



A REVIEW ON FORMULATION AND EVALUATION OF TABLETS

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ABSTRACT

Tablets are the most commonly prescribed dosage form as offer a convenient form of drug administration provides dosage uniformity from tablet to tablet. As per IP tablet, pharmaceutical tablet are solid, flat or biconvex dishes until dosage form prepare by compressing a drug or a mixture of drug, with or without diluents. Tablet are now the most popular dosage form accounting for some 70% of all ethical pharmaceutical preparation produced. The excipients include diluents, binders adhesive, disintegrant etc., Tablets vary in shape and differ greatly in size and weight depending on the amount of the medicinal substance. Among the various step involved in tablet manufacturing granulation is one of the most important until operation in the production of pharmaceutical tablet dosage form. The present work aims to comprehensively review the advantages ,disadvantages, formulative ingredients preparation methods, applications and evaluation of tablets.

KEYWORDS: Tablets, excipients, granulation techniques, equipments, evaluation test.

INTRODUCTION

Oral route is the most commonly preferred route of drug administration. The popularity of the oral route is due to patient acceptance, ease of administration, accurate dosing and cost effectiveness.^[1] Solid medicaments may be administered orally as powders, pills, cachets, capsules or tablets. Tablet is the most widely used dosage form among the total available dosage forms because it is simple administration, lower price of production, and elegance.^[2] The aesthetic quality like color, texture, mouth feels, and taste masking is depending on coating techniques. Tablets are solid dosage form manufactured either by dry granulation, wet granulation or direct compression medicaments with or without excipients, intended to produce desired pharmacological response.^[3] The oral route is the most popular route used for administration of drugs, which is due in part to the ease of administration and to the fact that gastrointestinal physiology offers more flexibility in dosage form design than other routes. Oral route is most popular for systemic effect due to its easy of ingestion, pain, avoidance, versatility and most importantly, patient compliance.^[4] Solid oral delivery systems (especially tablets) is system of choice among all drug delivery system and they do not require special treatment and are therefore less expensive to manufacture, likewise immediate release tablets are more among all the tablets. An ideal dosage regimen in the drug therapy of any disease or the goal of any delivery system is the one,

which immediately attains the desired therapeutic concentration of drug in plasma (or the site of action) and maintains it constant for the entire duration treatment.^[5] Oral drug delivery is most widely utilized route of administration among all the routes [nasal, ophthalmic, rectal, and Parental routes] that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage form. Oral route is considered most natural, uncomplicated, convenient and safe [in route] due to its ease of administration, patient acceptance, and costeffective manufacturing Pharmaceutical products designed for oral delivery are mainly immediate release type or conventional drug delivery systems, which are designed for immediate release of drug for rapid absorption.^{[6],[7]}

Definition

According to the Indian Pharmacopoeia (IP); Pharmaceutical tablets are solid, flat orbiconvex 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. According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, dosage form, prepared by compressing a drugs or a mixture of drugs, with or without diluents. It is the most popular dosage

form and 70% of the total medicines are dispensed in the form of Tablet.^{[8],[9]}

Advantages

1. The pharmacokinetic interaction (drug–drug) between concomitantly administered medications can be avoided in Tablet in Tablet dosage by creating the time interval in their release.
2. The Tablet in Tablet dosage form gives protection to the hygroscopic or thermo-labile drug.
3. In single Tablet in Tablet dosage form, immediate release and sustain release effect of a similar drug or different drug combination can be achieved.
4. Self-administration is possible Economic than other dosage forms.
5. Lighter and compact than other oral dosage forms.
6. Sustained release product is possible by using polymers.
7. 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.
8. Ease of accurate dose.
9. Release rate of the drug from tablets can be tailored to meet pharmacological requirements.
10. Easiest and cheapest to package and strip.
11. Easy to swallow with least tendency for hang-up.
12. Sustained release product is possible by enteric coating.
13. Objectionable odour and bitter taste can be masked by coating technique.
14. Greatest chemical and microbial stability over all oral dosage forms.
15. Product identification is easy and rapid requiring no additional steps when employing an embossed and/or monogrammed punch face.^{[10],[11],[12]}

Disadvantages

1. Decreased systemic availability in comparison to immediate release conventional dosage forms, which may be due to incomplete release increased first-pass metabolism, increased instability, insufficient residence time for complete release, site specific absorption, pH dependent stability etc.
2. Poor *in vitro* – *in vivo* correlation.
3. Possibility of dose dumping due to food, physiologic or formulation variables or chewing or grinding of oral formulations by the patient thus, increased risk of toxicity.
4. Retrieval of drug is difficult in case of toxicity, poisoning or hypersensitivity reactions.
5. Reduced potential for dosage adjustment of drugs normally administered in varying strengths.
6. Stability problems.
7. Increased cost.
8. More rapid development of tolerance and counseling.
9. Need for additional patient education and counseling.^[13]

Classification of tablets

1. USE Wise:

A. Oral tablets for ingestion

- 1) Standard Compressed Tablets
- 2) Multiple Compressed Tablets
Compression Coated Tablets – a) Sugar coated b) Film coated tablets, c) Gelatin coated tablets, d) Enteric coated tablets, e) Layered tablets
- 3) Targeted Tablets – a) Floating Tablet, b) Colon Targeting Tablet
- 4) Chewable tablets
- 5) Dispersible tablets

B. Tablets used in the oral cavity

- 1) Lozenges and troches
- 2) Sublingual tablets
- 3) Buccal tablet
- 4) Dental cones
- 5) Mouth dissolved / rapidly dissolving tablets

C. Tablets administered by other routes

1. Vaginal tablets
2. Rectal tablets
3. Implants

D. Tablets used to prepare solution

- 1) Effervescent tablets
- 2) Molded tablets
Hypodermic tablets
Dispensing /soluble tablet
- 3) Tablet Triturates.

2. Structure wise

- 1) Divisible Tablets
- 2) Aperture Tablet
- 3) Concave Convex Tablets
- 4) Core Tablet

3. Action wise

- 1) Modified release tablet

Based on the route of administration or the function, the tablets are classified as follows.

- 1) Tablets ingested orally.
 - a) Compressed tablet
 - b) Multiple compressed tablet
 - i) Layered tablet
 - ii) Compression coated tablet
 - c) Repeat action tablet
 - d) Delayed Action and Enteric coated tablet
 - e) Sugar and chocolate coated tablet
 - f) Film coated tablet
 - g) Chewable tablet
- 2) Tablets used in the oral cavity.
 - a) Buccal tablet
 - b) Sublingual tablet
 - c) Troches and Lozenges
 - d) Dental cones
- 3) Tablets administered by other routes.
 - a) Implantation tablet
 - b) Vaginal tablets

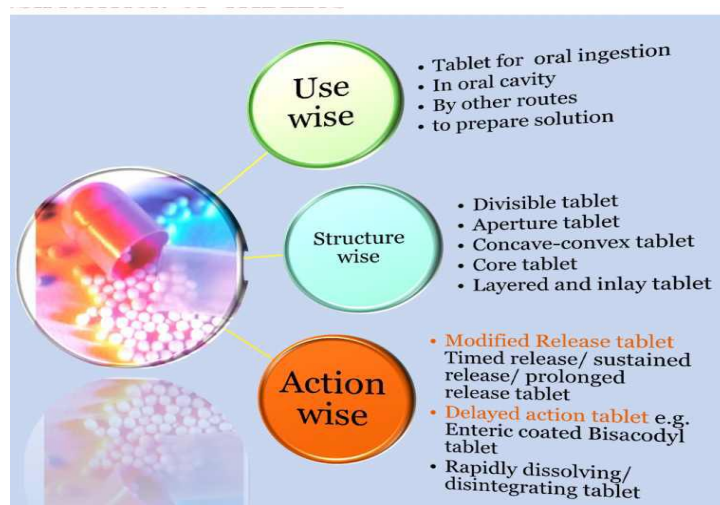
4) Tablets used to prepare solution.^{[14],[15]}

Figure 1

Formulation of tablets

Many excipients for pharmaceutical use are available in several grades. Both classes are often classified by physical and chemical properties. explanation for the grades is to modify the excipient performance characteristics. Excipients are chosen in a tablet formulation to perform variety of functions like for providing essential manufacturing technology functions (binders, glidant, lubricants may be added), for patient acceptance (flavors, colorants may be added), for providing aid in product identification (colorants may be added), for Optimizing or modifying drug release (disintegrant, hydrophilic polymers, wetting agents, biodegradable polymers may be added), for enhancing stability (antioxidant UV absorbers may be added).

a. Diluents (Fillers)

Diluents are fillers used to make the required bulk of the tablet when the drug dosage itself is inadequate to produce the bulk.

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.

To facilitate the handling of tablets during fabrication and to understand the uniformity of the targeted content, the tablet size should be above 2-3 mm and the weight of tablets above 50 mg usually in the range of diluent may vary from 5-80%. Tablet diluent or filler may also be on the basis of their solubility in water and are shown in Table No.1

Table No. 1: Types of diluents.

Sr. no.	Insoluble tablet diluents	Soluble tablet diluent
1.	Starch	Lactose
2.	Powdered cellulose	Sucrose
3.	Microcrystalline cellulose	Mannitol
4.	Calcium phosphates	Sorbital

b. Binders

Binders serve as an adhesive for 'locking together' powders, granules, and tablets to provide the required mechanical strength. Examples binders are dry binders

like pre-gelatinized starch, cross-linked PVP, solution binders like HPMC, PVP and soluble in water/ethanol mix etc.

Binders	Concentration	Comments
Acacia mucilage	Upto 20%	Gives very hard granule
Gulcose	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	Up to 20%	Gives hard granule

c. Disintegrant

Disintegrant, an essential excipient of tablet formulation, is always applied to the tablet to cause tablet breakdown when it comes into with an aqueous fluid, and this process of disintegrating constituent particles before product dissolution occurs is known as disintegrating

phase and disintegrating excipients are known as disintegrating. The aims behind adding disintegrant are to raise the surface area of the tablet fragments and to resolve cohesive forces that bind particles in a tablet together. Different types of disintegrant shown in Table No.2.

Table No. 2: List of disintegrant.

Sr. no.	Disintegrant	Concentration in granules (%w/w)	Special comments
1.	Starch USP	5-20	Higher amount is required, poorly Compressible
2.	Avicel®(PH 101 & 102)	10-20	Lubricant properties and directly Compressible
3.	Solka floc®	5-15	Purified wood cellulose
4.	Alginic acid	1-5	Acts by swelling
5.	Na alginate	2.5-10	Acts by swelling
6.	Explotab®	2-8	Sodium starch glycolate, superdisintegrant

d. Superdisintegrants

All over the world the demand for the faster disintegrating formulation is increased. So, the pharmacist needs to formulate disintegrant i.e

Superdisintegrants which are effective at low concentration and have greater efficiency in disintegrating and are more intra-granular efficient. Table No.3 contains different types of super disintegrant.

Table No. 3: List of Super-disintegrants.

Sr. no.	Superdisintegrants	Example of Superdisintegrants	Mechanism of action	Special Comment
1.	Crospovidone Crospovidone M® Kollidon® Polyplasdone	Crosslinked PVP	Swells very little and returns to original size after compression but act by capillary action	Water-insoluble and spongy in nature so get porous tablet
2.	Sodium starch glycolate Explotab® Primogel®	Crosslinked starch	Swells 7-12 folds in < 30 seconds	Swells in three dimensions and high level serve as sustain release matrix
3.	Alginic acid NF Satialgine®	Crosslinked alginic Acid	Rapid swelling in aqueous medium or wicking action	Promote disintegration in both dry or wet granulation

e. Anti-adherents

Some material has strong adhesive properties against punches and dies metal or the tablet formulation containing excessive moisture tends to cause picking and sticking problems. Anti-adherents or antiadhesive agents

thus prohibit the tablet surface from adhering to the die walls the punches. Talc, stearate from magnesium, and starch from corn have excellent anti-adherent properties. (Different types of antiadherents shown in Table No.4).

Table No. 4: List of Anti-adherents.

Sr. no.	Anti-adherent	Concentration Range (%w/w)	Comments
1.	Talc	1-5	Lubricant with excellent antiadherents Properties
2.	Corn starch	3-10	Lubricant with excellent antiadherents Properties
3.	Colloidal silica	0.1-0.5	It does not give satisfactory results due to the small surface area. Cab-O-Sil® and Syloid®

f. Glidants

It is applied to the formulation to enhance the flow properties of the material to be fed into the die cavity and to assist in the rearrangement particles within the die during the early compression stage. If the flow properties are extremely poor then glidant is ineffective and utilization of force-free mechanisms may be necessary. (e.g. talcum, starch, colloidal silica silicates, stearates calcium phosphate).

g. Wetting agents

Wetting agents in tablet formulation help to absorb water and thereby improve disintegration aid in drug dissolution. It is known to accelerate the dissolution by adding anionic surfactants as Sodium Lauryl Sulphate (SLS). It has been established that SLS improves the permeation drugs through biological membranes since it destroys the path through which the drug has to pass thus minimizing the path length for the drug to travel. (e.g. SLS, Sodium di-isobutyl are used as a wetting agent in tablet formulation)

h. Dissolution retardants

Dissolution retardants are introduced into tablet formulation when the controlled release of is necessary. e.g. stearic acid and their esters etc.

i. Dissolution enhancers

These are the agents that alter the molecular forces between ingredients to enhance dissolution of a solute in the solvent e.g. fructose, povidone, surfactants etc.

j. Adsorbents

The agents that can retain large quantities of liquids are known as adsorbents. Therefore liquids like Vitamin E can be incorporated into tablets by the addition of adsorbents. e.g. Anhydrous calcium phosphate, starch, magnesium carbonate, bentonite, kaolin, magnesium silicate magnesium oxide, and silicon dioxide.

k. Buffers

Buffers are added to maintain a required pH in the formulation. Since a change in pH may cause significant alteration in the stability e.g. Sodium bicarbonate, calcium carbonate, and citrate etc.

l. Antioxidants

Antioxidants are added in a tablet formulation to prevent oxidation. Antioxidants oxidation instead of drugs or block the reaction to oxidation, or act as synergists with other antioxidants. Chelators can act as antioxidants, too. e.g. ascorbic acid and their esters, alpha-tocopherol, ethylene di-amine tetra-acetic acid, sodium metabisulfite, sodium bisulfite, butylated hydroxy toluene (BHT), butylated hydroxy anisole (BHA), citric acid and tartaric acid.

m. Chelating Agents

Chelating agents tend to form complexes with trace amounts of heavy metal ions inactivate their catalytic activity in drug oxidation e.g. ethylene-di-amine tetra acetic acid and its salts, di hydroxy ethyl glycine, citric acid and tartaric acid.

n. Preservatives

Preservatives may be a part of tablet formulation. It prevents the growth of microorganisms in tablet formulation. e.g. parabens like methyl, propyl, benzyl, butyl p-hydroxybenzoate are used as preservatives.

o. Colorants

Colorants do not contribute to therapeutic action or boost the bioavailability or stability of the drug. But these are incorporated into tablets to facilitate identification of similar looking products within a product line; to avoid mix-ups; to facilitate identification of products of appearance that exist in the lines of different manufacturers; to overcome color change on aging, disguising of off-color drugs, for brand image in the market; to enhance the aesthetic appearance of product to have better patient acceptance. Some commonly used pharmaceutical colorants shown in No.5.

Table No. 5: Some Commonly Used Pharmaceutical Colorants (Synthetic)

Sr. no.	FD & C Colour	Common Name
1.	Red 3	Erythrosine
2.	Red 40	Allura Red AC
3.	Yellow 5	Tartrazine

p. Flavors

Flavors are commonly used to improve the taste of chewable and mouth dissolved tablets. Flavors may be incorporated as either solids (spray-dried flavors) or oils or aqueous (water-soluble flavors).

q. Sweeteners

Sweeteners are added primarily to chewable tablets. Table No.6 shows different types of pharmaceutical sweeteners).

Table No. 6: Some of the sweeteners used in tablet formulation.^[16]

Sr. no.	Natural sweeteners	Artificial sweeteners
1.	Mannitol	Saccharin
2.	Lactose	Cyclamate
3.	Sucrose	Aspartame

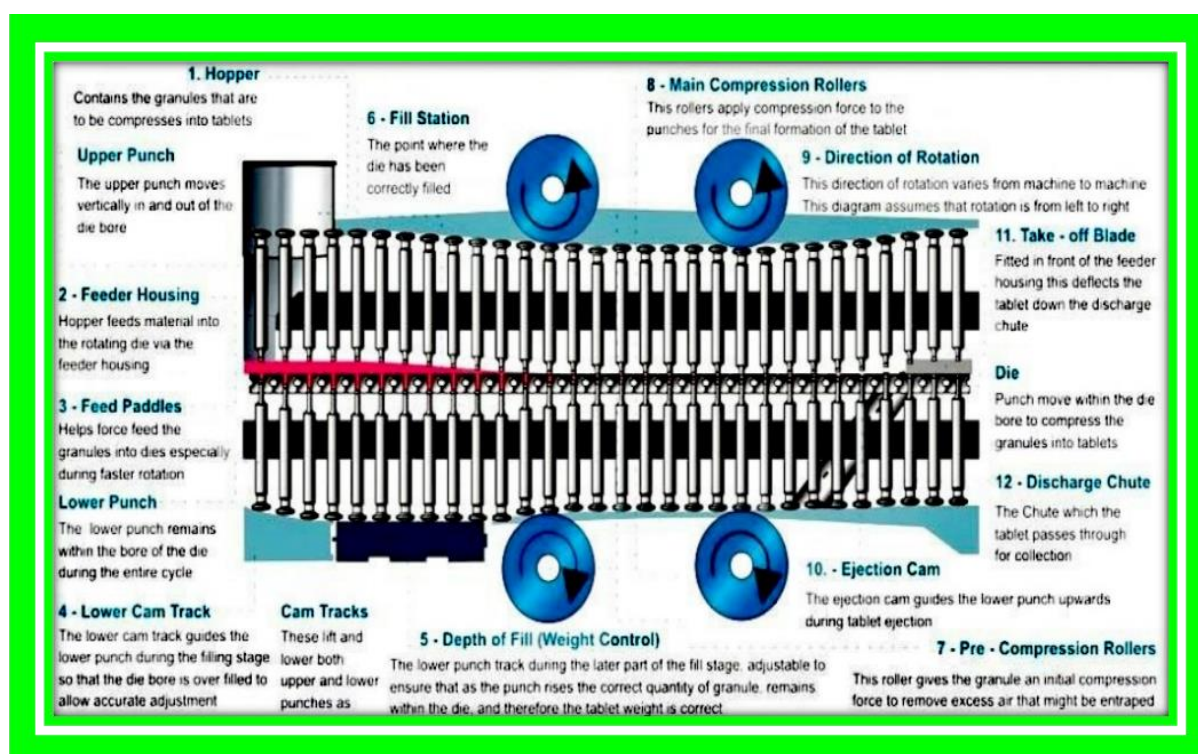
Equipments used

Figure 2: Different parts in tablet compression machine.

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/ then 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.

Various types of machine used are as follows:

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.

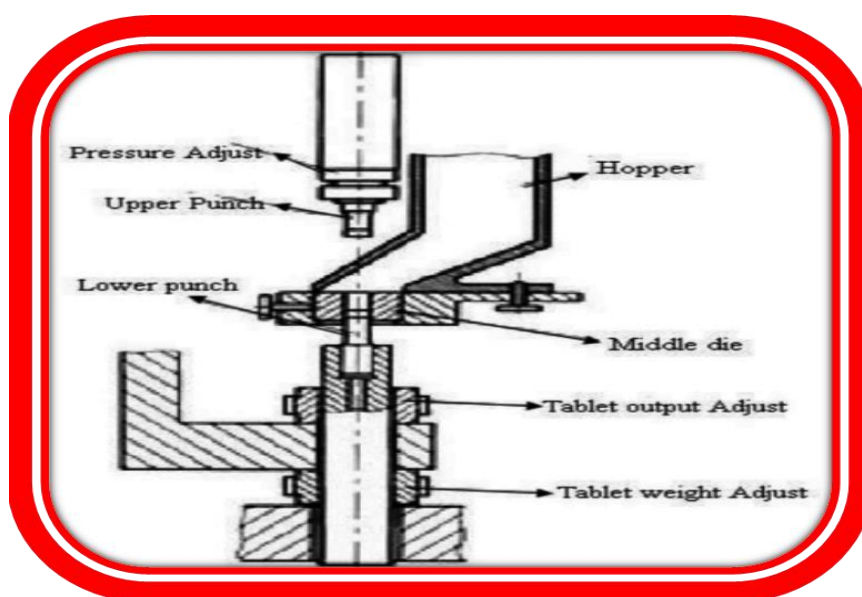


Figure 3

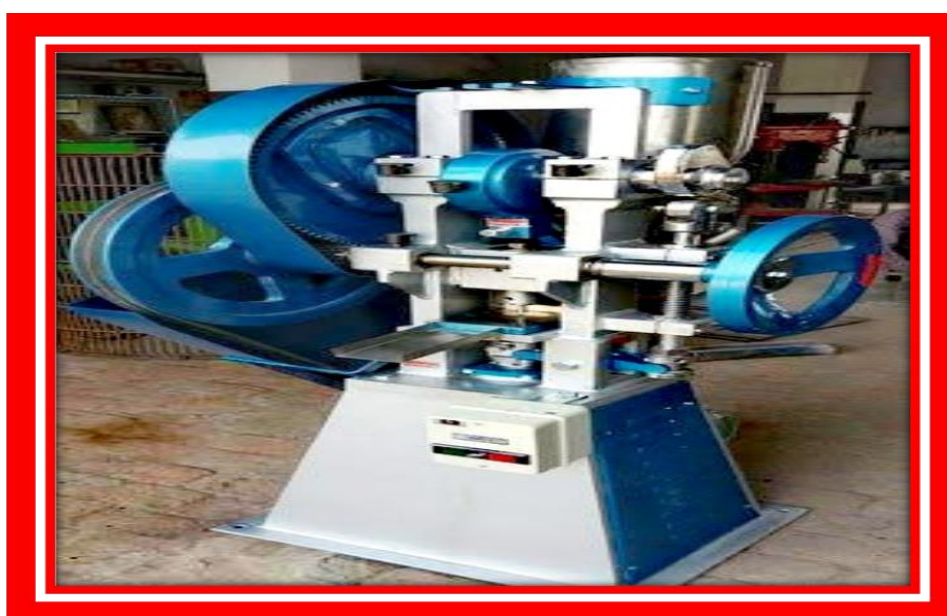


Figure 4: Single station machine.

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

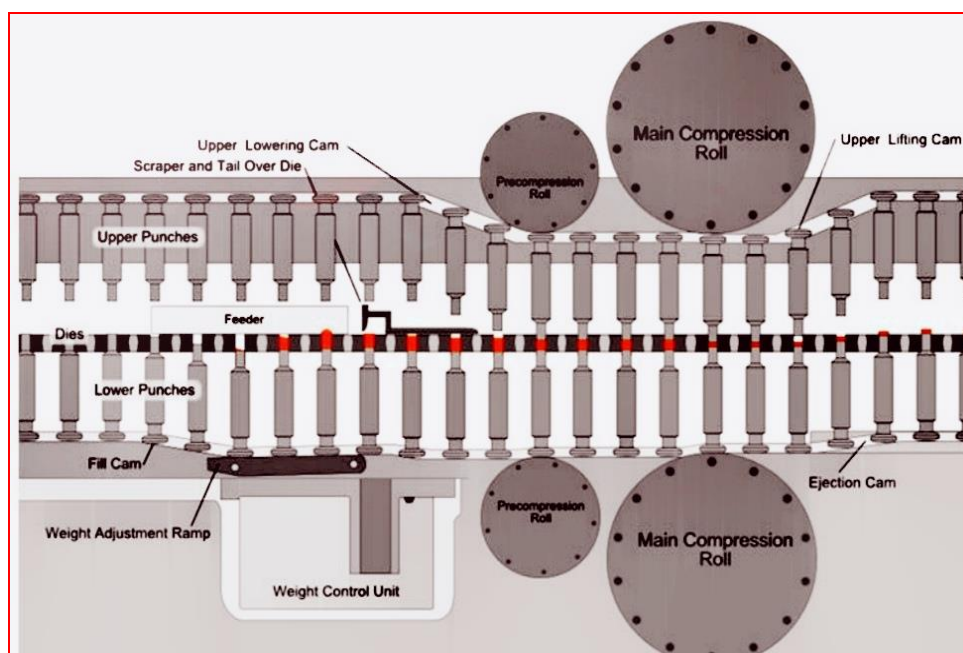


Figure 5: Multi station machine.

Multi station machine

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

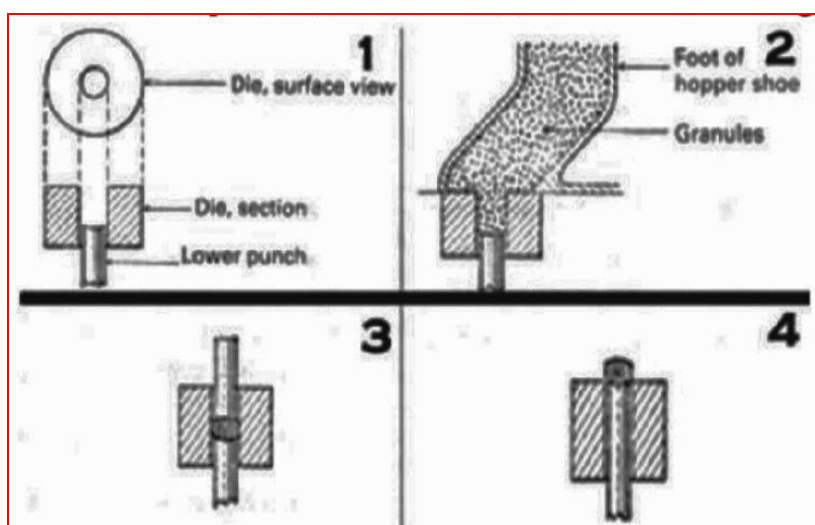


Figure 6

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.

Type of press for bilayer tablet

1. Single sided tablet press.
2. Double sided tablet press.
3. Bilayer tablet press with displacement monitoring.

Single sided tablet press:

The most basic layout is a single-sided press with the doublet feeder's two chambers kept apart. The two distinct layers of tablets are in each chamber using different power sources that are either forced or gravity fed. The first layer of powder and then the second layer of powder put onto the die as it passes beneath the feeder. The tablet is then compressed completely in one or two stages.



Figure 7: (a) Single sided tablet press.



Figure 8: (b) Double sided tablet press.



Figure 9: (c) Bilayer tablet press with displacement monitoring.

Limitations of the single sided press

There is no weight control or monitoring of the individual layers.

- 1) The two levels are not clearly separated visually.
- 2) Due to the small compression roller, the first layer dwell time was extremely brief, perhaps causing issues with capping, hardness, and poor deaeration.
- 3) This can be fixed by slowing down the turret rotation (to increase the dwell time), but the output of tablets will be reduced as a result.

Double sided tablet press: Compression force is used to monitor and regulate tablet weight in the majority of doublesided presses with automated production control. The control system measures, at primary compression of the layer, the effective peak compression force applied to each individual tablet or layer. The signal from this observed peak compression force is what the control system uses to reject out-of-tolerance and adjust the die fill depth as necessary.

Bilayer tablet press with displacement monitoring:

The press's design is based on displacement monitoring and it works on a principle that is fundamentally different from the principle based on compression force. The press design is sensitive when measuring displacement and it depends on the applied pre-compressed force unless the tablet weight.^{[17],[18]}

Evaluation on tablets

Precompression study

Angle of repose

Angle of repose is defined as the maximum angle viable between the surface of a pile of the powder and horizontal aircraft.^[1-6] The frictional pressure in a unfastened powder or granules can be measured by using angle of repose.

$$\tan \theta = h/r$$

$$\theta = \tan^{-1} (h/r)$$

Where, θ is the angle of repose his height of pile
r is radius of the base of pile

Different ranges of flow ability in terms of angle of repose are given in Table

Angle of Repose (degrees)	Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Relationship between angles of repeses and flow properties.

Bulk density

Bulk density is described because the mass of a powder divided via the bulk volume. the majority density of a powder relies upon primarily on particle length distribution, particle shape, and the tendency of the particles to stick to one another.

Method

Loose bulk density (LBD) and tapped bulk density (TBD) both were been determined. A quantity of accurately weighed powder (bulk) from every method,

formerly shaken to interrupt any agglomerates formed become introduced into a 25 ml Measuring cylinder. After the initial extent changed into observed, the cylinder changed into allowed to fall underneath its very own weight onto a difficult surface from the peak of 2.5cm at 2 sec c language. The taping changed into endured until no in addition exchange in extent was cited.

LBD and TBD were calculated using following formula;

$$\text{TBD} = \frac{\text{Weight of powder}}{\text{Volume of packing}}$$

$$\text{LBD} = \frac{\text{Weight of powder}}{\text{Tapped packing.}}$$

True density

True density of granules is carried out by using specific gravity bottle:

- First take the empty bottle weight i.e., W1
- Then add 3/4th of liquid in it, that the weight of that i.e., W2
- Add 1/4th quantity of powder then take the weight i.e., W3
- Finally take the weight of bottle., powder and liquid., W4

It is calculated by using the formula : $(W3 - W1)$

True density = $(W2 - W4) / (W1 - W3) / \rho$

Percentage porosity

This can be calculated by taking the value of bulk density and true density

Percent Porosity = $1 - \text{Bulk density} \times 100 / \text{True density}$

Postcompression studies

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:

- 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.
- 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.

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	0.4	0.4	1.0

Weight of medicament in each tablet

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

- Size and Shape:** The crown thickness of individual tablets may be measured with micrometres. Other techniques employed in 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.

- 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.

- 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:

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

Average weight of tablet

- 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 10: Pfizer hardness tester.



Figure 11: Erweka hardness tester.



Figure 12: 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 pre weighed 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.

$$\% \text{ friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

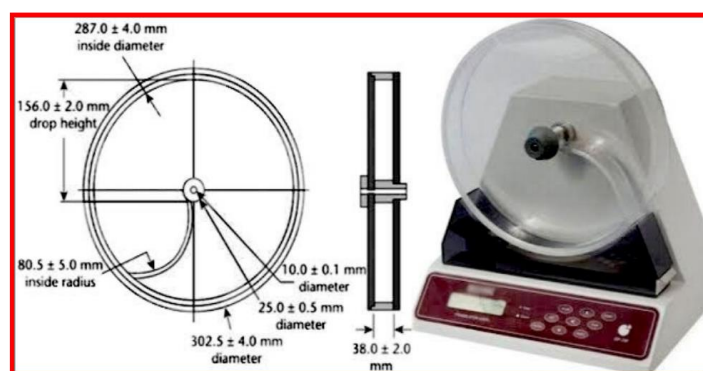


Figure 13: Friability apparatus.

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 conditions. This test is not applicable to sustained release tablets.

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

Disintegration testing condition and interpretation (IP)

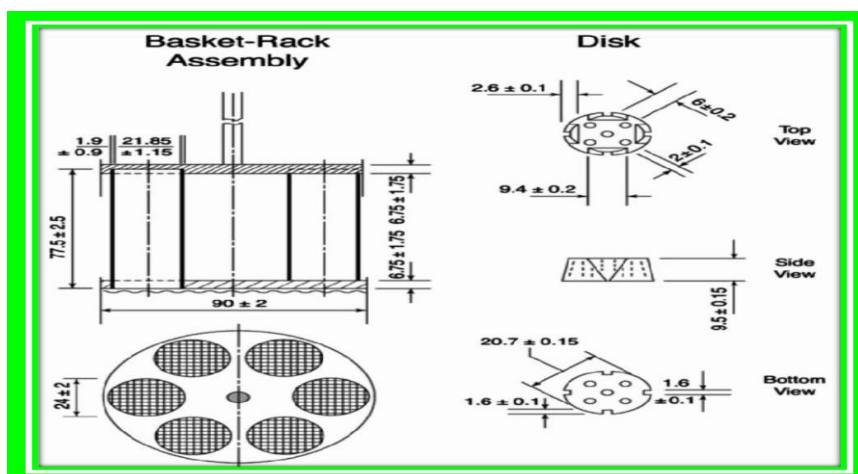


Figure 14

Dimensions in parts of disintegration apparatus



Figure 15: 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 37 degree Celcius. 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.

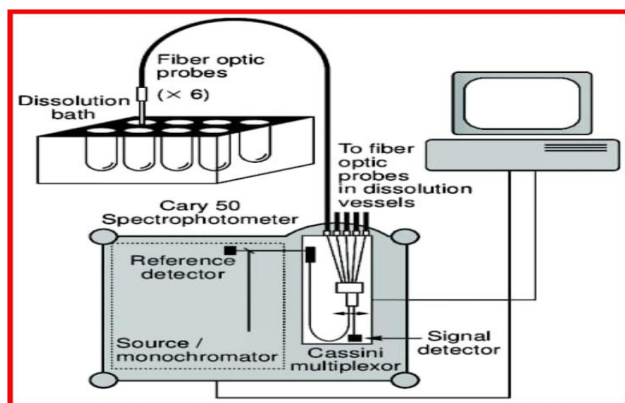


Figure 16



Figure 17: Dissolution apparatus.^{[19],[20]}

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