



A Review on Tablets: Its Formulation and Evaluation

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Abstract:

Solid dosage forms, such as tablets, are widespread in practice. This is due to the ease of administration and capability of mass production by the pharmaceutical industry. Tablets are the most popular dosage form, accounting for some 70% of all ethical pharmaceutical preparations produced. Tablets may be defined as solid pharmaceutical dosage forms containing drug substances with or without suitable excipients and prepared by either compression or moulding methods. 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.

In this review article; tablet and its types, ingredients, preparation and its evaluation have been discussed.

Keywords: Tablets, types, preparation and evaluation

Introduction:

Solid medicaments may be administered orally as powders, pills, cachets, capsules or tablets. These dosage forms contain a quantity of drug which is given as a single unit and they are known collectively as solid unit dosage forms, even in the case of sustained action preparations which, technically, contain the equivalent of several normal doses of drug. The stringent formulation requirements of modern medicaments, the many advantages of tablet and capsule medication, coupled with expanding health services and the commitment need for large-scale economic manufacture, have led to a steady decline in the prescribing of powders and pills, Tablets and capsules, on the other hand, currently account for well over two third of the total number and cost of medicines produced all over the world. Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients. According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drugs or a mixture of drugs, with or without diluents. They vary in shape and differ

greatly in size and weight, depending on amount of medicinal substances and the intended mode of administration. It is the most popular dosage form and 70% of the total medicines are dispensed in the form of Tablet. All medicaments are available in the Tablet form except where it is difficult to formulate or administer.[1]

Advantages:

1. They are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.
2. Cost is lowest of all oral dosage form.
3. Lighter and compact.
4. Easiest and cheapest to package and strip.
5. Easy to swallowing with least tendency for hang-up.
6. Sustained release product is possible by enteric coating.
7. Objectionable odour and bitter taste can be masked by coating technique.
8. Suitable for large scale production.
9. Greatest chemical and microbial stability over all oral dosage form.
10. Product identification is easy and rapid requiring no additional steps when employing an embossed and/or monogrammed punch face.[2]

Disadvantages:

1. Difficult to swallow in case of children and unconscious patients.
2. Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.
3. 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.
4. Bitter tasting drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost.[3]

General properties of Tablets:

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

8. They should be attractive in appearance.[3]

Different types of Tablets:

(A) Tablets ingested orally:

1. Compressed tablet, e.g. Paracetamol tablet
2. Multiple compressed tablet
3. Repeat action tablet
4. Delayed release tablet, e.g. Enteric coated Bisacodyl tablet
5. Sugar coated tablet, e.g. Multivitamin tablet
6. Film coated tablet, e.g. Metronidazole tablet
7. Chewable tablet, e.g. Antacid tablet

(B) Tablets used in oral cavity:

1. Buccal tablet, e.g. Vitamin-c tablet
2. Sublingual tablet, e.g. Vicks Menthol tablet
3. Troches or lozenges
4. Dental cone

(c) Tablets administered by other route:

1. Implantation tablet
2. Vaginal tablet, e.g. Clotrimazole tablet

(D) Tablets used to prepare solution:

1. Effervescent tablet, e.g. Dispirin tablet (Aspirin)
2. Dispensing tablet, e.g. Enzyme tablet (Digiplex)
3. Hypodermic tablet
4. Tablet triturates e.g. Enzyme tablet (Digiplex)[4]

Tablet Ingredients:

In addition to active ingredients, tablet contains a number of inert materials known as additives or excipients.

Different excipients are:

1. Diluent
2. Binder and adhesive
3. Disintegrants
4. Lubricants and glidants
5. Colouring agents
6. Flavoring agents
7. Sweetening agents

Sr. No.	Ingredients	Examples
1	Diluents	Calcium Phosphate; Carboxymethylcellulose Calcium; Cellulose; Dextrin; Lactose; Microcrystalline Cellulose; PR gelatinized Starch; Sorbitol; Starch
2	Binders	Acacia; Alginic Acid; Carboxymethylcellulose; Cellulose; Dextrin; Gelatin; Liquid Glucose; Magnesium Aluminum Silicate; Maltodextrin; Methylcellulose; Povidone; Sodium Alginate; Starch; Zein.
3	Lubricants	Calcium Stearate; Glyceryl Palmitostearate; Magnesium Oxide; Poloxamer; Polyvinyl Alcohol; Sodium Benzoate; Sodium Lauryl Sulfate; Sodium Stearyl Sulfate; Stearic Acid; Talc; Zinc Stearate
4	Glidants	Magnesium Trisilicate; Cellulose; Starch; Talc; Tribasic Calcium Phosphate
5	Anti – adherents	Corn Starch; Metallic Stearate; Talc
6	Disintegrants	Alginic Acid; Carboxymethylcellulose; Cellulose; Colloidal Silicon Dioxide; Croscarmellose Sodium; Crospovidone; Potassium Polacrillin; Povidone
7	Coloring agents	FD&C or D&C Dyes or Lake Pigments
8	Flavoring agents	Ethyl Maltol; Ethyl Vanillin; Menthol; Vanillin
9	Absorbents	Kaolin; Magnesium Aluminum Silicate; Tricalcium Phosphate

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

1. They must be non toxic
2. They must be commercially available in acceptable grade
3. Their cost must be low
4. They must be physiologically inert
5. They must be physically & chemically stable by themselves & in combination with the drugs.
6. They must be free from all microbial contamination.
7. They do not alter the bioavailability of drug.
8. They must be color compatible.

2. Binders: To form cohesive compacts for directly compressed tablet.

3) Lubricants: Lubricants are intended to prevent adhesion of the tablet materials to the surface of dies and punches, reduce inter particle friction and may improve the rate of flow of the tablet granulation.

4) Glidants: Glidants are intended to promote flow of granules or powder material by reducing the friction between the particles.

5) Anti-adherents: Anti-adherents are added to the tablet formulations to prevent the material from sticking to the walls of the tablet press.

6) Disintegrates: Added to a tablet formulation to facilitate its breaking or disintegration when it contact in water in the GIT.

7) Coloring Agents: The use of colors and dyes in a tablet has three purposes: (A) Masking of off color drugs (B) Product Identification (C) Production of more elegant product.

8) Flavoring Agents: Flavoring oils are needed for chewable tablets. The oil is generally added in a dry form such as spray-dried beadlets.

9) Absorbents: The inclusion of absorbents in a tablet formulation is necessary if the product contains a substance with a high affinity to water. Hygroscopic materials, if present, render the blend wet and difficult to handle during manufacture. [5-8]

Preparation:

Tablets are prepared by three methods

- 1) Direct compression
- 2) Wet granulation method
- 3) Dry granulation method

1) Direct Compression:

Direct compression involves direct compressing the powdered material into tablets. Direct compression is adopted, if drug constitutes major portion of tablet [86-90] total weight (Figure 1). Tablets containing 25% or less of drug substances can be formulated, with a suitable diluent which acts as a carrier or vehicle for the drug. Tablets prepared by above method are subjected to compression machine which may be single station or multiple stations

2) Wet Granulation Method:

It is the most common and widely used method. This method involves various steps like weighing of ingredients, mixing, granulation, and screening of damp pass, drying, lubrication and compression of tablets. The main active ingredient, diluent, disintegrant are blended together, and then it is allowed to pass through the sieve (sifting). Solutions of the binding agent are added to the initial mixture. with stirring. The amount of binding agent added should be sufficient, in order to avoid over wetting of the tablet. If the powder is not wetted properly, the granules will be too soft and can be broken down during lubrication, which is difficult during compression of tablet. Tray drying is most common method of drying the tablet granules, Tray drying was the most widely used method of drying tablet granulations in the past, which might be replaced by fluid –bed dryers as a novel approach. After drying the granules, they are allowed to pass through the screen; usually 60-100 mesh nylon cloth is used. After dry granulation, lubricant is added as fine powder, which is required for proper filling of the die cavity (Figure 1).

3) Dry Granulation Method:

This method is used for tablet preparation, in case tablet ingredients are highly sensitive to moisture, or unable to with stand elevated temperatures during drying, slugging may be used to form the granules. Dry granulation or double compression, usually eliminates various steps, which involves slugging of the powder mass. The active ingredient, diluent and lubricant are blended together, to form the slug. Thus, the compressed slug is passed through the mesh or through the mill, and the remaining lubricant is added to the granulation, blended properly and compressed to form the tablets (Figure 1). [5-8]

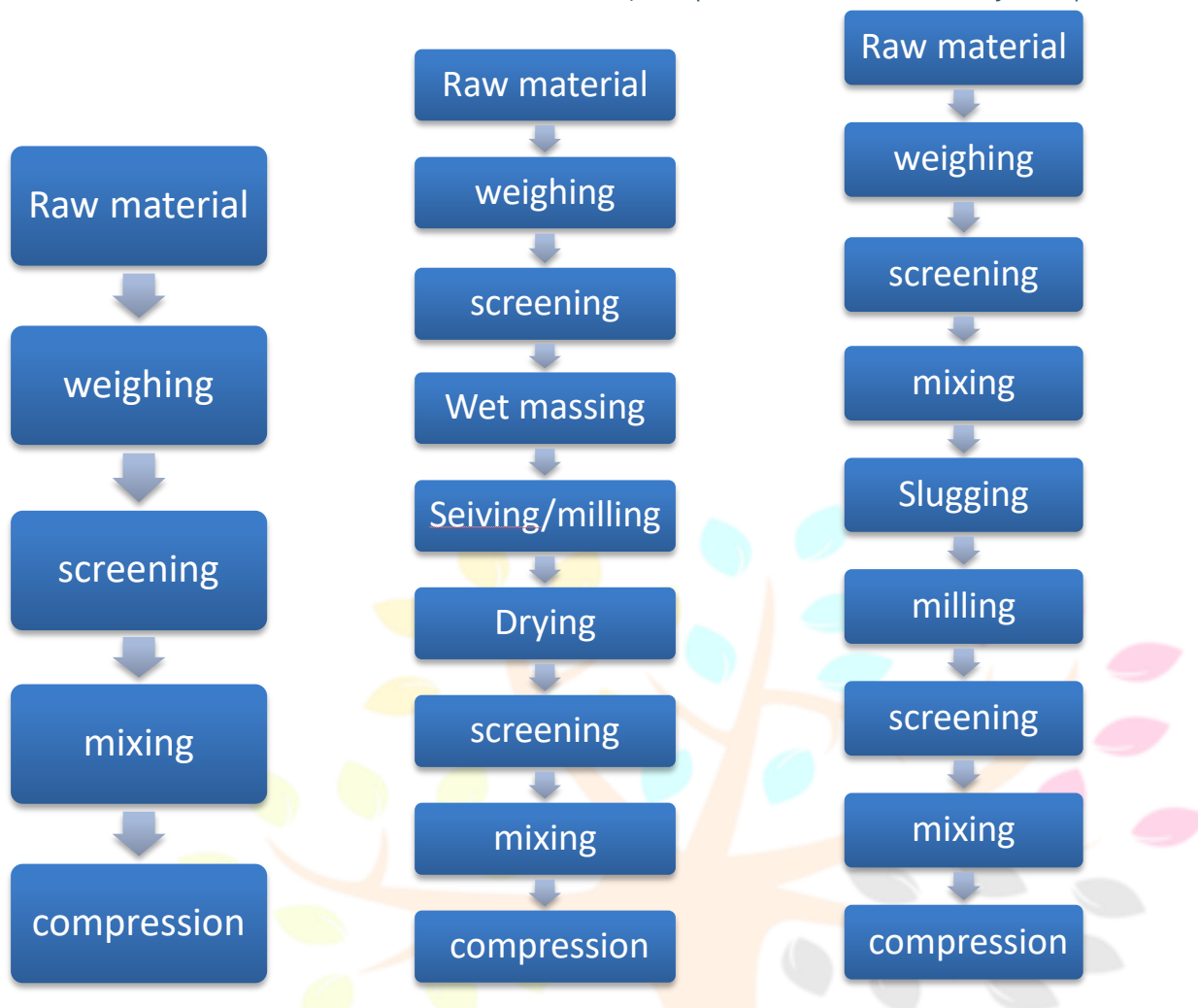


Fig. 1. Processing steps in Direct Compression, Wet Granulation and Dry Granulation

Evaluation of Tablet:

1. 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.

2. Size & Shape: It can be dimensionally described & controlled. The thickness of a tablet is only variables. Tablet thickness can be measured by micrometer or by other device. Tablet thickness should be controlled within a $\pm 5\%$ variation of standard value.

3. Unique identification marking: These marking utilize some form of embossing, engraving or printing. These markings include company name or symbol, product code, product name etc.

4. Organoleptic properties: Color distribution must be uniform with no mottling. For visual color comparison compare the color of sample against standard color.

5. Hardness and Friability: Tablet requires a certain amount of strength or hardness and resistance to friability to withstand mechanical shakes of handling in manufacture, packaging and shipping. Hardness generally measures the tablet crushing strength



Fig. 2. Pfizer type hardness tester



Fig. 3. Monsanto hardness tester

6. Friability: Friability of a tablet can determine in laboratory by Roche friabilator. This consist of a plastic chamber that revolves at 25 rpm, dropping the tablets through a Distance of six inches in the friabilator, which is then operate for 100 revolutions. The tablets are reweighed. Compress tablet that lose less than 0.5 to 1.0 % of the Tablet weigh are consider acceptable.



Fig. 4. Digital Friability Test Apparatus

7. Drug Content and Release:

(I) Weight Variation test (U.S.P.): Take 20 tablet and weighed individually. Calculate average weight and compare the individual tablet weight to the average. The tablet pass the U.S.P. test if no more that 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

(II) Content Uniformity Test: Randomly select 30 tablets. 10 of these assayed individually. The Tablet pass the test if 9 of the 10 tablets must contain not less than 85% and not more than 115% of the labeled drug content and the 10th tablet may not contain less than 75% and more than 125% of the labeled content. If these conditions are not met, remaining 20 tablet assayed individually and none may fall outside of the 85 to 115% range.

(III) Disintegration Test (U.S.P.): The U.S.P. device to test disintegration uses 6 glass tubes that are 3” long; open at the top and 10 mesh screen at the bottom end. To test for disintegration time, one tablet is placed in each tube and the basket rack is positioned in a 1-L beaker of water, simulated gastric fluid or simulated intestinal fluid at 37 ± 2 C such that the tablet remain 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm from the bottom of the beaker in their downward movement. Move the basket containing the tablets up and down through a distance of 5-6 cm at a frequency of 28 to 32 cycles per minute. Floating of the tablets can be prevented by placing perforated plastic discs on each tablet.

According to the test the tablet must disintegrate and all particles must pass through the 10 mesh screen in the time specified. If any residue remains, it must have a soft mass. Disintegration time: Uncoated tablet: 5-30 minutes
Coated tablet: 1-2 hours



Fig. 5. Disintegration test apparatus

3.Dissolution Test (U.S.P.): Two set of apparatus:

Apparatus-1: A single tablet is placed in a small wire mesh basket attached to the bottom of the shaft connected to a variable speed motor. The basket is immersed in a dissolution medium (as specified in monograph) contained in a 100 ml flask. The flask is cylindrical with a hemispherical bottom. The flask is maintained at $37\pm 0.50^{\circ}\text{C}$ by a constant temperature bath. The motor is adjusted to turn at the specified speed and sample of the fluid are withdrawn at intervals to determine the amount of drug in solutions.

Apparatus-2: It is same as apparatus-1, except the basket is replaced by a paddle. The dosage form is allowed to sink to the bottom of the flask before stirring. For dissolution test U.S.P. specifies the dissolution test medium and volume, type of apparatus to be used, rpm of the shaft, time limit of the test and assay procedure for. The test tolerance is expressed as a % of the labeled amount of drug dissolved in the time limit. [9-25]

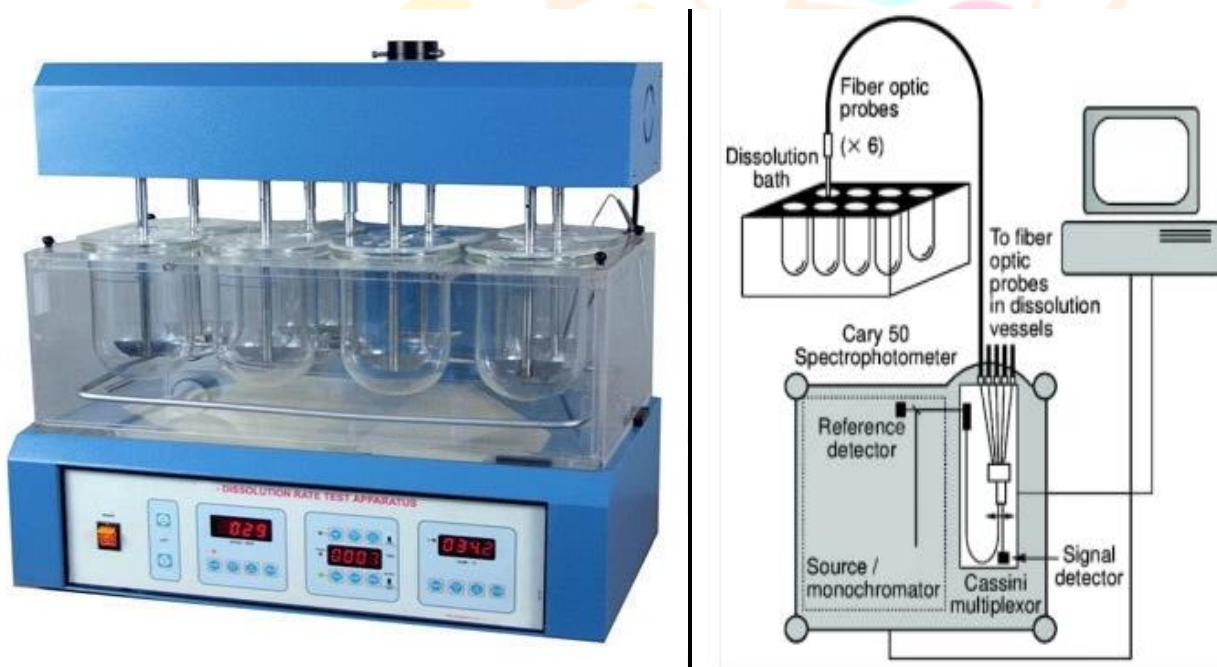


Fig. 6. Dissolution test apparatus

CONCLUSION:

Tablet manufacturing and its evaluation has become the backbone of pharmaceutical research. From the various data sources it could be concluded that tablets have got uniqueness and power of adaptability. The tablets have shown vast changes in the last few decades or so both in manufacturing and evaluation. The advances in the evaluation techniques have proven to be both economical and time saving. From the number of manufacturing and

evaluation parameters available the scope for the researchers also enhances and makes it possible for tablets to perfectly cement its place in this ever changing drug world.

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