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Solid dosage forms: Tablets

Nagashree K^{1*}

¹Department of Pharmaceutics, MNR college of pharmacy, Hyderabad, India

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*For Correspondence

Nagashree K, Department of Pharmaceutics, MNR college of pharmacy, Hyderabad, India, E-mail: nagashreek@gmail.com

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ABSTRACT

Oral drug delivery is most commonly route of administration, when compared to all other route of administration. Oral route is most convenient, safe route of administration. Solid medicaments may be administered orally like tablets, capsules, pills, powders etc. One of the solid dosage form administered orally is tablet. Tablets are solid dosage form containing medicaments with or without excipients. Tablets are prepared by compressing a drug with or without diluents.

INTRODUCTION

Tablets are solid dosage form manufactured either by dry granulation, wet granulation or direct compression containing medicaments with or without excipients, intended to produce desired pharmacological response. Various types of tablets [1-15] are being manufactured according the route of administration and type of dosage form.

Tablets ingested orally includes

1. Film coated tablet.
2. Sugar coated tablet
3. Chewable tablet
4. Delayed release tablet
5. Compressed tablet like paracetamol
6. Multiple compressed tablet
7. Enteric coated tablets

Sugar coated tablets: These are compressed tablets which are coated with sugar, in order to mask the bitter taste or odor of the drug.

Film-Coated Tablets (FCT) – These are compressed tablets covered with a thin layer or film of a water-soluble material. A number of polymeric substances may be used for film coating. Film coating imparts the same general characteristics as sugar coating, in addition it offers reduced time period required for the coating operation.

Enteric-Coated Tablets (ECT) – these are compressed tablets which are coated with substance, which disintegrates in intestine.

Compressed Tablets (CT)- these tablets are prepared by compression technique in which tablets are not coated with any material.

Multiple Compressed Tablets (MCT) – these tablets are subjected to more than one compression cycle.
Chewable tablet-these tablets are placed to mouth which are chewed and swallowed.

Tablets used in oral cavity includes

1. Sublingual tablet
2. Buccal tablet
3. Lozenges

Buccal and Sublingual Tablets: These are small flat oval tablets. These tablets are formulated and compressed with sufficient pressure to give a desired buccal tablet. These tablets are administered by inserting in buccal pouch which may dissolve slowly.

Sublingual tablets: Sublingual tablets or lozenges may dissolve rapidly and are absorbed readily .

Tablets used to prepare solution includes

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

Effervescent Tablets: They contain sodium bicarbonate and an organic acid such as tartaric or citric acid along with the drug. In the presence of water, they react liberating carbon dioxide which acts as a distintegrator and thus produces effervescence.

Molded Tablets: Tablet Triturates are made from moist material using triturate mold, must be completely and rapidly soluble.

Dispensing tablet: these tablets are prepared by molding or compression.

Tablets which are administered via other route includes:

1. Vaginal tablet
2. Implantation tablet

Implants-these are small tablets which are prepared for insertion under the skin.**Sub Heading**

Tablets preparation

Tablets [16-30] are usually prepared by compression technique, which includes various ingredients like diluents, binders, disintegrants, lubricants, glidants, etc

Diluents:Diluents are normally used as a fillers, in order to increase the bulk of the tablet. Example for diluents includes lactose, starch, mannitol, etc

Binders and adhesives: Binders are either added in wet form or dry form, which serves as a binding agent in the formulation. Commonly used binders includes starch, carboxy methyl cellulose, acacia.The type of the binder added vary with the formulation. The amount of binder added and type of binder influences the tablet properties.

Disinetegrants:These are added , in order to aid in disintegration or breaking of tablet in GIT.
Disintegrants like starch, clays, cellulose are used.

Lubricants:Lubricants prevents sticking of tablets to dies and punches. : talc, stearic acid, magnesiu stearate.

Glidant:They reduce the friction, thus aid in free flow of granules or powder. Commnly used glidants includes starch and talc

Colouring agents:Helps in elegant appearance of the product. Examples of coloring agents like brilliant blue

Sweeting agent:Seeting agent are added in order to mask the bitter taste of the drug.
Ex: aspartame, mannitol, lactose.

Flavouring agent:Added in order to impart flaovour or odour to the table formulation

Ex: Menthol, clove oil, vanilla

Role of excipients in tablet formulation:

- modify the drug release characteristics
- Enhance the solubility and bioavailability of dosage form
- Imparts weight, volume
- Increases better patient compliance

Tablet preparation methods:

Tablets [31-45] are prepared by three methods

- wet granulation method
- dry granulation method
- direct compression

Wet granulation method

It is the most common and widely used method. This method involves various steps like weighing of ingredients, mixing, granulation, screening of damp pass, drying, lubrication and compression of tablets.

The main active ingredient, diluent, disintegrant are blended together, 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 [46-60]. 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.

Dry granulation method

This method is used for tablet preparation, in case tablet [61-85] ingredients are highly sensitive to moisture, or unable to withstand 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.

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. 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 station .

Tablet should possess following characteristics

- Should be free from defects like cracks, discoloration, chips etc.
- Should able to withstand mechanical stress
- Physically and chemically stable

During processing of tablets [91-104] during compression, there several processing problems encountered such as:

-picking, sticking, capping, lamination, mottling

Picking: The tablet surface material may be removed by a punch during compression.

Sticking:adhesion of tablet to the die wall, which may occur due to excessive moisture in the tablet.

Capping: it is partial or complete separation of tablet from the top or bottom crowns of the tablet from the main body.

Lamination: Segregation of a tablet into two or more distinct layers. Capping and lamination may occur due to air entrapment during processing

Mottling: Unequal distribution of color on tablet surface results in mottling.

Advantages:

- Light and compact
- Easy to swallow
- Better patient compliance
- Bitter taste of the drug can be masked by coating
- Cheaper to other solid medication

Disadvantages:

- difficult to swallow in case of children and elderly patients.
- Drugs with poor wetting, show slow dissolution profile.
- Some drug resist compression, due to their amorphous nature.

Evaluation tests

After tablet compression, tablets [105-112] are subjected various evaluation tests to ensure the tablets withstand sufficient mechanical strength, etc.

General appearance: it includes overall appearance of the tablet like size, shape, odor, taste, color, surface, consistency, textures physical flaws. Tablet thickness should be controlled with $\pm 5\%$ variation of standard value.

Weight variation test: Twenty tablets are weighed randomly in a batch , and the average weight of the tablet is determined. As per the IP specification,if the tablet weight is

< 80mg- deviation upto 10% is allowed

80-250mg - deviation upto 7.5% is allowed

>250 mg- deviation upto 5% is allowed

If any tablet deviates from the specification, another 10 tablets are selected from the batch and the same procedure is repeated. In case of 30 tablets, not more than one tablet should deviate.

Hardness test: It is defined as the force required to break the tablet [113-120]. This test is performed in order to ensure that the tablet withstands mechanical shocks during manufacture, packaging and shipping of tablet. Various types of hardness testers are used to measure the hardness of the tablet like: Monsanto hardness tester, strong cobb testre, pfizer tester etc.The tablet hardness should be 2.5-5kg/cm² (for conventional tablets), for extended release tablets hardness should be 5-7.5 kg/cm².

Friability test: Friability test is performed, in order to ensure the mechanical strength of the tablet during transportation, packing etc. Roche friabilator is the instrument, used to carry out the friability test, in which tablets are weighed before friabilation, and subjected to friabilation with a speed of 25 rpm. Thus the tablets are weighed after friabilation, and the percentage friability is determined. The deviation should be between 0.5-1%.

Disintegration test: Disintegration is the breakdown of tablet into finely divided particles or granules in GI tract. Disintegration time for uncoated tablets [121-125] should be 15 minutes, 60 minutes for sugar coated tablets, and 30 minutes for film coated tablets.

Dissolution test: the time required for the given percentage of drug in tablet, to go into solution, under specified set of conditions as in invitro test. It can also be considered as solubilisation of drug in dissolution media. Several dissolution apparatus like paddle over disk, flow through cell, cylindrical apparatus, paddle over disk, etc. used depending on the type of dosage form. For tablets rotating basket and rotating paddle type is most commonly used.

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