



Study Between Two Different Brand Of Mouth Dissolving Tablet

Name: Bhosale Komal Appa

Under the Guidance: Dr. L. D. Hingane
(principal)

Introduction

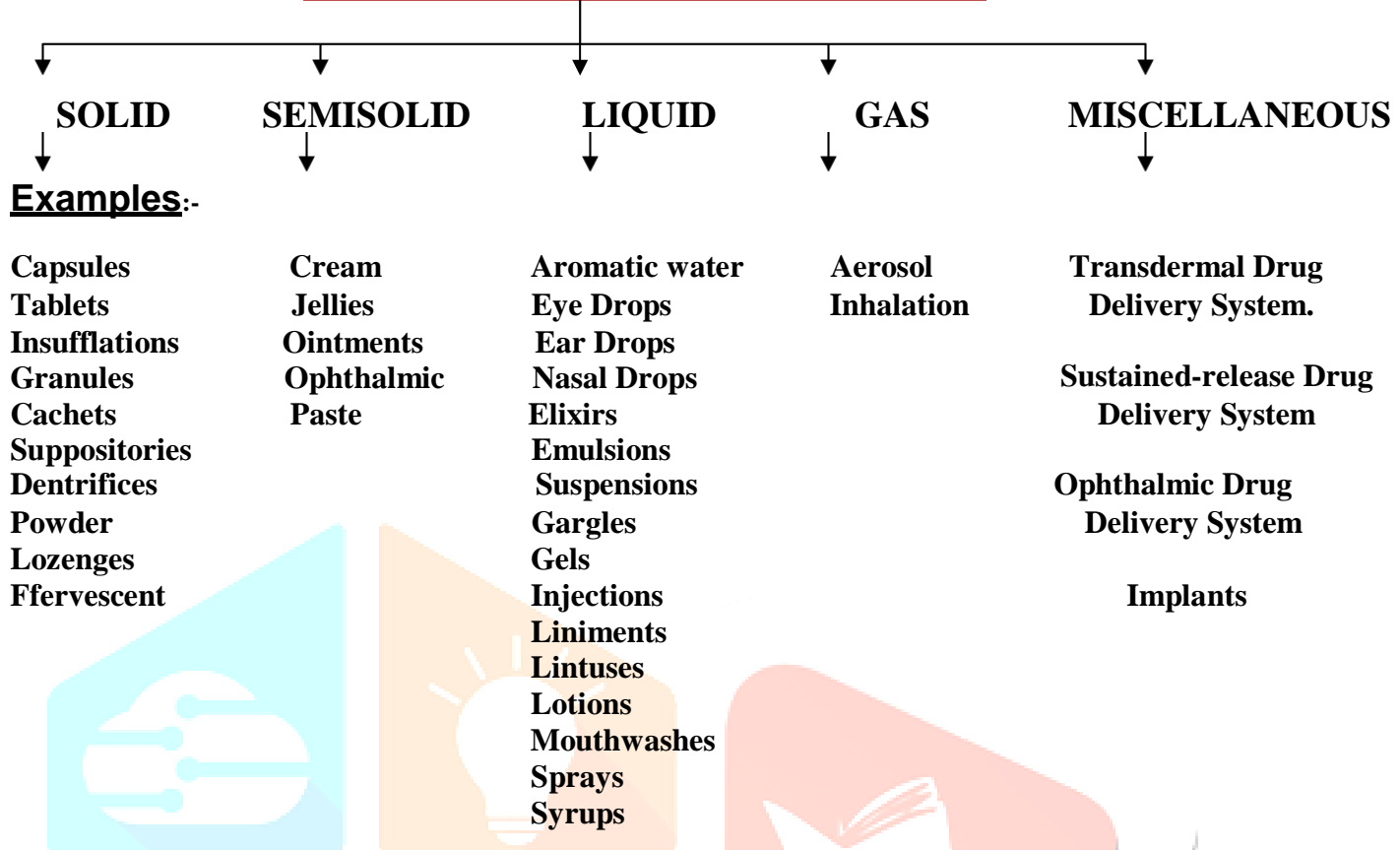
Dosage form means a suitable form of drug administration. These are essentially pharmaceutical products in the form in which they are marketed for use, typically involving a mixture of active drug components and nondrug components (excipients), along with other non-reusable material that may not be considered either ingredient or packaging [1]. The term unit dose can also sometimes encompass non-reusable packaging as well (especially when each drug product is individually packaged, although the FDA distinguishes that by unit-dose "packaging" or "dispensing." Depending on the context, the multiunit dose can refer to distinct drug products packaged together, or to a single drug product containing multiple drugs and/or doses. The term dosage form can also sometimes refer only to the chemical formulation of a drug product's constituent drug substance(s) and any blends involved, without considering matters beyond that (like how it's ultimately configured as a consumable product such as a capsule, patch, etc.). Because of the somewhat vague boundaries and unclear overlap of these terms and certain variants and qualifiers thereof within the pharmaceutical industry, caution is often advisable when conversing with someone who may be unfamiliar with another person's use of the term.[2,3]

Depending on the method/route of administration, dosage forms come in several types. These include many kinds of liquid, solid, and semisolid dosage forms. Common dosage forms include pill, tablet, or capsule, drink or syrup, and natural or herbal forms such as plant or food of sorts, among many others. Notably, the route of

Drug delivery systems are a magic tool for expanding markets/indications, extending product life cycles, and generating opportunities. Drug delivery systems make a

significant contribution to global pharmaceutical sales through market segmentation

1. CLASSIFICATION OF DOSAGE FORMS



1) SOLID DOSAGE FORM

A tablet is a pharmaceutical dosage form. It comprises a mixture of active substances and excipients, usually in powder form, pressed or compacted from a powder into a solid dose. The excipients can include diluents, binders or granulating agents, glidants (flow aids), and lubricants to ensure efficient tableting; disintegrants to promote tablet break-up in the digestive tract; sweeteners or flavors to enhance taste; and pigments to make the tablets visually attractive.

A polymer coating is often applied to make the tablet smoother and easier to swallow, to control the release rate of the active ingredient, to make it more resistant to the environment (extending its shelf life), or enhance the tablet's appearance.[5]

The compressed tablet is the most popular dosage form in use today. About two-thirds of all prescriptions are dispensed as solid dosage forms, and half of these are compressed tablets. A tablet can be formulated to deliver an accurate dosage to a specific site; it is usually taken orally, but can be administered sublingually, buccally, rectally or intravaginally. The tablet is just one of the many forms that an oral drug can take such as syrups, elixirs, suspensions, and emulsions. Medicinal tablets were originally made in the

shape of a disk of whatever color their components determined, but are now made in many shapes and colors to help distinguish different medicines. Tablets are often stamped with symbols, letters, and numbers, which enable them to be identified. Sizes of tablets to be swallowed range from a few millimeters to about a centimeter.[6]

TABLETS

Tablets are solid dosage form containing medicament or medicaments, usually circular in shape and may be flat or biconvex. Tablets are prepared by compression method and are hence called the compression tablet.



Figure no.1 showing tablets as a dosage forms

A. ADVANTAGES OF TABLETS

- Tablets are more stable dosage form
- They provide an accurately measured dose
- Tablets are simple and convenient to use.
- Easy to dispense
- Bitter and nauseous substance can be given easily in tablet form after giving a suitable coating to the tablet
- They are lightest and the most compact of all dosage forms
- Cheaper than other
- Colored coatings, embossed markings and printing can be used to aid tablet recognition.

Manufacturing processes and techniques can provide tablets special properties, for example, sustained release or fast dissolving formulations.

- A convenient portable package, and can be designed to protect

unstable medications or disguise unpalatable ingredients.[7,8]

B) DISADVANTAGES OF TABLETS

- Some drugs resist compression into tablet form due to their amorphous nature of low density character.
- Bitter tasting drugs, drugs with objectionable odour or drugs that are sensitive to oxygen or atmospheric moisture may require encapsulation or a special type of coating which may increase the cost of finished tablet.
- Drugs with poor wetting and slow dissolution properties are difficult to convert into tablets which provide full drug bioavailability.
- The oral bioavailability of some drugs may be low due to poor absorption from the gastrointestinal tract. Such drugs may need to be given in very high doses or by injection.
 - For drugs that need to have rapid onset, or that have severe side effects, the oral route may not be suitable. For example salbutamol, used to treat problems in the pulmonary system, can have effects on the heart and circulation if taken orally; these effects are greatly reduced by inhaling smaller doses direct to the required site of action.
 - Some drugs may be unsuitable for administration by the oral route. For example, protein drugs such as insulin may be denatured by stomach acids. Such drugs cannot be made into tablets. Some drugs may be deactivated by the liver when they are carried there from the gastrointestinal tract by the hepatic portal vein (the "first pass effect"), making them unsuitable for oral use. Drugs which can be taken sublingually are absorbed through the oral mucosae, so that they bypass the liver and are less susceptible to the first pass effect.
 - A proportion of the population have difficulties swallowing tablets either because they just don't like taking them or because their medical condition makes it difficult for them (dysphagia, vomiting). In such instances it may be better to consider alternative dosage form or administration route.[9]

B) TYPES OF TABLETS

- **The types of tablets are as following:**
 - Tablets ingested orally I.Compress tablets
 - Multiple compressed tablets
 - Multi layered
 - ✓ tablets
 - ✓ IV.Sustained
 - ✓ action tablets
 - ✓ V.Enteric coated
 - ✓ tablets VI.Sugar
 - ✓ coated tablets

- ✓ VII. Film coated tablets
- ✓ VIII. Chewable tablets
- Tablets used in oral cavity
 - I. Mouth dissolving tablets
 - II. Buccal tablets
- III. Sublingual tablets
- IV. Lozenges
- V. Dental cones
- Tablets administered by other routes
 - I. Implantation tablets
 - II. Vaginal tablets
- ✓ Tablets used to prepare solutions
 - I. Effervescent tablets
 - II. Dispensing tablets
 - III. Hypodermic tablets
 - IV. Tablet triturate

2. MOUTH DISSOLVING TABLETS

Mouth dissolving tablets have started gaining popularity and acceptance as new drug delivery systems, because they are easy to administer and lead to better these problems.

Recent development in fast disintegrating technology mainly works to improve the disintegration quality of these delicate dosage forms without affecting their integrity.[12]

The oral fast-disintegrating tablets is also known as fast dissolve, rapid dissolve, rapid melt and quick disintegrating tablets. However, the function and concept of all these dosage forms are similar. By definition, a solid dosage form that dissolves or disintegrates quickly in the oral cavity, resulting in solution or suspension without the need for the administration of water, is known as an oral fast-dispersing dosage form.

According to European Pharmacopoeia, the ODT should disperse/disintegrate in less than three minutes. Difficulty in swallowing (dysphagia) is common among all age groups, especially in elderly, and is also seen in swallowing conventional tablets and capsules. Allow the manufacture of tablets using conventional processing and packaging equipment at low cost and Allow high drug loading.

A . ADVANTAGES MOUTH DISSOLVING TABLETS

- a) No water needed
- b) No chewing needed
- c) Better taste
- d) Improved stability
- e) Suitable for controlled/sustained release actives
- f) Allows high drug loading.
- g) Ability to provide advantages of liquid medication in the form of solid preparation.

h) Adaptable and amenable to existing processing and packaging machinery

i) Cost- effective

j) rapid drug therapy intervention

k) Best for patient with oesophageal problems and have

l) difficulties of deglutition tablets.

m) High drug loading is possible.

n) Have acceptable taste and pleasant mouth feeling.

o) Leave minimum residue.

B. LIMITATIONS TO MOUTH DISSOLVING TABLETS

- Drugs with relatively larger doses are difficult to formulate into MDT e.g. antibiotics like ciprofloxacin with adult dose tablet containing about 500 mg of the drug.
- Patients who concurrently take anticholinergic medications may not be the best candidates for MDT. Similarly patients with Sjögren's syndrome or dryness of the
- mouth due to decreased saliva production may not be good candidates for
- these tablet formulations.

NEED TO FORMULATE MOUTH DISSOLVING TABLETS

1) The need for non-invasive drug delivery systems continues due to patient's poor acceptance and compliance with existing delivery regimes, limited market size for drug companies and drug uses coupled with high cost of disease management.

MDT is one such dosage form which is useful for

i) Geriatric patients mainly suffering from conditions like hand tremors and dysphasia.

ii) Pediatric patients who are unable to swallow easily because their central

nervous system and internal muscles are not developed completely.

iii) Traveling patients suffering from motion sickness and diarrhea that do not have easy access to water.

iv) Patients with persistent nausea for a long period of time are unable to swallow.

Especially cancer patients after taking their chemotherapy are too nauseous to swallow the H2 blockers, which are prescribed in order to avoid gastric ulceration.

v) Mentally challenged patients, bedridden patients and psychiatric patients

● IDEAL PROPERTIES OF MDT

1) It should not require any liquid or water to show its action.

2) It is moveable without frailty concern.

3) It should be less effective in environmental conditions like humidity, temperature etc.

4) It should be more rapid drug absorption from the pre-gastric area i.e. mouth, pharynx and esophagus.

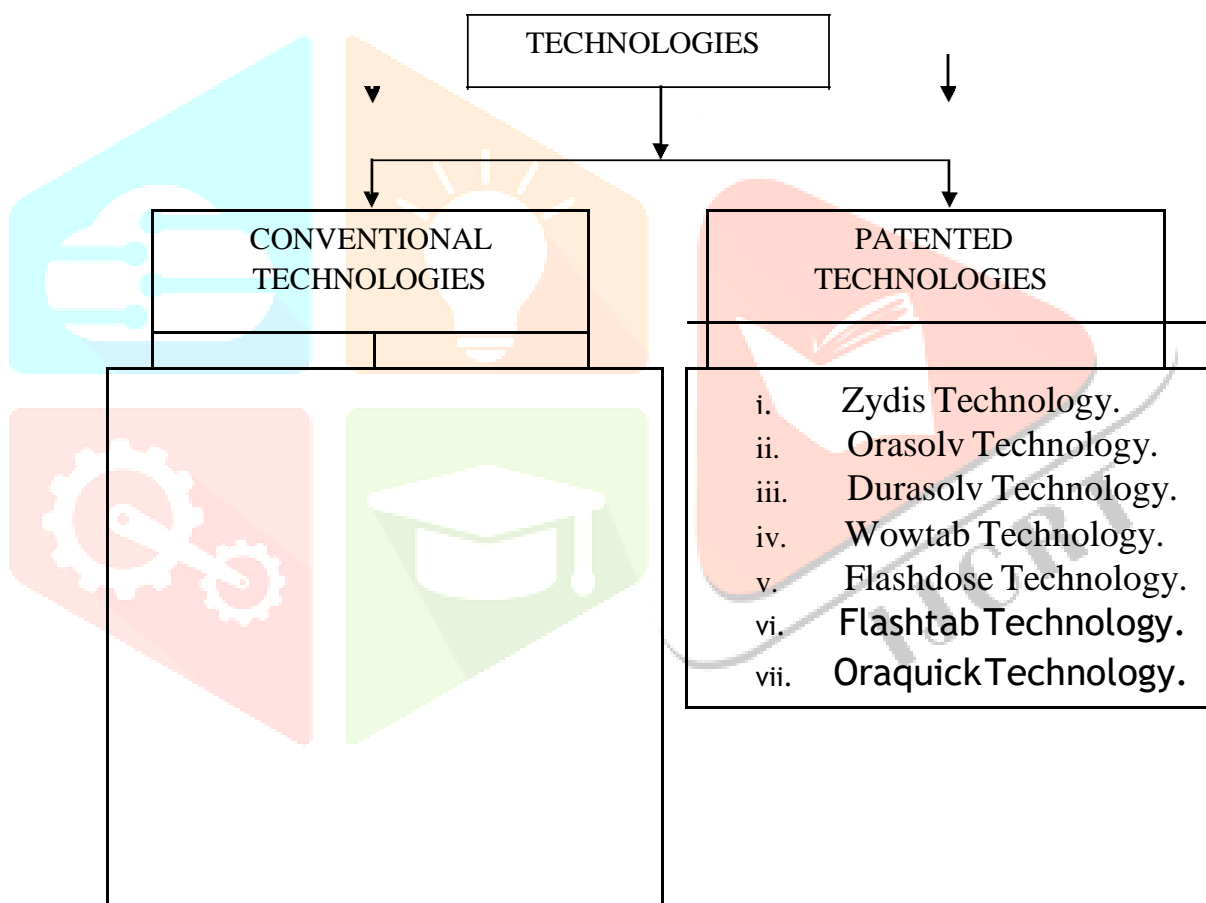
5) It should be produce rapid onset of action.

6) It should be compatible with taste masking and

- pleasing mouth feel
- 7) A MDT should be dissolve in the mouth within seconds.
- 8) The excipients should have high wettability.
- 9) It should be adaptable and amenable to existing processing and packaging machiner

5. TECHNOLOGIES USED TO MANUFACTURE MOUTH DISSOLVING TABLETS

The technologies used to manufacture mouth dissolving tablets can be classified as:



● FORMULATION OF MOUTH DISSOLVING TABLETS [19]

For preparation of mouth dissolving tablet drug & excipients are required.

A) DRUG

Criteria for drug selection in mouth dissolving tablets

- 1) It should not have bitter taste.
- 2) It should be of good solubility in saliva and water.
- 3) Molecular weight should be small to Moderate.
- 4) The dose should be less than 20 mg.

5) It should have oral tissue permeability

B) EXCIPIENTS COMMONLY USED FOR MDT PREPARATION Mainly seen excipients in FDT are as follows at least one disintegrant, a diluent, a lubricant, and, optionally, a swelling agent, a permeabilizing agent, sweeteners, and flavorings.

Table 1 Name and weight percentage of various excipients

Name of the excipients	Percentage Used
Disintegrant	1 to 15%
Binder Antistatic Agent 0 to 10%	5 to 10%
Diluents	0 to 85%

1) ROLE OF SUPER-DISINTEGRANTS IN MDT

The basic approach in development of MDTs is use of disintegrant. Disintegrant play a important role in the disintegration and dissolution of FDT. It is essential to choose a suitable disintegrant, in an optimum concentration so as to ensure quick disintegration and high dissolution rates.

Super disintegrant provide quick disintegration due to combined effect of swelling and water absorption by the formulation. Due to swelling of super disintegrant, the wetted surface of the carrier increases; this promotes the wettability and dispersibility of the system, thus enhancing the disintegration and dissolution. Care should be taken to taken while selecting concentration of the super disintegrant .super disintegrates are selected according to critical concentration of disintegrant. Below this concentration, the tablet disintegration time is inversely proportional to the concentration of the super disintegrant, whereas if concentration of super disintegrant is above critical concentration, the disintegration time remains almost constant or even increases.

Common disintegrants used in this formulation are croscarmellose sodium (Vivasol, Ac-Di-Sol), crospovidone (Polyplasdone), carmellose (NS-300), carmellose calcium (ECG-505), sodium starch glycolate (SSG) etc. Recently few ion exchange resins

(e.g. Indion 414) are found to have super-disintegrant property and are widely used in pharmaceutical industry. Swelling index of the super-disintegrants is commonly studied in simulated saliva. Volume occupied by the material at the end of 4 h should be noted and swelling index is calculated by the formula: $(\text{final volume} - \text{initial volume} / \text{initial volume}) \times 100$.

2) ROLE OF BINDERS IN MDT

Main role of Binders is to keep the composition of these fast-melting tablets together during the compression stage. Binders commonly used are cellulosic polymers, povidones, polyvinyl alcohols, and acrylic polymers. Among the cellulosic polymers it will be advantageous to select ethylcellulose, hydroxypropylcellulose (HPC), and hydroxypropylmethylcellulose (HPMC), alone or in admixtures, and the most commonly acrylic polymers are used are the ammonio-methacrylate copolymer (Eudragit. RL and RS), polyacrylate (Eudragit.NE), and polymethacrylate (Eudragit. E). The right selection of a binder or combination of binders is essential to maintain the integrity and stability of the tablet. The temperature of the excipient should be preferably around 30–35°C for faster melting properties. Further, its incorporation imparts smooth texture and disintegration characteristics to the system. Binders can either be liquid, semi solid, solid or mixtures of varying molecular weights such as polyethylene glycol. The choice of a binder is critical in a fast-dissolving formulation for achieving the desired sensory and melting characteristics, and for the faster release of active ingredient

3) ROLE OF ANTISTATIC AGENT AND DILUENTS IN MDT

The most common antistatic agents used are colloidal silica (Aerosil), precipitated silica (Sylod.FP244), micronized or non-micronized talc, maltodextrins, .beta.-cyclodextrins, etc. Magnesium stearate, stearic acid, sodium stearyl fumarate, micronized polyoxyethylene glycol (micronized Macrogol 6000), leucine, sodium benzoate are used as lubricant⁴. An additional thickening agent, generating a stabilized suspension, is added to avoid settling of the particles and moreover provide a pleasant mouth feeling. Commonly used Diluents are most commonly selected from cellulose derivatives and preferably microcrystalline cellulose, starches, lactose, polyols, and, preferably, mannitol.^{14,15}

4. TASTE-MASKING OF MDT

Taste-masking of bitter or with objectional-tasting drug substances is critical for any orally-administered dosage form. Less commonly, active pharmaceutical ingredients

to be incorporated are tasteless and do not require taste masking. Sugar based excipients are used for taste masking and as bulking agents. Most of the drugs are having unpleasant or bitter taste. And the basic requirement for designing MDTs is that the drug should not have disagreeable taste. So taste masking is necessary in most of the cases. Sorbitol, mannitol, xylitol, dextrose.

CONCLUSION

Now days mouth dissolving tablet get significant popularity among newly developed dosage forms. MDT formulations should have fast disintegration, dissolution, or melting in the mouth and this can be achieved by producing the porous structure of the tablet matrix or adding superdisintegrant and effervescent excipients. OndansetronHCl is a well-established and proven antiemetic drug. Therapeutic response of any formulation depends on its quality parameters. From the study it was identified that weight variation and friability test of both OndansetronHCl tablet brands complied the specification. Variation was obtained in hardness, disintegration time during the test procedure. It should be strictly considered that an ideal tablet will have sufficient hardness to maintain its mechanical stability but not more. Because harder tablet can delay disintegration time or alter dissolution profile. Finally, as quality control parameters are related to one another from initial step to pharmacological action of the drug, a high-quality tablet should meet all the standard quality parameter for getting its desired therapeutic

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