International Journal of Research and Development in Pharmacy and Life Sciences
Available online at http//www.ijrdpl.com
April - May, 2014, Vol. 3, No.3, pp 949-958
ISSN: 2278-0238

Review Article

FAST MOUTH DISSOLVING DISINTEGRATING TABLET AND PATIENT COUNSELLING POINTS FOR FDDTs - A REVIEW

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(Received: January 15, 2014; **Accepted:** March 17, 2014**)**

ABSTRACT

Recent developments in technology have presented viable dosage alternatives for patients who may have difficulty swallowing tablets or liquids. Traditional tablets and capsules administered with an 8-oz. glass of water may be inconvenient or impractical for some patients. For example, a very elderly patient may not be able to swallow a daily dose of antidepressant. An eight-year-old with allergies could use a more convenient dosage form than antihistamine syrup. A schizophrenic patient in the institutional setting can hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic. A middle-aged woman undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2-blocker. The convenience of administration and improved patient compliance are important in the design of oral drug delivery system which remains the preferred route of drug delivery inspite of various disadvantages. One such problem can be solved in the novel drug delivery system by formulating "mouth dissolving tablets" (MDTs) which disintegrates or dissolves rapidly without water within few seconds in the mouth due to the action of super-disintegrant or maximizing pore structure in the formulation. The review describes the various formulation aspects, technologies developed for MDTs, marketed formulation and drugs used in this research area.

Keywords: Mouth Dissolving Tablets, Orally Disintegrating Tablets, Super-disintegrates, Bioavailability and Fast-Dissolving/Disintegrating Tablet (FDDTs).

INTRODUCTION

MDTs disintegrate 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. According to European pharmacopoeia, these MDTs should dissolve/disintegrate in less than three minutes. The formulation is more useful for the bed- ridden and patients who have the swallowing problem.

Target populations for these new mouth-dissolving/disintegrating dosage forms:

- Ease of administration to patients who refuse to swallow tablet, pediatric, geriatric, and bedridden or developmentally disabled patients.
- Patients with persistent nausea, who are traveling, or who have little or no access to water are also good candidates for MDTs.1

- The ease of administration of a fast-dissolving/disintegrating tablet, along with its pleasant taste, may encourage a patient to adhere to a daily medication regimen.
- Fast-dissolving/disintegrating dosage forms increasingly available, it will be likely that prescribers will recommend such products for their noncompliant patients.
- In the near future, other patient populations will also be targeted. A novel application for MDTs is in veterinary medicine, for example, to avoid pilling a cat.
- MDTs/FDDTs is increased bioavailability compared to traditional tablets.1 Because of dispersion in saliva while still in the oral cavity, there can be pre-gastric absorption from some formulations in those cases where the drug dissolves quickly. Buccal, pharyngeal and gastric regions are all areas of absorption of the many formulations.3 However, other formulations show nearly identical plasma-concentration profiles.2
- Pre-gastric absorption avoids first pass metabolism and can be a great 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 disputable, it is clear that the major advantage of these formulations is convenience.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.

Major advantages of mouth dissolving tablets:

1. Administered without water, anywhere, any time.
2. Suitability for geriatric and pediatric patients, who experience difficulties in swallowing and for the other groups that may experience problems using conventional oral dosage form, due to being mentally ill, the developmentally disable and the patients who are uncooperative.
3. Beneficial in cases such as motion sickness, suede episodes of allergic attack or coughing, where an ultra rapid onset of action required.
4. An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
5. Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.

Salient feature of fast/mouth dissolving tablets:

- Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric & psychiatric patients.
- No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
- Rapid dissolution and absorption of the drug, which will produce quick onset of action.
- Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is increased.
- Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
- The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
- New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra rapid on set of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid

disintegration and dissolution of these tablets. Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.

Limitations of Mouth Dissolving Tablets:

1. Mechanical strength of final product.
2. Drug and dosage form stability.
3. Mouth feel.
4. Taste: the tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.
5. Rate of dissolution of drug formulation in saliva.
6. Swallowability.
7. Rate of absorption from the saliva solution and
8. Overall bioavailability.
9. Dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.

Technologies used for manufacturing of MDTs:

- Freeze-drying or Lyophilization
- Sublimation
- Spray drying
- Cotton candy process
- Moulding
- Mass extrusion
- Direct compression

Patented Technologies for Fast Dissolving Tablets

- Zydis Technology
- Durasolv Technology
- Orasolv Technology
- Flash Dose Technology
- Wowtab Technology
- Flashtab Technology

Freeze Drying or Lyophilization:

Lyophilization is a process, which includes the removal of solvent from a frozen suspension or solution of drug with structure-forming additives. Lyophilization is a pharmaceutical technology which allows drying of heat sensitive drugs and biological at low temperature under conditions that allow removal of water by sublimation. Figure 1 and 2 shows first of all; the material is frozen to bring it below its eutectic point. Then primary drying is carried out to reduce the moisture to around 4% w/w of dry product. Finally, secondary drying is done to reduce the bound moisture to the required volume. Due to lyophilization, bulking agent and sometimes drug acquire glossy amorphous structure and thus dissolution is enhanced 6. Lyophilization results in preparations, which are highly porous, with a very high specific surface area, which dissolve rapidly and show improved absorption and bioavailability. However the use of freeze-drying is limited due to high cost of equipment and processing 7. Other major disadvantages of the final dosage forms include lack of physical resistance in standard blister packs.

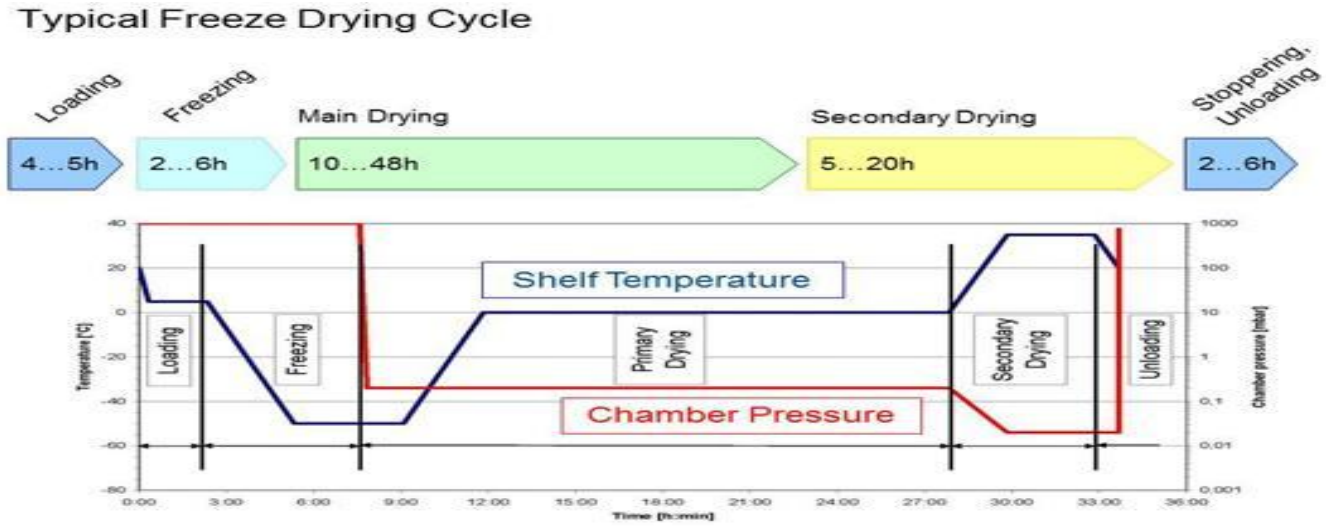

Fig. 1: Typical Freeze Drying Cycle

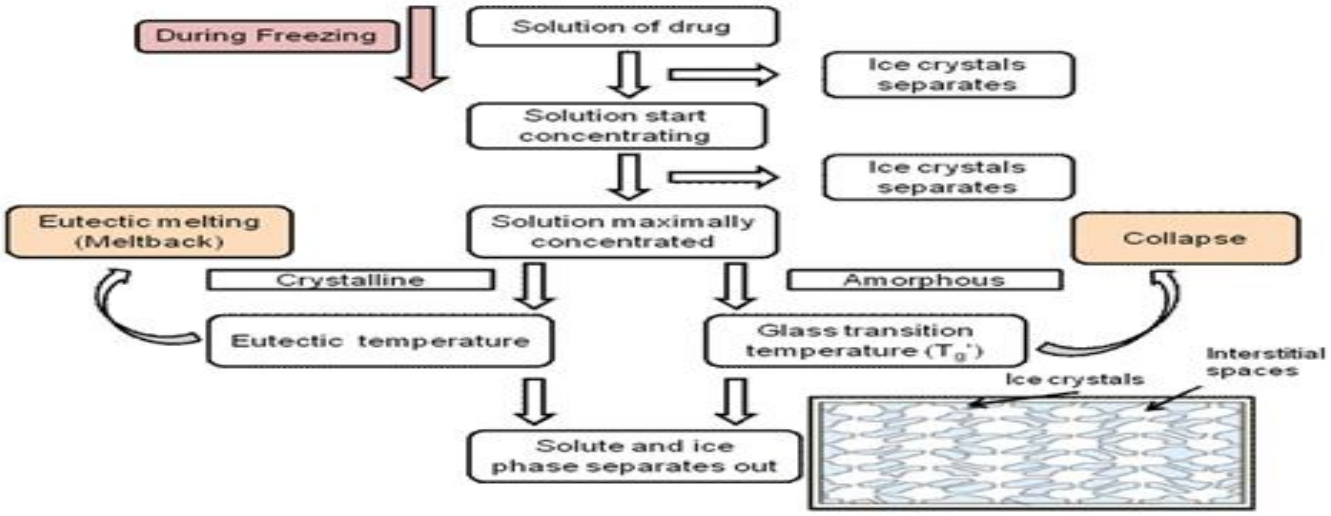

Fig. 2: Flowchart showing the concept of eutectic temperature and Tg (glass Transition) and their importance during primary drying.

Sublimation:

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.8, 9

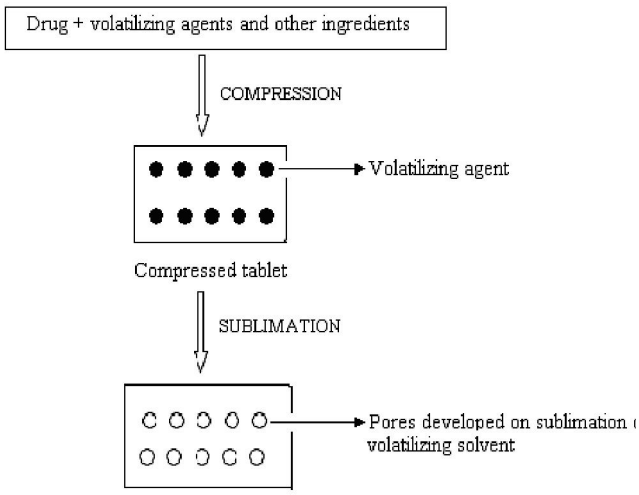

Fig. 3: Schematic Diagram of Sublimation Technique for Preparation of MDT

Spray drying:

A highly porous and fine powder is prepared by sprayed drying an aqueous composition containing support matrix and other components. This is then mixed with active ingredient and compressed into tablet. Allen and Wang10, 11 used this technique to prepare mouth-dissolving tablets, which disintegrated within 20 s.

Cotton candy process:

This process is so named as it utilizes a unique spinning mechanism to produce floss-like crystalline structure, which mimic cotton candy. Cotton candy process12 involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially re-crystallized to have improved flow properties and compressibility. This candy floss matrix is then milled and blended with active ingredients and excipients and subsequently compressed to MDTs.13

Moulding:

Tablets prepared by this method are solid dispersions. Physical form of drug in the tablets depends on whether and to what extent it dissolves in the wetted mass.14The drug can exist as discrete particles or micro particles in the matrix. It can dissolve totally to form a solid solution or dissolve partially in the molten carrier and remaining, if any, stays undissolved and dispersed in the matrix.15 Disintegration time, drug dissolution rate and mouth feel will depend on the

type of dispersion. Different moulding techniques can be used to prepare Mouth-dissolving tablets:

a. Compression moulding: The powder mixture previously wetted with a solvent like ethanol/water is compressed into mould plates to form a wetted mass.

b. Heat moulding: A molten matrix in which drug is dissolved or dispersed can be directly moulded into Mouth dissolving tablets.16

c. No vacuum lyophilization: This process involves evaporation of solvent from a drug solution or suspension at a standard pressure.17

Moulded tablets posess porous structure, which facilitates rapid disintegration and easy dissolution. Moulded tablets offer improved taste due to water-soluble sugars present in dispersion matrix. But moulded tablets lack good mechanical strength and can undergo breakage or erosion during handling and opening of blister packs.18 However, adding sucrose, acacia or polyvinyl pyrrolidone can increase mechanical strength.

Mass extrusion:

In this technique, a blend of active drug and other ingredients is softened using solvent mixture of water soluble polyethylene glycol, using methanol and then the softened mass is extruded through the extruder or syringe to get a cylinder of product, which is finally cut into even segments with the help of heated blades to get tablets. The dried cylinder can be used to coat the granules of bitter tasting drugs and thereby masking their bitter taste.19, 20

Direct compression:

The disintegrant addition technology 21, 22 (direct compression) is the most preferred technique to manufacture the tablets due to certain advantages:

a) High doses can be accommodated and final weight of the tablet can exceed that of other methods.
b) Easiest way to manufacture the tablets.
c) Conventional equipment and commonly available excipients are use.
d) A limited no. of processing steps are involved.
e) Cost-effectiveness.

Tablet size and hardness strongly affect the disintegrant efficacy. Hard and large tablets have more disintegration time than normally required. Very soft and small tablets have low mechanical strength. So, an optimum kind and concentration of disintegrant should be chosen to achieve quick disintegration and high dissolution rates. Above the critical concentration level, however, disintegration time remains approximately constant or even increases.23

Patented Technologies for Fast Dissolving Tablets 24, 26

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. Polymers such as gelatin, dextran or alginates are added to impart strength during handling. These form a glossy and amorphous structure. Mannitol or sorbitol is added to impart crystallinity, elegance and hardness. 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. If necessary, suspending agents and pH adjusting agents may be used. Preservatives may also be added to prevent microbial growth.

Drawbacks:

a. A water insoluble drug can be incorporated only up to 400 mg per tablet or less. On the other hand water soluble drug can be incorporated only up to 60 mg

b. Fragility and poor stability of dosage form during storage under stressful conditions.

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. Limitation of this technology that soft and fragile tablets are formed, therefore needed to be packed in specially designed pick and place package system.

Flash Dose Technology: Flash dose technology has been patented by Fuisz. Nurofen meltlet, 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 consist of self binding shearform matrix termed as floss. Shearform matrices are prepared by flash heat processing.

Drawbacks:

a. The dosage form can accommodate only up to 600 mg of drug.

b. Tablets produced are highly friable, soft and moisture sensitive. Therefore specialized packing is required.

Wowtab Technology: Wowtab Technology is patented by Yamanouchi Pharmaceutical Co.WOW means "Without Water ". In this process, combination of low mould ability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with allow mould ability saccharide and granulated with a high mouldability saccharide and compressed into tablet. The Wowtab product dissolves quickly in 15 s or less. Wowtab product can be packed in both into conventional bottle and blister packs.37

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 tabletting technology. These taste-masked micro crystals of active drug, disintegrating agent, a swelling agent and other excipients like soluble diluents etc are compressed to form a multiparticulate tablet that disintegrates rapidly.

Nanocrystal technology: NanoCrystal particles are small particles of drug substance, typically less than 1000 nanometers (nm) in diameter, which are produced by milling the d For fast dissolving tablets, Elan's proprietary NanoCrystal technology25 can enable formulation and improve compound activity and final product characteristics. Decreasing particle size increases the surface area, which leads to an increase in dissolution rate. This can be accomplished predictably and efficiently using NanoCrystal technology. NanoCrystal™ Fast dissolving technology provides for:

a. Pharmacokinetic benefits of orally administered nanoparticles (<2 microns) in the form of a rapidly disintegrating tablet matrix

b. Exceptional durability, enabling use of conventional packaging equipment and formats (i.e., bottles and/or blisters).

c. Wide range of doses (up to 200mg of API per unit).

d. Employment of non moisture sensitive substances

Patients Counseling Points for FDDTs: 27, 28

Pharmacists are in the ideal position to become familiar with the different technologies, and educate their patients on what to expect upon taking their first dose.

- Patients may be surprised when tablets begin to dissolve in the mouth.
- They might expect a faster onset of therapeutic action.
- Patients who concurrently take anticholinergic medications may not be the best candidates for these drugs.
- 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.
- Although no water is needed to allow the drug to disperse quickly and efficiently, most technologies utilize the body's own salivation.
- Decreased volume of saliva may slow the rate of dissolution/disintegration and decrease the bioavailability of the product.
- Chewable tablets are not the same as the new FDDTs. Patients for whom chewing is difficult or painful can use these new tablets easily. FDDTs can be used easily in children who have lost their primary teeth, but do not have full use of their permanent teeth.
- Patients may mistake fast-dissolving/disintegrating for effervescent tablets. Pharmacists may wish to stress the difference between the use of quick-dissolving and effervescent tablets.

- Pharmacists have been alerted to exercise additional care when dispensing new prescriptions for FDDT formulations. Most such products are available in the same strengths as traditional dosage forms.
- Verification with the prescribing practitioner may be necessary in some cases and can clear up any confusion.
- Pharmacists may wish to consider compounding as a unique way to treat the unmet needs of individual patients.
- A pharmacist's intervention and assistance, all of these patients could be more properly treated with greater convenience.

Table no. 1, 2, 3 and 4 listed various patented technologies and marketed preparations respectively.

Future prospects of MDT:

The technologies depicted in this article demonstrate how recent advances in formulation development and processing technologies meet the efforts to achieve more sophisticated drug delivery system (Oral Disintegrating/Mouth Dissolving Tablets). MDT needs to be formulated for pediatric, geriatric, bedridden, psychotic patients, for those patients who are busy in traveling, has difficulty in swallowing and may not have access to water. Mouth dissolving tablets can offer several biopharmaceutical advantages such as improved efficiency over conventional dosage forms. For example, they require smaller amounts of active ingredient to be effective, improve absorption profiles, and offer better drug bioavailability than regular tablets and capsules. In addition, MDTs may be suitable for the oral delivery of drugs such as protein and peptide-based therapeutics that have limited bioavailability when administered by conventional tablets. These products usually degrade rapidly in the stomach. Because drugs delivered in MDTs may be absorbed in the pre-gastric sites of highly permeable buccal and mucosal tissues of the oral cavity, they may be suitable for delivering relatively low-molecular weight and highly permeable drugs. Future possibilities for improvements in MDTs and drug delivery are bright, but the technology is still relatively new. Several drug delivery technologies that can be leveraged on improving drug therapy from MDTs have yet to be fully realized.

Table 1: Marketed Products of MDT

Trade Name	Active Drug	Manufacturer
Nimulid-MD	Nimesulide	Panacea Biotech, New Delhi, India
Feldene Fast Melt	Piroxicam	Pfizer Inc., NY, U.S.A
Zyrof Meltab	Rofecoxib	Zydus, Cadila, India
Pepcid RPD	Famotidine	Merck and Co., NJ, U.S.A
Romilast	Montelukast	Ranbaxy Labs Ltd., New Delhi, India
Torrox MT	Rofecoxib	Torrent Pharmaceuticals, Ahmedabad, India
Olanex Instab	Olanzapine	Ranbaxy Labs Ltd., New Delhi, India
Zofran ODT	Ondansetron	Glaxo Wellcome, Middlesex, UK
Mosid-MT	Mosapride citrate	Torrent Pharmaceuticals, Ahmedabad, India
Febrectol	Paracetamol	Prographarm, Chateauneuf, France
Maxalt MLT	Rizatriptan	Merck and Co., NJ, U.S.A
Zelapar TM	Selegiline	Amarin Corp., London, UK

Table 2: Some of Promising Drug Candidates for Mouth Dissolving Tablets[26]

S. No.	Category	Examples
1	Antibacterial agents	Ciprofloxacin, tetracycline, erythromycin, rifampicin, penicillin, doxycyclin, nalidixic acid,
2	Anthelmintics	Albendazole, mebendazole, thiabendazole, livermectin, praziquantel, pyrantel embonate,
3	Antidepressants	Trimipramine maleate, nortriptyline HCl, trazodone HCl, amoxapine, mianserin HCl, etc.
4	Antidiabetics	Glibenclamide, glipizide, tolbutamide, tolazamide, gliclazide, chlorpropamide etc.
5	Analgesics/anti-inflammatory	Diclofenac sodium, ibuprofen, ketoprofen, mefenamic acid, naproxen, oxyphenbutazone,

6	Antihypertensives:	Amlodipine, carvedilol, diltiazem, felodipine, minoxidil, nifedipine, prazosin HCl, nimodipine,
7	Antiarrhythmics	. Disopyramide, quinidine sulphate, amiodarone HCl, etc.
8	Antihistamines	Acrivastine, cetrizine, cinnarizine, loratadine, fexofenadine, triprolidine, etc.
9	Anxiolytics, sedatives hypnotics and	Alprazolam, diazepam, clozapine, amylobarbitone, lorazepam, haloperidol, nitrazepam ,
10	Diuretics	Acetazolamide, clorthiazide, amiloride, furosemide, spironolactone, bumetanide, ethacrynic
11	Gastro-intestinal agents	Cimetidine, ranitidine HCl, famotidine, domperidone, omeprazole, ondansetron HCl,
12	Corticosteroids	Betamethasone, beclomethasone, hydrocortisone, prednisone, prednisolone, methyl
13	Antiprotozoal agents	Metronidazole, tinidazole, omidazole, benznidazole, clioquinol, decoquinate etc.

Table 3: Patented technologies for fast dissolving tablets

Patented Technology	**Basis of Technology**	**Developing Company**	**Brand Names**	**Ref.**
Oraquick	Taste masking	KV Pharm.Co.,Inc.	Hyoscyamine Sulfate ODT	31
Advatab	CR Technology	Eurand International	AdvaTab	32,33
Wowtab	Direct compression	Yamanouchi Pharma Tech. Inc	Gaster D	30,38
Flashdose	Cotton Candy Process	Fuisz Technology Ltd.	Relivia Flash dose	34,35
Ziplets	Direct compression	Eurand International	Cibalgina DueFast	36
Orasolv	Direct compression	Cima Labs,Inc.	Tempra Quicklets, Zolmig Repimelt	30,37
Durasolv	Direct compression	Cima Labs, Inc.	NuLev , Zolmig ZMT	38
Flashtab	Direct compression	Ethypharm	Nurofen FlashTab	40
Zydis	Lyophilization	R.P.Scherer,Inc.Claritin Reditab,	Dimetapp Quick Dissolve	30,39
Lyoc	Lyophilization	Farmalyoc	Spasfon Lyoc	36
Quicksolv	Lyophilization	Janssen pharmaceutics	Propulsid Quicksolv, Risperdal M Tab	36

Table 4: Comparison of fast dissolving techniques

Novelty	Handling / Storage	Drug release / Bioavailability
ZYDIS (R.P. SCHERER, INC.)		
First to market **Freeze Dried**	Do not push tablet through foil Do not use dosage form from damaged package Sensitive to degradation at humidities > 65%	Dissolves in 2 -10 s May allow for pre-gastric absorption leading to enhanced bioavailability
ORASOLV (CIMA LABS, INC.)		
Unique taste masking **Lightly compressed**	Packaged in patented oil packs	Disintegrates in 5 – 45 s depending upon the size of the tablet No significant change in drug bioavailability
DURASOLV (CIMA LABS, INC.)		
Similar to Orasolv, but with better mechanical strength	Packaged in foil or bottles Package in bottles	Disintegrates in 5 – 45 s depending upon the size of the tablet No significant change in drug bioavailability
WOWTAB (YAMANOUCHI PHARMA TECHNOLOGIES, INC.)		
Proprietary taste masking **Compressed dosage form**	Avoid exposure to moisture or humidity Package in bottles	No significant change in drug bioavailability Disintegrates in 5 to 45 seconds depending upon the size of the tablet
FLASHDOSE (FUISZ TECHNOLOGIES, LTD.)		
Unique spinning mech^{m} producing floss-like crystalline structure as cotton candy	Avoid exposure to moisture and humidity	Dissolves within 1 min. Enhanced bioavailability.
FLASHTAB (PROGRAPHARM GROUP)		
Compressed dosage form containing drug as microcrystals		Dissolves within 1 min

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How to cite your article:

Gupta Dilip Kumar, Bajpai Meenakshi, Chatterjee D.P., A review on "Fast mouth dissolving disintegrating tablet and patient counselling points for FDDTs", Int. J. Res. Dev. Pharm. L. Sci., 2014, 3(3), pp. 949-958.

