

**FAST DISSOLVING TABLET – REVIEW ARTICLE****K.Umasankar\*, P.Jayachandra Reddy, V.Prabhakaran**

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**ABSTRACT**

Fast dissolving Tablets are disintegrating and/or dissolve rapidly in the saliva without the need for water. Some tablets are designed to dissolve in saliva remarkably fast, within a few seconds, and are true fast-dissolving tablets. Others contain agents to enhance the rate of tablet disintegration in the oral cavity, and are more appropriately termed fast-disintegrating tablets, as They may take up to a minute to completely disintegrate. Oral delivery is currently the goldstandard in the pharmaceutical industry where it is regarded as the safest, most convenient and most economical method of drug delivery having the highest patient compliance.

**KEY WORDS:** FDT, Orodispersible tablets, Fast dissolving/dispersing tablets, Melt in mouth tablets, Mass extrusion, Superdisintegrants.

**I. INTRODUCTION**

Oral Disintegrating Tablets (ODT) as defined as “A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.” Drug delivery through oral route has been the best route of administration since decades. It is most widely used routes of administration for the systemic delivery of drugs via various dosage forms. Orally disintegrating tablets also called as orodispersible tablets (ODTs), quick disintegrating tablets, and mouth dissolving tablets, fast disintegrating tablets, rapid disintegrating tablets, porous tablets or rapid melts. However USP approved these dosage forms as ODTs.<sup>1</sup> Criteria for fast dissolving tablets:-

1. Fast Melting tablets (FMT) or fast disintegrating/dissolving tablets (FDT) are single unit solid unit dosage forms that disintegrate or dissolve rapidly (in few seconds) in mouth without the need of water or chewing. These dosage forms show good stability, ease of

manufacturing and ease of handling by patient. The drug is immediately released from dosage form and is readily available for absorption, improving its onset of action and its bioavailability in some cases (soluble drugs), to some extent it is also possible to achieve absorption of some drugs across the oral mucosa directly into the systemic circulation, avoiding first pass metabolism & its subsequent side effects<sup>2</sup>.

2. Upon ingestion, the saliva serves to rapidly dissolve the dosage form. The saliva containing the dissolved or dispersed medicament is then swallowed and the drug absorbed in the GIT. Drug is absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In these cases bioavailability of drugs is greater than those observed from standard dosage forms<sup>4</sup>.

3. The main criteria for fast disintegrating (dissolving) tablet is to disintegrate or dissolve rapidly in oral cavity with saliva in 15 to 60 seconds, without need of water and should have pleasant mouth feel.

### **Salient Features & Advantages**

1. FDT passes all the advantages of solid dosage forms like good stability, easy manufacturing, unit and accurate dosing, easy handling.
2. Provides rapid drug therapy intervention.
3. Ease of administration to patients who are unable or refuses to swallow a tablet, such as pediatric, geriatric, psychiatric and disabled patients.
4. Does not require water while administration good disintegration and dissolution of the dosage form in oral cavity.
5. Ability to provide advantages of liquid medication in the form of solid preparation.
6. Can be designed to leave minimal or no residue in the mouth after administration and also to provide a pleasant mouth feel.
7. FDTs help avoid hepatic metabolism by allowing pre-gastric drug absorption thus reducing the dose of drug required.
8. Patient's compliance for disabled bedridden patients and for travelling and busy people, who do not have ready access to water.
9. Good mouth feel property of FDTs helps to change the basic view of medication as "bitter pill", particularly for pediatric patients due to improved taste of bitter drugs.
10. More rapid drug absorption from the pre-gastric area i.e. mouth, pharynx and oesophagus
11. Produce rapid onset of action.

**Limitations of Fast Dissolving Tablets**

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

**II. Characteristics And Challenges For Developing Fast Disintegrating Drug Delivery Systems****Time required for disintegration**

FDTs should disintegrate/dissolve/disperse or melt in mouth without the need of water in very short duration of time, possibly within 60 seconds.

**Taste of the active ingredient**

Delivery systems dissolve or disintegrate in patient's mouth, thus releasing the active ingredients which come in contact with the taste buds and hence, taste masking of the drugs becomes critical to patient compliance.

**Ease of administration**

Fast disintegrating drug delivery Systems are easy to administer and handle hence, leads to better patient compliance. Usually, elderly people experience difficulty in swallowing the conventional dosage forms (tablets, capsules, solutions and suspensions) because of tremors of extremities and dysphasia. Fast Dissolving Delivery Systems may offer a solution for these problems.

**Tablet strength, Friability and porosity**

In order to allow fast disintegrating tablets to disintegrate in the mouth, they are made of either very porous or soft-molded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, which are difficult to handle, often requiring specialized peel-off blister packaging.

**Hygroscopic nature**

Several fast disintegrating drug delivery dosage forms are hygroscopic and cannot maintain physical integrity under normal condition from humidity which calls for specialized product packaging.

**Superdisintegrant**

Increases the rate of disintegration and hence the dissolution. For the success of fast dissolving tablet, the tablet having quick dissolving property which is achieved by using the super disintegrant. Crosspovidone, Microcrystalline cellulose, sodium starch glycolate, sodium carboxy methylcellulose, pregelatinized starch, carboxymethylcellulose, and modified corn starch.

**Flavors**

Increases Patient compliance and acceptability. Peppermint flavor, cooling flavor, flavoring aromatic oil, clove oil, Flavoring agents include, vanilla, citrus oils, fruit essences.

**Sweeteners and sugar based excipients**

This is another approach to manufacture ODT by direct compression. Sugar base excipients acts as bulking agents. These exhibit high aqueous solubility and artificial sweeteners like Aspartame, Sugar derivatives. Bulking agents like dextrose, fructose, isomalt, lactitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol.

Sweetness, and hence impart taste masking property and a pleasing mouth feel. Binder Maintains integrity of dosage form prior to administration Polyvinyl pyrrolidone (PVP), Polyvinyl alcohol (PVA), Hydroxy propyl, methylcellulose. Color Enhances appearance and organoleptic properties of dosage form Sunset yellow, Amaranth, Red iron oxide. Lubricants Lubricant helps reduce friction and wear by introducing a lubricating film between mechanical moving parts of tablet punching machine. Stearic acid, Magnesium stearates, talc, polyethylene glycol, magnesium lauryl sulfate. Fillers Enhances bulk of dosage form Directly compressible spray dried Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate and calcium sulfate.

**III. Role Of Superdisintegrants In FDT<sup>3</sup>**

The basic approach in development of FDTs is use of disintegrant. Disintegrant play an 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. Superdisintegrant provide quick disintegration due to combined effect of swelling and water absorption by the formulation. Superdisintegrant's are selected according to critical concentration of disintegrant. Below this concentration, the tablet disintegration time is inversely proportional to the concentration of the superdisintegrant,

whereas if concentration of disintegrant is above critical concentration, the disintegration time remains almost constant or even increases.

### Mechanism of action of Disintegrants

The tablet breaks to primary particles by one or more of the mechanisms listed below:-

1. By capillary action
2. By swelling
3. Because of heat of wetting
4. Due to release of gases
5. By enzymatic action
6. Due to disintegrating particle/particle repulsive forces
7. Due to deformation

**Table.1:-Commonly used super disintegrants in fast dissolving dosage forms are.**

S.No	Source	Superdisintegrant	Optimum Concentration
1.	Modified Starches	Sodium Starch Glycolate	4-6%
2.	Cross Linked PVP	Crosspovidone	2-4%
3.	Modified Cellulose	Cross Linked Sodium Carboxy Methyl Cellulose	1-3% (Direct Compression) 2-4% (Wet Granulation)
4.	Cross Linked Algenic Acid	Algenic Acid NF	5%
5.	Natural	Soya polysaccharides, xanthumgum, gellan gum	2-5 %
6.	Others	Calcium silicate, ion exchange resin (indion 414)	20-40 %

### Formulation Aspects in developing FDT

Orally disintegrating tablets are formulated by utilizing several processes, which differ in their methodologies and the FDTs formed vary in various properties such as,

1. Mechanical strength of tablets
2. Taste and mouth feel
3. Swallowability
4. Drug dissolution in saliva
5. Bioavailability
6. Stability

### Various Approaches For Fast Dissolving Tablets<sup>4</sup>

The fast-dissolving property of the tablet is attributable to a quick ingress of water into the tablet matrix resulting in its rapid disintegration. Hence, the basic approaches to developing

fast dissolving tablets include maximizing the porous structure of the tablet matrix, incorporating the appropriate disintegrating agent, and using highly water-soluble excipients in the formulation.

### **Technologies**

1. Conventional
2. Patented

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### **IV. Technology Used For Mouth Dissolving Tablets Non-Patented Patented**

Freeze drying, Tablet molding, Spray drying, Sublimation, Direct compression, Melt granulation, ZyduS technology, Orasolv technology, Durasolv technology, Wowtab technology, Fashtab technology, Oraquick technology, Frosta technology.

### **Non Patented Technology**

#### **1. Freeze-Drying or Lyophilization<sup>6</sup>**

Freeze drying is the process in which water is sublimed from the product after it is frozen. This technique creates an amorphous porous structure that can dissolve rapidly. A typical procedure involved in the manufacturing of ODT using this technique is mentioned here. The active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer. The mixture is done by weight and poured in the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion. Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze-drying. After freeze-drying the aluminum foil backing is applied on a blister-sealing machine. Finally the blisters are packaged and shipped. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability. The major disadvantages of lyophilization technique are that it is expensive and time consuming; fragility makes

conventional packaging unsuitable for these products and poor stability under stressed conditions.

## **2. Tablet Molding<sup>7</sup>**

Molding process is of two types i.e. solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and possess a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at room temperature to form a jelly and drying at 30°C under vacuum. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology.

## **3. Spray Drying<sup>8</sup>**

In this technique, gelatin can be used as a supporting agent and as a matrix, mannitol as a bulking agent and sodium starch glycolate or croscarmellose or croscopolvidone are used as superdisintegrants. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.

## **4. Sublimation<sup>9</sup>**

This process involves addition of some inert volatile substances like urea, urethane, naphthalene, camphor, etc to other excipients and the compression of blend into tablet. Removal of volatile material by sublimation creates pores in tablet structure, due to which tablet dissolves when comes in contact with saliva. Additionally several solvents like cyclohexane, benzene etc can also be used as pore forming agents. Mouth dissolving tablets with highly porous structure and good mechanical strength have been developed by this method.

## **5. Direct compression<sup>10</sup>**

It is the easiest way to manufacture tablets. Conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression. Addition of disintegrants in fast dissolving tablets, leads to quick disintegration of tablets and

hence improves dissolution. In many fast dissolving tablet technologies based on direct compression, the disintegrants principally affect the rate of disintegration and hence the dissolution. The introduction of superdisintegrants and a better understanding of their properties have increased the popularity of this technology. Tablet disintegration time can be optimized by concentrating the disintegrants. Below critical concentration, tablet disintegration time is inversely proportional to disintegrants concentration.

**Table.2:-Ideal Requirements, Advantages and Limitations of Direct Compression**

S. No	Ideal requirements	Advantages	Limitations
1	Flowability	Cost effective production	Segregation
2	Compressibility	Better stability of API	Variation in functionality
3	Dilution Potential	Faster dissolution	Low dilution potential
4	Stability	Simple validation	Poor compressibility of API
5	Controlled Particle Size	Low microbial contamination	Lubricant sensitivity

## 6. Melt Granulation<sup>11</sup>

In this process, FDTs can be prepared by incorporating a hydrophilic waxy binder (superpolystate) like PEG-6-stearate. Super polystate is a waxy material with melting point of 33-37°C and a hydrophilic-lipophilic balance. It not only acts as a binder and increases the physical resistance of tablets, but also helps in the disintegration of tablets as it melts in the mouth and solubilizes rapidly leaving no residue. Super polystate was incorporated in the formulation of FDTs by melt granulation method where granules are formed by the molten form of this material.

## Patented Technology

### 1. Zydis Technology<sup>12</sup>

Zydis is a unique freeze dried oral solid dosage form that can be administered without water and it dissolves instantly on tongue in less than 3 sec. The drug is physically trapped in a water-soluble matrix, and then freeze dried to produce a product that rapidly dissolves. The matrix consists of water-soluble saccharides and polymer (gelatin, dextran, alginates) to provide rapid dissolution and to allow sufficient physical strength to withstand handling.

## Limitation

1. The amount of drug that could be incorporated should generally be less than 400mg for insoluble
2. Drug amount is much more less than that amount of 60mg for soluble drugs.



3. The particle size of the insoluble drugs should not be less than 50 $\mu$ m and not more than 200 $\mu$ m to prevent sedimentation during processing.

## **2. Orasolv technology<sup>13</sup>:**

It is CIMA lab's first fast dissolving formulation. Tablets are prepared by direct compression at low compression force in order to minimize oral disintegration and dissolution time. Orasolv technology is an example of slightly effervescent tablet that rapidly dissolves in the mouth. The active medicaments are taste masked and dispersed in saliva due to the action of effervescent agents.

### **Advantages**

1. The Orasolv technology formulation does not have hygroscopic characteristics.
2. The Orasolv technology formulations can accommodate very high doses.
3. It also provides a distinct, pleasant sensation of effervescence in the mouth.

## **3. Durasolv technology<sup>13</sup>**

This technology is patented by CIMA Labs. The tablets produced by this technology utilize the conventional tableting equipment. Tablets in this are formulated by using drug, non-direct compression fillers, and lubricants. Non-direct compressible fillers are dextrose, mannitol, sorbitol, lactose, and sucrose, which have the advantage of quick dissolution and avoid gritty texture, which is generally present in direct compressible sugar. The tablets obtained are strong and can be packed in conventional packing in bottles and blisters.

## **4. Wow tab technology<sup>14</sup>**

Yamanouchi patented this technology. WOW means without water. This technology utilizes conventional granulation and tableting methods to produce MDTs employing low- and high-moldability saccharides. Low moldability saccharides are lactose, mannitol, glucose, sucrose, and xylitol. High-moldability saccharides are maltose, maltitol, sorbitol, and oligosaccharides. When these low- and high-moldable saccharides are used alone, tablets obtained do not have desired properties of rapid disintegration and hardness, so combinations are used. This technology involves granulation of low-moldable saccharides with high-moldable saccharides as a binder and compressing into tablets followed by moisture treatment. Thus, tablets obtained showed adequate hardness and rapid disintegration.

**Advantages**

1. Offers Superior mouth feel due to the smooth melt action.
2. It is suitable for both conventional bottle and blister packaging.
3. Bit more stable to the environment than the Zydis and orasolv.

**5. Flash tab technology<sup>15</sup>**

This is patented by Ethypharm France. This technology includes granulation of excipients by wet or dry granulation method and followed by compressing into tablets. Excipients used in this technology are of two types. Disintegrating agents include reticulated polyvinylpyrrolidone or carboxy methylcellulose. Swelling agents include carboxy methylcellulose, starch, modified starch, microcrystalline cellulose, carboxy methylated starch, etc. These tablets have satisfactory physical resistance. Disintegration time is within 1 min.

**6. Oraquick<sup>16</sup>**

This technology is patented by K.V.S. Pharmaceuticals. It utilizes taste masking microsphere technology called as micro mask, which provides superior mouth feel, significant mechanical strength, and quick disintegration/dissolution of product. This process involves preparation of microparticles in the form of matrix that protects drug, which can be compressed with sufficient mechanical strength. Low heat of production in this process makes it appropriate for heat sensitive drugs. Oraquick product dissolves within few seconds.

**7. Frosta technology<sup>17</sup>**

This technology patents by Akina. It utilizes the concept of formulating plastic granules and compressing at low pressure to produce strong tablets with high porosity. Plastic granules composed of

1. Porous and plastic material,
2. Water penetration enhancer, and
3. Binder

The process involves usually mixing the porous plastic material with water penetration enhancer and followed by granulating with binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to 30 s depending on size of tablet.

**Drugs To Be Promising Incorporated In Fast Dissolving Tablets<sup>18</sup>****Table.3:- Drugs to be promising incorporated in FDT**

S.No	Class	Examples
01	<i>Analgesics and Antiinflammatory Agents</i>	Aloxiprin, Auranofin, Azapropazone, Benorylate, Diflunisal, Etodolac, Fenbufen, Fenoprofen Calcim, Flurbiprofen, Ibuprofen, Indomethacin, Ketoprofen, Meclofenamic Acid, Mefenamic Acid, Nabumetone, Naproxen, Oxaprozin, Oxyphenbutazone, Phenylbutazone, Piroxicam and Sulindac.
02	<i>Anthelmintics:-</i>	Albendazole, Bephenium Hydroxy naphthoate, Cambendazole, Dichlorophen, Ivermectin, Mebendazole, Oxarnniquine, Oxfendazole, Praziquantel, Pyrantel, Embonate and Thiabendazole,
03	<i>Anti-Arrhythmic Agents:-</i>	Amiodarone, Disopyramide, Flecainide Acetate and Quinidine Sulphate Res. 20: 3
04	<i>Anti-Epileptics:-</i>	Beclamide, Carbamazepine, Clonazepam, Ethotoin, Methoin, Methsuximide, Methylphenobarbitone, Oxcarbazepine, Paramethadione, Phenacemide, Phenobarbitone, Phenytoin, Phensuximide, Primidone, Sulthiame and Valproic Acid
05	<i>Anti-Hypertensive Agents:-</i>	Amlodipine, Carvedilol, Benidipine, Darodipine, Dilitazem, Diazoxide, Felodipine, Guanabenz Acetate, Indoramin, Isradipine, Minoxidii, Nicardipine, Nifedipine, Nimodipine, Phenoxo benzamine, Prazosin, Reserpine and Terazosin.
06	<i>Anti-Protozoal Agents:-</i>	Benznidazole, Clioquinol, Decoquinate, Diiodohydroxy quinoline, Diloxanide Furoate, Dinitolmide, Furzolidone, Metronidazole, Nimorazole, Nitrofurazone, Omidazole and Tinidazole.
07	<i>Anxiolytic, Sedatives, Hypnotics And Neuroleptics:-</i>	Alprazolam, Amyiobarbitone, Barbitone, Bentazeparn, Bromazepam, Bromperidol, Brotizoiam, Butobarbitone, Carbromal, Chlordiazepoxide, Chlormethiazole, Chlorpromazine, Clobazam, Clotiazepam, Clozapine, Droperidol, Ethinamate and Flunanisone, Flunitrazepam, Fluopromazine, Flupenuixol Decanoate, Fluphenazine Decanoate, Flurazepam, Haloperidol, Lorazepam, Lormetazepam, Medazepam, Meprobamate, Methaqualone, Midazolam, Nitrazepam, Oxazepam, Pentobarbitone, Perphenazine Pimozide, Prochlorperazine, Suipiride, Temazepam, Thioridazine, Triazolam and Zopiclone.

**Table.4:- List Of Mouth Dissoving Tablet Available In Market<sup>18</sup>**

Brand Name	Active ingredient	Company
Mosid MT	Mosapride	Torrent
Nimulid-MD	Nimesulide	Panacea
Olanex Instab	Olanzapine	Ranbaxy
Orthoref MD	Rofecoxib	Biochem
Topmide	Nimesulide	Antigen Health Care
Valus	Valdecocib	Glenmark
Veirid MD	Domperidone	Shreyam Health Care
Zotacet MD	Cetirizine Hcl	ZotaPharma

**Table.5:- Mouth Dissolving Tablet Available In International Market**

Brand Name	Active ingredient	Company
Aricept ODT	Donepezil HCL	Eisai and Pfizer
Benadryl Fastmelt	Diphenhydramine	Pfizer
Childrens Dimetapp ND	Loratadine	Wyeth Consumer Healthcare
Cibalginadue FAST	Ibuprofen	Novartis Consumer Health
Fazalco	Clonazapine	Alamo Pharmaceuticals
Febrectol	Paracetamol	Prographarm
Feldene Melt	Piroxicam	Pfizer
Imodium Instant melts	Loperamide HCL	Janssen
Maxalt-MLT	Rizatriptan benzoate	Merck
Nasea OD	Ramosetron	Yamanouchi
NurofenFlashTab	Ibuprofen	Boots Healthcare
Risperidal M-Tab	Risperidone	Janssen
Zofran ODT	Ondansetron	Glaxo Smith Kline
Zolpidem ODT	Zolpidem Tartrate	Bioavail

**Evaluation of Mouth Dissolving Tablet**

The formulated tablets have to evaluate the parameters mentioned in table 6.

**Table.6:-Evaluation Of The Mouth Dissolving Tablet**

S.No	Evaluation Parameters
1.	Weight variation
2.	Hardness
3.	Friability (F)
4.	Wetting time
5.	In vitro dispersion time
6.	In-vitro disintegration time
7.	Thickness Variation
8.	Stability study (Temperature dependent)
9.	Water absorption ratio

**CONCLUSION**

Fast disintegrating tablets technology gained more popularity in last decade. It emerged as a NewDrug Delivery system for treating various patients and diseases. FDT offers advantages of both solid and liquid oral dosage forms. This system allows easy self-administration without the need of water to swallow. It has provided new area for research and development both for industries and academics. The MDTs 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 manufacturers over a decade. MDTs formulations obtained by some of these technologies have sufficient mechanical strength,

quick disintegration/dissolution in the mouth without water. These MDTs can be used easily in children who have lost their primary teeth and in geriatric patients who have lost their teeth.

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