

A review on fast dissolving tablet

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ABSTRACT

These tablets are distinguished from conventional sublingual tablets, lozenges, and buccal tablets which require more than a minute to dissolve in the mouth. In the literature, ODTs also are called orally disintegrating, orodisperse, mouth-dissolving, quick-dissolve, fast-melt, and rapid-disintegrating tablets. Over the past three decades, orally disintegrating tablets (ODTs) have gained much attention as a preferred alternative to conventional oral dosage forms such as tablets and capsules. An ODT is a solid dosage form that disintegrates and dissolves in the mouth (either on or beneath the tongue or in the buccal cavity) without water within 60 seconds or less. The desire of improved palatability in orally administered products has prompted the development of numerous formulations with improved performance and acceptability, and the field has become a rapidly growing area in the pharmaceutical industry. The unique property of mouth dissolving tablet is that they are rapidly disintegrating and/or dissolving and release the drug as soon as they come in contact with saliva, thus obviate the requirement of water during administration. This article reviews the earlier applications and methodologies of taste masking and also emphasize on the recent developments and approaches of bitterness reduction for orally used pharmaceuticals. Apart from the conventional methods of fabrication, this review also provides the detailed concept of some unique patents; technologies developed and marketed formulations of Mouth Dissolving Tablets (MDTs).

Keywords: orally disintegrating tablets (ODTs), orodispersible tablets, taste masking, mouth dissolving tablets (MDTs).

Introduction

Definition: A mouth dissolving drug delivery system, in most cases, is a tablet that dissolves or disintegrates in the oral cavity without the need of water or chewing. Oral routes of drug administration are the most popular route of administration. The most popular solid dosage forms are being tablets and capsules. One important drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis. For these reason, tablet that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention.

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Oral dispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. MDTs are also called as FDTs, melt in mouth tablets, oral dispersible tablets, rapimelts, porous tablets, quick dissolving etc. [1]

Fast dissolving tablets (FDTs) are a solid single-unit dosage form that are placed in mouth, allowed to disperse/dissolve in the saliva without the need of water and provides a quick onset of action. Some drugs are absorbed from mouth, pharynx and oesophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablet dosage form. FDTs are appreciated by a significant segment of population, particularly children and elderly, which have difficulty in swallowing conventional tablets or capsules. FDTs are prepared by various techniques, mainly direct compression, lyophilization and moulding. The simplicity and cost effectiveness of the direct compression process have positioned this technique as an attractive alternate to traditional granulation technologies. Usually superdisintegrants are added to a drug formulation to facilitate the break-up or disintegration of tablet into smaller particles that can dissolve more rapidly than in absence of disintegrates [2]

One study showed that approximately 26% of 1576 patients do not take their prescribed medication as they encountered problems when swallowing conventional tablets. Often, the main complaints are the size, surface and taste of the tablets. An estimated 35% of the general population, and an additional 30–40% of elderly institutionalized patients and 18–22% of all persons in long-term care facilities, suffer from dysphagia. This disorder is associated with many medical conditions, including stroke, Parkinson's, AIDS, thyroidectomy, head and neck radiation therapy,

and other neurological disorders, including cerebral palsy. [3]

Those who are traveling or have little access to water are similarly affected. To fulfill these medical needs, pharmaceutical technologists have developed a novel oral dosage form known as Orodispersible Tablets (ODTs) which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to take water. Drug dissolution and absorption as well as onset of clinical effect and drug bioavailability may be significantly greater than those observed from conventional dosage form.

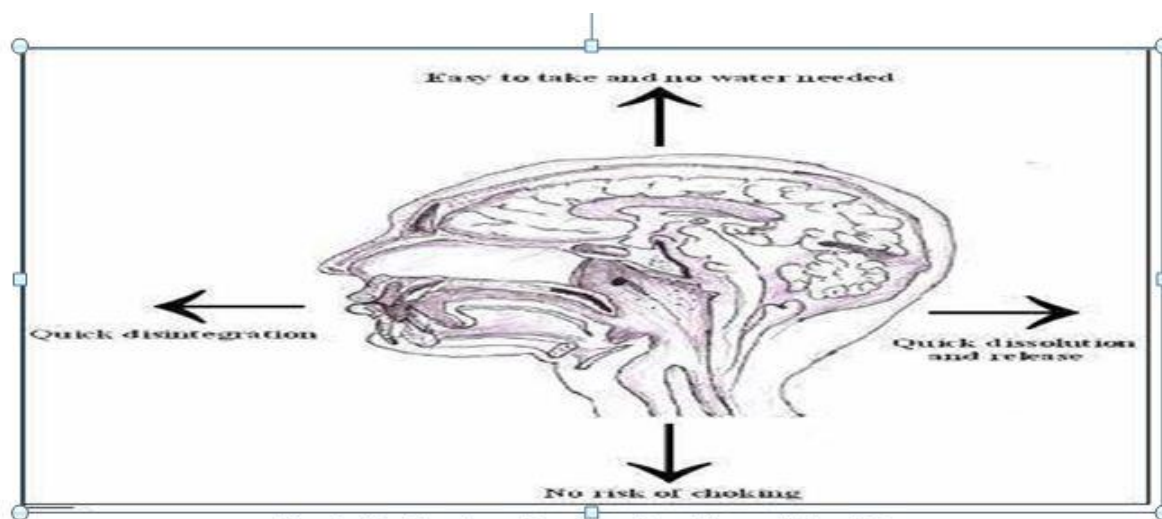


Fig: 1: Mechanism of action of orodispersible tablet

MDT's are mainly used in some serious conditions like:

- Motion sickness
- Parkinsonism
- Pediatric and geriatric patients
- Unconsciousness
- Mentally disabled patients
- Absence of water

MDT

These are the tablets which dissolve or disintegrate quickly in the saliva to show their action within few seconds without the help of water. A mouth dissolving tablet mainly dissolves in the mouth within 15sec-3mins. Mostly the MDT's superdisintegrants and taste masking agents [5]

The oral route of administration is considered as the most widely accepted route because of its convenience of self administration, compactness and easy manufacturing. But the most evident drawback of the commonly used oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patients' in compliance. Particularly in case of pediatric and geriatric patients. But it also applies to people who are ill in bed and to those active working patients who are busy or traveling, especially those who have no access to water.

Drug selection criteria

- The ideal characteristics of a drug for oral dispersible tablet include:
- Ability to permeate the oral mucosa.

- At least partially non-ionized at the oral cavity pH.
- Have the ability to diffuse and partition into the epithelium of the upper GIT.
- Small to moderate molecular weight.
- Low dose drugs preferably less than 50 mg.
- Short half life and frequent dosing drugs are unsuitable for ODT.
- Drug should have good stability in saliva and water.
- Very bitter or unacceptable taste and odor drugs are unsuitable for ODT. [6]

Ideal Properties

An ideal FDT should:

- Require no water for oral administration.
- Have a pleasing mouth feel.
- Have an acceptable taste masking property.
- Be harder and less friable.
- Leave minimal or no residue in mouth after administration.
- Exhibit low sensitivity to environmental conditions (temperature and humidity).
- Allow the manufacture of tablet using conventional processing and packaging equipments.

Advantages

- Administration to the patients who cannot swallow, such as the elderly, bedridden patients, patients affected by renal failure & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients.
- Rapid drug therapy intervention.
- Achieve increased bioavailability/rapid absorption through pre-gastric absorption of drugs from mouth, pharynx & esophagus as saliva passes down.
- Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients.
- The risk of choking or suffocation during oral administration of conventional.
- Formulations due to physical obstruction are avoided, thus providing improved safety.
- New business opportunity like product differentiation. [7].

Disadvantage

- Fast dissolving tablet is hygroscopic in nature so must be kept in dry place.
- Some time it possesses mouth feeling.
- MDT requires special packaging for properly stabilization & safety of stable product [8]

Significance of Oral Disintegrating Tablets

Oral Disintegrating Tablets offer dual advantages of solid dosage forms and liquid dosage forms along with special features which include -

Accurate Dosing

Being unit solid dosage forms, provide luxury of accurate dosing, easy Portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients.

Enhanced bioavailability

Bioavailability of drugs is enhanced due to absorption from mouth, pharynx and oesophagus.

Rapid action

Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity.

Patient compliance

No need of water to swallow the dosage form. Hence, it is convenient for patients who are traveling and do not have immediate access to water.

Ease of administration

Convenient to administer specially for geriatric, pediatric, mentally disabled and bed ridden patients who have difficulty in swallowing.

Obstruction free

No risk of suffocation in airways due to physical obstruction when swallowed, thus providing improved safety and compliance. [9]

Enhanced palatability

Good mouth feels, especially for pediatric patients as taste masking technique is used to avoid the bitter taste of drug.

Simple packaging

No specific packaging required. It can be packaged in push through blisters.

Business Avenue

Provide new business opportunities in the form of product differentiation, line extension, uniqueness and life cycle management.

Cost effective

Conventional processing and packaging equipments allow the manufacturing of tablets at low cost. [10]

Mechanism

Bioavailability of a drug depends in absorption of the drug, which is affected by solubility of the drug in gastrointestinal fluid and permeability of the drug across gastrointestinal membrane. The solubility of a drug mainly depends on physiochemical properties of the drug. The rate of drug dissolution is greatly influenced by disintegration of the tablet.

Disintegrates are important excipients of the tablet formulation, they are always added to tablet to induce breakup of tablet when they are comes in contact with aqueous fluid and this process of desegregation of constituent particles before the drug dissolution occurs, is known as disintegration process and excipients which induce this process are known as disintegrates. The objectives behind addition of disintegrates are to increase surface area of the tablet fragments and to overcome cohesive forces that keep particles together. [11]

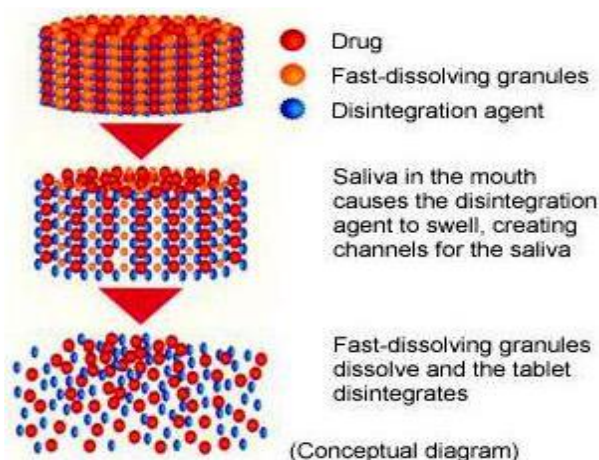


Fig. 2: Mechanism of Fast dissolving Tablet

Pharmacokinetics

In this consideration, study has done on absorption, distribution, metabolism and excretion. After absorption, drug attains therapeutic level and therefore elicits pharmacological effect, so both rate and extend of absorption is important. In conventional dosage form there is delay in disintegration and therefore dissolution while RDT is rapidly disintegrates in oral cavity and dissolution is rapid. Due to disintegration of RDT in mouth absorption in started from mouth, pharynx and esophagus. Some factors like age, GI pH, and blood flow through GI are taken into consideration, because elders may be considered as separate unique Medicare population. Drug distribution depends on many factors like tissue permeability, perfusion rate, binding of drug to tissue, disease state, drug interaction etc. In geriatric patients, decrease in body mass and total body water result in decreased volume of distribution of water-soluble drugs and increased volume of distribution (Vd) of lipid soluble drugs. Duration and intensity of action depends upon rate of drug removal from the body or site of action i.e. biotransformation. Decrease in liver volume, regional blood flow to liver reduces the biotransformation of

drug through oxidation, reduction and hydrolysis. Excretion by renal clearance is slowed, thus half-life of renal excreted drugs increase. [12]

Pharmacodynamics

Drug reception interaction impaired in elderly as well as ion young adults due to undue development of organ. Decreased ability of body to respond baro reflexive stimuli, cardiac output and orthostatic hypotension may see in taking anti hypertensive like prazosin. Decreased sensitivity of CVS to beta adrenergic agonist and antagonist. Immunity is less and taken into consideration while administered antibiotics. Altered response to drug therapy-elderly show diminished bronchodilator effect of theophylline shows increased sensitivity to barbiturates. Concomitant illness is often present in elderly, which is also taken into consideration while multiple drug therapy prescribed. Research workers have clinically evaluated drug combination for various classes' cardiovascular agents, diuretics, anti-hypertensive in geriatrics. The combination choice depends on disease state of the patient. [13]

Limitations of Mouth Dissolving Tablets

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.

Technologies used for manufacturing of MDTs

In the recent past, several new advanced technologies have been introduced for the manufacturing of MDTs with ideal properties like less disintegration time, pleasant mouth feel, exceptional taste masking and sugar free tablets for diabetic patients. The technologies used for manufacturing of MDTs broadly classified in two category one is patented another one is no patented technologies.

Lyophilization or Freeze-drying

Formation of porous product in freeze-drying process is exploited in formulating MDTs. Lyophilization is a process, which includes the removal of solvent from a frozen suspension or solution of drug with structure-forming additives. Freeze drying of drug along with additives imparts glossy amorphous structure resulting in highly porous and lightweight product. The resulting tablet has Rapid disintegration and dissolution when placed on the tongue and the freeze-dried unit dissolves instantly to release the drug. However, the MDTs formed by lyophilization have low mechanical strength, poor stability at higher temperature, and humidity.

Molding

In this method, molded tablets are prepared by using water-soluble ingredients so that the tablets dissolve completely and rapidly. The powder blend is moistened with a hydroalcoholic solvent and is molded into tablets under pressure lower than that used in conventional tablet compression. The solvent is then removed by air-drying. Molded tablets are very less compact than compressed tablets. These possess porous structure that increase dissolution.

Spray drying

This technology produces highly porous and fine powders as the processing solvent is evaporated during the process. In this method to prepare MDTs hydrolyzed and nonhydrolyzed gelatin were used as supporting matrix, mannitol as bulking agent and sodium starch glycolate or croscarmellose sodium as superdisintegrant. Disintegration and dissolution were further increased by adding acidic substances like citric acid or alkali substance like sodium bicarbonate. This formulation technique gives porous powder and disintegration time < 20 sec.

Mass extrusion

This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol and methanol and subsequent expulsion of softened mass through the extruder or syringe to get a Cylinder of the product into even segments using heated blade to form tablets. [14]

Melt granulation

It is a unique method for the preparation of orodispersible tablets by incorporating superpolystate. superpolystates are hydrophilic waxy binders with a melting point 33-37°C and hydrophilic -lipophilic balance value is 9. They play a dual role as a binder that increases the physical resistance of the tablets and also as a disintegrants, which help the tablet to melt in the mouth, and solubilize rapidly leaving no residue in the mouth. Superpolystates were introduced in the formulation of orodispersible tablets by melt-granulation method. Here, granules are formed by the molten form of this material. Crystallized paracetamol was used as a model drug along with mannitol and croscarmellose sodium.

Effervescent method

Orodispersible tablets are also prepared by effervescent method by mixing sodium bicarbonate and tartaric acid of concentration 12% (w/w) along with super disintegrants like pregelatinized starch, sodium starch glycolate, crospovidone, and croscarmellose. First, sodium bicarbonate and tartaric acid were preheated at a temperature of 80°C to remove absorbed/residual moisture and thoroughly mixed in the motor. Finally, the blends are compressed in the punch. [15]

Phase transition process

It is concluded that a combination of low and high melting point sugar alcohols, as well as a phase transition in the manufacturing process, are important for making FDTs without any special apparatus. FDT were produced by compressing powder containing erythritol (melting point: 122°C) and xylitol (melting point: 93-95°C), and then heating at about 93°C for 15 min. After heating, the median pore size of the tablets was increased and tablet hardness was also increased. The increase of tablet hardness with heating and storage did not depend on the crystal state of the lower melting point sugar alcohol.

Sublimation

In this method a subliming material like camphor, is removed by sublimation from compressed tablets and high porosity is achieved due to the formation of many pores where camphor particles previously existed in the

compressed tablets prior to sublimation of the camphor. A high porosity was achieved due to the formation of many pores where camphor particles previously existed in the compressed mannitol tablets prior to sublimation of the camphor. These compressed tablets which have high porosity (approximately 30%) rapidly dissolved within 15 seconds in saliva. Granules containing nimusulide, camphor, crospovidone, and lactose were prepared by wet granulation technique. Camphor was sublimed from the dried granules by vacuum exposure. Conventional methods like dry granulation, wet granulation and direct compression with highly soluble excipients, superdisintegrants and/or effervescent systems can also be used.

Cotton Candy Process

The FLASHDOSE is a MDDDS manufactured using Shearform™ technology in association with Ceform TI™ technology to eliminate the bitter taste of the medicament. The Shear form technology is employed in the preparation of a matrix known as ‘floss’, made from a combination of excipients, either alone or with drugs. The floss is a fibrous material similar to cotton-candy fibers, commonly made of saccharides such as sucrose, dextrose, lactose and fructose at temperatures ranging between. However, other polysaccharides such as polymaltodextrins and polydextrose can be transformed into fibers at 30–40% lower temperature than sucrose.

This modification permits the safe incorporation of thermo labile drugs into the formulation. The tablets manufactured by this process are highly porous in nature and offer very pleasant mouth feel due to fast solubilization of sugars in presence of saliva. The manufacturing process can be divided into four steps as detailed below.

Floss Blend

In this step, 80% sucrose in combination with mannitol/dextrose and 1% surfactant is blended to form the floss mix. The surfactant acts as a crystallization enhancer in maintaining the structural integrity of the floss fibers. It also helps in the conversion of amorphous sugar into crystalline form from an outer portion of amorphous sugar mass and subsequently converting the remaining portion of the mass to complete crystalline structure. This process helps to retain the dispersed drug in the matrix, thereby minimizing migration out of the mixture.

Floss Processing

The floss formation machine uses flash heat and flash flow processes to produce matrix from the carrier material. The machine is similar to that used in ‘cotton-

candy’ formation which consists of a spinninghead and heating elements. In the flash heat process, the heat induces an internal flow condition of the carrier material. This is followed by its exit through the spinning head (2000–3600 rpm) that flings the floss under centrifugal force and draws into long and thin floss fibers, which are usually amorphous in nature.

Floss Chopping and Conditioning

This step involves the conversion of fibers into smaller particles in a high shear mixer granulator. The conditioning is performed by partial crystallization through an ethanol treatment (1%) which is sprayed onto the floss and subsequently evaporated to impart improved flow and cohesive properties to the floss.

Blending and Compression

Finally, the chopped and conditioned floss fibers are blended with the drug along with other required excipients and compressed into tablets. In order to improve the mechanical strength of the tablets, a curing step is also carried out which involves the exposure of the dosage forms to elevated temperature and humidity conditions, (40 °C and 85% RH for 15 min). This is expected to cause crystallization of the floss material that results in binding and bridging to improve the structural strength of the dosage form.[16]

Direct Compression

Direct compression represents the simplest and most cost effective tablet manufacturing technique. This technique can now be applied to preparation of ODT because of the availability of improved excipients especially superdisintegrants and sugar based excipients.

a) Superdisintegrants

In many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants principally affects the rate of disintegration and hence the dissolution. The presence of other formulation ingredients such as water-soluble excipients and effervescent agents further hastens the process of disintegration. For the success of fast dissolving tablet, the tablet having quick dissolving property which is achieved by using the super disintegrants. Some important examples of super disintegrants are given in Table 1 with their mechanism of action.

b) Sugar Based Excipients:

This is another approach to manufacture ODT by direct compression. The use of sugar based excipients especially bulking agents like dextrose, fructose,

isomalt, lactitol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol, which display high aqueous solubility and sweetness, and hence impart taste masking property and a pleasing mouth feel. Mizumito *et al* have classified sugar-based excipients into two types on the basis of molding and dissolution rate.

Nanonization

A recently developed Nanomelt technology involves reduction in the particle size of drug to nano size by milling the drug using a proprietary wet-milling technique^[39]. The nanocrystals of the drug are stabilized against agglomeration by surface adsorption on selected stabilizers, which are then incorporated into MDTs. This technique is especially advantageous for poor water soluble drugs. Other advantages of this technology include fast disintegration/dissolution of nanoparticles leading to increased absorption and hence higher bioavailability and reduction in dose, cost effective manufacturing process, conventional packaging due to exceptional durability and wide range of doses (up to 200 mg of drug per unit)^[17]

Patented Technologies for Fast Dissolving Tablets

Zydis Technology

Zydis, the best known of the fast-dissolving/disintegrating tablet preparations was the first marketed new technology tablet. The tablet dissolves in the mouth within seconds after placing on the tongue. A Zydis tablet is produced by lyophilizing or freeze-drying the drug in a matrix usually consisting of gelatin. The product is very lightweight and fragile, and must be dispensed in a special blister pack. Patients should be advised not to push the tablets through the foil film, but instead peel the film back to release the tablet. The Zydis product is made to dissolve on the tongue in 2 to 3 seconds. The Zydis formulation is also self-preserving because the final water concentration in the freeze-dried product is too low to allow for microbial growth.

Durasolv Technology

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of a drug, fillers and lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packed into conventional packaging system like blisters. Durasolv is an appropriate technology for products requiring low amounts of active ingredients.

Orasolv Technology

Orasolv Technology has been developed by CIMA labs. In this system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce the tablets. The tablets produced are soft and friable and packaged in specially designed pick and place system.

Flash Dose Technology

Flash dose technology has been patented by Fuisz. Nurofenmeltlet, a new form of Ibuprofen as melt-in-mouth tablets, prepared using flash dose technology is the first commercial product launched by Biovail Corporation. Flash dose tablets consists of self binding shearform matrix termed as floss. Shearform matrices are prepared by flash heat processing.

Wowtab Technology

Wowtab Technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with allow mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet.

Flashtab Technology

Prographarm laboratories have patented the Flashtab technology. Tablets prepared by this system consist of an active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like Coacervation, microencapsulation, and extrusion spheronisation. All the processing utilized conventional tableting technology.[18]

Evaluation of MDTs

Precompression parameters

Evaluation of blend for the following parameters to be carried out before compression of MDT's

i) Untapped Bulk Density: Powder weighing 10 g is placed into 100 ml measuring cylinder. Volume occupied by the powder is noted without disturbing the cylinder and bulk density is calculated by the following equation:

$$\text{Untapped Bulk Density} = \frac{\text{Mass of bulk drugs}}{\text{Volume of bulk drug}}$$

ii) Tapped Bulk Density: Powder weighing 10 g is placed into 100 ml measuring cylinder. The cylinder is

then subjected to a fixed number of taps (~100 times) until the powder bed volume had reached the minimum level. The final volume is recorded and the tap density is calculated by the following equation:

$$\text{Tapped Bulk Density} = \frac{\text{Mass of bulk drugs}}{\text{Volume of bulk drug on tapping}}$$

iii) **Compressibility:** Compressibility of the drug is found out using the following formula:

$$\% \text{ Compressibility} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

iv) **Hausner Ratio:** Hausner of the drug is found out using the following formula.

$$\text{Hausner Ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Table: 1 commercially available fast dissolving tablet

Trade Name	Active Drug	Manufacturer
Cefadur DT	Cefadroxil	Cipla (protec)
Cefinar DT	Cefixime	Zydus Alidac
Zofran ODT; Vomokind MD	Ondansetron	Glaxo Wellcome; Mankind
Torrox MT; Dolib MD;	Rofecoxib	Torrent pharmaceuticals; Panacea;
Acivir DT	Acyclovir	Cipla
Dom DT; Domestol DT	Domperidone	Dr. Morepen; Torrent Pharma
Nexus MD; Nimex MD; Nimed MD; Nimulid MD	Nimesulide	Lexus; Mexon Health Care; Zota pharma; Panacea Biotech
Romilast	Montelukast	Ranbaxy
Mosid MT	Mosapride	Torrent Pharma

Conclusion

The FDTs have potential advantages over conventional dosage forms, with their improved patient compliance; convenience, bioavailability and rapid onset of action had drawn the attention of many manufactures over a decade. FDT formulations obtained by some of these technologies have sufficient mechanical strength, quick disintegration/dissolution in the mouth without water. This FDT can be used easily in children who have lost their primary teeth and in geriatric patients who have lost their teeth permanently which made them popular. As they have significant advantages of both solid and liquid dosage forms, as they remain solid during storage, which aid in stability of dosage forms and transform into liquid form within few seconds after its administration. Thus FDT may be developed for most of the available drugs in near future.

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v) **Angle of repose:** The angle of repose gives an indication of the flow ability of the substance. Funnel is adjusted such that the stem of the funnel lies 2 cm above the horizontal surface. The drug powder is allowed to flow from the funnel under the gravitational force till the apex of the pile just touched the stem of the funnel, so the height of the pile is taken as 2 cm. drawing a boundary along the circumference of the pile and taking the average of six diameters determined the diameter of the pile. These values of height and diameter are then substituted in the following equation: [19]

$$\text{Angle of Repose } (\theta) = \tan^{-1} (2d/h)$$

Where, h - Height of the pile and d - Diameter of the pile

necessary facilities to write a review article in the form of priceless advices and Institutional facilities.

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