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PROCESSING OF TABLETS

Introduction

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

- According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drug or a mixture of drugs, with or without diluents.

Advantages:

- More stable than liquid dosage forms, may have longer shelf –life.
- Portable, easy to handle.
- Better in accuracy & precision of dose.
- Cost is lowest of all oral dosage form.
- Easiest and cheapest to package and strip.

Cont…

- Objectionable odour and bitter taste can be masked by coating technique.
- Greatest chemical and microbial stability over all oral dosage form.
- Sustained release product is possible by enteric coating.

Disadvantages:

- Difficult to swallow in case of children and unconscious patients.
- Disintegration & dissolution of tablets are rate-determining factors for drug absorption & usually they show slow onset of action.
- Slower onset of action than parental dosage form.
- Drugs having low bulk density cannot be formulated into dense compact tablets.
- Tablets cannot be used in emergency cases.

TYPES OF TABLETS

- (A) TABLETS INGESTED ORALLY:

1. Compressed tablet
2. Multiple compressed tablet
3. Multilayered tablet
4. Sustained action tablets
5. Enteric coated tablets
6. Sugar coated tablet
7. Film coated tablet
8. Chewable tablet

Cont…

(B) TABLETS USED IN ORAL CAVITY:

1. Buccal tablet
2. Sublingual tablet
3. Troches or lozenges
4. Dental cone

Cont…

(C) TABLETS ADMINISTERED BY OTHER ROUTE:

1. Implantation tablet

2. Vaginal tablet, e.g. Clotrimazole tablet

Cont…

D) TABLETS USED TO PREPARE SOLUTION:

1. Effervescent tablet
2. Dispensing tablet
3. Hypodermic tablet
4. Tablet triturates

MULTILAYERED TABLETS

LOZENGE TABLETS

BUCCAL TABLET

SUBLINGUAL TABLET

DENTAL CONES

EFFERVESCENT TABLETS

VAGINAL TABLETS

TABLET TRITURATES

TABLETS INGESTED ORALLY

- **Compressed tablet (C.T):** These tablets are uncoated, provides rapid disintegration & drug release. These tablets contains water soluble drugs.
- **Multiple compressed tablets (M.C.T):** To avoid incompatibility, the ingredients of the formulation except the incompatible material are compressed into a core tablet & then incompatible substance along with excipients are compressed over the previously compressed core tablet.
- **Multilayered tablets:** These tablets co r layers of materials compressed succes tablets. These tablets having layers of c known as "multicoloured tablets". These to separate incompatible ingredients phy

Cont..

Sustained action tablets: These tablets gives a sustained action of medicaments. These tablets release the medicaments in a sufficient quty. as & when required to maintain the maximum effective con. of the drug in the blood throughout the period of treatment.

- **Enteric coated tablets:** These tablets are designed in a such a way that it bypass the stomach & get disintegrated in the intestine only. e.g. anthelmentics & amoebicides.
- **Sugar coated tablets :** use for mask the unpleasant odour, taste of the medicament & also protect from the atmospheric effect.
- **Film coated tablets :** Use the polymers for coating purpose such as, HPMC, hydroxypropyl cellulose, ethyl cellulose for protection from atmospheric effect. Those polymers little increases in weight & have less elegance than that of sugar coated tablets & tasteless.

TABLETS USED IN ORAL CAVITY

- **Buccal Tablets:** These tablets are placed in t
betw. the gums & lips. Those tablets m
disintegrate & absorbed directly without
alimentary canal .e.g. tablets of ethisterone

- **ets :** These tablets are place
lve or disintegrate quickly
G.I.T .e.g. tablets of glyceryl trinitrite.
- **& troches :** These tablets are designed to exert a
ne mouth or throat. These tablets are used at sore
hroat or to control coughing in common

- **Dental Cone :** These are minor compressed tablets meant for placing them in the empty sockets after tooth extraction. They prevent the bacterial action by using antib
to reduce bleeding by containing the a
contains lactose, sodium bicarbonate, sodi
tablets dissolved in 20 to 40 mint. time.

TABLETS ADMINISTERED BY OTHER ROUTES

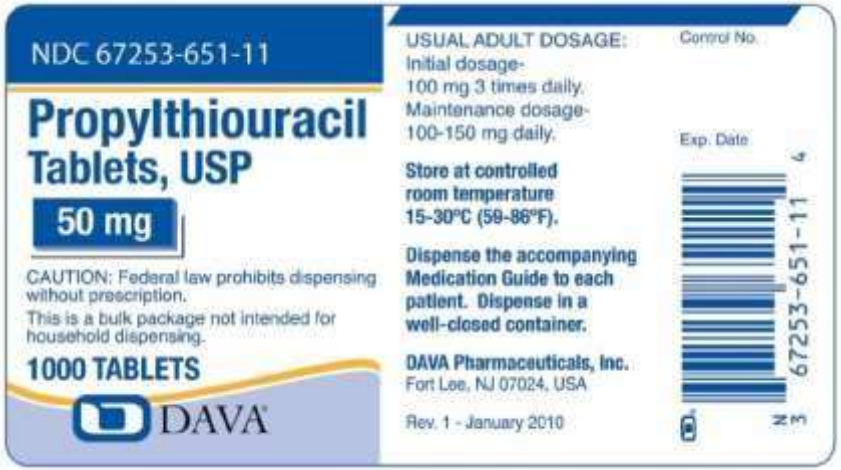
- **Implantation Tablets :** These tablets are placed under the skin by minor surgical operation & are slowly absorbed. The implants must be sterile & should be packed individually in sterile condition. Those are mainly used for administration of hormones such as testosterone etc.

- **Vaginal Tablets :** These tablets are dissolve slowly in the vaginal cavity. These are oval or pear shaped. These tablets used to release steroids, antibacterial agents, antiseptic or astringents to treat vaginal infection.

TABLETS USED TO PRODUCE SOLUTIONS

- **Effervescent Tablets:** These type of tablet in water & produce effervescence due to ch e between alkali bicarbonate & citric acid o combination of both. These tablets should tight containers for prevention of moisture.

- **Dispensing Tablets :** These ta orally. This type of tablets are water to produce a solution of a tablets include mild silver prote merbromin and quarternary a enzyme tablets (Digiplex)



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- **Hypodermic Tablets :** These are compressed tablets which are contains one or more drugs with readily water soluble ingredients. These tablets are dissolved in sterile water or water for injection and administered by parenteral route. So, special precautions are needed to be taken during their preparations. These tablets however are not preferred nowadays because chances that the solution prepared from hypodermic tablets may be a non-sterile.

PREPARATION OF GRANULES FOR COMPRESSION

- The following steps are involved during the preparation of granules:

- **Weighing of the ingredients.**
- **Mixing the powdered ingredients and excipients.**
- **Converting the mixed ingredients into granules.**

Methods of Granules Preparation

- **MOIST GRANULATION METHOD**
- **DRY GRANULATION METHOD**
- **GRANULES BY PRELIMINARY COMPRESSION**

MOIST GRANULATION METHOD

- ✓ API + excipients such as diluents, binding agents, disintegrating agents with q.s. moistened granulating agent.
- ✓ Make a coherent mass.
- ✓ Pass through sieve no. 8 or 10.
- ✓ Dried at 60°C.
- ✓ Then dried granules passed through sieves.
- ✓ Then add lubricating agent, any volatile subst. & mixed well.
- ✓ Ready for compression.

DRY GRANULATION

- Dry granulation process are generally use for those drugs having crystalline properties or for having present in granules & having it's own binding property.
- Those drugs are passed through sieve no.20 or any other specified sieve.
- Then mix with additional excipients such as diluents & lubricants.
- Ready for compression.
- e.g. Aspirin tablets, sodium bromide tabletsetc.

GRANULES BY PRELIMINARY COMPRESSION

- This method is also called as “SLUGGINGMETHOD”.
- This method is used for those drugs which are unstable in presence of moisture.
- In this method firstly dry powder is compressed into large tablets or slugs.
- Then those tablets or slugs broken into small pieces & passed through a specified sieve to obtained a suitable size granules.
- Then mixed with a suitablelubricating , disintegrating & granulating agents.
- Ready for compression.

EXCIPIENTS USED IN FORMULATION OF TABLETS

1. Diluents
2. Granulating agents
3. Binding agents
4. Disintegrating agents
5. Lubricants
6. Adsorbents
7. Colouring agents, Flavouring agents and Sweetening agents.

Cont...

- **DILUENTS :**

- The diluents is needed in the formulation of tablets, when the quantity of medicament in each tablet is very small & it is not possible to make a good tablet.
- **E.g. Lactose, Sucrose, Sodium chloride, Dextrose, Starch, Mannitol, Sorbitol, Calcium sulphate dihydrate, dibasic calcium phosphate dihydrate.**

- **GRANULATING AGENTS :** Those agents converts the fine powder into granules .

- By providing proper moisture to convert fine powder to damp mass.
- **E.g. Water, Alcohol, Mucilage of starch, Mucilage of acacia, Mucilage of tragacanth, Gelatin solution, Iso-propyl alcohol, Acetone etc.**

Cont...

BINDING AGENTS :

- These agents provides good strength to the granules, in order to keep the tablet intact after compression.
- Concentration of binding agents depends upon the type of tablet i.e. In lozenges & implants tablets have very high conc. of binding agents.
- Whereas in other cases where the tablets has to disintegrate quickly in that conc. of binding agent used in lower proportion.
- Binding agents used along withgranulating agents.
- **E.g. Acacia powder, Tragacanth, Gelatin, Sucrose, Methyl cellulose.**

Cont...

DISINTEGRATING AGENT :

- Disintegration agents gives ensured to disintegrate of the tablets into smaller particles when swallowed.
- These agents are used in the formulation of oral or sublingual tablets.
- Those agents divided into two parts, one part is mixed with other excipients before granulation & other part is mixed with the dry granules before compression.
- They act in three ways:

1. By swelling : in contact with water or moisture e.g. maize starch, potato starch, methyl cellulose & bentonite.
2. By producing effervescence : e.g. sodium bicarbonate, citric acid & tartaric acid.
3. They melt at body temperature : e.g. cocabutter.

Cont...

- **LUBRICANTS :** They provide to improve appearance, flow properties & use to prevent the sticking of the materials to the dies & punches.
- Means they play three roles Viz.. Lubricant, Glidants & anti-adhesive agents.
- **E.g Talc, Magnesium stearate, calcium stearate, sodium chloride, Boric acid, Starch, Liquid paraffin, Stearate acid etc.**

- **ADSORBING AGENTS :** These substances are used to adsorb volatile oil, liq.extract & tinctures etc. which are included in the formulation of tablets.

- **E.g. Magnesium carbonate, Kaolin & Starch**

Cont...

- **COLOURS, FLAVOUR & SWEETNING AGENTS:**

- Colours produce elegance effect on tablet.
- Certified F.D & C dyes are used. They mixed with granulating agents or mixed with other ingredients before granulation.
- Flavours are used mainly in Lozenges, effervescent & in chewable tablets.
- Falvouring agents is dissolved in organic solvents & then sprayed on the granules.
- Sweetening agents use to improve the tasteof tablets.
- Now a days artificial sweetening agents are used e.g. Saccharin & Cyclamates.
- Commonly used sweetening agents are Sucrose, Lactose, Mannitol.

COMPRESSION OF GRANULES INTO TABLETS

- The various type of machines used for this purpose, are:

1. Single punch tablet machine which may be hand operated or electrically operated

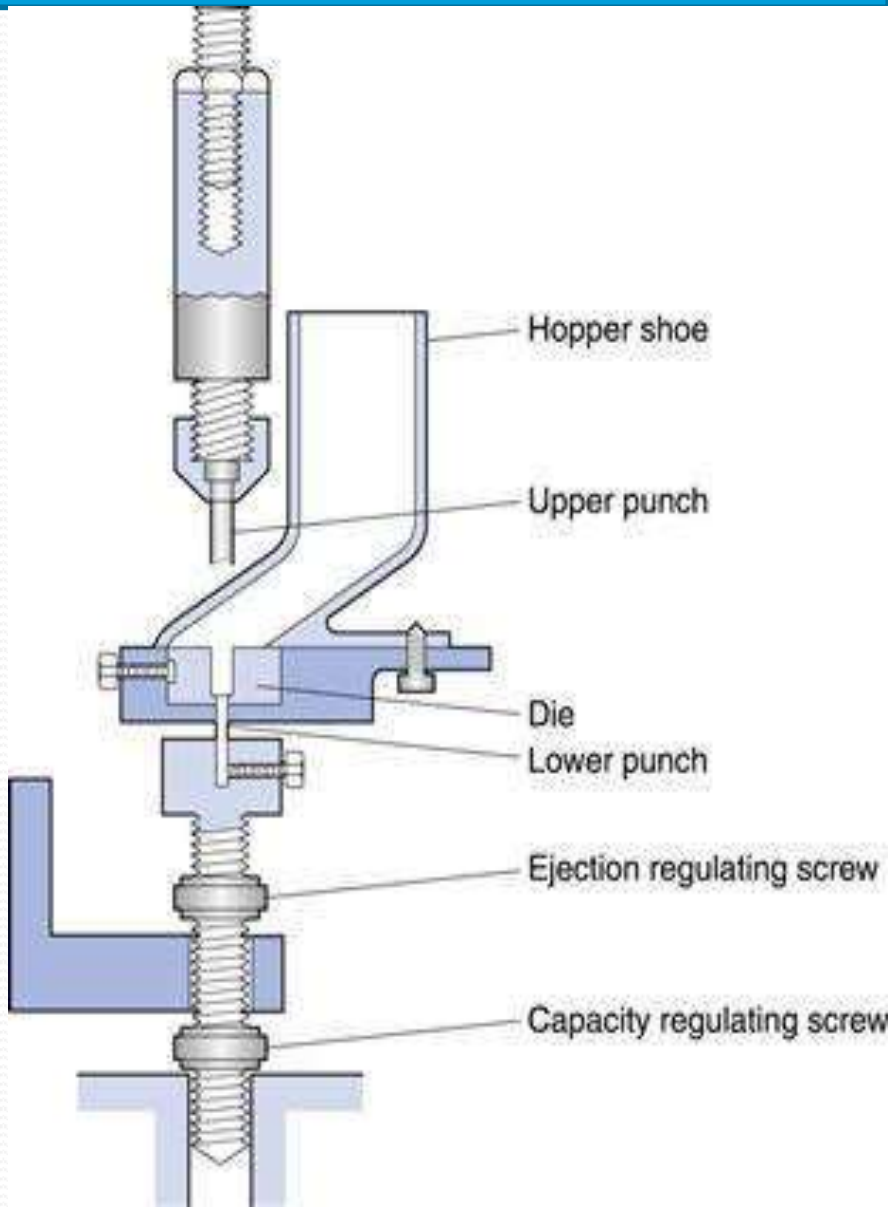
2. Multi-punch tablet machine

3. Rotary tablet machine

4. Dry cota tablet machine

SINGLE PUNCH TABLET MACHINE

- Hopper shoe
- Lower punch
- Upper punch
- Capacity regulator : To adjust the position of lower punch to accommodate the required qty. of granules by the die.
- Ejection regulator
- Die
- Driving wheel



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Working:

- The upper punch rises to allow the hopper shoe to move over the die.
- The lower punch drops & granules feed in the die from the hopper shoe.
- The shoe moves aside & the upper punch drops, thus compressing the granules into a tablet.
- The upper punch rises upward & the lower punch rises upto the surface of the dies to eject the tablet.

Punches & Dies

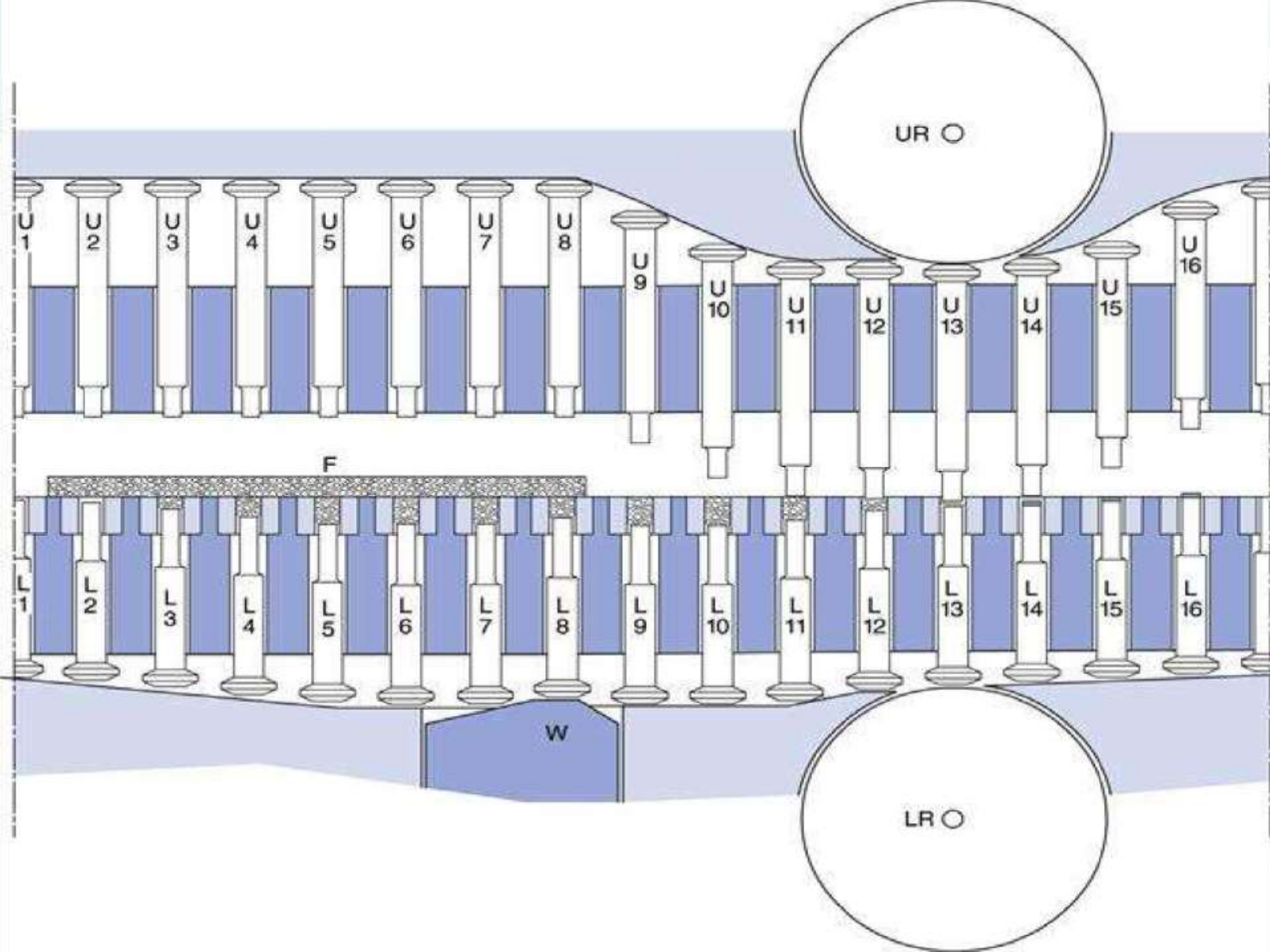
MULTI-PUNCH TABLET MACHINE

- In a multi-punch tablet machine there are 2 to 12 dies on a big platform.

- The working of this machine similar to that of a single punch machine but in this machine one stroke as many tablets are compressed .

ROTARY TABLET MACHINE

- It is used in large scale production unit.
- In this machine 1200 tablets are prepared in one minute.
- There are 70 sets of dies &punches.
- A rotary tablet machine has a circular rotating head, carrying a number of punch & diesassembles.
- There is uniform filling of thedie.
- In that compression of granules takes place as the upper & the lower punches pass between a pair of rollers.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Working...

- Fix the upper & lower punch & dies.
- Then adjust the feed hopper.
- Adjusting the tablet weight & hardness.
- Fill the hopper with granules.
- When the machine starts, the hopper delivers the granules to the dies.
- Then circulate rotating head & compressed the granules with help of upper & lower punch.


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DRYCOTA TABLET MACHINE

- The machine is used for manufacturing of multi-compressed, multi-coloured & press coated tablets.
- In this machine two rotary machines work simultaneously.
- The core tablet is prepared in one machine which is transferred to the second machine for compress coating.

MANUFACTURING DEFECTS IN TABLETS

- CAPPING
- PICKING & STICKING
- MOTTLING
- WEIGHT VARIATION
- HARDNESS VARIATION
- DOUBLE IMPRESSION

CAPPING

- Means, partial or completely remove of top or bottom portion of the tablet.

- **Reasons:**

✓ Excessive fines in granules.

✓ Defective punches & dies.

✓ High speed of tablet machine.

✓ The granules are toodry.

- **Defects can be overcome by:**

✓ Reduce the % of fines

✓ Defective punches should be replaced or polish before use.

✓ Regulate the speed of tablet machine.

✓ Maintain moisture content.

PICKING & STICKING

- Means, picked the material by upper punch & sticking case, stick the material to wall of thedie.
- **Reasons:**

✓ Use of small qty. of lubricants

✓ Defected punch & dies used

✓ Presence of moisture content ingranules.

- **Defects can be overcome by:**

✓ A new set of die & punches.

✓ Use of required qty. of lubricant

✓ Use dry granules.

MOTTLING

- Means, unequal distribution of colours on tablet surface.
- **Reasons:**

✓ Not properly mix colours with granules

✓ Use of different coloration of medicaments& excipients.

✓ Migration of dye in the granules during the process of drying

- **Defects can be overcome by:**

✓ Drying the granules at low tempr.

WEIGHT VARIATION

- **Reasons:**

✓ Granules are not in uniformsize.

✓ No proper mixing of lubricants.

✓ No uniform flow of the granules from the hopper.

✓ Use of excess amount of finepowder.

- **Defects can be overcome by:**

✓ Use of required qty. of lubricant

✓ Reduce the % of fines

✓ Regulate the speed of tabletmachine.

DOUBLE IMPRESSION

- This defect occurs when the lower punch has a monogram or some other engraving on it.
- Due to some defect in the machine, lower punch moves slightly upward before ejection of a tablet & gives second, though light, imprint on thetablet.
- This defect can be overcome by controlling the undesirable movement of the lowerpunch.

COATING OF TABLETS

- **Tablets are coated for following purposes:**

✓ To mask the unpleasant taste and odour

✓ To improve the appearance of tablets

✓ To prevent the medicament from atmospheric effects

✓ To control the site of action of drugs (Enteric coating)

✓ To produce the sustained released product.

- **The tablet coating is generally done by using any of the following processes:**

❖ Pan coating

❖ Press coating

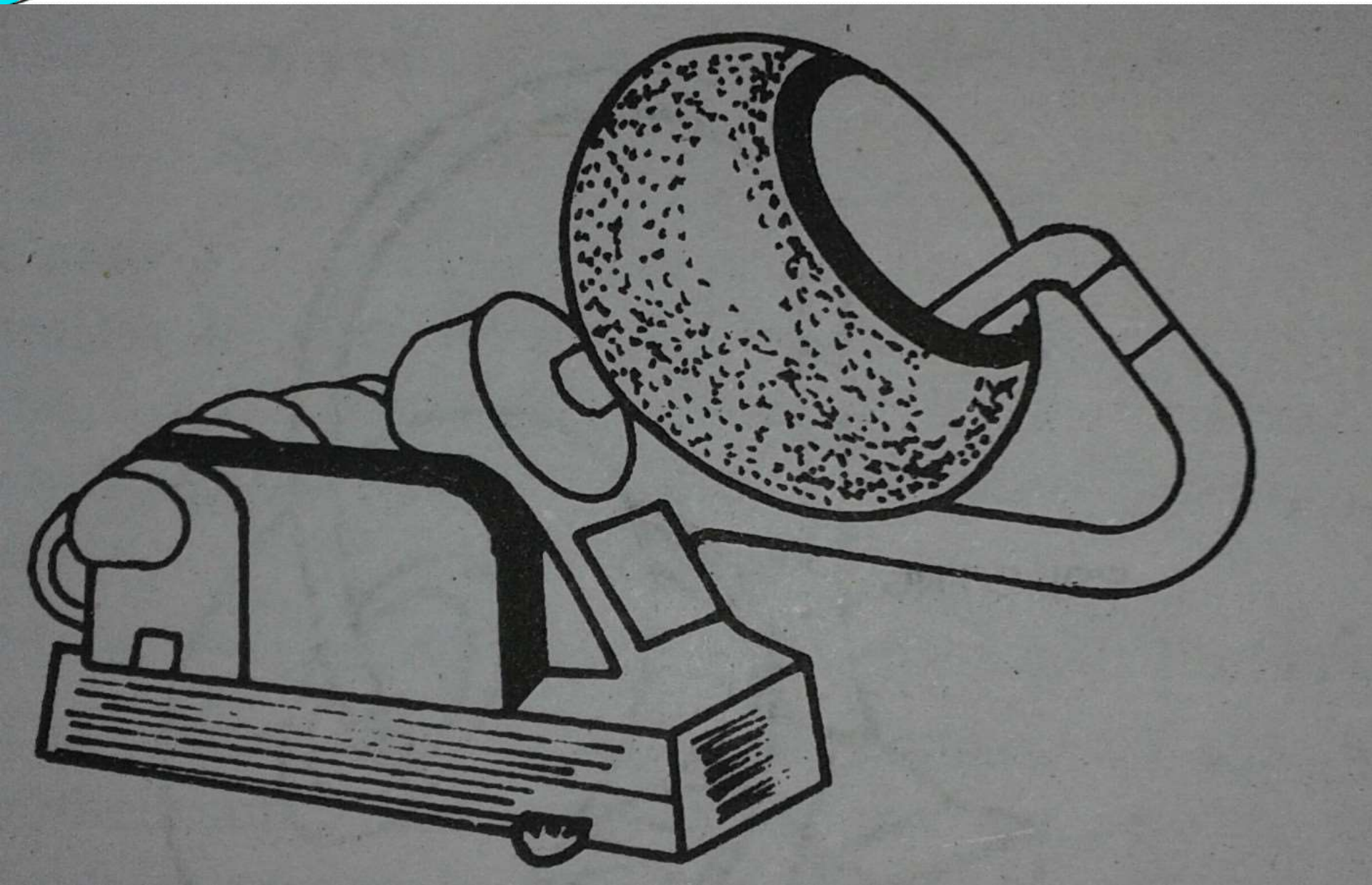
PAN COATING

- In this technique coating is done in pan.
- This pan made up of copper or stainless steel.
- This pan rotated with the help of an electric motor.
- Hot air is blow in & the speed of the pan adjusted in a such a way that the tablet remain separated from each other.
- After coating polishing is done in polishing pan.
- Pan coating technique used for sugar coating, film coating & enteric coating.

PRESS COATING

- In this technique firstly prepared coatingmaterial.
- Then, this coating material spread on performed tablets in a Drycota rotary tablet machine.
- The whole operation is carried out automatically in a number of series.

TABLET COATING PAN



SUGAR COATING

- Sugar coating technique it is the oldest method for mask the taste of tablets.
- But now a days a various stages involved in sugar coating for improving it's aesthetic value.
- The various stages are as follows:

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

Cont..

- **Sieving :** The tablets to be coated are shaken in a suitable sieve to remove the fine powder or broken pieces of tablets.
- **Sealing :** At this stage prepared the water proof layer on the surface of the tablet. This is done by using shellac or cellulose acid phthalate.
- Firstly shellac or cellulose acid phthalate is dissolved in alcohol or acetone & it's several coats are given in a coating pan.
- **Subcoating :** At this stage building up the tablet size by several coats of concentrated syrup containing acacia or gelatin. After each addition of syrup, dusting powder is sprinkled. The dusting powder is a mixture of starch, acacia & talc. Dusting powder does not allow the tablets to stick together. That all process done in coating pan.

Cont..

- **Syrup Coating :** At this stage sugar coat, opacity & colour apply to the tablets.
- Several coats of the syrup with syrup contains coloring material & opacifying agents are applied to the tablets.

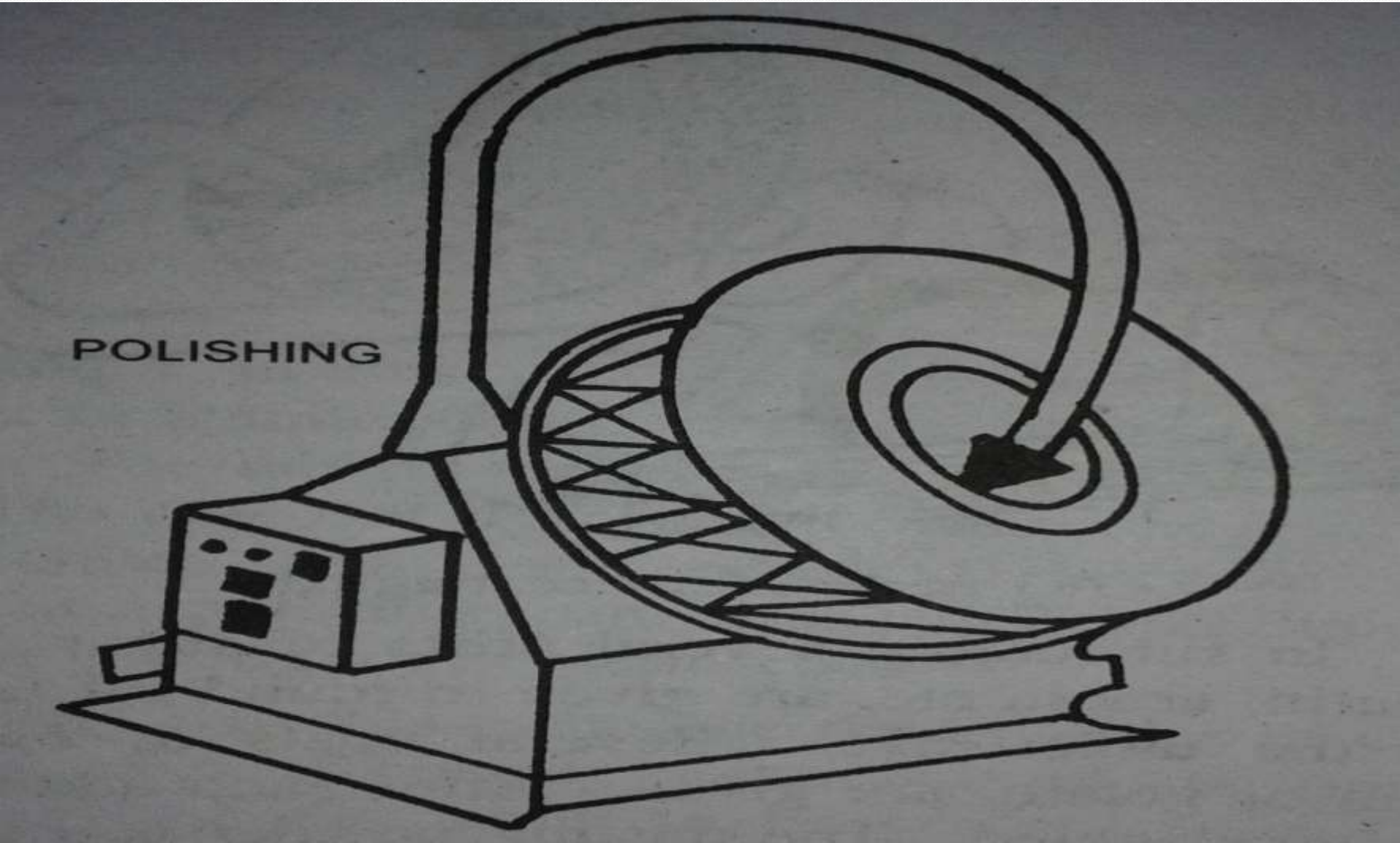
- **Finishing :** Three to four coats of syrup are applied in rapid succession without dusting powder & cold air is circulated to dry each coat. This forms a hard smooth coat.

Cont..

- **Polishing :**

- In that stage, firstly beeswax is dissolved in volatile organic solvent.
- Then this solvent use to polishing on tablets.
- For polishing purpose polishing pan is used, which is made of canvas cloth.
- The polishing pan rotated at a suitable speed so that the wax coated tablets are rubbed on the canvas cloth.
- This gives a proper shining to the tablets.

POLISHING PAN



FILM COATING

- Film prepared or coated by using single or mixture of polymers such as, HPMC, hydroxyethyl methyl cellulose, carbowax, PEG-400 etc.
- In film coating firstly polymers is dissolved in some volatile organic solvent & is sprayed over the tablets in rotating pan or pan coating.
- This process is continue until the a uniform good film is formed over the tablets.
- Film coating is also used to make the tablets water proof before the sugar coating. Film coating can be enteric or non-enteric.

Advantages of film coating

- It protects the drug from atmospheric changes, such as light, air & moisture.
- Coating is resistant to cracking & chipping.
- It does not increases the weight.
- The tablets become elegant.
- Not much labour required.
- It is less time-consuming technique.

ENTERIC COATING

- Enteric coated tablets is given to ensure that these tablets will not disintegrate in stomach but pass in the intestine & get disintegrate.
- Using the rotating pan for coatingpurpose.
- salol, cellulose acetate phthalate, shellac which are dissolved in a volatile organic solvent for coating purpose.
- **Reasons for enteric coating:**

➢ Medicaments produce some irritation in the stomach.

➢ The action of medicaments is required in the intestine e.g. anthelmintics & amoebicides.

➢ Medicaments get decomposed or destroyed by the acidic medium of stomach.

➢ Delayed action is needed.

MICROENCAPSULATION

- Microencapsulation is a technique by which coating can be applied to small particles of solids, droplets of liquid or dispersion thus forming microencapsulation.

- It is different from other coating methods because in that process is used to coat the particles having particle size range from several tenth of a micron to 5000 μ.

- Microencapsulation method based on:

✓ Chemical process (chemical or phase change)

✓ Mechanical process (physical change)

Cont..

- Following techniques are used for microencapsulation:

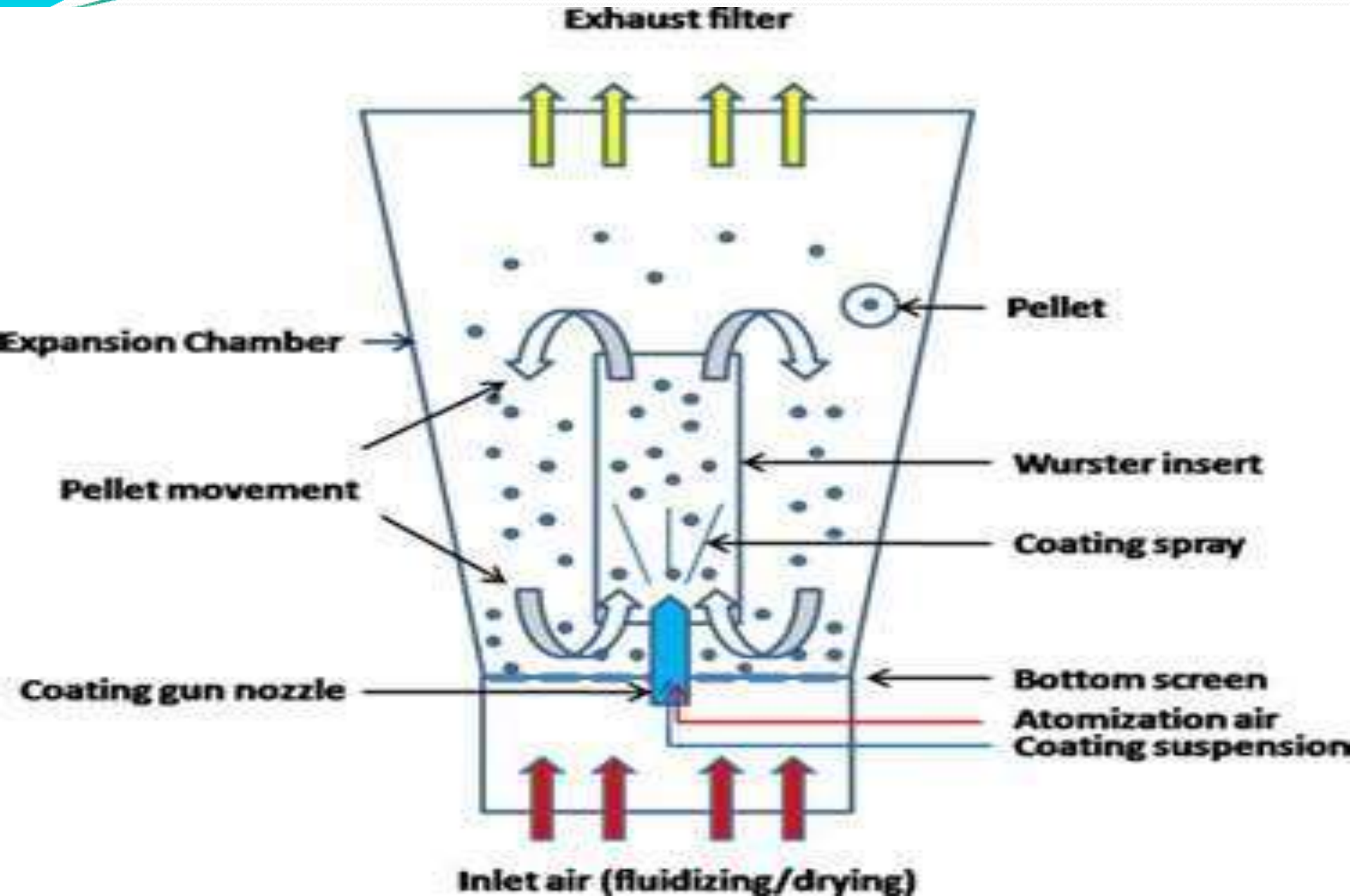
- Pan coating
- Fluidised bed coating
- Coacervation
- Electrostatic deposition
- Vacuum deposition
- Polymerisation
- Multiorifice centrifugal process

Cont..

- **Pan Coating :** This technique is suitable in those cases where the particle size is larger than 600μ. In that API charged on to spherical pellets of sugar & then coated with coating material in coating pan with hot air is circulated simultaneously in order to speed up the drying process.

- **Fluidised bed coating :** In this method solid materials are suspended with turbulent flow of air in a chamber & coating material is introduced in the chamber with help of nozzles. In this chamber the tempe. Is controlled in a such way that the volatile organic solvent is vapourised. After cooling, the heavy solid materials or particles fall on the screen near the outlet form where these can be removed.

FLUIDISED BED COATING



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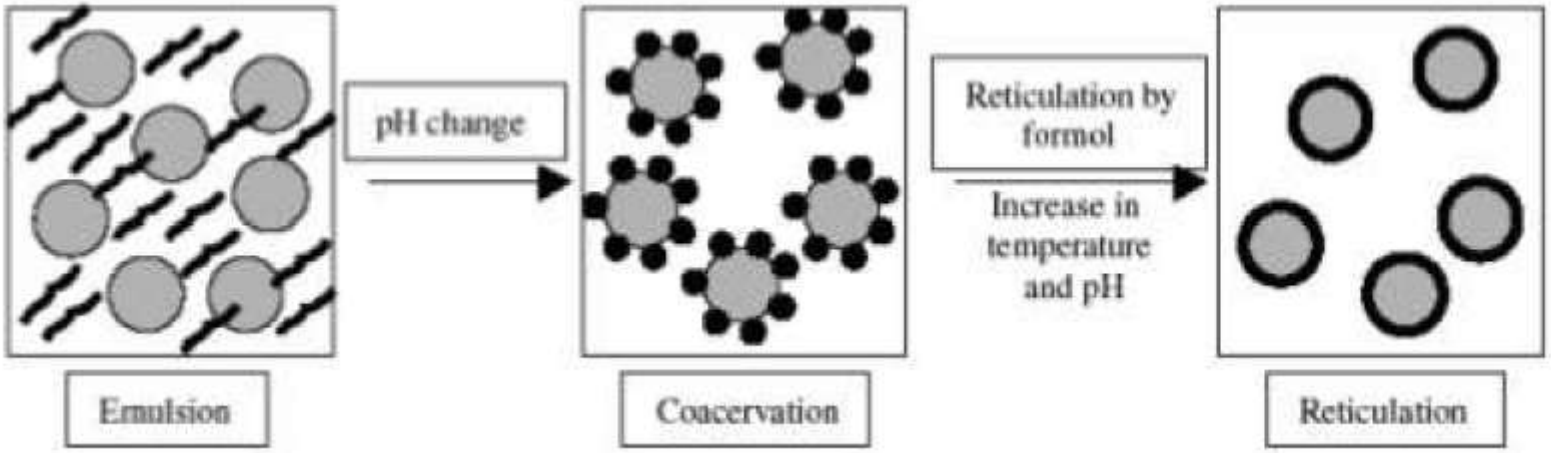
Coacervation : Coacervation means the separation of a liquid or phase when solution of two hydrophilic colloids are mixed under suitable conditions.

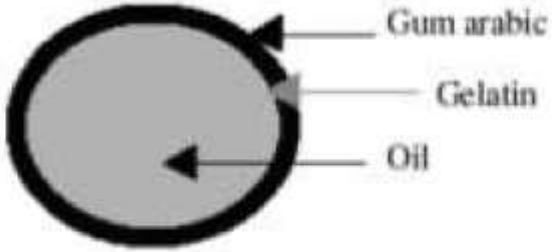
- In this method, the three immiscible phases of core material, solvent and coating material are formed followed by deposition of coating material on the core.

- The coating material is dissolved in a suitable solvent and the core material is uniformly dispersed in the solution of the coating material.

- Then the coating material is phased out of its solution which starts getting deposited on the particles of the core material.

Coacervation Formation





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Electrostatic deposition :

- The method is useful both for solid particles and liquid droplets.
- In this process, the core and coating materials are electrically charged by means of high voltage such as 10,000 volts etc.
- The core is charged and placed in the coating chamber.
- The coating material is also charged before it is sprayed as a mist.
- Because the charges are of opposite kind, the coating material gets deposited on the core due to electrostatic attraction.

Cont..

Vacuum Deposition : In that technique the coating material gets deposited on the core particles & coating material is vaporized undervacuum.

- **Polymerisation :** This is a new technique. In that technique core material is dispersed in a liquid or gas in which monomeric units of the coating material are present. These monomers get polymerised at the interface between core particles & the liquid gas phase which forms coat over the core.

- **Multiorifice centrifugal process :** In that process the particles of the core material are forced through an envelop of coating material in solution by centrifugal force.

Advantages:

- Mask the taste of bitter drug.
- It is used in formation of sustained release dosage form.
- It is used to separate an incompatible material.
- Used to protect drug from moisture &oxidation.

EVALUATION TESTS FOR TABLETS

1. Shape of tablets
2. Appearance
3. Content of active ingredient in tablets
4. Uniformity of weight
5. Disintegration test for tablets
6. Dissolution test for tablets
7. Mechanical strength
8. Friability test

Cont..

- **SHAPE OF TABLETS :** As per pharmacopoeia the shape of a tablet defined as circular with flat or convex face.

- **APPEARANCE :** check the appearance by either a relatively uniform texture. The coated tablets have a smooth surface.

- **CONTENT OF ACTIVE INGREDIENT IN TABLETS :** % of API in case of official tablets are mentioned in the individual monographs. The variation may be due to several factors such as weight, purity of API, errors in preparing granules. In that process carried out assay which are mentioned in IP for specific tablets & those are based on 20 tablets. If 20 tablets are not available at least 5 tablets should be used.

Cont..

% of API in tablets .This table stated limits are between 90% & 110% of medicaments.

Wt. of drug in each tablet	Subtract from the lower limits for sample of			Add to the upper limits for sample of		
	15	10	05	15	10	05
120 mg or less	0.2	0.7	1.6	0.3	0.8	1.8
More than 120 mg & less than 300 mg	0.2	0.5	1.2	0.3	0.6	1.5
More than 250 mg	0.1	0.2	0.8	0.2	0.4	1.0

Cont..

UNIFORMITY OF WEIGHT : This test use to determine the uniform of weight of each tablet in a batch. But small variation in the weight of the individual tablet is liable to occur. Therefore a litter variation is allowed in the weight of a tablet by the pharmacopoeia.

- **wt. of 20 tablets selected randomly & determine their average weight.**

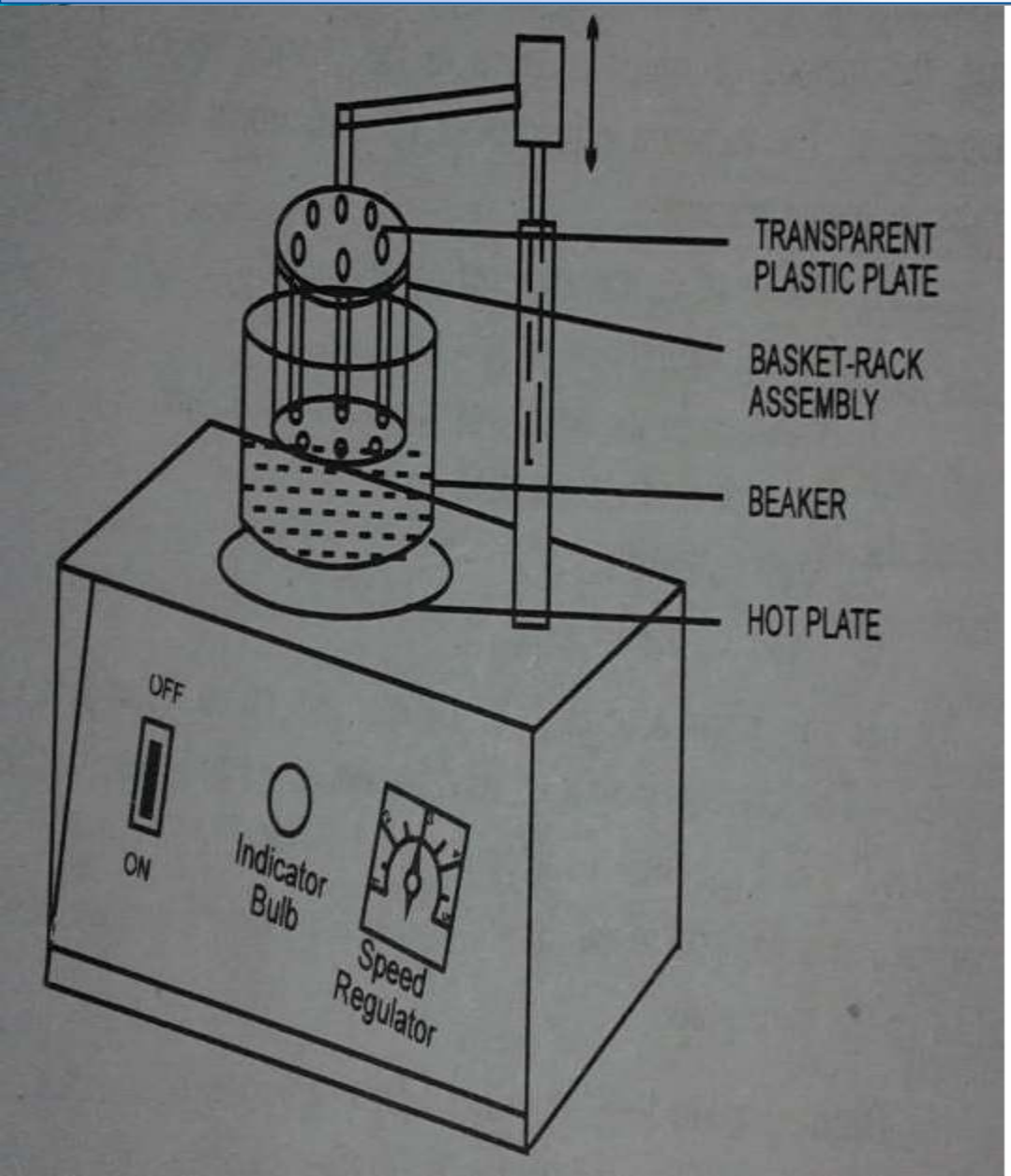
- **Not more than 2 of the individual weight may deviate from the average wt. by more than the % deviation.**

Cont..

Uniformity weight of tablets

Sr.No.	Average weight of a tablet deviation	Percentage
1.	80 mg or less	10
2.	More than 80 mg & less than 250 mg	7.5
3.	250 mg or more	5

DISINTEGRATION TEST FOR TABLETS



DISINTEGRATION TEST FOR TABLETS

- Tablet disintegration test apparatus use for compressed tablets but not use for lozenges tablets.
- Pharmacopoeia specified limit for 15 mint.
- The assembly should be raised & lowered betw. 28 to 32 times per minute in the liquid at 37°C.
- The tablets are kept immersed in the liquid within tube.
- A cylindrical disc is made of transparent plastic having thickness of 9.5 mm & diameter of 20.7 mm.
- The assembly is suspended in the liquid medium in a 1000ml beaker.

Cont..

DISINTEGRATION METHOD FOR UNCOATED TABLETS:

- ✓ Place one tablet in each of the 6 tubes of the basket.
- ✓ Then maintained temp. of water at 37°C.
- ✓ After completion of 15 mints or the specified time in the individual monograph.
- ✓ Observe the tablets .
- ✓ If, one or two tablets are not disintegrate then again repeat the test on 12 additional tablets & observe the tablets.
- ✓ The tablets passes the test if not less than 16 of the 18 tablets tested get disintegrated.

Cont..

- DISINTEGRATION METHOD FOR COATED TABLETS:

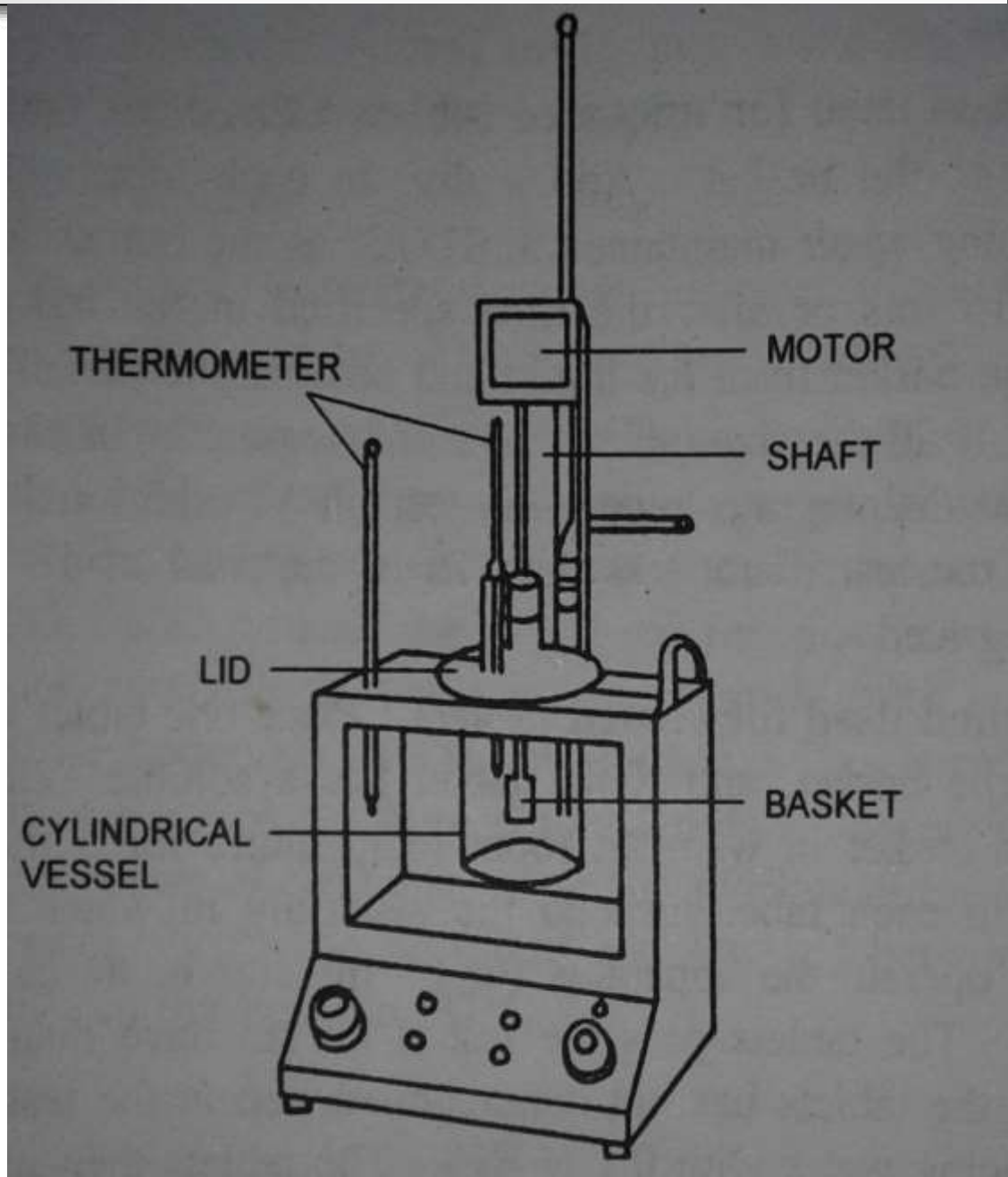
- Place one tablet in each of the 6 tubes of the basket.
- If the tablet has a soluble external coating, immerse the basket in water at room temp. for 5 mint.
- Then add disc to each tube & suspend the assembly in water at temp. 37°C. & operate for 60 mint. or as per monograph.
- If any case tablet has not disintegrate then replace the water with 0.1 N HCl & again add 6 tablets.
- The test is repeated on 12 additional tablets if one or two tablets still to fail disintegrate.
- The tablets passes the test if not less than 16 of the 18 tablets tested get disintegrated.

Cont..

- DISINTEGRATION METHOD FOR ENTERIC-COATED TABLETS:

- ✓ Place one tablet in each of the 6 tubes of the basket.
- ✓ If the tablet has a soluble external coating, immerse the basket in water at room temp. for 5 mint.
- ✓ Then operate apparatus without disc in 0.1N HCl for two hours at 37°C.
- ✓ If no any tablet show to disintegrate or crack then add a disc & operate the apparatus using phosphate buffer pH 6.8 at 37°C. For 60 mints.
- ✓ Then observe the tablets.
- ✓ The test is repeated on 12 additional tablets if one or two tablets still to fail disintegrate.
- ✓ The tablets passes the test if not less than 16 of the 18 tablets tested get disintegrated.

DISSOLUTION TEST FOR TABLETS



Cont..

- Place the 1000ml water or specific solvent mentioned in the monograph into the vessel & those solvent which was previously warmed at 36.5 or37.5°C.
- Place the specified number of tablets in the dry basket.
- Then start the motor & adjust the rotation speed to 100 rpm or as per monograph.
- Withdraw the stated volume of solution from the vessel after 45 mints or as per monograph.
- Then determine the active ingredient present in the solution by the method given in the monograph.
- Repeat the complete operation 4 times.
- The tablet pass the test if the amount of active ingredient in solution is not less than 70% of the stated amount.

MECHANICAL STRENGTH

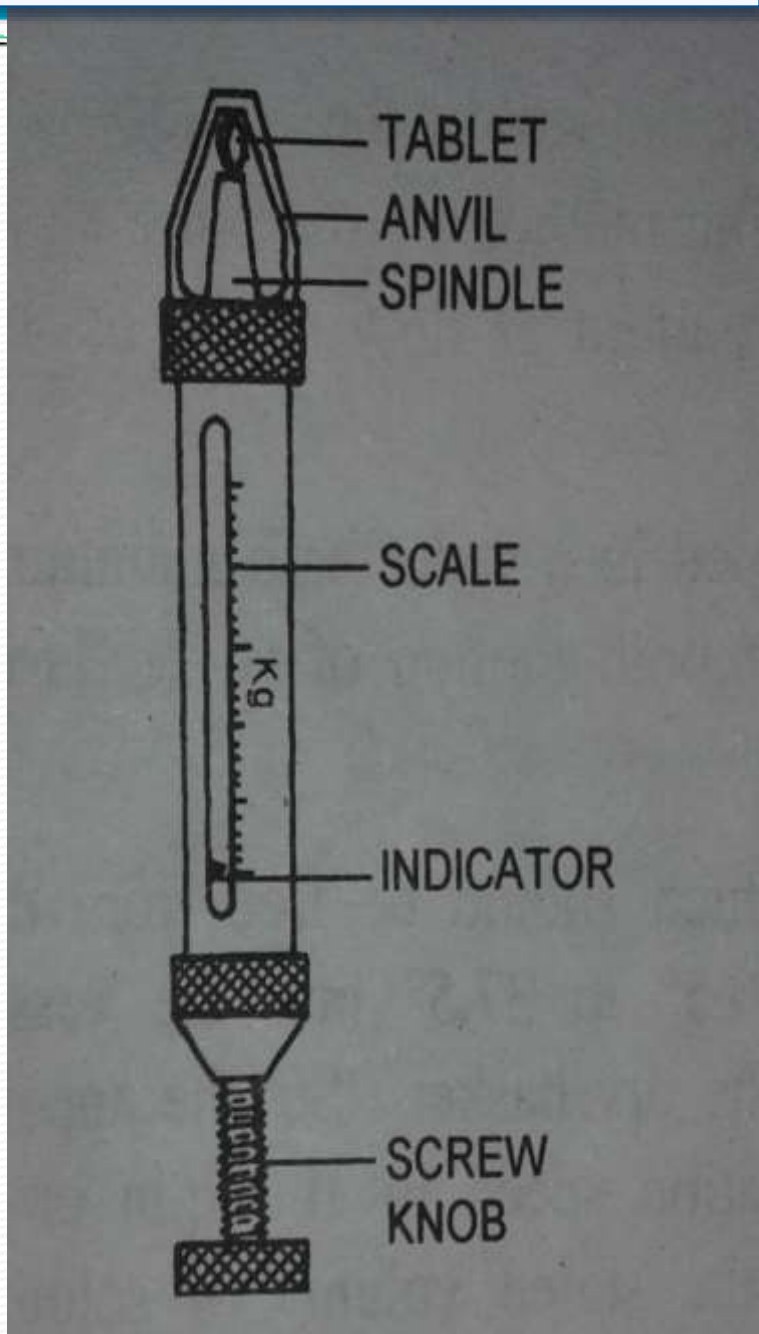
- The pharmacopoeia has not fixed any standards for the mechanical strength or hardness of tablets.

- The following devices are commonly used by manufacturers

  - Monsanto hardness tester
  - Pfizer tablet hardness tester

MONSANTO HARDNESS TESTER

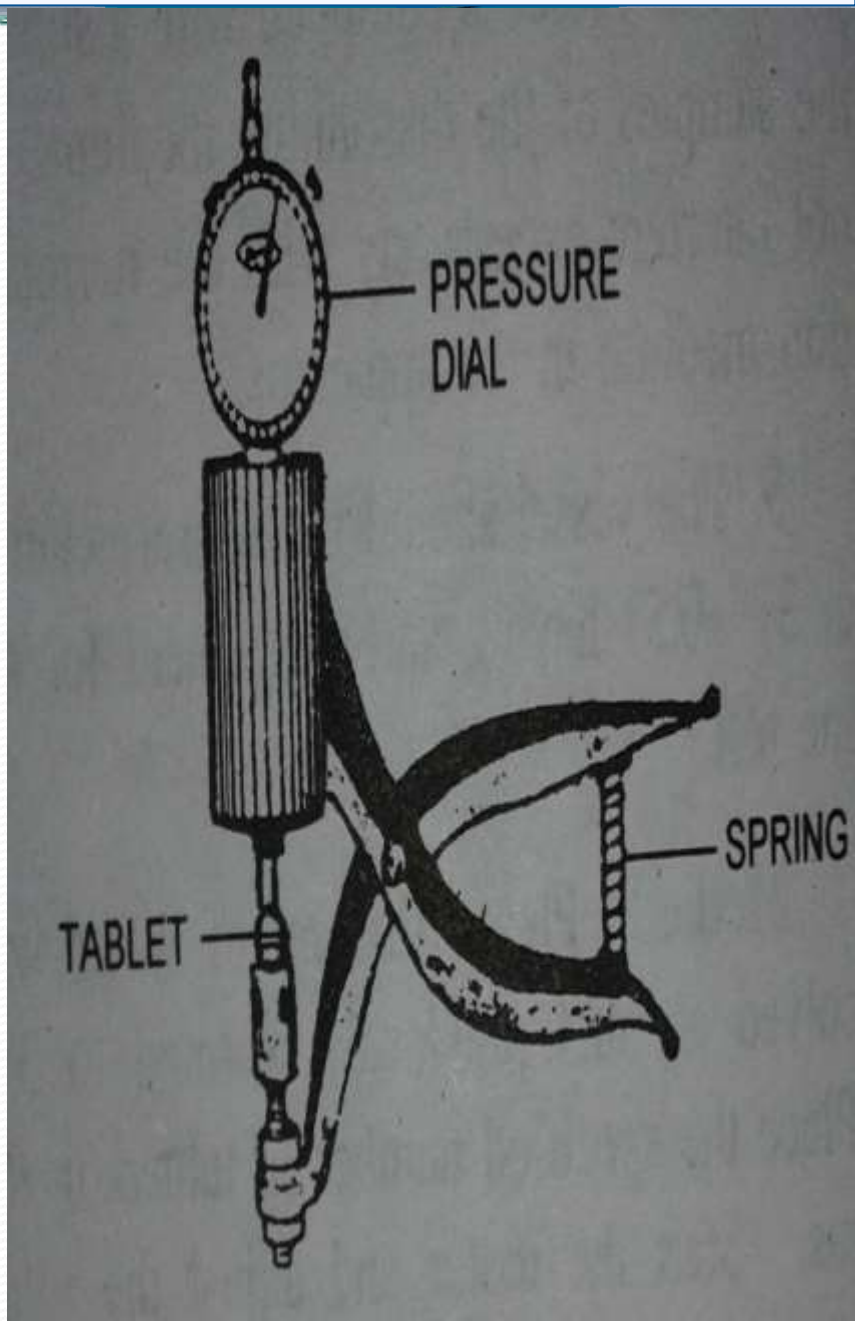
- Designed by Monsanto chemicals Co. Ltd.
- The reading unit Kg/Sq cm.
- Tested tablet placed in between spindle & anvil.
- Then adjust to zero reading.
- Then apply the pressure as clockwise till the tablet break.
- Then noted the reading.
- That reading indicates the pressure which is needed to break the tablet.



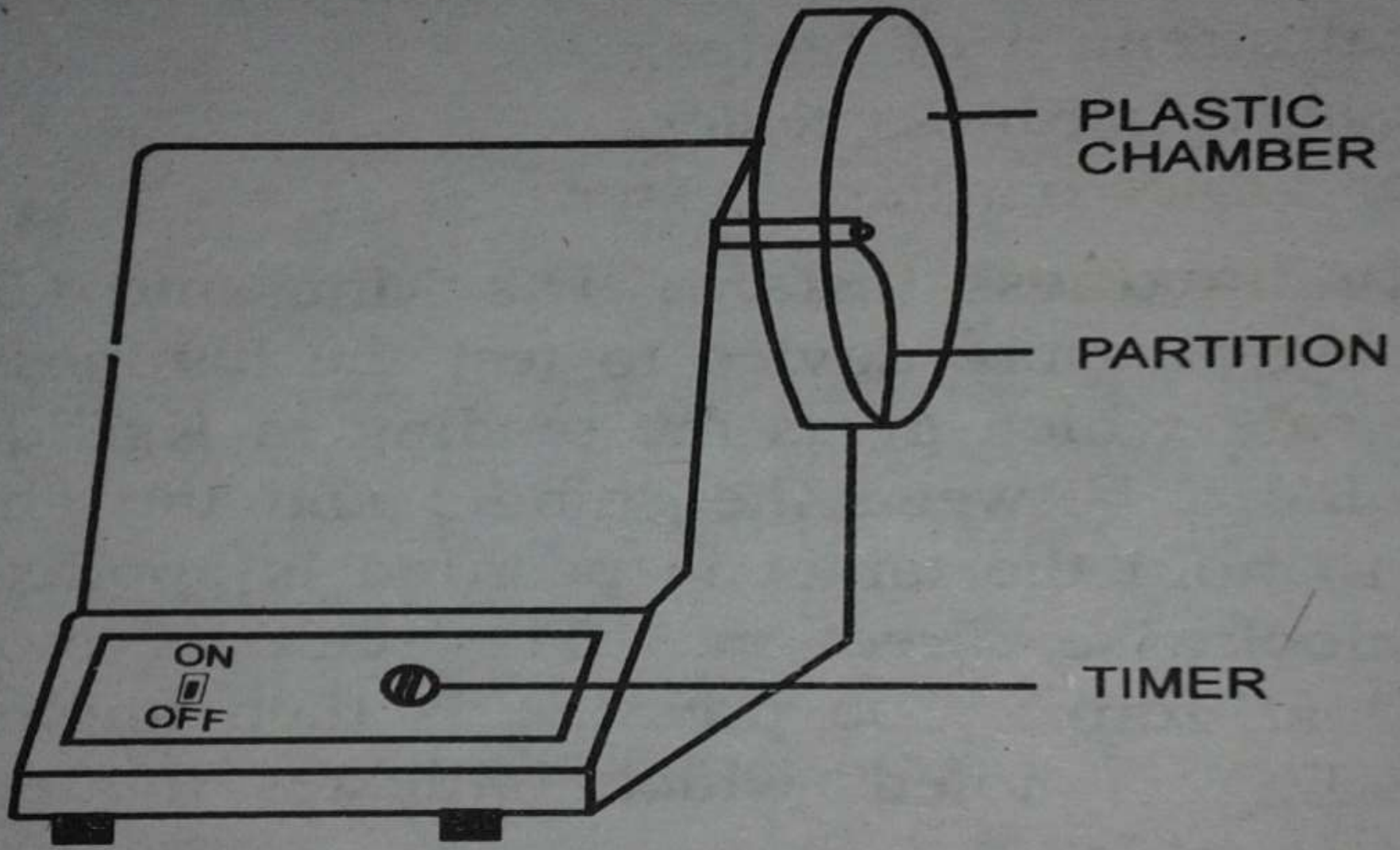
PFIZER TABLET HARDNESS TESTER

It is based on principle of plier.

- This tester is a plier fitted with a pressure dial.
- The tablet is placed between the jaw of the plier & pressure is applied by pressing the handle with hand unit until the tablet breaks.
- The reading of the dial indicates the pressure needed to break the tablet.



FRIABILITY TEST



Friabilator

Cont...

- Friability test is performed to evaluate the ability of the tablet to withstand wear and tear in packing, handling and transporting.
- This apparatus consist of a plastic chamber, which is divided into two parts & it revolves at a speed of 25 rpm.
- 20 tablets are weighed & placed in the plastic chamber.
- The chamber is rotated for 4 mint or 100 revolutions.
- During each revolution the tablet falls from a distance of 6 inch.
- The tablets are removed for the chamber after 100 revolutions & weighed.
- Loss in weight indicates the friability.
- The tablet are considered to be good quality if the loss in weight is less than 0.8%.