

9. Tablet

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9.1 Introduction:

- Tablets are usually circular compressed solid unit dosage form containing medicament or medicaments which may be flat or biconvex.
- Tablet is defined as a solid dosage form containing medicaments with or without excipients.
- Pharmaceutical tablets are circular, solid, biconvex or flat dishes, unit dosage form, prepared by compressing mixture of drugs, with or without diluents.
- About 70% of the total medicines are dispensed in the form of Tablets so it is most widely used.

9.2 Advantages & Disadvantages:

Advantages of Tablets:

- Easy to dispense.
- More stable.
- Accuracy in dose.
- Nauseas and bitter substance can be easily dispensed.
- Light and compact.
- Economical.
- Sustained and controlled release product is possible by enteric coating.

Disadvantages of tablets:

- Compression to crystalline drug may cause problems.
- Compressed tablets are not suitable for hygroscopic drugs.
- It is difficult to formulate drugs with low or poor water solubility, slow dissolution.
- Because of coating and encapsulation to remove bitter and unpleasant taste, which may increase the cost.
- For children and ill (unconscious) patients swallowing is difficult.

9.3 Types of Tablets:

A. Tablets ingested orally:


- Compressed tablets e.g., paracetamol tablet
- Multiple compressed tablets e.g., aspirin tablet

- Delayed release tablet, e.g., Enteric coated Bisacodyl tablet
- Sugar coated tablet, e.g., Multivitamin tablet.

B. Tablets used in oral cavity:

- Buccal tablet, e.g., Vitamin-c tablet
- Sublingual tablet e.g., Vicks Menthol tablet
- Troches or lozenges e.g., Delsym tablet
- Dental cone e.g., parasorb cone

C. Tablets administered by another route:

- Implantation tablet e.g., Testosterone tablet
- Vaginal tablet e.g., Clotrimazole 

D. Tablets used to prepare solution:

- Effervescent tablet, e.g., Disprin tablet (Aspirin)
- Dispensing tablet, e.g., Enzyme tablet (Digiplex)
- Hypodermic tablet e.g., morphine sulfate
- Tablet triturates e.g., Enzyme tablet (Digiplex)

9.3.1 Tablets Ingested Orally:

- A. Compressed tablet:** Compression of granules gives uncoated tablets. These provide rapid drug release and disintegration. e.g. Paracetamol tablet.
- B. Multiple compressed tablet:** These tablets are prepared to produce repeat action or prolonged action products or to separate physically or chemically incompatible ingredients. The ingredients of formulation are compressed into a core tablet and the incompatible substance with other excipients are compressed over the previously compressed core tablet.
- C. Sustained action tablet:** These tablets when taken orally, then it releases the medicament in such a sufficient quantity as and when required to maintain maximum effective concentration of drug in the blood.
- D. Enteric coated tablet:** 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. These tablets dissolve in intestine and are site specific.
- E. Sugar coated tablet:** The compressed tablets with sugar coating are called sugar coated tablets. It is basically done to mask the bitter and unpleasant taste and odour of the medicament. It enhances the appearance and protects the drug from atmospheric effects. e.g., Multivitamin tablet
- F. Film coated tablet:** It is used to protect the formulation from atmospheric effects. These are the compressed tablets having a film coating of film coating polymer like hydroxypropyl cellulose, ethyl cellulose, HPMC. These are tasteless, it increases the tablet weight and have less elegance. e.g., Metronidazole tablet

- G. Chewable tablet:** These tablets are chewed in mouth and are broken into small pieces. In this Disintegration time is reduced and rate of absorption increases. Easily administered for infants and elderly persons. e.g., Antacid table

9.3.2 Oral Cavity Tablets:

These tablets are to be placed in buccal pouch or between the gum & lip or cheek. Tablet dissolve & disintegrated slowly & absorb directly.

- A. Sublingual Tablet:** These tablets are to be placed under the tongue. They dissolve & disintegrated quickly & absorbed directly without passing into G.I.T. Buccal and sublingual tablet should be formulated with bland excipients, which do not stimulate salivation.
- B. Lozenge tablet & troches:** These tablets are designed to exert a local effect on mouth or throat. These tablets are usually used in treatment of sore throat or control coughing. The tablets are usually used to such drug as anaesthetic, antiseptic and antibacterial agent, demulcent, astringent and antitussive agent. Lozenges were earlier called pastilles.
- C. Dental cones:** These are relatively minor compressed tablet meant for placing them in the empty socket after tooth extraction. Usually, these tablets contain an antibacterial, compound which is released slowly. Prevent the growth of bacteria. These tablets may contain an astringent or coagulant to reduce bleeding. The base for these types is sodium bicarbonate, sodium chloride or it may be amines acid. These cones generally get dissolved in 20 to 40 min time.

9.3.3 Tablets Administered by Other Route:

- A. Implantation Tablet:** These tablets are placed below the skin or inserted subcutaneously by means of a minor surgical operation and are slowly absorbed. These must be sterile and are made by heavy compression and fusion. e.g., Testosterone tablet.
- B. Vaginal Tablet:** These tablets are meant to dissolve slowly in vaginal cavity. These are ovoid or pear shaped and are used to release steroids, antibacterial and antiseptics to avoid infections. e.g., Clotrimazole tablet

9.3.4 Tablets Used to Prepare Solutions:

- **Effervescent Tablet:** These tablets when added in water produce effervescence. So, they dissolved rapidly in water due to the chemical reaction which takes place between alkali bicarbonate and citric acid or tartaric acid. These tablets are to be protected from atmospheric moisture during storage (in well closed container). e.g. Disprin tablet (Aspirin)
- **Dispensing Tablet:** These are intended to be added to a given volume of water to produce a solution of a given concentration. The medicaments given are silver protein and quaternary ammonium compounds. These are highly toxic if taken orally and great care must be taken in packaging and labelling. e.g., Enzyme tablet (Digiplex)
- **Hypodermic Tablet:** These are compressed tablets which are composed of one or more drugs. These tablets are dissolved in sterile water and administered parenterally.

- **Tablet Triturates:** These are small cylindrical, moulded or compressed tablets which contains a potent medicament with a diluent. On small scale hand operated whereas for bulk production automated machines are used. e.g., Enzyme tablet (Digiplex)

A. Excipients in Tablet Formulation:

- **Diluents:** The diluent is needed to increase the bulk when quantity of medicament is very small in each tablet. e.g. Lactose, sucrose, sodium chloride, dextrose and starch etc.
- **Disintegrating agents:** To break the tablet in smaller particles when swallowed. These acts by three ways: swelling, by producing effervescence and by melting at body temperature. The disintegrating agent is divided into two parts. One part is mixed with other excipients before granules formation and the other is mixed with the dry granules before compression. e.g., Potato, maize, wheat starch etc
- **Granulating agents:** These provides moisture to convert the fine powder into damp mass which after passing through sieve forms granules. E.g., Starch paste, acacia, tragacanth, gelatin solution, isopropyl alcohol etc.
- **Glidants:** To improve the flow properties of granules. E.g., magnesium stearate & Talc
- **Lubricants:** To reduce the inter particular friction during compression and between tablet and die wall during ejection of tablet. e.g., Talc & magnesium stearate.
- **Binding agents:** these provides strength to the granules to keep the tablet intact and selection of which depends on the type of tablet e.g., gum tragacanth, methyl cellulose etc.
- **Adsorbing agents:** these are used to adsorb volatile oil, liquid extracts and tincture etc. Prevent sticking e.g., Mg stearate, stearic acid etc.
- **Colors, flavors and sweetening agents:** All coloring agents must be approved and certified by FDA. Two forms of colors are used in tablet preparation – FD & C and D & C dyes. These dyes are applied as solution in the granulating agent or Lake form of these dyes.

9.4 Manufacturing of Compressed Tablets:

9.4.1 Preparation of Granules for Compression:

Methods includes:

A. Wet Granulation: Wet granulation is a widely employed method for the production of compressed tablets. The steps required are:

- Weighing and blending the ingredients
- Preparing a dampened powder or a damp mass
- Screening the dampened powder or damp mass into pellets or granules
- Drying the granulation
- Sizing the granulation by dry screening
- Adding lubricant and blending
- Forming tablets by compression

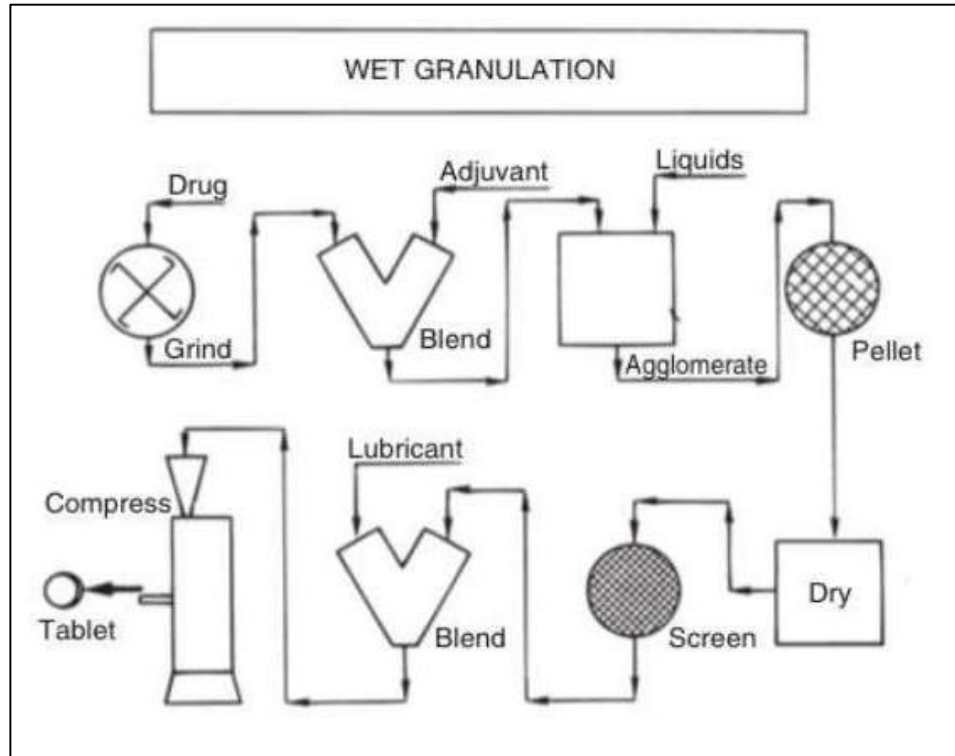


Figure 9.1: Wet Granulation

Advantages:

- Reduced segregation of formulation components during storage and/or processing
- Useful technique for the manufacture of tablets containing low and or high concentrations of therapeutic agent.
- Employs conventional excipients and therefore is not dependent on the inclusion of special grades of excipients.

Disadvantages:

- Often several processing steps are required.
- Solvents are required in the process: this leads to a number of concerns.
- Drug degradation may occur in the presence of the solvent.
- The drug may be soluble in the granulation fluid.
- Heat is required to remove the solvent.

B. Dry Granulation:

- By the dry granulation method, the powder mixture is compacted in large pieces and subsequently broken down or sized into granules.
- For this method, either the active ingredient or the diluent must have cohesive properties.

- Dry granulation is especially applicable to materials that cannot be prepared by wet granulation because they degrade in moisture, or the elevated temperatures required for drying the granules.

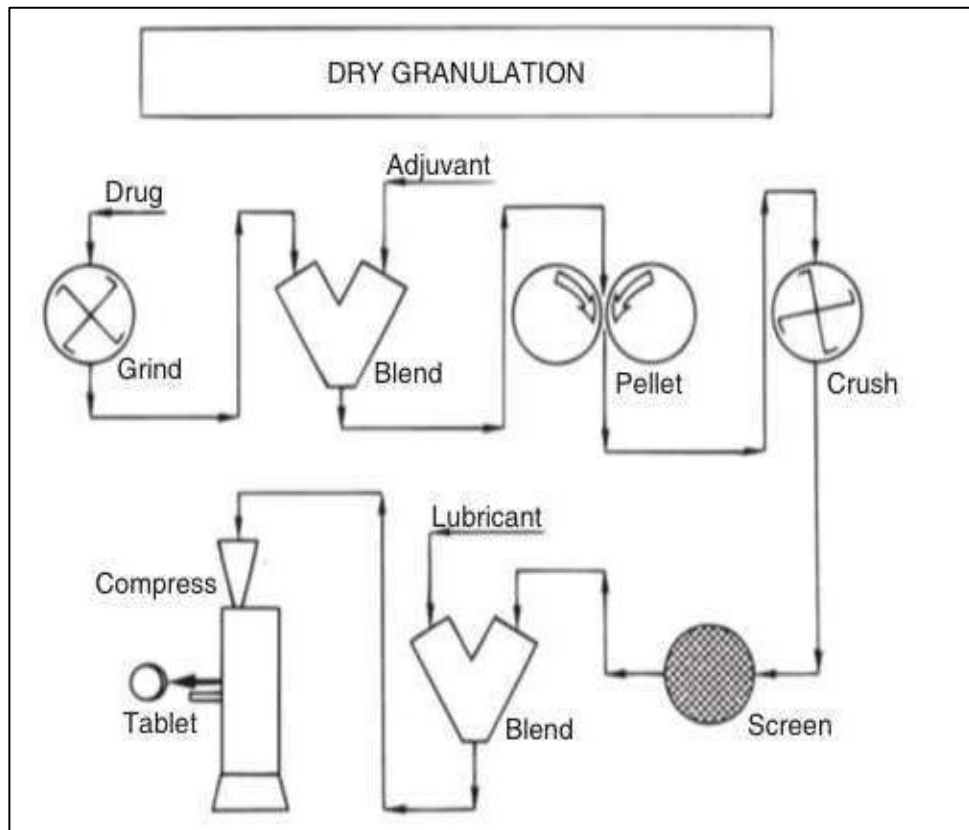


Figure 9.2: Dry Granulation

Advantages:

- These methods are not generally associated with alterations in drug morphology during processing.
- No heat or solvents are required.

Disadvantages:

- Specialist equipment is required for granulation by roller compaction.
- Segregation of components may occur during mixing.
- There may be issues regarding powder flow.
- The final tablets produced by dry granulation tend to be softer than those produced by wet granulation.
- Slugging and roller compaction lead to the generation of considerable dust.

Slugging:

- After weighing and mixing the ingredients, the powder mixture is slugged, or compressed, into large flat tablets or pellets about 1 inch in diameter.
- The slugs are broken up by hand or by a mill and passed through a screen of desired mesh for sizing.
- Lubricant is added in the usual manner, and tablets are prepared by compression.
- Aspirin, which is hydrolyzed on exposure to moisture, may be prepared into tablets after slugging.

9.5 Compression of Granules into Tablet:

9.5.1 Tablet Compression Machine Consist of:

- Hopper for holding and feeding granulation to be compressed.
- Dies that define the size and shape of the tablet.
- Punches for compressing the granulation within the dies.
- Cam tracks for guiding the movement of the punches.
- Feeding mechanisms for moving granulation from the hopper into the die
- Tablet ejector

9.5.2 Types of Compression Machine:

A. Single Punch Machine: The compression is applied by the upper punch making the single punch machine a “stamping press.”

B. Multi-Station Rotary Presses:

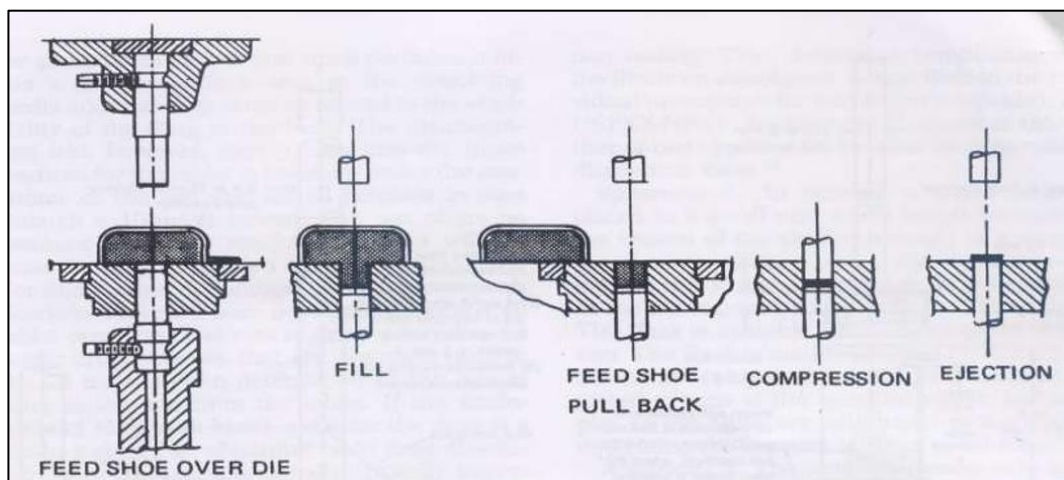


Figure 9.3: The Compression Cycle of a Single-Punch Tablet Press. (Courtesy of Vector Corporation, Marion, IA.)

Multi-Station Rotary Presses:

- The head of the tablet machine holds the upper punches, dies and lower punches in place rotates.
- As the head rotates, the punches are guided up and down by fixed cam tracks, which control the sequence of filling, compression and ejection.
- The portions of the head that hold the upper and lower punches are called the upper and lower turrets.
- The portion holding the dies is called the die table.
- The pull-down cam (C) guides the lower punches to the bottom, allowing the dies to overfill.
- The punches then pass over a weight-control cam (E), which reduces the fill in the dies to the desired amount.
- A swipe off blade (D) at the end of the feed frame removes the excess granulation and directs it around the turret and back into the front of the feed frame.
- The lower punches travel over the lower compression roll (F) while simultaneously the upper punches ride beneath the upper compression roll (G).
- The upper punches enter a fixed distance into the dies, while the lower punches are raised to squeeze and compact the granulation within the dies.
- After the moment of compression, the upper punches are withdrawn as they follow the upper punch raising cam (H).
- The lower punches ride up the cam (I) which brings the tablets flush with or slightly above the surface of the dies.
- The tablets strike a sweep off blade affixed to the front of the feed frame (A) and slide down a chute into a receptacle.
- At the same time, the lower punches re-enter the pull-down cam (C) and the cycle is repeated

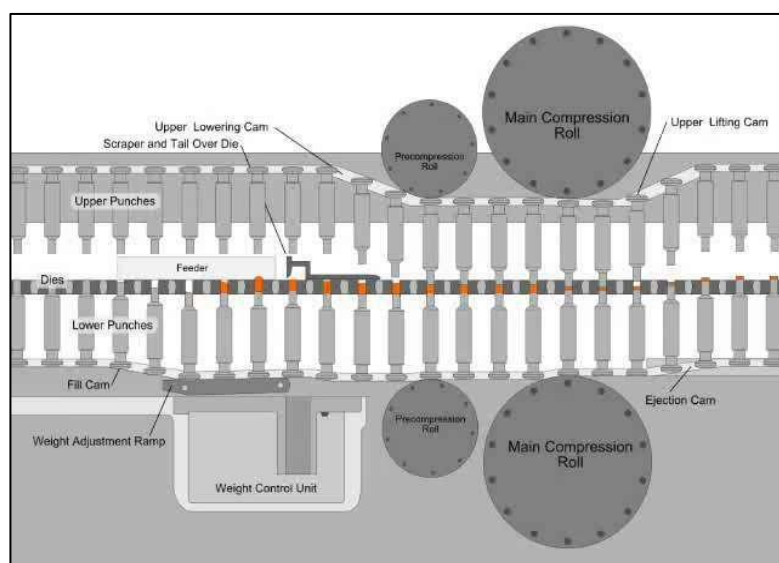


Figure 9.4: Multi-Station Rotary Press

9.6 Tablet Coating:

9.6.1 Reasons for Coating:

- To mask unpleasant taste and odor.
- To improve the appearance of tablets.
- To prevent the medicament from atmospheric effects.
- To control the site of action of drugs.
- To produce the sustained release product.

9.6.2 Methods of Tablet Coating:

- A. Sugar coating:
- B. Film coating
- C. Enteric coating

A. Sugar Coating:

Steps of sugar coating of tablet:

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

b. Sealing: Sealing is done to ensure that a thin layer of waterproof 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.

c. 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 gelatin are given. After each addition of the syrup, dusting powder is sprinkled. The dusting powder is a mixture of starch, talc & powdered acacia.

d. Syrup coating: This is done to give sugar coats, opacity & colour to tablets. Several coats of the syrup are applied. Colouring materials & opacity agent are also added to the syrup. The process of coating is repeated until uniform-coloured tablets are obtained.

e. 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.

f. Polishing: Beeswax is dissolved in organic solvent and few coats of it are given. The finished tablets are transferred to a polishing pan is rotated at a suitable speed so the wax coated tablets are rubbed on the canvas cloth. This gives a proper shining to the tablets. Sugar coating is an art.

B. Film Coating:

- In these tablets are coated by a single or mixture of film forming polymers, such as Hydroxypropyl methyl cellulose, Hydroxy ethyl methyl cellulose, methyl cellulose, carbowax, PEG 400 etc. the polymer is dissolved in some volatile organic solvent and is sprayed over the tablets in a rotating pan.
- It is also used to make tablets waterproof before sugar coating. Filmcoating may be enteric or nonenteric.

Advantages:

- It is a less time-consuming technique.
- Not much labour is required.
- It has no adverse effect on disintegration of tablets.
- Product cost is less.
- It protects the drug from the atmospheric changes such as light, air and moisture.
- Coating is resistant to cracking and chipping.
- It does not increase the weight of the tablet.
- No waterproofing is required before actual film coating.

C. Enteric Coating:

a. Enteric Coated Tablet:

- 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.
- These tablets dissolve in intestine.
- These are site specific.

b. Enteric coating is given to the tablets when:

- Medicaments produce severe irritation in stomach.
- Action required in intestine.
- Medicament may decompose or destroyed by stomach pH.
- Drug absorption is better in intestine.
- Delayed action is needed.

9.7 Microencapsulation:

- Microencapsulation:
- Micro-encapsulation is a process in which tiny particles or droplets are surrounded by a coating to give small capsules of many useful properties.
- In a relatively simple form, a microcapsule is a small sphere with a uniform wall around it.

- The material inside the microcapsule is referred to as the core, internal phase, or fill, whereas the wall is sometimes called a shell, coating, or membrane.
- Microencapsulation techniques:
The methods are based on:
 - Chemical Process
 - Mechanical Process
- The following techniques are commonly used:
 - Pan coating
 - Fluidised bed coating
 - Coacervation
 - Electrostatic deposition
 - Polymerisation
 - Multi-orifice centrifugal process
- Most microcapsules have diameters between a few micrometers and a few millimeters.
- Applications:
 - To mask the bitter taste of drugs like Paracetamol, Nitrofurantoin etc.
 - To reduce gastric and other gastrointestinal (G.I) tract irritations, Froth., sustained release.
 - A liquid can be converted to a solid for easy handling and storage,
 - Hygroscopic properties of core materials may be reduced by microencapsulation.
 - Protection against external environment.
 - Microencapsulation has been employed to provide protection to the core materials.
 - Separation of incompatible substance has been achieved by encapsulation.

9.8 Defects in Tablets:

A. Capping:

- In this there is partial or complete removal of top or bottom portion of tablet.
- Reasons:
 - Excessive fine.
 - Defective punch die.
 - High speed of machine.
 - Granules too dried.
- Defect can be removed:
 - Setting the die and punch properly.
 - Reduce % of fine.
 - Punches should be polished.
 - Maintain the desired moisture in granules.
 - Maintain the speed at optimum & regulate the pressure of punches.

B. Picking and Sticking:

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

- Reasons:
 - Use of worn out die and punch.
 - Use of small quantity of lubricants.
 - Presence of excess moisture in the granules.
 - Scratches on the surface of the face of the punches.
 - Defect in formulation.
- Defect can be removed:
 - Using new set of die and adding proper quantity of lubricants in granules.
 - Dry granules

C. Mottling:

- An unequal distribution of colour on the surface of a coloured tablet.
- Reasons:
 - Migration of dye in the granules during drying.
 - Use of different coloration of medicaments and excipients.
 - Defect can be avoided:
 - Drying the granules at low temperature.
 - Using the dye which can mask the colour of all medicaments.

D. Weight Variation:

- Weight variation occur during the compression of granules in a tablet machine and the tablet do not have the uniform weight.
- Reasons for this defect:
 - Granules are not in uniform size.
 - Presence of excess amount of powder in the granules.
 - No proper mixing of lubricants and no uniform flow of granules.
 - During compression change in capacity of die.
 - Variation in the speed of the tablet machine.

E. Hardness Variation:

- The tablet does not have a uniform hardness.
- It depends on the weight of the material and space between the upper and lower punch during the stage of compression.
- If volume of the material varies and distance varies between punches, the hardness also varies.

F. Double Impression:

- This effect occurs when the lower punch has a monogram or some
- other engraving on it.
- During compression, tablet receive an imprint of the punch.
- Due to some defect in machine lower punch move slightly upward before ejection of tablet and give second impression.

- This can be controlled by managing the movement of punch.

9.9 Evaluation of Tablet:

Official Tests:

- A. Size and shape and appearance of tablet.
- B. Content of active ingredient.
- C. Uniformity of weight/weight variation test
- D. Uniformity of content
- E. Disintegration.
- F. Dissolution.

Unofficial Tests:

- A. Hardness test.
- B. Friability

9.9.1 Official Tests:

A. Size, Shape & Appearance:

- General Appearance: The general appearance of a tablet, its identity and general elegance is essential for consumer acceptance, for control of lot-to-lot uniformity and tablet-to-tablet uniformity. The control of general appearance involves the measurement of size, shape, color, presence or absence of odor, taste etc.
- Size & Shape: It can be dimensionally described & controlled. The thickness of a tablet is only variable. Tablet thickness can be measured by micrometer or by another device. Tablet thickness should be controlled within a $\pm 5\%$ variation of standard value.
- Unique identification marking: These markings utilize some form of embossing, engraving or printing. These markings include company name or symbol, product code, product name etc.
- Organoleptic properties: Color distribution must be uniform with no mottling. For visual color comparison compare the color of sample against standard color.

B. Content of Active Ingredient:

- Procedure:
- Perform the assay of 20 tablets as per monograph.
- The result should lie within the range for the content of active ingredient stated in the monograph.
- If small no. of tablets (min 5) is used then the limits specified in the monograph may be relaxed to the extent indicated in the table.

Table 9.1: Content of Active Ingredient

Weight of medicament in each tablet	Subtract from the lower limit for sample of			Add to the upper limit for sample of		
	15	10	05	15	10	05
0.12 g or less	0.2	0.7	1.6	0.3	0.8	1.8
>0.12 g & < 0.3 g	0.2	0.5	1.2	0.3	0.6	1.5
0.3 g or more	0.1	0.2	0.8	0.2	0.4	1.0

C. Uniformity of Weight:

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

Table 9.2: Uniformity of Weight

Sr. No.	Average Wt. of a tablet deviation	Percentage (%)
1	80 mg or less	10
2	More than 80 mg and less than 250 mg	7.5
3	250 mg or more	5

D. Uniformity of Content:

- Content uniformity test:
- It is used to ensure that every tablet contains the amount of drug substance intended with little variation.
- Procedure:
- 10 tablets are assayed,
- 9 tablets should have % limit of 85-115%.
- If more than 1 tablet deviates from 85-115%,
- 20 tablets are assayed.
- Not more than 1 tablet should have the % limit of 75-125%

E. Disintegration Test:

- Disintegration of a tablet means to break a tablet into smaller particles after swallowing. The time required to disintegrate the tablet is called disintegration time.
- The apparatus consists of a rigid basket-rack assembly supporting 6 cylindrical glass tubes held vertically by two superimposed transparent plastic plates with six holes having the same diameter as the tubes. Woven wire gauze made from stainless steel is attached to the underside of the lower plate. The assembly should be raised and lowered between 28 and 32 times per minute in the liquid at 37°C.

- The tablets are kept immersed in the liquid within the tubes by means of cylindrical guided discs. The assembly is suspended in the liquid medium in a 1000 ml beaker. The apparatus is operated generally for 15 minutes and observed for disintegration of tablets.
- The tablets pass the test if all the tablets disintegrate. In case one or two tablets fail to disintegrate, repeat the test on 12 additional tablets. The tablets pass the test if not less than 16 of the total 18 tablets tested have disintegrated.

a. For Uncoated Tablets:

- Start the disintegration test on 6 tablets, if one or two tablets from the 6 tablets fail to disintegrate completely within 30min, repeat the same test on another 12 tablets.
- Not less than 16 tablets should disintegrate completely within the time and if more than two tablets (from the 18) fail to disintegrate, the batch must be rejected.

b. For Coated tablets:

- To remove or dissolve the coat, immerse the tablet in distilled water for 5 min.
- Put the tablet in the apparatus in water or 0.1 N HCl for 30min at 37°C (according to the U.S.P).
- If not disintegrated, put in intestinal fluid. If one or two tablets fail to disintegrate, repeat on 12 tablets.
- So, 16 tablets from the 18 must completely disintegrate within the time.
- If two or more tablets do not disintegrate within the time the batch is rejected.

c. For Enteric coated tablets:

- Put the tablet in distilled water for five minutes to dissolve the coat.
- Put in simulated gastric fluid for two hours (emptying time)
- Put in phosphate buffer (PH 6.8) for one hour.
- If one or two tablets fail to disintegrate repeat on 12 tablets.
- So, 16 tablets should disintegrate. If more than two tablets fail to disintegrate, reject the batch.

F. Dissolution Test:

- It is the solubilization of the drug or active moiety in to the dissolution media.
- It is done for measuring the amount of time required for a given percentage of the drug substance in a tablet to go into solution under specified condition.
- Apparatus:
 - A cylindrical vessel (made up of glass or other transparent material) having 1000 ml capacity, fitted with a lid having four holes, one for shaft of stirrer, second for placing the thermometer and remaining two for sample removal.
 - An electric motor
 - A cylindrical stainless-steel basket made of wire with aperture size of 425 μm
 - attached to the disc on the driving shaft.
 - Suitable device for withdrawal of sample.

- Method:
 - Place 1000 ml of water into the vessel. Place the specified number of tablets in the dry basket and set the apparatus. Start the motor and adjust the temperature and rotation speed to 36.5°C to 37.5°C and 100 rpm or as given in monograph. Withdraw the sample after specified time intervals. Filter and determine the amount of active ingredient present in it by the method given in the monograph.
- Acceptance criteria:
 - S1= 6 tablets are taken Acceptable: If all of the tablets are not less than $Q \pm 5\%$
 - If S1 fails, S2= 12 tablets are taken Acceptable: If average of 12 tablets is $\geq Q$ and no tablet is less than $Q-15\%$
 - If S2 fails, S3= 24 tablets are taken Average of 24 $\geq Q\%$ not more than 2 tablets should be less than $Q-15\%$ and None should be less than $Q-25\%$

9.9.2 Unofficial Tests:

A. Hardness Test:

- It is defined as the force required to break a tablet in a diametric compression test. Tablet requires a certain amount of strength or hardness and resistance to friability to withstand mechanical shocks of handling in manufacture, packaging and shipping.
- Types of hardness testers used are:
 1. Monsanto hardness tester.
 2. Strong cob tester.
 3. Pfizer tester.
- Conventional tablets hardness: 2.5- 5 kg/sq cm
- Dispersible/ chewable tablets hardness: 2.25- 2.5 kg/sq cm
- Extended-release tablets hardness: 5- 7.5 kg/sq cm

B. Friability Test:

- It is performed to evaluate ability of the tablet to withstand wear and tear in packing, handling, and transporting.
- The apparatus used to perform this test is known as "Friabilator".
- The apparatus consists of a plastic chamber, which is divided into two parts and it revolves at a speed of 25 rpm.
- Twenty tablets are weighed and placed in a plastic chamber. The chamber is rotated for 4 minutes or 100 revolutions.
- During each revolution the tablet falls from a distance of 6 inches.
- The tablets are removed from the chamber after 100 revolutions and weighed. Loss in weight indicates the friability. The tablets are considered to be of good quality if the loss in weight is less than 0.8%.