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### An Overview on fast Dissolving Tablet

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#### Abstract

Oral route having the highest patient compliance is regarded as the most convenient, safest and also the most economical method of drug delivery. Fast dissolving tablets is one such most advantageous example of the oral drug delivery. These tablets readily dissolve or disintegrate in the saliva i.e. within <60sec without the need for water. They have been formulated for pediatric, geriatric and bedridden patients. These type of dosage forms are also ideal for active patients who are busy and traveling and may not have access to water. FDTs have gained considerable attention for those patients who have difficulties in swallowing because of dysphagia, hand tremors problems and have additional advantage for unconscious, young patients with underdeveloped muscular and nervous system. This review describes the various advantages, limitations, desired characteristics, formulation aspects, super-disintegrants employed, technologies developed for FDTs, evaluation tests, and marketed formulations.

**Key words:** Fast dissolving tablets, Oral route, dysphagia, rapimelts, porous tablets.

#### Introduction

Solid dosage forms like tablets, capsules are the most popular form among all other dosage forms existing today because of its convenience of compactness, easy manufacturing and self administration. It is difficult to swallow tablets as well as hard gelatin capsules and also when water is not available in the case of motion sickness, allergic attacks of coughing during the common cold and bronchitis. For these reasons tablets which rapidly dissolve or disintegrate in the oral cavity play an important role and are called fast dissolving tablets. These tablets disintegrate instantaneously when put on tongue, releasing the drug, which dissolve or disperses within 60 seconds in the saliva in the absence of water. FDTs are not formulated for people who have swallowing difficulties, but also are ideal for active people. Fast dissolving tablets are also called as mouth dissolving tablets, melt-in-mouth tablets, orodispersible tablets, rapimelts, porous tablets, quick dissolving tablets etc. some drugs are absorbed from the 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. The faster the drug into the solution,

quicker the absorption and onset of clinical effect. The use of superdisintegrants like croscarmellose, sodium starch glycolate, polyvinylpyrrolidone, croscopolidone etc which provide rapid disintegration of tablet and release drug in saliva is the basic approach in development of FDTs. Moreover, the amount of drug that is subjected to first pass metabolism is reduced as compared to standard tablet. Patients for whom chewing is difficult and painful can use FDTs easily. Fast dissolving tablets can also be used easily by children who have lost their teeth but donot have full use of their permanent teeth. The technologies used for manufacturing fast- dissolving tablets are freeze-drying, tablet molding, spray- drying, sugar-based excipients, sublimation, tablet compression, disintegration addition and many other patented technologies. Recent market study indicate that more than half of the worldwide population prefer FDTs as compare to other dosage form today.

#### **Advantages of fast disintegrating tablets** <sup>(1,2,3,7)</sup>

Fast dissolving technology offers:

1. Ease of administration for those patients who have difficulty in swallowing tablet.
2. No need of water to swallow the dosage form.
3. Useful for pediatric, geriatric and psychiatric patients.
4. Have acceptable taste masking property.
5. Achieve increased bioavailability through pregastric absorptionof drugs from mouth, pharynx and oesophagus as saliva passes down.
6. Have a pleasant mouth feel and leave minimal or no residuein the mouth after drug administration.
7. Have rapid dissolution and absorption of the drug which will produce quick onset of action.
8. It combines advantages of solid dosage form in terms of stability and liquid dosage form in term of bioavailability.

#### **Limitations to mouth dissolving tablets** <sup>(1,5,7)</sup>

- Careful handling is required because tablets usually have insufficient mechanical strength.
- If tablets are not formulated properly they may leave unpleasant taste or grittiness in the mouth.
- Drugs difficult to formulate into FDT with relatively larger doses.
- Drugs with short half-life and frequent dosing and those whom require controlled or sustained release are unsuitable candidates of FDTs.

#### **Desired Characteristics of Fast Dissolving Tablets** <sup>(5)</sup>

##### **Fast Disintegration**

These tablets should disintegrate in the mouth without additional water or with a very small amount of water. The disintegration fluid is provided by the saliva of the patient. The disintegrated tablet should become a soft paste or liquid suspension, which can provide smooth swallowing and good mouth feel

##### **Drug Properties**

Many drug properties could potentially affect the performance of FDTs. For example, the solubility, crystal morphology, particle size, hygroscopicity, compressibility, bioavailability, flow property and bulk density of a drug can significantly affect the final tablets characteristics, such as disintegration and tablet strength.

##### **Taste of Active Ingredients**

FDTs dissolve or disintegrate in the patient's mouth, the drug will be partially dissolved in close proximity to the taste buds. After swallowing, there should be minimal or no residue in the mouth. An ideal taste-masking technology should provide drugs with good mouth feel and without grittiness.

##### **Moisture Sensitivity**

These tablets should have low sensitivity to humidity. This problem can be especially challenging because many highly water soluble excipients are used in formulation to enhance fast dissolving properties as well as to create good mouth feel. Those highly water soluble excipients are susceptible to moisture; some will even deliquesce at high humidity.

##### **Tablet strength and porosity**

The tablet porosity is usually maximized to ensure fast water absorption into the tablets. The key properties of the tablets are fast absorption or wetting of water into the tablets and disintegration associated particles into individual components for fast dissolution. This requires that excipients should have high wettability, and the tablet structure

should also have a highly porous network. Because the strength of a tablet is related to compression pressure, and porosity is inversely related to compression pressure, it is important to find the porosity that allows fast water absorption while maintaining high mechanical strength.

#### Drug Selection Criteria

- Have better solubility. E.g. promethazine
- Low dose. E.g. terazosin Hcl
- Have better availability to permeate oral mucosal tissue.
- Less or not bitter in taste.
- Good stability in both water as well as in saliva. E.g. rizatriptine benzoate

**Table 1 Promising Drugs to be incorporated In Fast Dissolving**

S.NO.	DRUG CATEGORY	EXAMPES OF DRUG
1.	Analgesic and anti-inflammatory agents	Ibuprofen, indomethacin, naproxen, oxaprozin, phenylbutazone, piroxicam, meloxicam, ketoprofen etc.
2.	Anthelmintics	Albendazole, cambendazole, dichlorophen, mebendazole, thiabendazole, praziquantel
3.	Anti-arrhythmic agents	Quinidine sulphate, amiodrone, disopyramide, flecainide acetate
4.	Anti-coagulants	Phenindione, nicoumalone, dipyridamole, dicoumarol
5.	Anti-depressants	Trimipramine, trazodone, nortriptyline, mianserin, maprotiline, amoxapine
6.	Anti-bacterial	Trimetoprim, tetracycline, sulphapyridine, sulphafurazole, sulphadiazine, sulphacetamide, spiramycin, rifampicin, nitrofurantoin, nalidixic acid, ethionamide, erythromycin, ciprofloxacin, clarithromycin
7.	Anti-epileptics	Valproic acid, sulthiame, primidone, phenisuximide, phenytoin, phenobarbitone, oxcarbazepine, methoin, ethotoin, clonazepam, carbamazepine
8.	Anti-gout agents	Sulphinpyrazone, allopurinol, probenecid
9.	Anti-fungal agents	Clotrimazole, econazole nitrate, fluconazole, flucytosine, griseofulvin, itraconazole, ketoconazole, miconazole
10.	Anti-hypertensive agents	Amlodipine, carvedilol, prazosin, benidipine, darodipine, diltiazam, diazoxide, felodipine, minoxidil, nifedipine, nimodipine, terazosin
11.	Anti-malarial agents	Proguanil, mefloquine, halofant-trine, chlorproguanil, chloroquine
12.	Anti-neoplastic agents	Busulphan, chlorambucil, cyclosporin, dacarbazine, tamoxifen toposide, lomustine, melphalan, methotrexate, procarbazine, citrate, mitomycin
13.	Anti-migraine agents	Dihydroergotaminemesylate, sumatriptan, ergotamine maleate
14.	Anti-Protozoal agents	Furazolidone, metronidazole, nimorazole, nitrofurazone, amidazole, tinidazole
15.	Anti-thyroid agents	Carbimazole, propylthiouracil
16.	Anxiolytic, sedative, hypnotics and neuroleptics	Alprazolam, amyobarbitone, barbitone, chlormethiazole, chlorpromazine, clobazam, clozapine, diazepam, droperidol, lorazepam, haloperidol, oxazepam
17.	Corticosteroids	Beclomethasone, betamethasone, budesonide, cortisone acetate, prednisolone, hydrocortisone
18.	Anti-parkinsonian agents	Lysuride maleate, bromocriptine mesylate
19.	Diuretics	Acetazolamide, amiloride, bumetanide, chlorothiazide, chlorthalidone, frusemide
20.	Gastro-intestinal agents	Cimetidine, cisapride, ranitidine, domperidone, famotidine
21.	Anti-histaminic agents	Cinnarizine, cyclizine, flunarizine, loratidine, meclozine, triprolidine
22.	Local anaesthetics	Lidocaine
23.	Neuro-muscular agents	Pyridostigmine

24.	Nitrates and other anti-anginal agents	Amyl nitrate, glyceryl trinitrate, isosorbide dinitrate, isosorbide mononitrate, pentaerythritol tetranitrate
25.	Nutritional agents	Betacarotene, vitamin A, B2, D, E and K
26.	Opioid analgesics	Codeine, diamorphine, dihydrocodiene, meptazinol, methadone, morphine, pentazocine
27.	Oral vaccines	Vaccines prevent against:- influenza, tuberculosis, meningitis, hepatitis, whooping cough, polio, tetanus, diphtheria, malaria, cholera, typhoid, HIV, measles, mumps
28.	Proteins and peptides	Insulin, glucagons, growth hormones
29.	Sex hormones	Clomiphene citrate, danazol, mestranol, methyl testosterone, norgestrel, oestradiol, conjugated oestrogens, progesterone, testosterone, tibolone
30.	Stimulants	Amphetamine, pemoline, dexamphetamine, mazindol, dexfenfluramine, fenfluramine

### Super-Disintegrants

Superdisintegrants are the agents added to tablet formulations to promote the breakup of the tablets into smaller fragments in an aqueous environment there by increasing the available surface area and promoting a more rapid release of the drug substance.

#### Mechanism of Superdisintegrants

There are four major mechanisms for tablet disintegration as follows:

#### Swelling

General mechanism of action for tablet disintegration which is most widely accepted is swelling. Tablets with high porosity due to lack of adequate swelling force show poor disintegration. Sufficient swelling force with low porosity is exerted in the tablet. If the packing fraction is very high, fluid is unable to penetrate in the tablet & disintegration is again slows down.

#### Porosity and Capillary Action (Wicking)

Effective disintegrants that do not swell are believed to impart their disintegrating action through porosity and capillary action. Tablet porosity provides pathways for the preparation of fluid into tablets. The disintegrant particles themselves act to enhance porosity and provide pathways into the tablet. Liquid is drawn up or "wicked" into these pathways through capillary action and rupture the interparticulate bonds causing the tablet to break apart.

#### Due to disintegrating particle/particle repulsive forces

Another mechanism of disintegrating attempts to explain the swelling of tablet made with 'nonswellable' disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that nonswelling particle also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it.

#### Due to deformation

Disintegrated particles get deformed; during tablets compression and when these deformed particles come in contact with aqueous media or water they get into their normal structure. Swelling capacity of starch was improved during compression. Due to this increase in size of the deformed particles produces a breakup of the tablet.

### List of Superdisintegrants

Table 2 List of Superdisintegrants

Superdisintegrants	Example	Mechanism of action
Crosspovidone M® Kollidon® Crosspovidone Polyplasdone®	Crosslinked PVP	-Swells very little and returns to original size after compression but act by capillary action
Crosscarmellose® Ac-Di-Sol® Nymce ZSX® Primellose® Solutab® Vivasol® L-HPC	Crosslinked cellulose	-Swells 4-8 folds in < 10 seconds. -Swelling and Wicking both.
Sodium starch glycolate Explotab®	Crosslinked starch	-Swells 7-12 folds in < 30 seconds

Primogel®		
Calcium silicate		-Wicking action
Alginic acid NF Satialgine®	Crosslinked alginic acid	-Rapid swelling in aqueous medium or wicking action
Soy polysaccharides Emcosoy®	Natural super disintegrant	

### Examples of Other Excipients Used In Fdts Formulation <sup>(8)</sup>

**Flavours:** Peppermint flavour, cooling flavour, flavour oils, flavouring aromatic oil, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, oil of bitter almonds. Flavouring agents include vanilla, citrus oils, fruit essences.

**Sweetners:** Aspartame, sugars derivatives.

**Fillers:** Directly compressible spray dried Mannitol, sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, calcium sulphate, pregelatinized starch, magnesium trisilicate, aluminium hydroxide.

**Surface active agents:** sodiumdoecylsulfate, sodiumlaurylsulfate, polyoxyethylene sorbitan fatty acid esters (Tweens), sorbitan fatty acid esters (Spans), polyoxyethylene stearates.

**Binders:** Polyvinylpyrrolidone (PVP), polyvinylalcohol (PVA)

**Colour:** Sunset yellow, amaranth etc.

**Lubricants:** Stearic acid, magnesium stearate, zinc stearate, calcium stearate, talc, polyethylene glycol, liquid paraffin, magnesium lauryl sulfate, colloidal silicon dioxide.

### Conventional Techniques used for Preparation of Fdts <sup>(3,6,7)</sup>

#### 1. Disintegration Addition:

Disintegration addition technique is one popular techniques for formulating FDTs because of its easy implementation and cost-effectiveness. The basic principle involved in formulating FDTs by disintegrant addition technique is addition of superdisintegrants in optimum concentration so as to achieve rapid disintegration along with the good mouth feel.

#### 2. Freeze drying :

A process in which water is sublimated from the product after freezing. Lyophilization is a pharmaceutical technology which allows drying of heat sensitive drugs and biological at low temperature under condition that allow removal of water by sublimation. Lyophilization results in preparations which are highly porous, with a very high specific surface area, which dissolve rapidly show improved absorption and bioavailability.

#### 3. Moulding:

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 hydro-alcoholic solvent and is molded into tablets under pressure lower than that used in conventional tablet compression.

#### Sublimation:

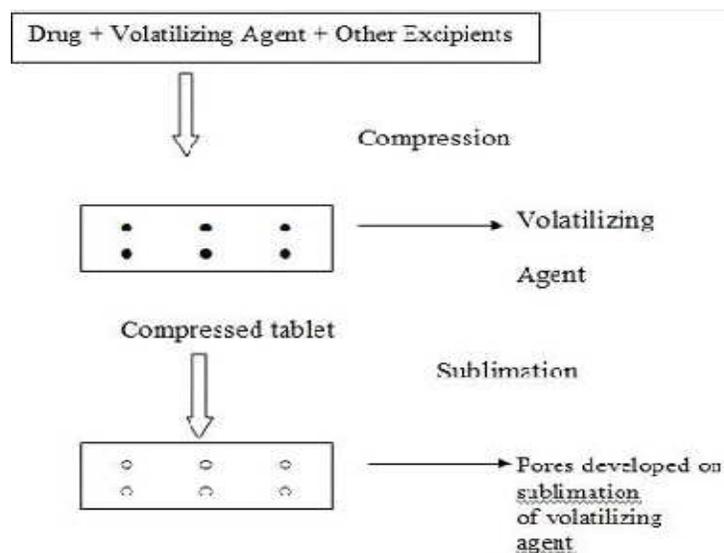


Figure 1: Steps Involved in Sublimation

**Spray- Drying:**

Spray drying can produce highly porous and fine powders that dissolve rapidly. The formulations are incorporated by hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or crosscarmellose sodium as disintegrating and an acidic material(e.g. citric acid) and/or alkali material(e.g. sodium bicarbonate)to enhance disintegration and dissolution.

**Mass- Extrusion:**

This technology involves softening the active blend using the solvent mixture of water soluble polyethylene glycol, using methanol and expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blades to form tablets.

**Direct Compression:**

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. Also high doses can be accommodated and final weight of tablet can easily exceed that of other production methods.directly compressed tablets disintegration and solubilization depends on single or combined action of disintegrants, water soluble excipients and effervescent agent.

**Melt granulation:**

It is a process by which pharmaceutical powders are efficiently agglomerated by a meltable binder. The advantage of this technique compared to a conventional granulation is that no water and organic solvent is needed. Because there is no drying step, the process is less time consuming and uses less energy than wet granulation. It is a useful technique to enhance the dissolution rate of poorly water-soluble drugs.

**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

**Patented Technologies For Fast Dissolving Tablets<sup>(1,7)</sup>**

- 1) Zydis technology.
- 2) Durasolv technology.
- 3) Orasolv technology.
- 4) Wowtab technology.
- 5) Flashtab technology.
- 6) Ziplets/Advatab technology.
- 7) Pharmaburst
- 8) Nanocrystal technology.
- 9) Lyoc

**Table 3 Patented Technologies For Fast Dissolving Tablets**

Technology	Company's Name	Technology based
Zydis	R.P Scherer Inc.	Freeze drying
Durasolv	CIMA Labs Inc.	Compressed tablet
Orasolv	CIMA Labs Inc.	Compressed tablet
Wowtab	Yamanouchi pharma	Molding
Pharmaburst	SPI Pharma	Compressed tabled
Ziplets/ advatab	Furand	Molding
Nanocrystal	Flan Crop.	Lyophilization
Lyoc	Pharmalyoc Inc.	Freeze drying
Flashtab	Ethypharm Inc.	Compressed tablet

**Evaluation of Blend<sup>(3,6)</sup>**

Preformulation studies:-

**1. Angle of Repose**

The angel of repose can be measured by the friction forces in a loose powder. It is defined as the maximum anfle possible between the surface of the pile of the powder and the horizontal plane. The angle of repose was determined by the funnel method suggested by Newman. The weighted amount was taken in a funnel. The height of funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap of blend. The blend was now allowed to flow through the funnel freely on the surface.

The diameter of the powder cone was determined and Angle of repose is determined by the following formula:-

Angle of repose =h/r

h=height of the cone

r=radius of the cone base

## 2. Bulk Density(D<sub>b</sub>)

Bulk density(D<sub>b</sub>) is defined as the mass of the powder divided by the bulk volume and is expressed as gm/ cm<sup>3</sup>. The bulk density is then obtained by dividing the weight of sample in gms by final volume in cm<sup>3</sup>.

$$D_b = M/V_b$$

Where M=mass of powder in gm

V<sub>b</sub> =bulk volume of the powder

## 3. Tapped Density(D<sub>t</sub>)

It is the ratio of total mass of the powder to the tapped volume of the powder. It was determined by placing a graduated cylinder containing a known mass of drug-excipients blend. The cylinder was allowed to fall under its own weight onto a hard surface from the height of 10 cm at 2 second intervals. The tapping was continued until the difference between successive volumes is less than 2%. It is expressed in gm/ml.

$$D_t = M/V_t$$

Where M=mass of powder

V<sub>t</sub>=volume of the tapped packing

## 4. Hausner's Ratio

Hausner ratio is an indirect index of ease of powder flow and is given by-

$$\text{Hausner ratio} = D_t / D_b$$

Where D<sub>t</sub>=tapped density

D<sub>b</sub> =bulk density

<1.25- Good flow property

1.25- Poor flow property

## 5. Carr's index(or)%compressibility

It is expressed in percentage and indicates powder flow properties and is given by-

$$I = \frac{D_t - D_b}{D_t} \times 100$$

D<sub>t</sub>

Where, D<sub>t</sub>=tapped density of the powder

D<sub>b</sub> =bulk density of the powder

## Evaluation tests for fast dissolving tablets<sup>(3,4,6)</sup>

### In vitro evaluation methods

#### General Appearance

The general appearance of a tablet, its visual identity and over all "elegance" is essential for consumer acceptance. Include in are tablet's size, shape, colour, presence or absence of an odour, taste, surface texture, physical flaws and consistency and legibility of any identifying marking.

#### 2. Tablet thickness

Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets were taken and their thickness was recorded using micrometer.

#### 4. Uniformity of weight

I.P. procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance.

**Table 4 I.P. Specification for uniformity of weight**

Sr.No.	Average weight of Tablets(mg)	Maximum percentage different allowed
1	130 or less	10
2	130-324	7.5
3	More than 324	5

#### 5. Tablet hardness

Hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. Hardness of the tablet of each formulation was determined using Monsanto Hardness tester and many other

testers like the Strong-Cobb tester, the Pfizer tester, the Erweka tester, and the Schleuniger tester available for determining hardness of particular tablet.

#### 6. Friability (F)

It is measured of mechanical strength of tablets. Roche friabaiator was used to determine the friability by following procedure. A preweighed tablet was placed in the friabaiator. Friabaiator consist of a plastic-chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets were rotated in the friabaiator for at least 4 minutes. At the end of test tablets were dusted and reweighed, the loss in the weight of tablet is the measure of friability and is expressed in percentage as

$$F = \frac{W_{\text{initial}} - W_{\text{final}}}{W_{\text{initial}}} \times 100$$

#### 7. Disintegration test

The standard procedure of performing disintegration test for FDTs has several limitations and they do not suffice the measurement of very short disintegration times. The disintegration time for ODT needs to be modified as disintegration is required without water, thus the test should mimic disintegration in salivary contents. For this purpose, a petridish (10

cm diameter) was filled with 10 ml of water. The tablet was carefully put in the center of petridish and the time for the tablet to completely disintegrate into fine particles was noted.

#### 8. Wetting time

The method reported by Yunxia et al., was followed to measure tablet wetting time. A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small petridish (ID = 6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet was put on the paper, and the time for complete wetting was measured. Three trials for each batch and the standard deviation was also determined.

#### 9. In Vitro Dispersion Time

In vitro dispersion time was measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH 6.8. Three tablets from each formulation were randomly selected and in vitro dispersion time was performed. Time required for complete dispersion of a tablet was measured.

#### 10. Stability Study (Temperature Dependent)

The fast dissolving tablets are packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines for accelerated studies.

(i)  $40 \pm 1^\circ\text{C}$

(ii)  $50 \pm 1^\circ\text{C}$

(iii)  $37 \pm 1^\circ\text{C}$  and RH  $75\% \pm 5\%$

The tablets were withdrawn after a period of 15 days and analyzed for physical characterization (Visual defects, Hardness, Friability, Disintegrations, Dissolution etc.) and drug content. The data obtained is fitted into first order equations to determine the kinetics of degradation. Accelerated stability data are plotting according Arrhenius equation to determine the shelf life at  $25^\circ\text{C}$ .

#### In Vivo Disintegration Test

The test was carried out on 6 tablets using the apparatus specified in I.P.-1996 distilled water at  $37^\circ\text{C} \pm 2^\circ\text{C}$  was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palable mass remaining in the apparatus was measured in seconds.

**Table 5 Marketed Fast Dissolving Tablets in India**

Name of the product	Active ingredients
Imodium lingual	Imodium
Pepcidin rapitab	Pepcid
Mosid-MT	Mosapride citrate
Calritin reditabs	Claritin
Nimulid-MD	Nimesulide
Zyrof-meltab	Rofecoxib
Claritin reditab	Micronized loratadine
Feldene melt	Piroxicam

Maxalt-MLT	Rizatriptan
Pepcid RPD	Famotidine
Zyprexa Zydis	Olanzapine
Zofran ODT	Ondansetron
Remeron Soltab	Mirtazepine

### Conclusion

Introduction of fast disintegrating dosage forms has solved some of the problems encountered in administration of drugs to the pediatric and elderly patient, which constitutes a large proportion of the world's population. Hence, patient demand and availability of various technologies have increased the acceptance of fast disintegrating tablets, which in prolongs the patient life of a drug. Keeping in view of the advantages of the delivery system, fast disintegrating dosage forms have been successfully commercialized and these dosage forms very well accepted at doctors as well as patient level.

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