies
Due to damaged punches	Setting the dies and punches properly
Excessive fines in granules	By reducing the percentage of fines
Low level of binder	By using proper level of binders
Machine speed	Maintaining the speed of machine

**3. Picking and sticking** :- In some case the material is picked up by the upper punch from the upper surface of the tablet is called as Picking

When material of tablet stick to the wall of dies is called a sticking

Reasons	Remedies
Presence of excessive moisture in granules	Drying the granules properly
Use of less quantity of lubricants	By using proper quantity of lubricants
Defect in dies and punches	By using proper set of punches and dies
Excess of powder in granules	By using proper quantity of powders

**4. Mottling** :- An unequal distribution of color on the surface of tablet with light and dark portion appearing on the tablet is called as mottling

Reasons	Remedies
Difference in color of drug and excipients	Addition of appropriate coloring agent
Color dyes migration to either the small or large granules during granulation process	By reducing drying temperature
Uneven distribution of color	



**5. Weight variation** :- When there is a change in weight of 1 tablet to another tablet is known as weight variation

Reasons	Remedies
Difference in the size of granules	Make the size of granules uniform
Speed of machine	Control the speed of machine
Flow of granules is not uniform from hopper to die	Make sure that the flow of granules is uniform

**6. Hardness** :- It is the change in hardness from one tablet to another tablet. When did tablet do not have sufficient mechanical strength and they do not have uniform hardness and they break easily under pressure

**7. Double impression** :- This defect occurs mostly in the tablet having monogram on the lower punch lower punch moves slightly upward before the removal of tablet and this leads to double impression of monogram on the tablet.

## 11) Write about disintegration and dissolution test for tablet?

**Ans.**

### Disintegration test

Disintegration of tablet means to break the tablet into small particles or granules after swallowing. The time required to break the tablet is called as disintegration time. The test used to record the time of disintegration of tablet is called as disintegration test.

Rate of disintegration of tablet differ from tablet to tablet because of nature of drug and type of tablets. Disintegration time of tablet may vary from one minute to long time up to 30 minutes. Pharmacopeia prescribed a limit of 15 minutes for most of the tablets.

• The official disintegration test is as follows;-

The big integration test apparatus as per Indian pharmacopeia specification consists of;-

1) Disintegration test apparatus uses 6 glass tubes about 3 inches long open at the top and held against 10 mesh screens at the bottom

2) To test for disintegration time one tablet is placed in each tube the tablets are kept immersed in the liquid with the tube.

3) This basket rack is placed in one liter beaker of water, stimulated gastric fluid, or stimulated intestinal fluid t 37 degree Celsius with difference of 2 degree Celsius.

4) Basket rack assembly is suspended soon as that highest point is at least 2.5 cm below the surface of liquid and lowest point is at least 2.5 cm above the bottom of the beaker.

The basket rack assembly should be raised and lowered between 28 to 32 times per minute in liquid. Tablet passes the test if all six tablets have disintegrated in time specified in Indian pharmacopeia if one or two tablet fail to disintegrate the test is repeated on twelve additional tablets and not less than 16 of the 18 tablets must disintegrate.

Disintegration time for coated tablet is 1 hour, Disintegration time for enteric coated tablet;-

Tablet should not disintegrate for two hours in 0.1N HCL (1.2ph) Solution and should disintegrate in alkaline solution (6.8ph) Within one hour

### Dissolution test

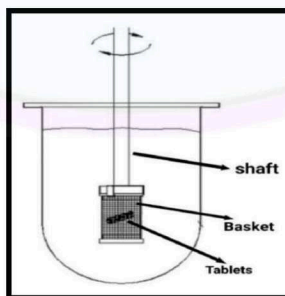
Dissolution is a process in which a solid substance solubilize in a given solvent.

Dissolution test is performed to check the percentage of drug release from the dosage form in the body

Dissolution test is carried out in two types of apparatus i.e., rotating basket apparatus and paddle apparatus.

#### • Design of rotating basket apparatus

- A cylindrical vessel consists of a glass made from borosilicate glass
- The capacity of the class is about 1000 ML
- In rotating basket apparatus one stainless steel basket of 36 mash is present at the bottom of the shaft.
- This basket rotates with the help of shaft at 100 rpm and this shaft is connected with an electric motor

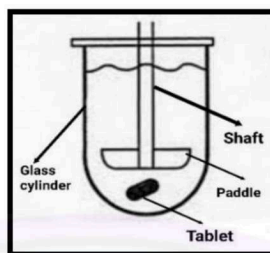


#### • Procedure:-

- A single tablet is placed in a small wire mesh basket attached to the bottom of the shaft connected to a speed motor
- The basket is emerged in a dissolution medium present in 1000ML beaker
- The flask is maintained at 37 degrees Celsius with a difference of 0.5 degree Celsius By a constant temperature bath
- The motor is adjusted so that they basket and shaft rotate at a specific speed and sample of the fluid are withdrawn at interval to determine the amount of drug in this solution

#### • Design of Paddle apparatus

- A cylindrical vessel consists of a glass made from borosilicate glass
- The capacity of the glass is about 1000 ML
- In paddle apparatus one paddle is present at the bottom of shaft this paddle is made up of stainless steel or Teflon.
- This pedal rotates with the help of shaft at 100 rpm and this shaft is connected with an electric motor



#### • Procedure

- A single tablet is placed in glass beaker which contain 1000ml of dissolution medium.
  - The flask is maintained at 37 degrees Celsius with a difference of 0.5 degree Celsius By a constant temperature bath
  - The motor is adjusted so that shaft rotate at a specific speed and sample of the fluid are withdrawn at interval to determine the amount of drug in this solution
- Dissolution test is performed on five tablet the dissolution limit for different tablets have been specified in monograph.

### 12) Define capsule and write about advantages and disadvantages of capsule?

**Ans.**

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

#### Advantages of capsules

1. Capsules are attractive in appearance
2. They are easy to carry and handle
3. They are economical
4. Capsules are available in various shapes and sizes
5. Capsules can be easily swallowed due to its slippery surface
6. Capsules protect the medicament from atmospheric effects
7. The drug which have unpleasant odor and taste can be administered by enclosing the drug in a capsule shell

#### Disadvantages of capsules

1. The hygroscopic drug cannot be filled in capsules because they absorb the water present in the capsule shell and make them brittle which ultimately breaks into pieces.
2. The concentrated preparations which need previous dilution are unsuitable for capsules because it may lead to irritation in the stomach if administered

### 13) Difference between following:-

**Ans.**

#### A) Hard Gelatine Capsule & Soft Gelatine Capsule

Hard Gelatine Capsule	Soft Gelatine Capsule
➤ Hard gelatine capsule shell consists of two parts body and cap	➤ Soft gelatine capsule shell consists of single unit
➤ cylindrical in shape	➤ Round, oval and tube like shape
➤ In hard gelatine capsule powder and granules can be filled	➤ In soft gelatine capsule paste, ointments & creams can be filled
➤ Filling and sealing of hard gelatine capsule can occur in different steps	➤ Filling and sealing of soft gelatine capsule are done in one single step
➤ Shell is completely dried	➤ Shell is not perfectly dried
➤ Eight different types of sizes are available	➤ No specific size is available
➤ Difficult to swallow because the shell is dry and hard	➤ Easy to swallow since the shell are soft
➤ Capsule shell are made up of hard gelatine	➤ Capsule shell are made up of soft gelatine



## B) Suspension & Emulsion

Emulsion	Suspension
1. It is Heterogeneous mixture of two immiscible liquids	1. It is heterogeneous mixture of solid and liquid
2. Dispersed particle do not settle on standing	2. Dispersed particle settle on standing
3. Dispersed particle size is 1 to 1000nm	3. Dispersed particle size is more than 1000nm
4. Particles are not visible through the naked eye	4. Particles are visible through the naked eye
5. It cannot be separated by filtration	5. It can be separated by filtration
6. Emulsifying agent is required	6. Suspending agent is required
7. Freezing should be avoided during storage as it leads to cracking	7. Freezing should be avoided during storage as it leads to aggregation

## C) Syrup and Elixir

Syrup	Elixir
1. Alcohol is not used in syrup	1. Alcohol is used in elixir
2. Sweeter than elixir	2. Less sweet than syrup
3. More viscous than elixirs	3. Less viscous than syrup
4. Amount of sugar is high	4. Amount of sugar is low
5. Syrups are less stable	5. Elixirs are more stable
6. It cannot be used for diabetic patient	6. It can be used for diabetic patient
7. May not be a clear formulation	7. These are clear formulations

## D) Cream and Ointment

Cream	Ointment
1. Quickly absorbed by the skin	1. Not easily absorbed
2. Consistency is lighter	2. Consistency is thicker
3. Less greasy	3. More greasy
4. Cream have a lower concentration of oil than ointment	4. Ointment have a higher concentration of oil than cream
5. Spreading ability is high	5. Spreading ability is low
6. Healing power of cream is fast	6. Healing power of cream is slow

## 14) What is Novel Drug Delivery System? Write Advantages & Disadvantages?

**Ans.** Novel drug delivery system refers to the approaches, formulations, technologies and systems for transporting of pharmaceutical compounds in a body as needed to safely achieve its desired therapeutic effect.

### Advantages

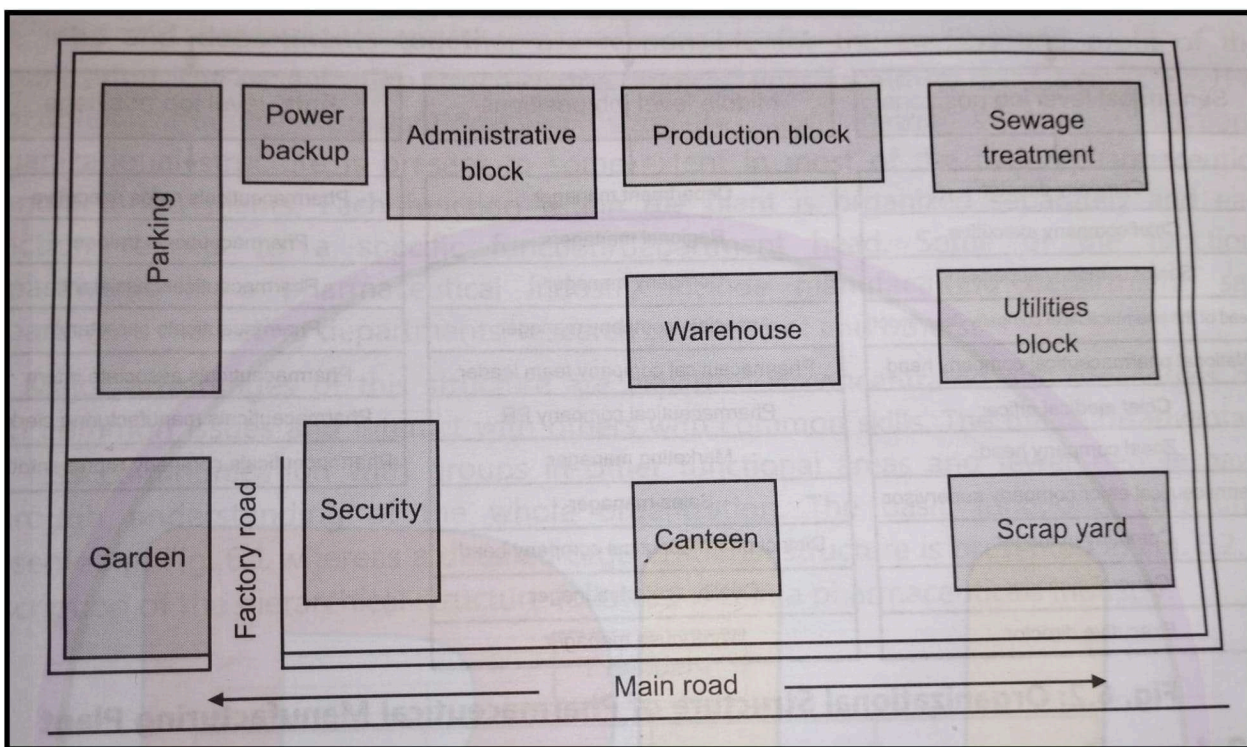
1. Total dose is low
2. This drug delivery system reduces gastrointestinal side effects
3. This drug delivery system reduces dosing frequency
4. It has better patient acceptance
5. The effect of drug is more uniform

### Disadvantages

1. Dose dumping
2. This drug delivery system requires additional patient education
3. This drug delivery system has stability problem
4. Cost of formulation is high

**15) Draw basic structure of pharmaceutical manufacturing plant?**

**Ans.**



### **Very Imp Note :-**

- Please Read All the chapters very carefully before Pharmaceutics Exam
- These questions are only for the reference purpose