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## Mouth Dissolving Tablets: A Review

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### ABSTRACT

Conventional dosage forms like tablets and capsules are now a days facing the problems like dysphagia, resulting in the high incidence of non compliance and making the therapy ineffective. To obviate the problems associated with conventional dosage forms, mouth dissolving tablets have been developed having good hardness, dose uniformity, easy administration and serves as the first choice of dosage form for paediatrics, geriatrics and travelling patients. The MDTs were developed with an aim of having sufficient hardness, integrity and faster disintegration without water. Various approaches for the formulation of MDTs include Direct compression, Wet granulation, Freeze drying, Spray drying, Moulding, Cotton candy process and Sublimation. Novel technologies like Zydis Orasolv, Durasolv, Flash dose technology, Wowtab etc are available as patented technologies, most commonly used in preparation of MDTs. Drugs belonging to antibiotics, antiviral etc are now formulated as MDTs to minimize the draw backs of conventional dosage forms. Examples of Marketed MDTs are Cefadur DT, Zofran ODT, Acivir DT etc. Due to wide significance of MDT, this drug delivery system may lead to better patient compliance and ultimate clinical output.

**Keywords:** Mouth dissolving tablet, Disintegration, Patented technologies, Marketed MDTs

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## INTRODUCTION:

Conventional tablets and Capsules are now a days facing the problems likes dysphagia, resulting in the high incidence of non compliance and making the therapy ineffective. This problem is arising from 50% of the population.

To obviate the problems associated with conventional dosage forms, mouth dissolving tablets have been developed having good hardness, dose uniformity, easy administration and serves as the first choice of dosage form for pediatrics, geriatrics and travelling patients. The MDTs were developed with an aim of having sufficient hardness, integrity and faster disintegration without water.

Drugs for treating diseases like cancer, diabetes, heart diseases, and GI diseases are suitable candidates for formulating MDTs. The choice of excipients and the method of formulation seriously affects the disintegration time and mechanical integrity of the MDT. Various approaches for the formulation of MDTs include Direct compression, Wet granulation, Freeze drying, Spray drying, Moulding, Cotton candy process and Sublimation. Excipients like Mannitol (Diluent), Saccharin (Sweetening agent) and Super disintegrants like MCC, SSG, Kollidon CL are used in formulation of MDTs<sup>1,2,3</sup>. Novel technologies like Zydis Orasolv, Durasolv, Flash dose technology, Wowtab etc are available as patented technologies, most commonly used in preparation of MDTs. Drugs belonging to antibiotics, antiviral etc are now formulated as MDTs to minimize the draw backs of conventional dosage forms. Examples of Marketed MDTs are Cefadur DT, Zofran ODT, Acivir DT etc. Due to wide significance of MDT, this drug delivery system may lead to better patient compliance and ultimate clinical output. This article gives a brief review of formulation of MDTs, preparation techniques, patented technologies, various marketed MDTs and evaluation parameters for MDTs.

### **Definition:**

Definition of a Mouth Dissolving Tablet is not clearly defined. Definition of MDT is different in different Pharmacopoeias.

The Center for Drug Evaluation and Research (CDER), US FDA defined Oral Disintegrating Tablets (ODT) as “A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.”<sup>1,3</sup>

European pharmacopoeia defined the term “Oro dispersible tablet” as a “tablet that to be placed in the mouth where it disperses rapidly, before swallowing”.<sup>1,3</sup>

Various synonyms of MDT are Fast disintegrating tablets, Fast dissolving tablets, Melt in mouth tablets, Rapimelts, Porous tablets, Oro dispersible tablets, Quick dissolving or Rapidly disintegrating tablets.

#### **Problems with Conventional Tablets and Capsules:**<sup>1,2,3,5,6</sup>

- Swallowing of solid dosage forms like tablet and capsules is difficult in paediatrics (incomplete development of muscular and nervous system) and geriatrics (dysphasia).
- Difficult for administration of powders and liquids by patients with hand tremors.
- Irritation to oral mucosa due to administration of buccal and sublingual tablets.
- Formation of gastrointestinal ulcers due to adherence of capsules to GI tract.
- Uniformity in the content of dose cannot be achieved in case liquid dosage forms like suspension and emulsion.
- Parenteral products are of higher cost and cause discomfort.

#### **Desired Characteristics of MDTs:**<sup>3,4</sup>

To be a superior dosage form, MDTs should possess the following characteristics:

- Should dissolve or disintegrate in the mouth within matter of seconds
- Do not require water for drug administration
- Should have dosage uniformity
- Should have rapid onset of action.
- Should have higher bioavailability of drug within a short period of time.
- should be non-fragile
- Should have a pleasant mouth feel.
- Be compatible with taste masking
- Should leave minimal or no residue in the mouth after administration.
- Ease of administration in patients with tremors, paediatrics and geriatrics.
- Should be of low cost
- Should exhibit low sensitivity to environmental conditions.
- Should minimize the unwanted side effects which occur due to high dosing.

#### **Ideal Characteristics:**<sup>5</sup>

The ideal characteristics of MDTs include:

- Pleasant mouth feel
- Resistant environmental conditions like humidity and temperature

- Good mechanical integrity and hardness
- High drug loading

### FORMULATION OF MDTs:<sup>2-10</sup>

#### **Drug:**

The ultimate characteristics of a drug for dissolution in the mouth and pre gastric absorption from MDTs include:

- Free from bitter taste
- Dose lower than 20 mg
- Small to Moderate molecular weight
- Good solubility in saliva
- Ability to permeate through oral mucosal tissue

#### **Bulking materials:**<sup>5-9</sup>

Bulking materials are significant in the formulation of fast-melting tablets. The material contributes functions of a diluent, filler and cost reducer. Bulking agents improve the textural characteristics that in turn enhance the disintegration in the mouth, besides; adding bulk also reduces the concentration of the active in the composition. The recommended bulking agents for this delivery system should be more sugar-based such as mannitol, polydextrose, lactitol, DCL (direct compressible lactose) and starch hydrolystate for higher aqueous solubility and good sensory perception. Mannitol in particular has high aqueous solubility and good sensory perception. Bulking agents are added in the range of 10 percent to about 90 percent by weight of the final composition.

#### **Emulsifying agents:**

Emulsifying agents are important excipients for formulating fast-melting tablets they aid in rapid disintegration and drug release without chewing, swallowing or drinking water. In addition, incorporating emulsifying agents is useful in stabilizing the immiscible blends and enhancing bioavailability. A wide range of emulsifiers is recommended for fast-tablet formulation, including alkyl sulfates, propylene glycol esters, lecithin, sucrose esters and others. These agents can be incorporated in the range of 0.05 percent to about 15 percent by weight of the final composition.

#### **Lubricants:**

Lubricants, though not essential excipients, can further assist in making these tablets more palatable after they disintegrate in the mouth. Lubricants remove grittiness and assist in the drug transport mechanism from the mouth down into the stomach.

**Flavours and sweeteners:**

Flavours and taste-masking agents make the products more palatable and pleasing for patients. The addition of these ingredients assists in overcoming bitterness and undesirable tastes of some active ingredients. Both natural and synthetic flavours can be used to improve the organoleptic characteristic of fast-melting tablets. Formulators can choose from a wide range of sweeteners including sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols and sucralose. The addition of sweeteners contributes a pleasant taste as well as bulk to the composition.

**Superdisintegrants:**

A disintegrant is an excipient, which is added to a tablet or capsule blend to aid in the breakup of the compacted mass when it is put into a fluid environment. Table: 1 enlists various existing superdisintegrants and also their mechanism of action.

**Table1: List of super disintegrants and their mechanism of action**

Name of disintegrant	Brand Name	Concentration (%)	Mechanism of action
Sodium Starch Glycolate	Explotab, Primogel	2-8%	Swelling
Micro Crystalline Cellulose	Avicel, Celex	2-15%	Water wicking
Cross linked povidone	Crospovidone	2-5%	Water wicking, swelling
Low substituted Hydroxy Propyl Cellulose	LH-11, LH-12 (Grades)	1-5%	Swelling
Crosscarmellose sodium	Ac-Di-Sol	1-3% - direct compression 2-4% - wet granulation	Wicking and swelling
Pre gelatinized Starch	Starch 1500	1-20%	Swelling

**Advantages:**

1. Effective in lower concentrations
2. Less effect on compressibility and flowability

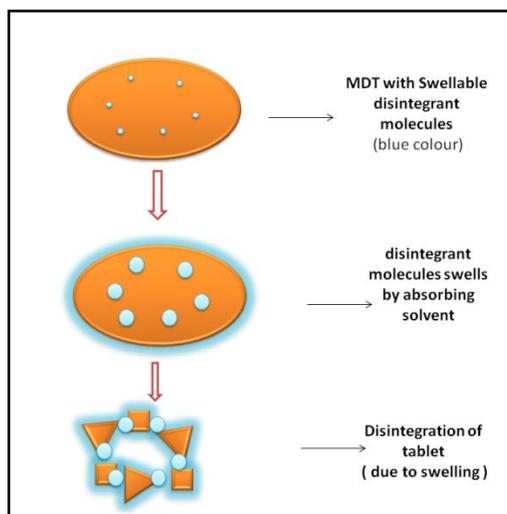
**MECHANISM OF ACTION:** <sup>10, 11</sup>

There are four major mechanisms for tablets disintegration as follows

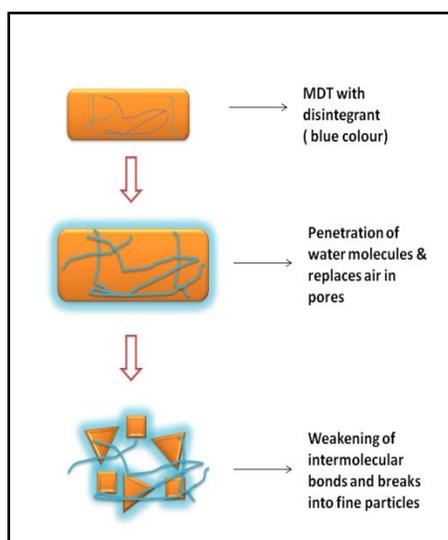
**1. Swelling:**

Perhaps the most widely accepted general mechanism of action for tablet disintegration is swelling. Swelling is believed to be a mechanism in which certain disintegrating agents (such as starch) impart the disintegrating effect. By swelling in contact with water, the adhesiveness of other ingredients in a tablet is overcome causing the tablet to fall apart (Figure 1). Tablets with high porosity show poor disintegration due to lack of adequate swelling force. On the other hand, sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that if

the packing fraction is very high, fluid is unable to penetrate in the tablet and disintegration is again slows down.



**Figure 1: Swelling Mechanism of a Disintegrant in which the disintegrant swells, absorbs the surrounding medium aiding in fast disintegration**



**Figure 2: Wicking mechanism. This mechanism involves capillary action aiding faster disintegration**

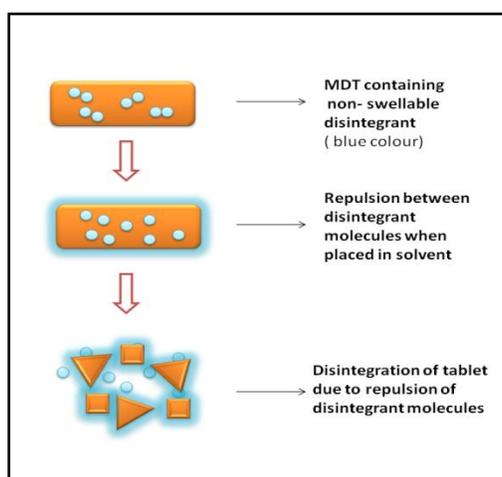
## 2. Porosity and capillary action (Wicking):

Effective disintegrants that do not swell are believed to impart their disintegrating action through porosity and capillary action. When we put the tablet into suitable aqueous medium, the medium penetrates into the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bond and breaks the tablet into fine particles. Tablet porosity provides pathways for the penetration of fluid into tablets. The disintegrant particles (with low cohesiveness &

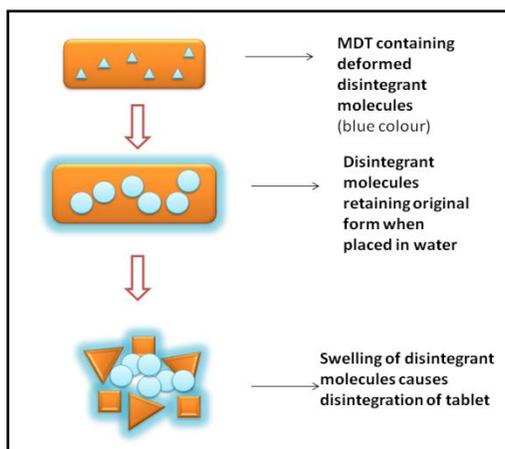
compressibility) themselves act to enhance porosity and provide these pathways into the tablet (Figure 2). Water uptake by tablet depends upon hydrophilicity of the drug /excipient and on tableting conditions. For these types of disintegrants maintenance of porous structure and low interfacial tension towards aqueous fluid is necessary which helps in disintegration by creating a hydrophilic network around the drug particles.

### 3. Due to disintegrating particle/particle repulsive forces:

Another mechanism of disintegration attempts to explain the swelling of tablet made with 'non-swelling' disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that non-swelling particle also cause disintegration of tablets (Figure 3). The electric repulsive forces between particles are the mechanism of disintegration and water is required for it. Researchers found that repulsion is secondary to wicking.



**Figure 3: Repulsion mechanism of Disintegrant. In this mechanism, repulsion forces between the molecules causes tablet to disintegrate**



**Figure 4: Deformation mechanism of Disintegrant. In this mechanism, irregular arrangement of molecules (in contact with medium) causes fast disintegration**

#### 4. Due to deformation:

During tablet compression, disintegrated particles get deformed and these deformed particles get into their normal structure when they come in contact with aqueous media or water. Occasionally, the swelling capacity of starch was improved when granules were extensively deformed during compression. This increase in size of the deformed particles produces a breakup of the tablet (Figure 4). Starch grains are generally thought to be “elastic” in nature meaning that grains that are deformed under pressure will return to their original shape when that pressure is removed. But, with the compression forces involved in tableting, these grains are believed to be deformed more permanently and are said to be “energy rich” with this energy being released upon exposure to water.

#### PREPARATIVE TECHNIQUES:<sup>2-17</sup>

Various manufacturing or preparative techniques for preparation of Mouth dissolving tablets include:

1. Lyophilization or Freeze drying
2. Moulding
3. Direct Compression
4. Cotton Candy Process
5. Spray Drying
6. Sublimation
7. Mass Extrusion
8. Nanonization
9. Fast Dissolving Films

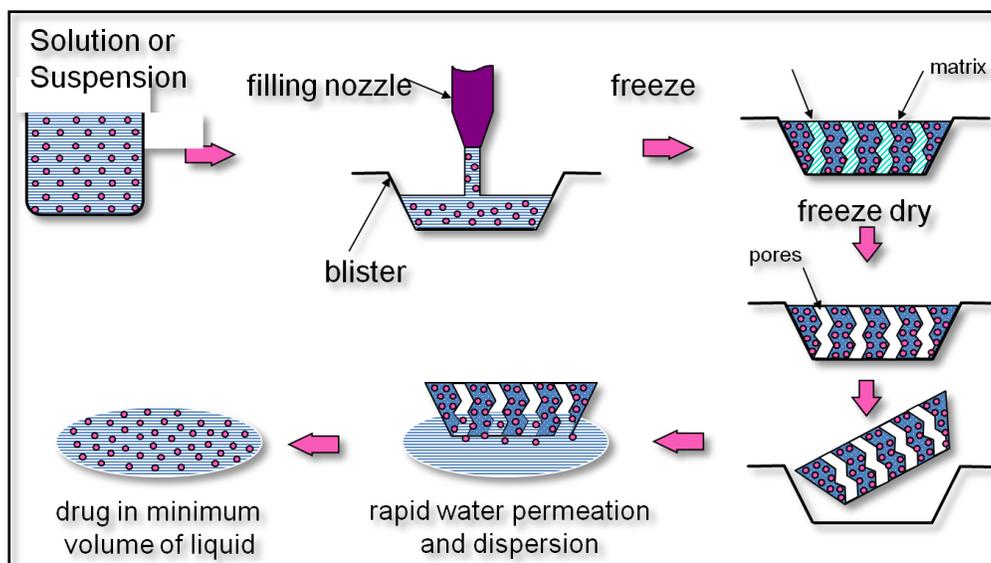
Of the above 1 to 7 are commonly used techniques in formulation of mouth dissolving tablets.

#### **Lyophilization:**<sup>3,6</sup>

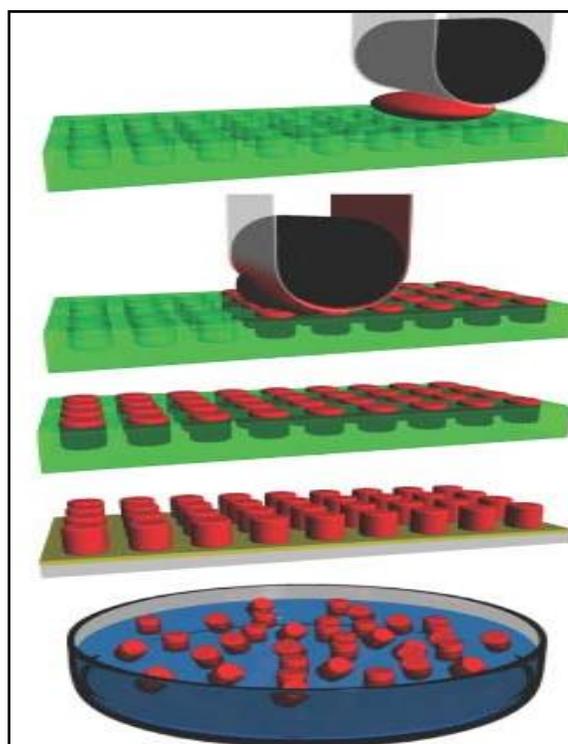
Lyophilization can be used to prepare tablets that have very porous open matrix network into which saliva rapidly moves to disintegrate lyophilized mass after it is placed in mouth.

The drug is entrapped in a water soluble matrix which is freeze dried to produce a unit which rapidly disperses when placed in mouth (Figure 5). Apart from the matrix and active constituents, the final formulation may contain other excipients like suspending agents, wetting agents, preservatives, antioxidants, colours and flavours, which improve the process characteristics or enhance the quality of final product. The preferred drug characteristics for freeze drying formulations are water insoluble, low dose, chemically stable, small particle size

and tasteless. The major advantage of using this technique is that the tablets produced by this technology have very low disintegration time and have great mouth feel. However, this technique is relatively expensive and time consuming. The tablets obtained are with poor mechanical strength and highly fragile and exhibit less resistance to environmental conditions.



**Figure 5: Lyophilization Technology.** Patented technology based on this process is Zydis technology



**Figure 6: Molding technique.** In this technique, drug and polymer mixture were poured into moulds and subjected to drying

**Molding:**<sup>7-9</sup>

In this technology, water-soluble ingredients are used so that tablet disintegrate and dissolve rapidly. The powder blend is moistened with a hydro alcoholic solvent and is molded in to tablet using compression pressure lower than used in conventional tablets compression (Figure 6). The solvent is then removed by air-drying. Molded tablets have a porous structure that enhances dissolution. Less mechanical strength and poor taste masking are the two major problems with molding. However, by using binding agents such as sucrose, acacia or poly vinyl pyrrolidone can increase the mechanical strength of the tablet.

**Spray drying:**

In this method, processing solvent is evaporated rapidly and can produce highly porous, fine powder. Spray drying can be used to prepare rapidly disintegrating tablets. This technique is based on a particulate support matrix, which is prepared by spray drying an aqueous composition containing support matrix and other components to form a highly porous and fine powder. This is then mixed with active ingredients and compressed into tablets.

**Direct compression:**

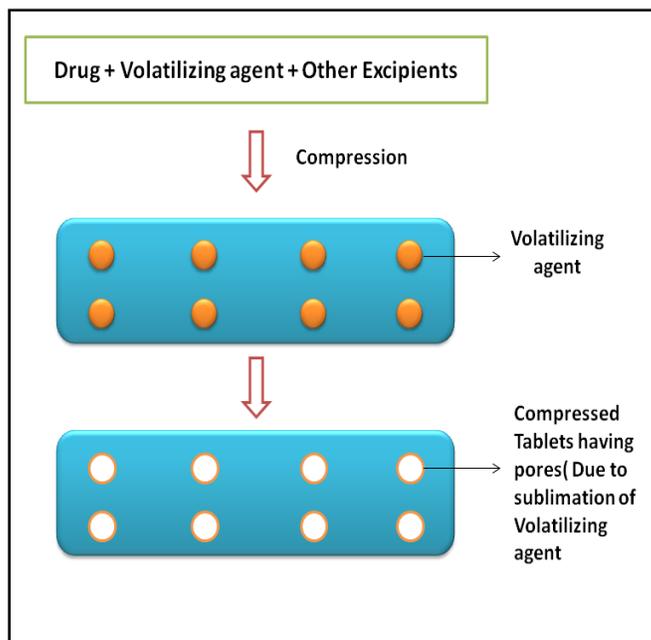
In this method, tablets are compressed directly from the mixture of the drug and excipients without any preliminary treatment. The mixture to be compressed must have adequate flow properties and cohere under pressure. A type of disintegrant and its proportion are of prime importance. The other factors to be considered are particle size distribution, contact angle, pore size distribution, tablet hardness and water absorption capacity. All these factors determine the disintegration. The disintegrant addition technology is cost effective and easy to implement at industrial level.

**Sublimation:**<sup>7,8</sup>

The basis of this technique is to add inert solid ingredients that volatilize readily, (e.g. camphor, ammonium bicarbonate, naphthalene, urea, urethane etc) to other tablet excipients and the mixture is then compressed into tablets (Figure 7). Volatile material is then removed via sublimation, which generate a porous structure.

**Mass extrusion:**<sup>4,5</sup>

This method 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. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking.



**Figure 7: Sublimation technique. Evaporation of volatile agent results in formation of porous tablets there by causing fast disintegration**

#### PATENTED TECHNOLOGIES:

Currently, there are 9 to 11 patented technologies in formulation of MDTs. However, only 4 of 11 had reached the US market like Zydis, WOWTAB, Orasolv and Durasolv.

Other patented technologies include Flash dose, Flash tab, Oraquick, Pharmafreeze, Lyoc, Pharmaburst and Advatab.

These technologies differ from each other in Mechanical strength, Dosage form stability, Mouth feel, Taste, Rate of dissolution, Rate of absorption in oral fluids and Bioavailability.

#### **Zydis Technology<sup>1,3,8,16,17</sup>:**

Zydis, the best known of the fastdissolving/ disintegrating tablet preparations, and was the first marketed new technology tablet. The tablet dissolves in the mouth within seconds after placement on the tongue. Zydis tablet is produced by lyophilizing or freeze drying the drug in a matrix usually consisting of gelatine. The product is very lightweight and fragile, and must be dispensed in a special blister pack. 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. A major claim of the Zydis product is increased bioavailability compared to traditional tablets. Because of its dispersion and dissolution in saliva while still in the oral cavity, there can be a substantial amount of pre-gastric absorption from this formulation. Buccal, pharyngeal and gastric regions are all areas of absorption of the Zydis formulation. Any pre gastric absorption

avoids first pass metabolism and can be an advantage in drugs that undergo a great deal of hepatic metabolism. However, if the amount of swallowed drug varies, there is the potential for inconsistent bioavailability. While the claimed increase in bioavailability is debatable, it is clear that the major advantage of the Zydis formulation is convenience. The amount of drug that could be incorporated should generally be less than 60 mg for soluble drugs. The particle size of the insoluble drugs should be less than 50mm and not more than 200mm to prevent sedimentation during processing.

There are some disadvantages to the Zydis technology. The process of freeze drying is a relatively expensive manufacturing process. As mentioned earlier, the Zydis formulation is very lightweight and fragile, and therefore should not be stored in backpacks or the bottom of purses. Finally, the Zydis formulation has poor stability at higher temperatures and humidity. It readily absorbs water, and is very sensitive to degradation at humidity greater than 65%.

#### **Orasolv technology<sup>1,8</sup>:**

The OraSolv technology, unlike Zydis, disperses in the saliva with the aid of almost imperceptible effervescence. The OraSolv technology is best described as a fast-disintegrating tablet; the tablet matrix dissolves in less than one minute, leaving coated drug powder. The taste masking associated with the OraSolv formulation is two-fold. The unpleasant flavour of a drug is not merely counteracted by sweeteners or flavours; both coating the drug powder and effervescence are means of taste masking in OraSolv. This technology is frequently used to develop over-the-counter formulations. The major disadvantage of the OraSolv formulations is its mechanical strength. An advantage that goes along with the low degree of compaction of OraSolv is that the particle coating used for taste masking is not compromised by fracture during processing. Lyophilisation and high degrees of compression, as utilized in OraSolv's primary competitors, may disrupt such a taste masking approach. The OraSolv technology is utilized in six marketed products. These formulations can accommodate single or multiple active ingredients and tablets containing more than 1.0 g of drug have been developed. Their disintegration time is less than 30s.

#### **Durasolv technology<sup>6,8</sup>:**

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

Advantages:

- Durasolv has much higher mechanical strength than its predecessor due to the use of higher compaction pressures during tableting.
- The Durasolv product is thus produced in a faster and in more effective manner.

Disadvantages:

- It is not compatible with larger doses of active ingredients because the formulation is subjected to high pressures on compaction.
- The drug powder coating may fractured during compaction, exposing the bitter tasting drug to patient's taste buds.

### **Wowtab Technology<sup>8,17</sup>:**

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 a low mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet.

Advantages:

- Offers Superior mouthfeel due to the smooth melt action
- It is suitable for both conventional bottle and blister packaging
- Bit more stable to the environment than the zydis and orasolv.

### **Flash Dose Technology<sup>8,17</sup>:**

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 bindingshearform matrix termed as "floss". Shearform matrices are prepared by flash heat processing.

### **Flashtab Technology<sup>8,17</sup>:**

Prographarm laboratories have patented the Flashtab technology. Tablets prepared by this system consist of an active ingredient in the form of microcrystals. Drug microgranules may be prepared by using the conventional techniques like coacervation, microencapsulation, and extrusion-spheronisation. All the processing utilized conventional tableting technology.

### **OraQuicktechnology<sup>8,17</sup>:**

The OraQuick fast-dissolving/disintegrating tablet formulation utilizes a patented taste masking technology. KV Pharmaceutical claims its microsphere technology, known as MicroMask, has

superior mouthfeel over taste-masking alternatives. The taste masking process does not utilize solvents of any kind, and therefore leads to faster and more efficient production. Also, lower heat of production than alternative fast-dissolving/disintegrating technologies makes OraQuick appropriate for heat-sensitive drugs. KV Pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particles is more pliable, meaning tablets can be compressed to achieve significant mechanical strength without disrupting taste masking. OraQuick claims quick dissolution in a matter of seconds, with good tastemasking. There are no products using the OraQuick technology currently on the market, but KV Pharmaceutical has products in development such as analgesics, scheduled drugs, cough and cold, psychotropics, and anti-infectives.

#### **EVALUATION PARAMETERS:<sup>10-14</sup>**

##### **Weight variation test:**

Randomly selected 20 tablets were taken and their individual weights & the average weight of 20 tablets were determined. The deviation of each individual tablet from the average weight was calculated and compared with the standard values given in Pharmacopoeia.

The % weight variation of each individual tablet from the average weight is calculated by the given formula:

$$\% \text{ Weight Variation} = \frac{\text{Individual weight of each tablet} - \text{Average weight of 20 tablets}}{\text{Average weight of 20 tablets}} \times 100$$

##### **Hardness test:**

Hardness of the tablets was measured by using hardness testers like Monsanto hardness tester, Pfizer hardness tester etc. The pressure required to break the tablets is measured as a function of hardness ( kg/ cm<sup>2</sup> ). The values obtained must meet the standard value.

##### **Friability:**

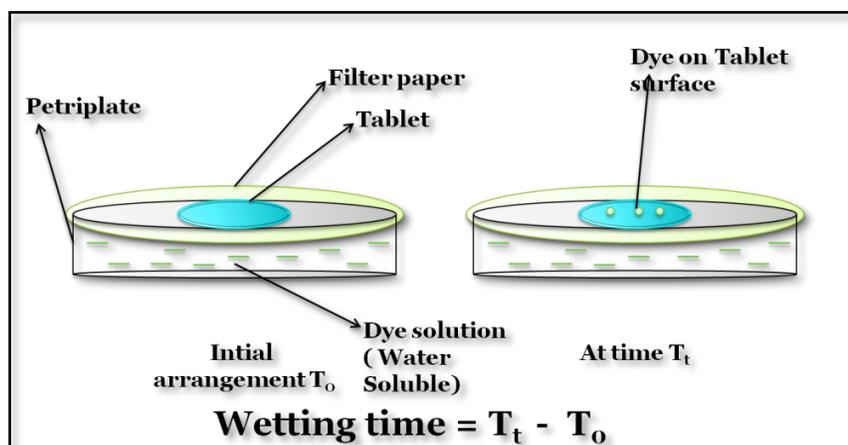
Friability is to measure the extent of tablet breakage during physical stress conditions like Packing, transportation etc. A sample of randomly selected 6 tablets was evaluated for friability using Roche friabilator at 25 rpm for 4 minutes. The % weight loss is calculated by measuring the total weight of 6 tablets before and after operation. Formula for calculating the % weight loss is given below:

$$\% \text{ Weightloss} = \frac{\text{Total weight of tablets before} - \text{Total weight of tablets after}}{\text{Total weight of tablets before}} \times 100$$

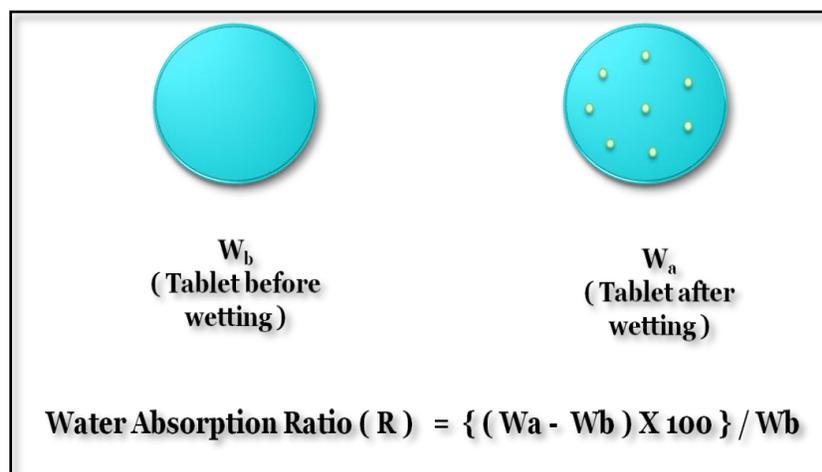
**Wetting time:**<sup>11-17</sup>

Wetting time and water absorption ratio are the significant parameters for mouth dissolving tablets. The following method for calculating the wetting time of the tablet.

A piece of filter paper (circularly cut) was placed in a small petri plate containing water soluble dye solution. Tablet was placed on the paper and the time required for complete wetting of the tablet was determined (Figure 8). Bi Y. et al. used a tissue paper folded twice and was placed in a small culture dish (i.d = 6.5 cm) containing 6 ml of water.



**Figure 8: Wetting time of Mouth dissolving tablet. The time taken for appearance of dye colour on tablet is wetting time**



**Figure 9: Calculation of water absorption ratio for MDTs. Difference between initial and final weights of tablet is noted**

**Water absorption ratio**<sup>17</sup>:

Similar to the procedure followed in determination of wetting time (Figures 8, 9). However, here the initial weight and the final weight (after complete wetting) of tablet were calculated and the water absorption ratio was calculated by given formula:

$$R = \frac{(W_a - W_b)}{W_b} \times 100$$

Where, R is water absorption ratio,  $W_a$  and  $W_b$  are the weights of tablet before and after wetting respectively.

**Disintegration time:**

Disintegration time for randomly selected 6 tablets was measured using disintegration test apparatus. The average time required for disintegration was calculated and compared with standards.

**Invitro dissolution studies:**

Randomly selected 6 tablets were subjected to drug release studies using USP dissolution apparatus, in dissolution medium volume of 900 ml was used and a temperature of  $37 \pm 0.5^\circ\text{C}$  was maintained. 5 ml of the sample was collected for every 5 minutes interval till 30 minutes and replaced with 5 ml of fresh buffer solution. The samples were filtered and suitably diluted and the drug assay was performed using UV spectrophotometer or HPLC system. The results were compared with standard values.

**Taste or mouth feel:**

Healthy human volunteers were used for evaluation of mouth feel of the tablet. One tablet was evaluated for its mouth feel. A panel of 5 members evaluate the mouth feel by time intensity method. Sample equivalent to 40 mg was held in mouth for 10 seconds and the opinion is rated by giving different score values. (0: good, 1: tasteless, 2: slightly bitter, 3: bitter, 4: awful).

**Stability studies:**

Various stability studies like accelerated stability study, intermediate and long term stability studies were done during preformulation. The sample was subjected to higher temperature or humidity or both, to know their impact on the stability of mouth dissolving tablet.

**Uniformity of dispersion:**

Two randomly selected tablets were kept in 100 ml water and stirred for two minutes. The dispersion was passed through 22 meshes. The tablets were considered to pass the test if no residue remains on the screen.

**MARKETED MDTs:<sup>6-17</sup>**

Table: 2 enlist various mouth dissolving tablets available in the market at present. Drugs belonging to classes of antibiotics, antiviral, anti bacterials are widely formulated as MDTs.

**Table 2: Various marketed MDTs**

<b>Trade Name</b>	<b>Active Drug</b>	<b>Manufacturer</b>
Cefadur DT	Cefadroxil	Cipla (protec)
Cefinar DT	Cefixime	ZydusAlidac
Zofran ODT; Vomokind MD	Ondansetron	GlaxoWellcome; Mankind
Torrox MT; Dolib MD	Rofecoxib	Torrent pharmaceuticals; Panacea
Acivir DT	Acyclovir	Cipla
Dom DT; Domestall DT	Domperidone	Dr. Morepen; Torrent Pharma
Nexus MD; NimexMD; Nimed MD; Nimulid MD	Nimesulide	Lexus; Mexon Health Care; ZotaPharma; Panacea Biotech
Mosid MT	Mosapride	Torrent Pharma
Allegra ODT	Fexofenadine	Sanofi Aventis
Benadryl Allergy Fast Melt	Diphenhydramine	Pfizer Consumer Healthcare
Cibalginadue FAST	Ibuprofen	Novartis Consumer Health
Pepcid RPD	Famotidine	Merck & Co.
ClaratinRediTabs	Loratadine	Schering-Plough Corporation
Maxalt-MLT	Rizatriptan	Merck & Co
Mirtazapine ODT	Mirtazapine	Teva Pharmaceuticals
Zotacet MD	Cetirizine HCl	ZotaPharma
Romilast	Montelukast	Ranbaxy

**CONCLUSION:**

Future challenges for many ODT manufacturers include reducing costs by finding ways to manufacture with conventional equipment, using versatile packaging, and improving mechanical strength and taste-masking capabilities. MDT need to be formulated for pediatric, geriatric, bedridden, psychotic patients, for those patients who are busy in traveling, patients who are may not have access to water. Such products provide opportunity for the product line extension in the market place and extension of patent term of innovator. Due to this wide significance of MDT, this drug delivery system may lead to better patient compliance and ultimate clinical output. Future might witness many more classes of drugs developed in the form of MDT.

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