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A Review: Tablet Including its Formulation and Evaluation

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ABSTRACT

According to the Indian Pharmacopoeia (IP); 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. Tablet is also defined as a compressed solid dosage form containing medicaments with or without excipients. Tablets are now the most popular dosage form, accounting for some 70% of all ethical pharmaceutical preparations produced. Pharmaceutical oral solid dosage forms have been used widely for decades mainly due to their convenience of administration and their suitability for delivery of drugs for systemic effects. A tablet contains one or more medicaments with or without suitable excipients and prepared either by molding or by compression. The excipients include diluents, binders and adhesives, disintegrants etc. Tablets vary in shape and differ greatly in size and weight depending on the amount of the medicinal substance. The ingredients must be granulated prior to compression to assure an even distribution of the active compound in the final tablet. There are two basic techniques which can be used to granulate powders for compressions into a tablet are wet granulation and dry granulation.

In this review article; tablet and its types, formulation and manufacturing processes, evaluation parameters and its defects including its packaging have been discussed.

Keywords: Types of tablets, Formulation, Manufacturing, Tablet Defects, Evaluation Parameters, Packaging.

Introduction

According to the Indian Pharmacopoeia (IP); 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.

According to the United States of Pharmacopoeia (USP); Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients.

ADVANTAGES OF TABLET DOSAGE FORM

- They are unit dosage forms and offer the greatest capabilities of all oral dosage forms for the greatest dose precision and the least content variability.
- Ease of accurate dose.
- Release rate of the drug from tablets can be tailored to meet pharmacological requirements.
- Easiest and cheapest to package and strip.
- Easy to swallow with least tendency for hang-up.
- Sustained release product is possible by enteric coating.
- Objectionable odour and bitter taste can be masked by coating technique.
- Greatest chemical and microbial stability over all oral dosage forms.
- Product identification is easy and rapid requiring no additional steps when employing an embossed and/or

monogrammed punch face (Lachman et al., 1990; Herbert et al., 2006; Kaur, 2012; Hymavathi et al., 2012).

DISADVANTAGES OF TABLET DOSAGE FORM

- Difficult to swallow in case of children and unconscious patients.
- Some drugs resist compression into dense compacts, owing to their amorphous nature, low density character.
- Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT may be difficult to formulate or manufacture as a tablet that will still provide adequate or full drug bioavailability.
- Bitter testing drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, a capsule may offer the best and lowest cost (Lachman et al., 1990; Herbert et al., 2006; Kaur, 2012; Hymavathi et al., 2012).

QUALITIES OF GOOD TABLETS (Kaur, 2012)

- They should be accurate and uniform in weight.
- The drug should be uniformly distributed throughout the tablets.
- The size and shape should be reasonable for easy administration.
- The tablet should not be too hard so that it may not disintegrate in the stomach.
- There should not be any incompatibility.
- They should be chemically and physically stable during storage.
- They should not break during transportation or crumble in the hand of a patient.
- They should be attractive in appearance.

TYPES OF TABLETS (Tejaswi et al., 2020; Sharma et al., 2011)

1. Tablets ingested orally

- **Compressed tablets:** Paracetamol tablet
- **Delayed release tablets:** Enteric coated Bisacodyl tablet
- **Sugar coated tablet:** Multivitamin tablet
- **Film coated tablet:** Metronidazole tablet
- **Chewable tablets:** Antacid tablets
- **Multi Compressed tablets**
- **Repeat action tablet.**

2. Tablets used in oral cavity

- **Buccal tablets:** Vitamin C tablet
- **Sublingual tablet:** Vicks menthol tablet
- **Troches or Lozenges**
- **Dental cone**

3. Tablets used to prepare solutions

- **Effervescent tablet:** Disprin tablets
- **Dispensing tablets:** Enzyme tablet (Digiplex)
- **Tablet triturates:** Enzyme tablet (Digiplex)
- **Hypodermic tablets**

4. Tablets administered by other route

- **Implantation tablet**
- **Vaginal tablet:** Clotrimazole tablet

COMPONENT OF TABLETS (Jain et al., 2006; Lachman et al., 1990)

1. DILUENT: Diluents are fillers used to make the required bulk of the tablet when the drug dosage itself is inadequate to produce the bulk. Secondary reasons are to provide better tablet properties such as improve cohesion, to permit use of direct compression manufacturing or to promote flow.

A diluents should have following properties:

- They must be non toxic.
- Their cost must be low.
- They must be physiologically inert.
- They must be physically & chemically stable by themselves & in combination with the drugs.
- They must be free from all microbial contamination.
- They do not alter the bioavailability of drugs.
- They must be color compatible.

Table 01: Diluents used in tablets

DILUENTS USED IN TABLETS	
DILUENTS	**COMMENTS**
Calcium carbonate	Insoluble in water
Glucose	Hygroscopic, reducing sugar
α Lactose	Inexpensive, inert
Mannitol	Popular for chewable tablets Freely soluble in water & Cool taste
Sodium chloride	Freely soluble in water Use in solution tablet taste problem
Sucrose	Hygroscopic & Sweet taste Used in lozenges in conjunction with lactose
Calcium hydrogen phosphate	Insoluble in water

2. BINDERS & GRANULATING AGENTS: These materials are added either in dry or in liquid form during wet granulation or to improve cohesive compacts for directly compressed tablets. The binders most commonly used are from natural sources such as Starch or Cellulose derivatives.

Table 02: Binders and granulation used in tablets

BINDERS	CONCENTRATION	COMMENTS
Acacia mucilage	Upto 20%	Gives very hard granule
Glucose	Upto 50%	Strong adhesive but hygroscopic
Gelatin	5-20%	Used as warm solution, strong adhesive
Povidone (PVP)	2-10%	Soluble in water Can be used for non aqueous granulation
Starch mucilage	5-10%	Adhesive
Sucrose	Upto 70%	Hygroscopic, Tablet hardens on storage
Tragacanth mucilage	Upto 20%	Gives hard granule

3. DISINTEGRANTS: They are added to a tablet formulation to facilitate its breaking or disintegration when it comes in contact with water in the GIT.

Table 03: Disintegrants used in tablets

DISINTEGRANTS	CONCENTRATION
Alginic acid, Sodium alginate	2-10%
Microcrystalline cellulose	Upto 10%
Starch	2-10%
Sodium starch glycolate	1-10%
Aluminium magnesium silicate	Upto 10%

4. GLIDANTS: They are intended to promote flow of tablet granulation or powder material by reducing the friction between the particles.

Table 04: Glidants used in tablets

GLIDANTS	CONCENTRATION
Colloidal silica	0.1 – 0.5%
Talc	1 – 2%

5. ANTIADHERENTS: They have the purpose of reducing sticking or adhesion of any tablet granules or powder to the faces of the punches or to the die wall.
Common Examples: Talc, Magnesium stearate, Starch derivatives.

6. LUBRICANTS: They are intended to reduce the tablet friction during tablet ejection between the wall of the tablet and the wall of the die cavity in which the tablet is formed.

Table 05: Lubricants used in tablets

LUBRICANTS	CONCENTRATION
Fumaric acid	Upto 5%
Hydrogenated vegetable oil	0.5 – 2.0%
Liquid paraffin	Upto 5%
Macrogol 4000 & 6000	2 – 5%
Sodium benzoate	Upto 5%
Sodium lauryl sulphate	0.5 – 5.0%
Sodium stearyl fumarate	1 – 2%

7. COLORS, FLAVOURS & SWEETENERS

- **Colors:** Two forms of colours have typically been used in tablet preparation: Eg, FD & C, D&C Dyes.
- **Flavours:** They are usually limited to chewable tablets or other tablets intended to dissolve in the mouth. Flavour oils at 0.5 – 0.75% concentration are added to tablet granules.
- **Sweeteners:** They are primarily limited to chewable tablets to evaluate or limit the use of sugar in the tablets. Eg, Saccharin, Mannitol, Aspartame.

GRANULATION

Granulation may be defined as a size enlargement process which converts small particles into physically stronger & larger agglomerates.

Ideal Characteristics of Granules:

The ideal characteristics of granules include spherical shape, smaller particle size distribution with sufficient fines to fill void spaces between granules, adequate moisture (between 1-2%), good flow, good compressibility and sufficient hardness.

The effectiveness of granulation depends on the following properties.

Particle size of the drug and excipients.

Type of binder (strong or weak).

Volume of binder (less or more).

Wet massing time (less or more).

Amount of shear applied.

Drying rate (Hydrate formation and polymorphism) (Jain et al., 2016).

METHOD OF TABLET PREPARATION

The manufacture of granulation for tablet compression may follow one or a combination of three established methods.

1. Direct Compression Method: Crystalline substances like sodium chloride, Sodium bromide and potassium chloride may be compressed directly.

Direct compression materials should possess:

Good flow property and compressibility.

Must be inert & tasteless.

Should be able to disintegrate.

It should be inexpensive (Gelaw et al., 2015).

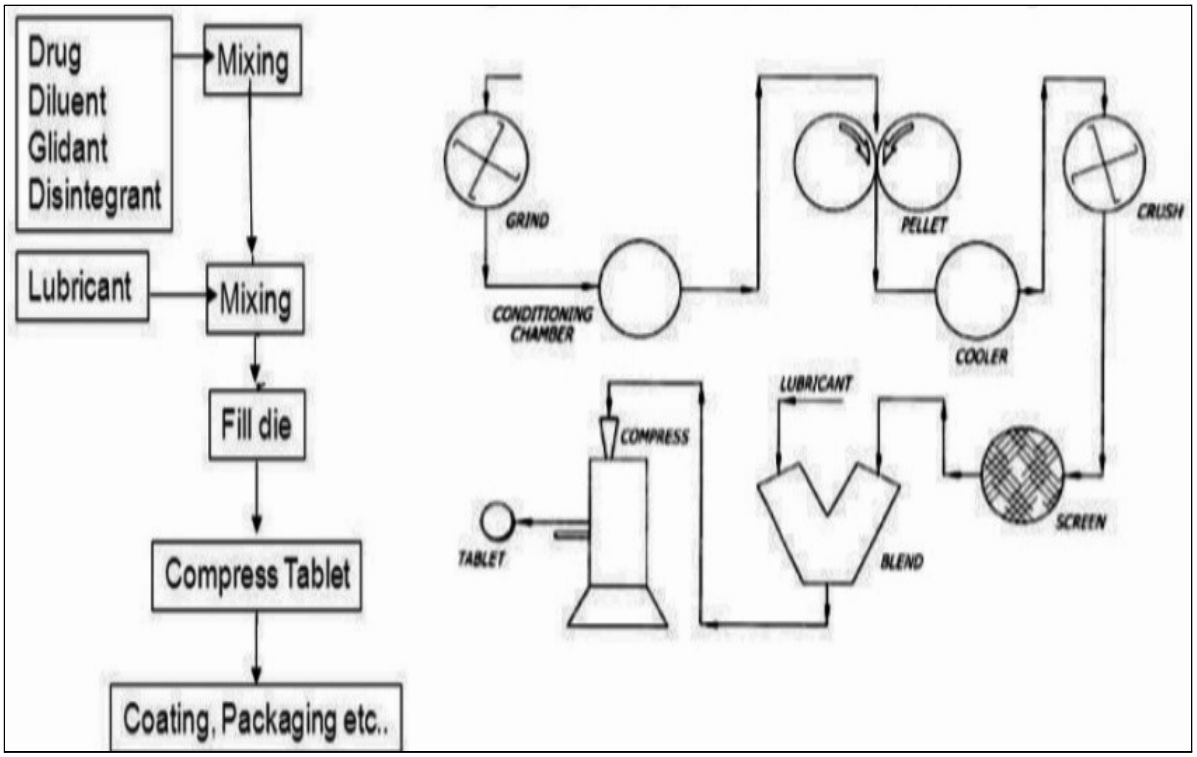

Figure 01: Direct compression method

2. Dry granulation, Slugging or Pre-compression Method:

- In the dry granulation process the powder mixture is compressed without the use of heat and solvent.
- Two methods are used for dry granulation.
- Most widely used method is slugging, where the powder is precompressed and the resulting tablet or slug are milled to yield the granules.
- The other method is to precompress the powder with pressure rolls using a machine such as Chilosonator.

Advantages of Dry Granulation:

Slugging can be used in the following situations:

- For moisture sensitive material.
- For heat sensitive material.
- For improved disintegration since powder particles are not bonded together by a binder.

Disadvantages of Dry Granulation:

- It requires a specialized heavy duty tablet press to form a slug.
- It does not permit uniform colour distribution as can be achieved with wet granulation where the dye can be incorporated into binder liquid.
- The process tends to create more dust than wet granulation, increasing the potential contamination (Vergeire-Dalmacion, 2015).

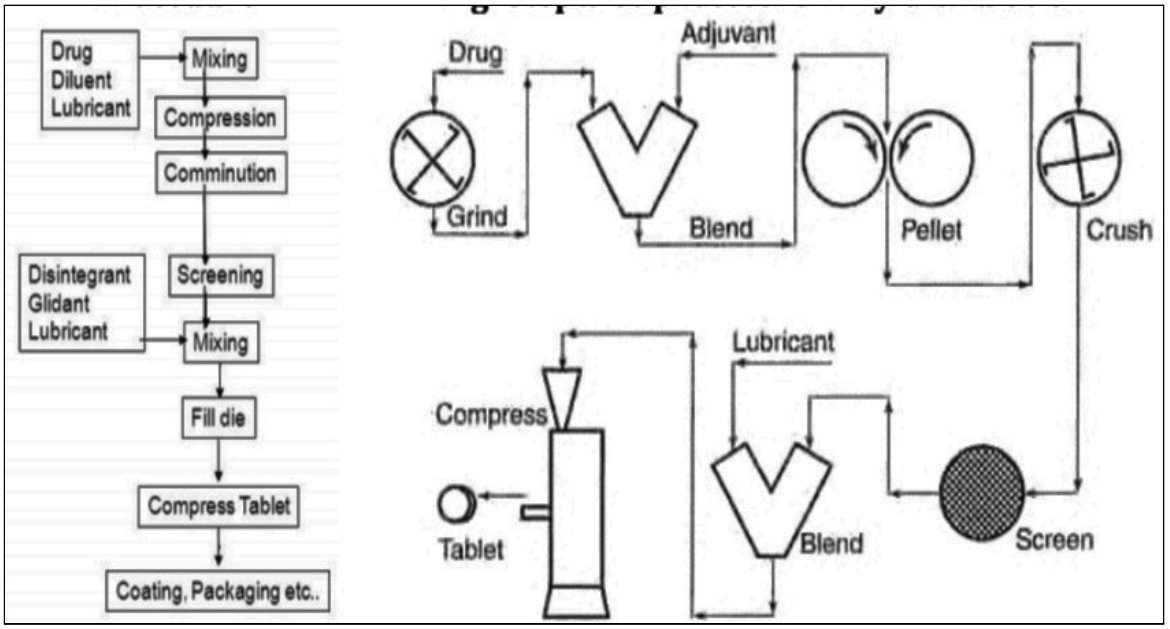

Figure 02: Dry granulation method

3. Wet Granulation Method: Wet granulation process simply involves wet massing of the powder blend with a granulating liquid, wet sizing and drying.Wet granulation forms the granulation by binding the powders together with an adhesive, instead of by compaction.

Limitations of wet granulation:

- The greatest disadvantage of wet granulation is its cost.
- It is an expensive process because of labor, time, equipment, energy and space requirements.
- Loss of material during various stages of processing.
- Stability may be a major concern for moisture sensitive or thermolabile drugs.
- Multiple processing steps add complexity and make validation and control difficult (Hassali et al., 2016).

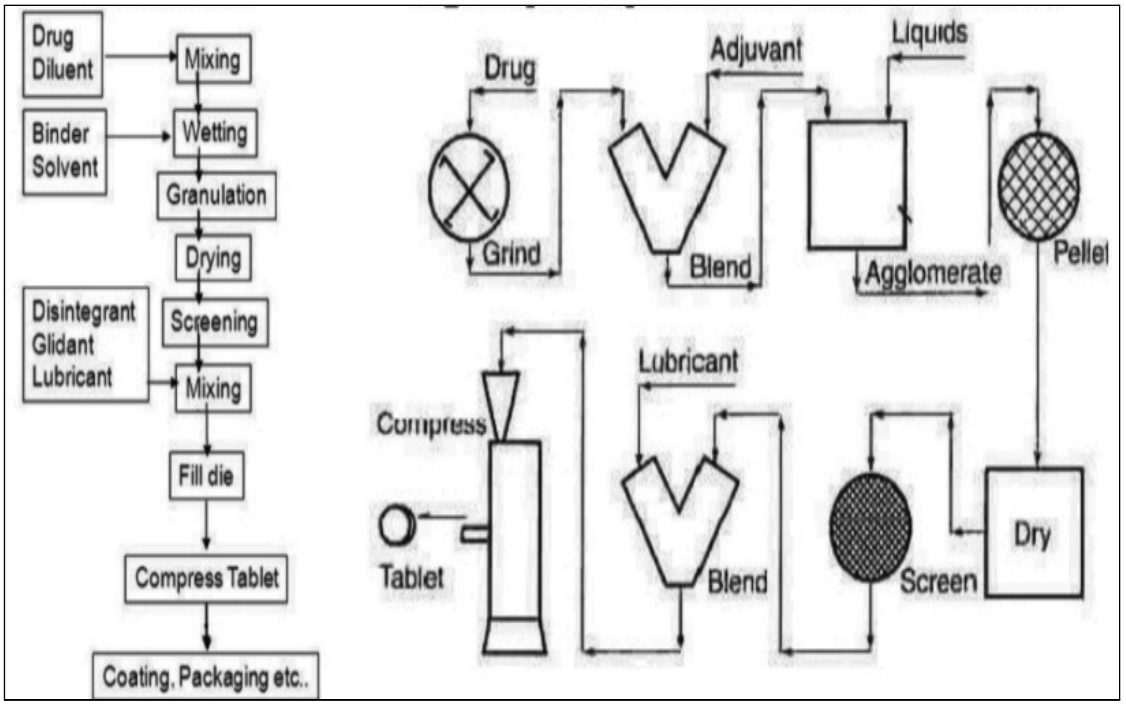

Figure 03: Wet granulation method

TABLET COMPRESSION MACHINE

Tablet compression machine or tablet press are designed with the following basic components:

1. Hopper: The hopper holds the granules/powder mixture (API plus excipient) that are to be compressed into a tablet.

2. Die Cavity: This is where the powder granules are compressed into tablets and it determines.

- The diameter of the tablet.
- The size of the tablet.
- To some extent the thickness of the tablet.

3. Feed Paddle: Helps to force the feed/ the granules into the dies especially during faster rotation.

4. Punches: This comprises the upper and the lower punches. They move within the die bore to compress granules into tablets.

5. Lower Cam Track: This guides the lower punch during the filling stage so that the die bore is overfilled to allow accurate adjustment.

6. Cam Tracks: This guides the movement of both the upper and lower punches.

7. Dept of Fill/Capacity Control: This adjusts the lower punch track during the latter part of the fill stage to ensure that the appropriate quantity of granules remains within the die prior to compression.

8. Recompression Rollers: This roller gives the granules an initial compression force to get rid of excess air that might be entrapped in the die.

9. Main Compression: This roller applies the final compression force needed for the formation of a tablet.

10. Ejection Cam: Guides the lower punch upwards facilitating the ejection of the tablet from the die cavity after compression.

11. Take-off Blade: This is fitted in front of the feeder housing and it deflects the tablet down the discharge chute.

12. Discharge Chute: This is where the tablet after being deflected by the takeoff blade passes through for collection (Lachman et al., 1990; Herbert et al., 2006).

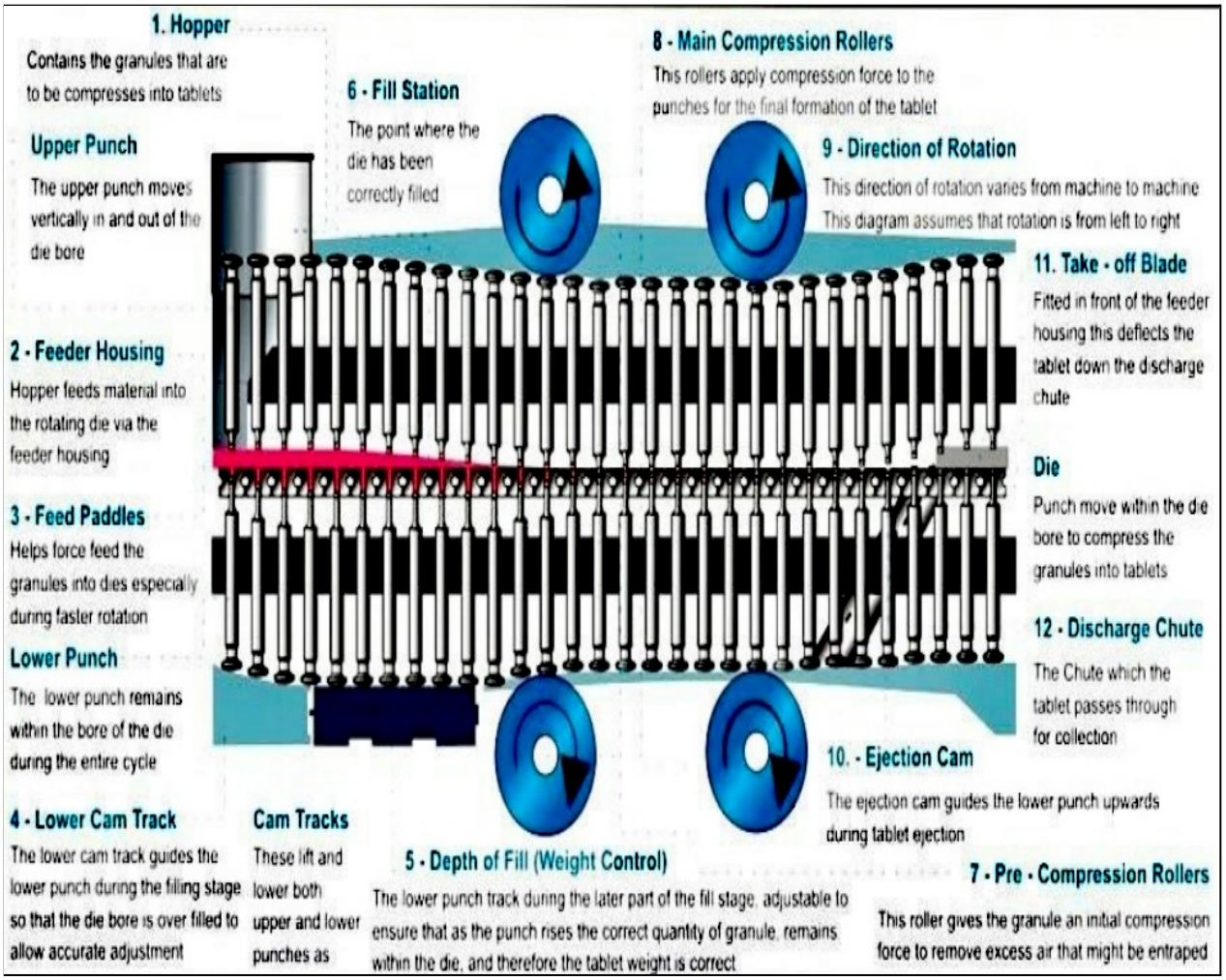

Figure 04: Different parts in tablet compression machine

<u>Various types of machine used are as follows:</u>

1. Single Station Machine:

- It is also called as single punch or eccentric press.
- Simplest of all machine type. It uses a single tooling station that has a die and a pair of upper and lower punch.
- Manual or power operated.
- The compression force is exerted by the upper punch whereas the lower punch stays immovable.
- The instrument used in the press is the compaction of the powder that happens when pressure is exerted through the upper and lower punch.
- The resulting tablet is then formed in the die cavity. Compression involves only the upper punch.

Advantages of Single Punch Tablet Press:

- The single punch structure is rational and small.
- Easy to operate and it operates at a high utilization ratio.
- It can manufacture odd shaped products with a diameter of up to 20 mm.
- It is ideal for development of tablets and small batch production.
- Single punch tablet press utilizes a high amount of pressure to reduce weight variations between tablets while maintaining a low noise level at the same time (Lachman et al., 1990; Larry et al., 2006).

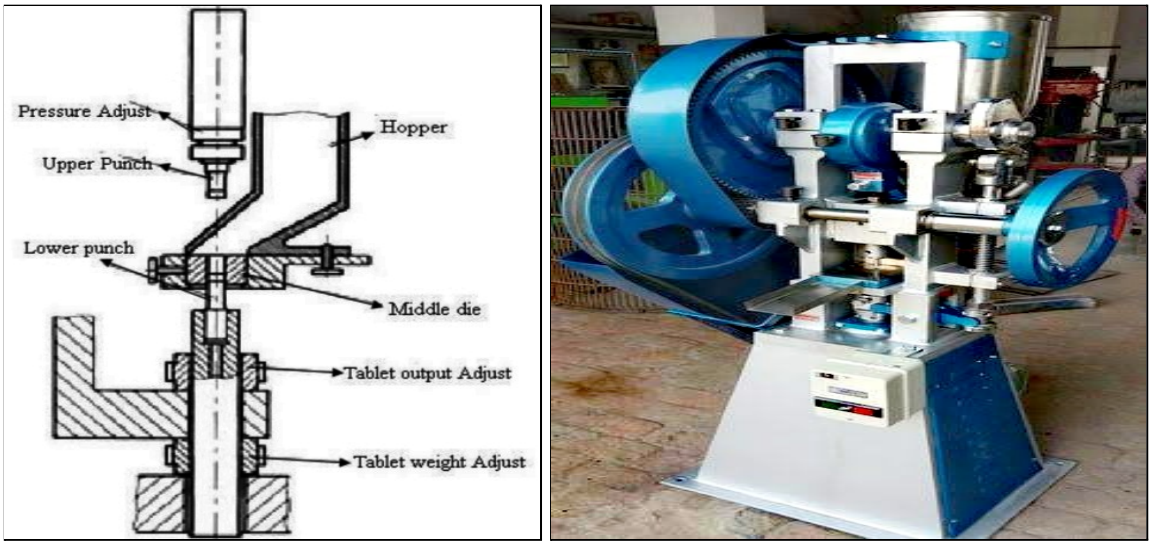

Figure 05: Single Station Machine

2. Multiple Station Machine:

- It is also called the Rotary press.
- The machine head holds the die and the upper and lower punches where the lower punches are in the rotary motion.
- As the head of the machine rotates, the punches move up and down the track. The fixed cam track controls the compression, filling and the ejection process.
- Part of the head that holds the upper and lower punch is also called the upper and lower turrets. The portion that holds the die on the other hand is called the die table.

Advantages of Multi Station or Rotary Press:

- High productivity can be gained with a minimal amount of labour while saving money.
- Rotary press has an output of between 9000 – 234000 tab/hour thus saves time and meets up with the high demand of tablet dosage form.
- The powder filled cavity can be automatically managed by a moving feeder.
- Rotary press decreases waste of valuable formulation in non-specific tablets.
- The machine allows independent control of both weight and hardness (Lachman et al., 1990; Larry et al., 2006).

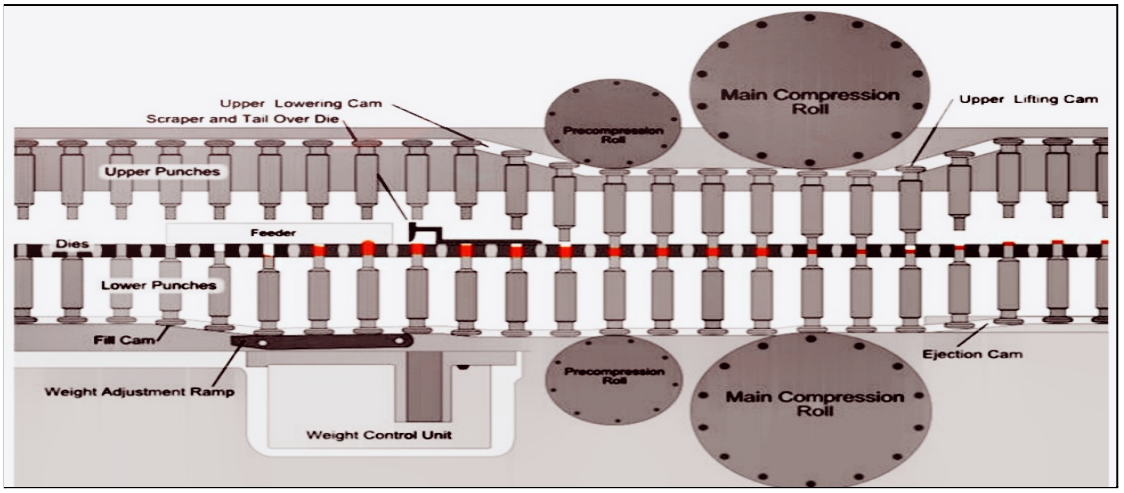

Figure 06: Multi Station Machine

TABLET FORMATION

The events involved in tablet production can be divided into 3 stages;

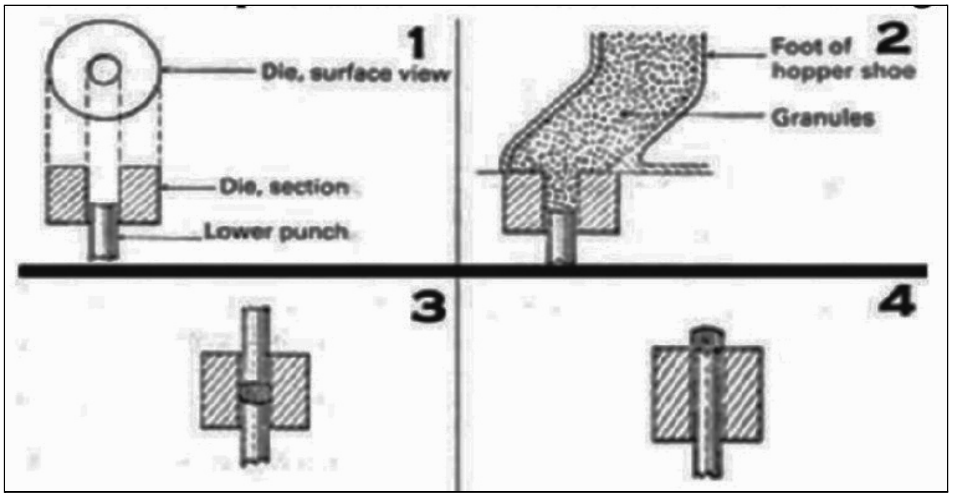

Figure 07: Events involved in tablet production

1. Filing:

- **Position 1:** The upper punch is raised and lower punch drops to create a cavity in the die.
- **Position 2:** Feed shoe moves over the die cavity and granules fall into the die cavity under the influence of gravity from the hopper.

2. Compression:

- **Position 3:** Feed shoe moves out of the way and the hopper punch descends to compress the granules/powder mixture into tablets by progressive reduction of the porosity of the die content and forcing of the particles into close contact with one another.

3. Ejection:

- **Position 4:** The upper punch retracts and the lower punch moves upwards too to eject the compressed tablet. The whole event repeats over and over again until the feed material is exhausted (Lachman et al., 1990; Larry et al., 2006).

TABLETING MACHINE TOOLING

The compression machine tooling determines the shape, identification marking as well as the size of the tablet. Each of the tooling sets includes upper and lower punch as well as dies. As many of the tablets are formed by these equipment, the latter must meet several guidelines in order to produce uniformity in terms of dosage, aesthetic appearance as well as production efficiency (Lachman et al., 1990).

Table 06: Different compression machine tooling

Character	D-tooling	BB Tooling
Barrel diameter	1 inch	0.75 inch
Dies outer diameter	0.945 inch	30.16 mm
Length	5.25 inch	5.25 inch
Head Diameter	1 and 1/4 inch	1 inch

DEFECTS IN TABLET (Katta et al., 2020; Lachman et al., 1990; Herbert et al., 2006).

1. CAPPING: "Capping" is the term used, when the upper or lower segment of the tablet separates horizontally, either partially or completely from the main body of a tablet and comes off as a cap, during ejection from the tablet press, or during subsequent handling.
Reason: Capping is usually due to the air–entrapment in a compact during compression, and subsequent expansion of tablet on ejection of a tablet from a die.

Table 07: Capping related to Granulation

CAUSES	REMEDIES
Large amount of fines in the granulation	Remove some or all fines through 100 to 200 mesh screen
Too dry or very low moisture content	Moisten the granules suitably. Add hygroscopic substance e.g.: sorbitol
Not thoroughly dried granules	Dry the granules properly

Table 08: Capping related to Dies, Punches

CAUSES	REMEDIES
Poorly finished dies	Polish dies properly. Investigate other steels or other materials
Deep concave punches	Use flat punches
Incorrect adjustment of sweep-off blade	Adjust sweep-off blade correctly to facilitate proper ejection
High turret speed	Reduce speed of turret (Increase dwell time)

2. LAMINATION: "Lamination" is the separation of a tablet into two or more distinct horizontal layers.
Reason: Air entrapment during compression and subsequent release on ejection. The condition is exaggerated by the higher speed of the turret.

Table 09: Lamination related to Granulation

CAUSES	REMEDIES
Oily or waxy materials in granules	Modify mixing process. Add adsorbent or absorbent
Too much of hydrophobic lubricant e.g.: Magnesium-stearate	Use a less amount of lubricant or change the type of lubricant

Table 10: Lamination related to Dies, Punches.

CAUSES	REMEDIES
Rapid relaxation of the peripheral regions of a tablet, on ejection from a die.	Use tapered dies, i.e. upper part of the die bore has an outward taper of 3° to 5°
Rapid decompression	Use a pre-compression step. Reduce turret speed and reduce the final compression pressure

3. CHIPPING: "Chipping" is defined as the breaking of tablet edges, while the tablet leaves the press or during subsequent handling and coating operations.
Reason: Incorrect machine settings, specially mis-set ejection take-off.

Table 11: Chipping related to granulation

CAUSES	REMEDIES
Sticking on punch faces	Dry the granules properly or increase lubrication
Too dry granules.	Moisten the granules to plasticize. Add hygroscopic substances
Too much binding causes chipping at bottom	Optimize binding, or use dry binders

Table 12: Chipping related to Dies, Punches

CAUSES	REMEDIES
Groove of die worn at compression point.	Polish to open end, reverse or replace the die
Barreled die (center of the die wider than ends)	Polish the die to make it cylindrical

4. CRACKING: Small, fine cracks observed on the upper and lower central surface of tablets, or very rarely on the sidewall are referred to as "Cracks".
Reason: It is observed as a result of rapid expansion of tablets, especially when deep concave punches are used.

Table 13: Cracking due to Granulation

CAUSES	REMEDIES
Large size of granules	Reduce granule size
Too dry granules	Moisten the granules properly and add proper amount of binder
Tablets expand	Improve granulation. Add dry binders
Granulation too cold	Compress at room temperature

Table 14: Cracking due to Dies, Punches

CAUSES	REMEDIES
Tablet expands on ejection due to air entrapment	Use tapered die
Deep concavities cause cracking while removing tablets	Use special take-off

5. STICKING OR FILMING: "Sticking" refers to the tablet material adhering to the die wall. Filming is a slow form of sticking and is largely due to excess moisture in the granulation.
Reason: Improperly dried or improperly lubricated granules.

Table 15: Sticking related to Granulation

CAUSES	REMEDIES
Granules not dried properly	Dry the granules properly
Too little or improper lubrication	Increase or change lubricant
Too much binder	Reduce the amount of binder
Oily or way materials	Modify mixing process. Add an absorbent
Too soft or weak granules	Optimize the amount of binder and granulation technique

Table 16: Sticking related to Dies, Punches

CAUSES	REMEDIES
Concavity too deep for granulation	Reduce concavity to optimum
Too little pressure	Increase pressure
Compressing too fast	Reduce speed

6. PICKING: "Picking" is the term used when a small amount of material from a tablet is sticking to and being removed off from the tablet-surface by a punch face.
Reason: Picking is of particular concern when punch tips have engraving or embossing letters, as well as the granular material is improperly dried.

Table 17: Picking related to Granulation

CAUSES	REMEDIES
Excessive moisture in granules	Dry properly the granules, determine optimum limit
Too little or improper lubrication	Increase lubrication; use colloidal silica as a "polishing agent"
Too warm granules when compressing	Compress at room temperature
Too much amount of binder	Reduce the amount of binder, change the type or use dry binders

Table 18: Picking related to Dies, Punches

CAUSES	REMEDIES
Rough or scratched punch faces	Polish faces to high luster
Embossing or engraving letters on punch faces such as B, A, O, R, P, Q, G	Design lettering as large as possible
Pressure applied is not enough; too soft tablets	Increase pressure to optimum

7. BINDING: "Binding" in the die, is the term used when the tablets adhere, seize or tear in the die. A film is formed in the die and ejection of the tablet is hindered. With excessive binding, the tablet sides are cracked and it may crumble apart.
Reason: Binding is usually due to excessive amounts of moisture in granules, lack of lubrication and/or use of worn dies.

Table 19: Binding related to Granulation

CAUSES	REMEDIES
Too moist granules and extrudes around lower punch	Dry the granules properly
Insufficient or improper lubricant	Increase the amount of lubricant or use a more effective lubricant
Too coarse granules	Reduce granular size, add more fines, and increase the quantity of lubricant
Too hard granules for the lubricant to be effective	Modify granulation. Reduce granular size

Table 20: Binding related to Dies, Punches

CAUSES	REMEDIES
Poorly finished dies	Polish the dies properly
Rough dies due to abrasion, corrosion	Investigate other steels or other materials or modify granulation
Undersized dies. Too little clearance	Rework to proper size. Increase clearance
Too much pressure in the tablet press	Reduce pressure or Modify granulation

8. MOTTLING: "Mottling" is the term used to describe an unequal distribution of colour on a tablet, with light or dark spots standing out in an otherwise uniform surface.
Reason: One cause of mottling may be a coloured drug, whose colour differs from the colour of excipients used for granulation of a tablet.

Table 21: Mottling related to Granulation

CAUSES	REMEDIES
A coloured drug used along with colourless or whitecoloured excipients	Use appropriate colourants
A dye migrates to the surface of granulation while drying	Change the solvent system.Change the binder
Improper mixing of a coloured binder solution	Incorporate dry colour additive during powder blending step, then add fine powdered adhesives such as acacia and tragacanth.

9. DOUBLE IMPRESSION: "Double Impression" involves only those punches, which have a monogram or other engraving on them.
Reason: At the moment of compression, the tablet receives the imprint of the punch.

Table 22: Double impression related to Punches

CAUSES	REMEDIES
Free rotation of either upper punch or lower punch during ejection of a tablet	Use keying in tooling, i.e. inset a key alongside the punch, so that it fits the punch and prevents punch rotation.
	Newer presses have anti-turning devices which prevent punch rotation

EVALUATION OF TABLET (Indian Pharmacopoeia, 2010)
To design tablets and later monitor tablet production quality, Quantitative evaluations and assessments of a tablet's chemical, Physical and bioavailability properties must be made.

Tablet should comply with the following requirements:

i) Appearance: Uncoated tablet - When a broken section of uncoated tablet is examined under a lens either a relatively uniform texture (single layer tablet) or a stratified structure (multi layer tablet) is seen, there are no signs of coating.

ii) Content of Active Ingredient In Tablet: Determine the amount of active ingredient by the method in the assay; calculate if necessary, the amount of active ingredient in the tablets taken for the assay and divide by the number of tablets taken. The result lies within the range for the content of active ingredients stated in the monograph. These ranges are expressed in terms of the weight stated. The ranges are based on the requirement that 20 tablets or such other numbers as may be indicated in the monograph are used in the assay.

Tablet 23: Weight of medicament in each tablet

Weight of medicament in each tablet	Subtract from the lower limit for sample of			Add to the upper limit for sample of		
	15	10	5	15	10	5
0.12 g or less	0.2	0.7	1.6	0.3	0.8	1.8
More than 0.12 g & less than 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

The requirements of the table apply when the stated limits are between 90 & 110 percent.

iii) Size and Shape: The crown thickness of individual tablets may be measured with micrometres. Other techniques employed in production control involve placing 5 to 10 tablets in a holding tray, where their total crown thickness may be measured with a sliding caliper scale. Total thickness should be controlled within a 5% variation of a standard value.

iv) Organoleptic Properties: The presence of an odor in a batch of tablets could indicate a stability problem, such as the characteristics odor of acetic in degrading aspirin tablets; however the presence of an odor could be characteristics of the drug, (Vitamin have a characteristic odor), added ingredients (flavoring agents have pleasant odor), or the dosage form.

v) Uniformity of Weight: Uncoated tablets comply with the following tests: Weight 20 tablets selected at random and determine the average weight. Not more than two of the individual weights deviate from the average weight by more than the % deviation shown in given table:

Table 24: Average weight of tablet

Average weight of tablet	% deviation
80 mg or less	10
> 80 mg & < 80 mg	7.5
250 mg or more	5.0

vi) Hardness Test: Tablet hardness can be defined as the force required breaking a tablet in a diametric compression. In this test the tablet is placed between two anvils, force is applied to the anvils and the crushing strength that just causes the tablet to break is recorded.

Generally used hardness tester are:

- Monsanto hardness tester
- Strong cobb hardness tester
- Pfizer hardness tester
- Erweka hardness tester
- Schleuniger hardness tester

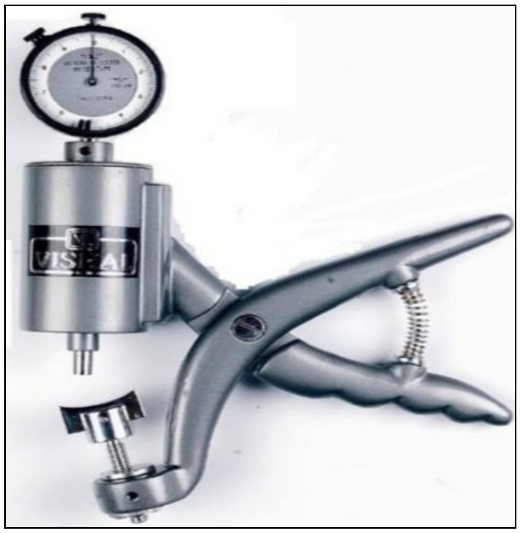

Figure 08: Pfizer hardness tester

Figure 09: Erweka hardness tester

Figure 10: Monsanto hardness tester

vii) Friability Test: The friability tester is also known as the Roche friabilator, a plastic camber that revolves at 25 rpm, dropping the tablets at a distance of six inches with each revolution. Normally, a preweighed tablet sample is placed in the friabilator, which is then operated for 100 revolutions. The tablets are then dusted and reweighed. Conventional compressed tablets that do not lose more than 0.5 to 1.0% of their weight are generally considered acceptable.

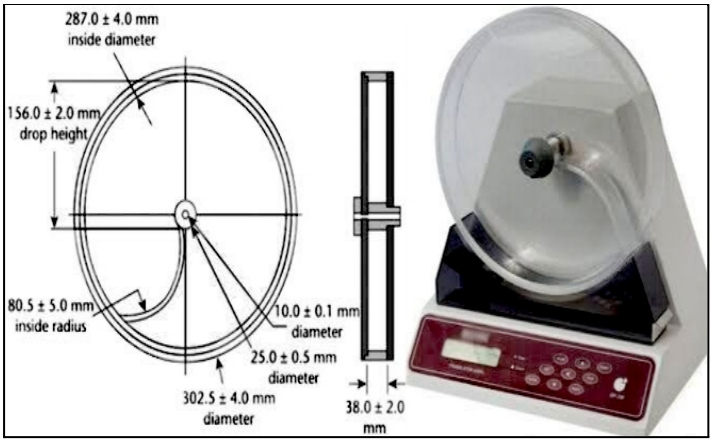

Figure 11: Friability Apparatus

viii) Disintegration Test: Disintegration is defined as that state in which any residue of tablet, except fragments of insoluble coating remaining on the screen of test apparatus, consist of a soft mass having no palpably firm, un moistened core. This test is provided to determine whether uncoated and coated tablets disintegrate within a prescribed time when placed in a liquid medium under the prescribed experimental conditions. This test is not applicable to sustained release tablets.

Table 25: Disintegration testing condition and interpretation (IP)

Type of Tablets	Medium	Temperature	Limit
Uncoated Tablet	Water/Buffer	37 +- 2 °C	15 min or as per individual monograph
Film Coated Tablet	Water	37 +- 2 °C	30 min or as per individual monograph
Sugar Coated Tablet	Water/0.1 N HCL	37 +- 2 °C	60 min or as per individual monograph
Dispersible Tablet	Water	25 +- 1 °C	03 min or as per individual monograph
Effervescent Tablet	Water	25 +- 5 °C	05 min or as per individual monograph
Enteric Coated Tablet	0.1 M HCL mixed phosphate buffer (pH 6.8)	37 +- 2 °C	02 hour in HCL: No disintegration 60 min in buffer: Disintegration
Soluble Tablet	Water	20 +- 5 °C	03 min or as per individual monograph

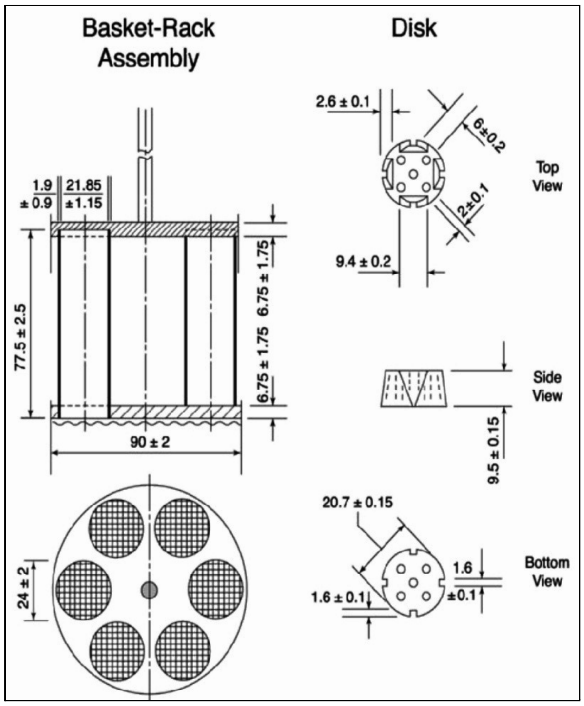

Figure 12: Dimensions in parts of disintegration apparatus

Figure 13: Disintegration Apparatus

ix) Dissolution Test: Unless otherwise specified in the monograph, introduce the vessel 1000ml of water free from dissolved air and previously warmed at 370C. place the specified number of tablets or capsule in the dry basket assembly apparatus, adjusting the distance between the bottom of the basket and the bottom interior surface of the vessel to between 23mm & 27mm. start the motor and adjust the rotational speed to 100rpm or such other speed as indicated in the monograph. Withdraw the starting volume of the solution from the vessel at 45 minutes or at the time or time specified; filter immediately through an inert medium with a nominal pore size of 1µm or less. Determine the amount of active ingredient present by the method given in the monograph. Repeat the complete operation four times.

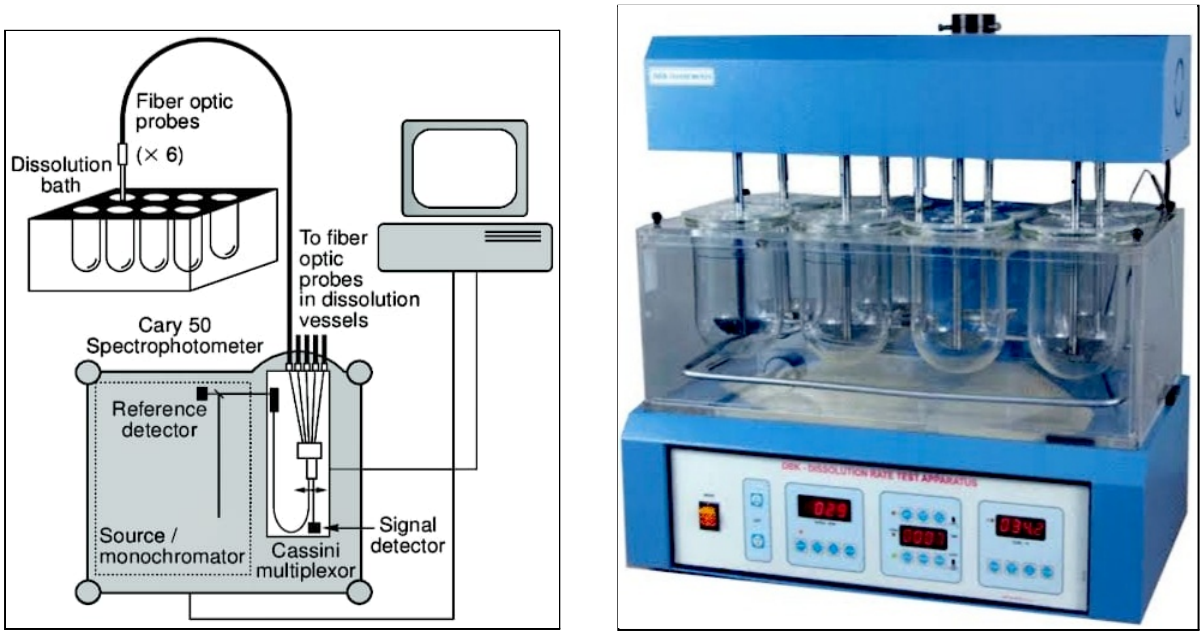

Figure 14: Dissolution Apparatus

PACKING

Packing is the science, art and technology of enclosing or Protecting products.Packing can be described as a coordinated system of preparing goods for transport, warehousing, storage, sale, and end use. Packaging can be defined as a process which confines pharmaceutical products from its genesis in the production unit till it reaches the end user (Yam, 2009).

Any product to reach from the manufacturer to the end user must be packed accordingly to protect itself from the external environment. In the same context especially pharmaceutical products need packaging which is superior to other products so that the product fulfils its main requirement, i.e., uniformity, safety, efficacy, integrity, purity and thereby exhibiting good shelf-life stability profile (Katta et al., 2020).

Factors influencing the type of packaging used for the pharmaceutical product:

- Type of dosage form through which drug will be delivered.
- Route of administration intended for drug delivery.
- The mode from which the medicines will be sold.
- The technique used in dispensing via a combined device/pack.

Types of tablet packing:

Based on the level of contact of formulation with the container;

- **Primary Packaging:** This packaging material is in direct contact with the formulation. Hence it is mandatory to ensure that packaging material doesn't interact with

the drug. E.g. blister packs, strip packs, containers of liquid dosage forms, etc.

- **Secondary Packaging:** This packaging type is in contact with primary packaging, keeping multiple units of products in place during transportation. E.g. 1-ply, 2-ply and 3-ply corrugated boxes.
- **Tertiary Packaging:** This packaging material conceals the above two units of packed products and is in direct contact with secondary packaging. E.g. shrink wraps, plain boxes, cardboard.

Usually, the secondary package is a composite of primary packaging material with the product and Patient information leaflet (PIL). PIL is a document added by the manufacturer which gives information about clinical indications of the drug, type of dosage form, route of administration, storage condition, adverse drug reactions, contraindications and details of the manufacturer.

- **Blister Packing:** WHO defines a blister pack as a multi-dose container consisting of two layers, of which one is shaped to contain the individual doses and is heat-sealed with another layer which may be aluminum, paper, or PET (Polyethylene terephthalate). Blister packs are commonly used as unit-dose packaging for pharmaceutical tablets or capsules. Blister packs are created by means of a form-fill-seal process at the pharmaceutical company or designated contract packer.
- **Strip Packing:** As per WHO strip pack is defined as A multi-dose container consisting of two layers, usually provided with perforations, suitable for containing single doses of solid or semi-solid preparations. The two layers are made of heat sealable paper alloy, aluminum films, glassine.9,10. Strip packaging is a cost-effective packaging solution that enables small sized tablets and capsules to be packed in unit doses for distribution. Strip packaging is the most popular because of its many unique advantages (Katta et al., 2020; Yam, 2009).

Packaging Materials Used For Tablets:

- **Polyvinyl Chloride (PVC):** PVC is highly moisture resistant and is available in different gauges. It can be transparent or can be made opaque or can be tinted in different colors to block specific wavelengths of light. It is the most commonly used blister material because of its affordability and its characteristics like flexibility, thermoforming and rigidity.11
- **Polychlorotrifluoroethylene (PCTFE) Laminations:** It is thermoplastic manufactured by modification of polyethylene (PE). It is fixed to PVC by the aid of adhesive.
- **Aluminium:** The various combinations of packs are formed by combining. E.g. Alu-Alu, Aluminumpaper, aluminum-PET. Aluminum is widely used in strip packs and as lid material in the blister pack.
- **Cellulose Polymers:** Are the main components of paper-based packs. Based on the concentration pulp they are used as lid material for Aluminum or PVC blister packs.

These are the materials used in the packaging of tablets. However, the manufacturer cannot use material of his choice to prepare containers or packages for any dosage form. The list of materials published by the FDA (Food and Drug Administration) which are “Generally regarded as safe (GRAS)” have to be used in packaging material. If the manufacturer intends to use a material that is out of the GRAS list, he has to conduct tests for the intended material and file a New Drug Application to FDA (Katta et al., 2020; Yam, 2009).

DISCUSSION AND CONCLUSION

As a solid dosage form, tablets are popular among patients and practitioners alike as they provide a means of self administration. The formulation of a tablet contains, in addition to the API, various substances to assure proper delivery of the API to the patient. With advancement in technology and increase in awareness towards modification in standard tablets to achieve better acceptability as well as

bioavailability, newer and more efficient tablet dosage forms are being developed. From the above compiled data it was concluded that pharmaceutical tablets can be produced by three methods viz. direct compression, dry granulation and wet granulation. Out of these three methods, direct compression is the most convenient and cheaper method. However, attributing to the few disadvantages of this method, wet and dry granulation methods are used nowadays to produce quality tablets. The main reasons behind formulation of different types of tablets are to create a delivery system that is relatively simple and inexpensive to manufacture. Provide the dosage form that is convenient from the patient's perspective and utilize an approach that is unlikely to add complexity during the regulatory approval process.

In this review article; tablet and its types, formulation and manufacturing processes, evaluation parameters and its defects including its packaging was studied successfully. These studies may be employed as supplement information in respect of the formulation and evaluation parameters in the way of acceptability and quality control for the process of tablet making as solid dosage form.

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