

CHAPTER 11

TABLETS

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Abstract

Tablets are the most widely used solid dosage form in pharmaceutical practice, offering advantages such as precise dosing, stability, and patient convenience. This section explores the various types of tablets, including immediate-release, modified-release, and orally disintegrating tablets, each designed to meet specific therapeutic needs. The composition of tablets, including active ingredients and excipients such as diluents, binders, disintegrants, and lubricants, is discussed in detail. Tablet manufacturing processes, from wet granulation and dry granulation to direct compression, are examined, highlighting the factors influencing the choice of method. Critical quality attributes of tablets, such as hardness, friability, disintegration time, and dissolution rate, are explored along with their testing methods. The principles of tablet press operation and the impact of compression forces on tablet properties are addressed. Coating processes, including film coating and sugar coating, are discussed in relation to their functional and aesthetic benefits. Common tablet defects, their causes, and remedies are outlined to aid in troubleshooting manufacturing issues.

Keywords: *Solid dosage form, Compression, Granulation, Dissolution, Coating, Quality control*

Learning Objectives

After completion of the chapter, the student should be able to:

- Define tablets and explain their advantages as a dosage form.
- Describe the different types of tablets and their specific applications.
- Explain the composition and function of various tablet ingredients.
- Outline the manufacturing processes for different types of tablets.
- Discuss the quality control tests and specifications for tablets.
- Analyze common problems in tablet manufacturing and their solutions.
- Evaluate the factors affecting tablet disintegration, dissolution, and bioavailability.

Tablets may be defined as solid pharmaceutical dosage forms containing drug substances with or without suitable diluents and prepared either by compression or moulding methods. This dosage form is intended to be administered through oral route.

Definition: “Pharmaceutical tablets are flat or bi-convex discs prepared by compressing a drug or a mixture of drugs with or without suitable diluents.”

Advantages of tablet dosage form over other oral drug delivery systems:

From patients stand point:

1. They are easy to carry.
2. They are easy to swallow.
3. They are attractive in appearance.
4. Unpleasant taste can be masked by sugar coating .

5. They do not require any measurement of dose. The strip or blister packing has further facilitated the process of taking the dose by the patient. Moreover, it provides a sealed covering which protects the tablets from atmospheric conditions like air, moisture and light etc.
6. Some of the tablets are divided into halves and quarters by drawing lines during manufacturing to facilitate breakage whenever a fractional dose is required.

From the standpoint of manufacturer:

7. An accurate amount of medicament, even if very small, can be incorporated.
8. Tablets provide prolonged stability to medicament. They have the best combined properties of chemical, mechanical and microbiological stability of all the oral dosage forms.
9. The incompatibilities of medicaments and their deterioration due to environmental factors are less in tablet forms.
10. Since they are generally produced on a large scale, therefore, their cost of production is relatively low, hence economical.
11. They are in general the easiest and cheapest to package and ship among all oral dosage forms.
12. Some specialized tablets like enteric coated tablet, sustained release tablets may be prepared for modified release profile of the drug.
13. Product identification is potentially the simplest and cheapest requiring no additional processing steps when employing an embossed or monogrammed punch face.

Disadvantages of tablet dosage forms:

- (i) Some drugs resist compression into dense compacts, owing to their amorphous nature or flocculent, low-density character.
- (ii) Drugs with poor wetting, slow dissolution properties, intermediate to large dose, or any combination of these

features may be difficult or impossible to formulate and manufacture as a tablet that will still provide adequate bioavailability.

- (iii) Bitter tasting drugs, drugs with objectionable odour, or drugs sensitive to oxygen or atmospheric moisture may require encapsulation or entrapment prior to compression (if feasible or practical) or the tablets may require coating.

TYPES OF TABLETS

Tablets are classified according to their route of administration or function. The following are the four main classification groups:

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| (A) <u>Tablets ingested orally:</u> | (C) <u>Tablets administered by other routes:</u> |
| (i) Compressed tablets | (i) Implantation tablets |
| (ii) Multiple compressed tablets | (ii) Vaginal tablets |
| (iii) Enteric coated tablets | (D) <u>Tablets used to prepare solutions:</u> |
| (iv) Sugar coated tablets | (i) Effervescent tablets |
| (v) Film coated tablets | (ii) Dispensing tablets |
| (vi) Chewable tablets | (iii) Hypodermic tablets |
| (B) <u>Tablets used in the oral cavities:</u> | (iv) Tablet triturates |
| (i) Buccal cavities | |
| (ii) Sublingual tablets | |
| (iii) Lozenges | |
| (iv) Dental cone | |

(A) TABLETS INGESTED ORALLY

These tablets are designed to be swallowed except the chewable tablets. The tablets covered in this category are:

Compressed tablets (C.T.)

These tablets are formed by compression and contain no

special coating. They are made from powdered, crystalline or granular materials, alone or in combination with diluent, binders, disintegrants, lubricants, antiadherants and in many cases colorants.

These tablets contain water soluble drugs which after swallowing get disintegrated in the stomach and its drug contents are absorbed in the gastrointestinal tract and distributed in the whole body. e.g. Aspirin (Dispirin) paracetamol tablets (Crocin)

Multiple compressed tablets:

These are compressed tablets made by more than one compression cycle:

Layered tablets

Such tablets are prepared by compressing additional tablet granulation on a previously compressed granulation. The operation may be repeated to produce multilayered tablets of two or three layers. Special tablet presses are required to make layered tablets such as *Versa press*. (Stokes/Pennwalt) These tablets are prepared to separate physically or chemically incompatible ingredients or to produce repeat action or prolonged action products.

To avoid incompatibility, the ingredients of the formulation except the incompatible material are compressed into a tablet and then incompatible substance along with necessary excipients are compressed over the previously compressed tablet.

Sustained action tablets

These are the tablets which after oral administration release the drug at a desired time and prolong the effect of the medicament. These tablets when taken orally release the medicament in a sufficient quantity as and when required to maintain the maximum effective concentration of the

drug in the blood throughout the period of treatment.

e.g. Diclofenac SR tablets.

Enteric coated tablets

These are compressed tablet meant for administration by swallowing and are designed to by-pass the stomach and get disintegrated in the intestine only.

These tablets are coated with materials resistant to acidic pH (like cellulose acetate phthalate, CAP) of the gastric fluid but get disintegrated in the alkaline pH of the intestine. These tablets are made to release the drug undiluted and in the highest concentration possible within the intestine, e.g. tablets containing anthelmintic and amoebicides.

Sugar coated tablets

These are compressed tablets containing a sugar coating. Such coatings are done to mask the bitter and unpleasant odour and the taste of the medicament. The sugar coating makes the tablet elegant and it also safeguard the drug from atmospheric effects.

Film coated tablets

The compressed tablets having a film coating of some polymer substance, such as hydroxy propyl cellulose, hydroxy propyl methyl cellulose and ethyl cellulose. The film coating protects the medicament from atmospheric effects. Film coated tablets are generally tasteless, having little increase in the tablet weight and have less elegance than that of sugar-coated tablets.

Chewable tablets

These are the tablets which are required to be broken and chewed in between the teeth before ingestion. These tablets are given to the children who have difficulty in swallowing and to the adults who dislike swallowing.

A number of antacid tablets and multivitamin tablets are prepared as chewable tablets.

For the preparation of chewable tablets mannitol is used as a sweetening base. Since mannitol is expensive other substances like sorbitol, lactose, chocolate powder, dextrose and glycerin can be substituted in place of mannitol. these tablets do not require any disintegrating agents to be present in the formulation.

These tablets should have very acceptable taste and flavour.

e.g. antacid tablets

Vitamin C chewable tablets e.g. CELIN - (Glaxo)

(B) TABLETS USED IN ORAL CAVITY

Buccal tablets

These tablets are to be placed in the side of the cheek (buccal pouch) where they dissolve or erode slowly and are absorbed directly in the buccal cavity without passing into the alimentary canal.

therefore, they are formulated and compressed with sufficient pressure to give a hard tablet e.g. Progesterone tablets.

Sublingual tablets

These tablets are to be placed under the tongue where they dissolve or disintegrate quickly and are absorbed directly without passing into GIT e.g. tablets of nitroglycerin, isoproterenol hydrochloride or erythrityl tetranitrate.

Lozenges tablets

These tablets are designed to exert a local effect in the mouth or throat. These tablets are commonly used to treat sore throat to control coughing in common cold. They may contain local anaesthetics, antiseptics, antibacterial agents, astringents and antitussives.

These are prepared by compression at a high pressure by the moulding process and generally contain a sweetening agent, flavouring agent (e.g. peppermint, clove oil) and a substance which produces a cooling effect (e.g. mentha). e.g. Vicks lozenges.

Dental cones:

These are compressed tablets meant for placement in the empty sockets after tooth extraction. They prevent the multiplication of bacteria in the socket following such extraction by using slow-releasing antibacterial compounds or to reduce bleeding by containing the astringent.

These tablets contain an excipient like lactose, sodium bicarbonate and sodium chloride.

These cones generally get dissolved in 20 to 40 minutes time.

(C) TABLETS ADMINISTERED BY OTHER ROUTES

Implantation tablets

These tablets are placed under the skin or inserted subcutaneously by means of minor surgical operation and are slowly absorbed. These may be made by heavy compression but are normally made by fusion. The implants must be sterile and should be packed individually in sterile condition. Implants are mainly used for the administration of hormones such as testosterone steroids for contraception. These tablets are very usefully exploited for birth control purpose in human beings.

The disadvantages of implant tablets are their administration changing rate of release with change of surface area and possibility of tissue reactions.

Vaginal tablets

These tablets are meant to dissolve slowly in the vaginal cavity. The tablets are typically ovoid or pear shaped for the

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