

FAST DISSOLVING DOSAGE FORMS: AN OVERVIEW**Lohithasu Duppala*^{1,2}, Shabari Girinath K.³ and D. Midhun Kumar¹**¹AU College of Pharmaceutical Sciences, Andhra University, Visakhapatnam-530003.²GITAM Institute of Pharmacy, GITAM University, Visakhapatnam, Andhra Pradesh, India-530045.³Sree Dattha Institute of Pharmacy, Ibrahimpatnam, R.R District, India-501510.Article Received on
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Corresponding Author*Lohithasu Duppala**AU College of
Pharmaceutical Sciences,
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Visakhapatnam-530003.**ABSTRACT**

Oral route of administration having the conventional and maximum patient compliance as the most convenient, safest and also the most economical method of drug delivery. Fast dissolving dosage forms are containing medicinal substances which dissolve or disintegrates into smaller granules rapidly in the saliva without water or chewing within few seconds (<60sec) to more than a minute depending on the formulation (due to the action of superdisintegrant or maximizing pore structure in the formulation) and the size for enhancement of patient convenience and compliance and these are advantageous particularly for pediatric, geriatric, psychiatric patients who have difficulty in

swallowing conventional tablets and capsules. These type of dosage forms are also ideal for active patients who are traveling and may not have to take water. Fast dissolving dosage forms have gained considerable attention for those patients who have difficulties in swallowing due to dysphagia, hand tremors problems and have additional advantage for unconscious, young patients with underdeveloped muscular and nervous system. The present review describes the various advantages, limitations, desired characteristics, various formulation challenges, super-disintegrants employed; technologies developed for FDTs, evaluation tests.

KEYWORDS: Fast dissolving dosage form, super-disintegrant, saliva.**INTRODUCTION**

Solid conventional dosage forms like tablets, capsules are the most usual dosage forms because of its convenience, compactness, easy manufacturing and easy administration. In

some cases, it is very difficult to swallow tablets as well as hard gelatin capsules and when water is also not available in the case of motion sickness, allergic attacks of coughing during the common cold and bronchitis. Due to these reasons, Fast dissolving tablets were developed which rapidly dissolve or disintegrate in the mouth play an essential role. As the cost for developing a generic molecule is too high, the wide research is being done on the new dosage forms for having better compliance as compared to the different dosage forms of which the oral route serves to make an attribution. Fast-dissolving drug delivery systems have rapidly gained acceptance as an important new way of administering drugs. 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 as the saliva passes down into the stomach. In such cases, bioavailability of drug is considerably greater than those observed from conventional tablet dosage form. The faster the drug into the solution, faster the absorption and onset of effect. The use of super disintegrants like croscarmellose, sodium starch glycolate, polyvinylpyrrolidone, crospovidone etc which provide rapid disintegration of tablet and release drug in saliva is the critical approach in development of FDTs. Furthermore, the amount of drug that is subjected to first pass metabolism is reduced as compared to conventional tablet. Patients for whom swallowing is difficult and painful can use FDTs easily. Fast dissolving tablets can also be used easily by children who have lost their teeth but do not 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.^[1-7]

Advantages of fast disintegrating tablets

Fast dissolving technology offers:

1. Ease of administration.
2. No need of water to swallow the dosage form unlike conventional dosage forms. This is very useful for patients who are travelling or do not have immediate access to water and thus, provide improved patient compliance.
3. Provide accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric, geriatric patients and psychiatric patients.
4. Acceptable taste masking property for pediatric patients is achieved.

5. Bioavailability is enhanced through pregastric absorption of drugs from mouth, pharynx and oesophagus as saliva passes down and it leads to reduce dose, improved clinical performance through a reduction of unwanted effects.
6. Have a pleasant mouth feel and leave minimal or no residue in the mouth after drug administration.
7. Have rapid dissolution and absorption of the drug which will produce quick onset of action.
8. No specific packaging is required
9. Provide new business opportunities in the form of product differentiation, patent-life extension, uniqueness, line extension and life-cycle management and exclusivity of product promotion.
10. It combines advantages of solid dosage form in terms of stability and liquid dosage form in term of bioavailability.^[1-7]

Limitations to mouth dissolving tablets

1. Patients who concurrently take anti-cholinergic medications may not be the best candidates for FDTs.
2. FDTs usually have insufficient mechanical strength. Hence, it requires careful packaging and handling.
3. FDTs may leave unpleasant taste and/or grittiness in mouth if not formulated properly.
4. Fast dissolving dosage forms are hygroscopic in nature and more susceptible to degradation by humidity and temperature.
5. Some time it possesses mouth feeling.
6. MDT requires special packaging for properly stabilization & safety of stable product.
7. Drugs difficult to formulate into FDT with relatively larger doses.
8. Drugs with short half-life and frequent dosing and those whom require controlled or sustained release are unsuitable candidates of FDTs.
9. Drugs with short half-life and frequent dosing and those whom require controlled or sustained release are unsuitable candidates of FDTs.^[1-7]

CHARACTERISTICS AND CHALLENGES IN FORMULATION DEVELOPMENT^[5]

Fast Disintegration without water

These tablets should disintegrate or dissolve in the mouth without water become a soft paste or liquid suspension, which can provide easy of swallowing and comfortable mouth feel.

Aqueous solubility

Water-soluble drugs create various formulate ion challenges due to they form eutectic mixtures, which leads to freezing-point depression and the format ion of a glassy solid that may collapse upon drying due to loss of supporting structure in sublimation ion process and it can be prevented by using various matrix-forming excipients such as mannitol than can persuade crystallinity and hence, impart rigidity to the amorphous composite.

Hygroscopicity

Hygroscopicity is an important characteristic of a powder. It can be shown, roughly, for a fairly soluble compound that the hygroscopicity is related with its solubility. They should have low sensitivity to humidity and it is major challenge in formulation development and storage because many highly water-soluble excipients are used in formulation to enhance fast-dissolving charcterstics, and these are susceptible to moisture; some will even deliquesce at high humidity. The protection from environmental conditions done by good package design or other strategies.

Amount of drug

The application of technologies used for fast dissolving dosage forms is limited by the amount of drug that can be incorporated into each unit dose. In case of lyophilized dosage forms, the drug dose is limited must be lower than 400 mg for insoluble drugs and less than 60 mg for soluble drugs. This characteristic is particularly challenging when formulating a fast-dissolving oral films or wafers.

Size of tablet

It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve.

Mouth feel

They should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the dosage form should be as small as such as possible. Moreover addition of flavors and cooling agents such as menthol enhance the mouth feel.

Sensitivity to environmental condition

They should show low sensitivity to various environment conditions like humidity and temperature as most of the materials used in dosage forms are meant to dissolve in minimum quantity of water.

Cost

The technology used for dosage forms should be acceptable in terms of cost of the final product. Methods like Zydis and Orasolv that require special technologies and specific packaging increase the cost to a remarkable extent.

Tablet strength, Friability and porosity

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

Drug Properties

Many drug properties could potentially affect the performance of dosage forms such as 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

Drugs, which are unpalatable, rapid disintegrating drug delivery systems usually contain the medicament after swallowing, there should be minimal or no residue in the mouth. An novel ideal taste-masking technology should provide drugs with palatable 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 basic properties of the tablets are fast absorption or wetting of water into the tablets and disintegration associated particles into individual components for fast dissolution. It requires that excipients should have high wettability and the 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

1. Drugs should have good solubility. E.g. promethazine
2. Suitable for low dose. E.g. terazosin hcl
3. Drugs should have better availability to permeate oral mucosal tissue.
4. Drugs should have less or not bitter in taste.
5. Good stability in both water as well as in saliva. E.g. rizatriptine benzoate
6. Partially non- ionized at the oral cavities p^H .
7. Small to moderate molecular weight
8. Good stability in water and saliva
9. Short half-life and frequent dosing drugs are unsuitable
10. Very bitter taste and odor drugs are unsuitable
11. Drugs which require controlled or sustained release are unsuitable

Table 1 Promising Drugs to be incorporated In Fast Dissolving

S.NO.	Category	Suitable Drugs
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, etoposide, lomustine, melphalan, methotrexate, procarbazine, tamoxifen citrate, mitomycin
13.	Anti-migraine agents	Dihydroergotamine mesylate, sumatriptan, ergotamine maleate
14.	Anti-protozoal agents	Furazolidone, metronidazole, nimorazole, nitrofurazone, omidazole, tinidazole
15.	Anti-thyroid agents	Carbimazole, propylthiouracil
16.	Anxiolytic, sedative, hypnotics and neuroleptics	Alprazolam, amylbarbitone, 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, caries, mump
28.	Proteins and peptides	Insulin, glucagons, growth hormones
29.	Sex hormones	Clomiphene citrate, danazol, mestranol, methyltestosterone, norgestrel, oestradiol, conjugated oestrogens, progesterone, testosterone, tibolone
30.	Stimulants	Amphetamine, pemoline, dexamphetamine, mhazindol, dexfenfluramine, fenfluramine

SUPER-DISINTEGRANTS

Superdisintegrants are the agents added to formulations to promote the breakup of the dosage forms 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 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.

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 break up of the tablet.

LIST OF DISINTEGRANTS

Table 2. Disintegrants list in Fast Dissolving Dosage forms

S.no.	Super disintegrants	Effective Concentration	Nature	Mechanism of Action	Brand Names
01	Crosslinkedcroscarmellose sodium	Upto 5% w/w	Modified cellulose or Cross linked cellulose, Swells 4-8 folds in < 10 seconds. -Swelling and wicking both.	Wicking due to fibrous structure swelling with minimal gelling	Ac-Di-Sol Nymce 25 X Nymcel
02	Crosspovidone	1-3 % w/w	Cross linked PVP, Swells very little And returns to original size aftercompression but act by capillary action	Water wicking, swelling and possibly some deformation recovery	Kollidon Polyplasdone
03	Aliginic acid NF	-	Cross linked Aliginic acid	Wicking action	Satialgine
04	Soy polysaccharides	-	Natural disintegrant	-	EMCOSOY
05	Calcium silicate	-	-	Wicking action	-
06	Sodium starch glycolate	4-6 % w/w	Modified starch, Swells 7-12 folds in < 30 seconds	Rapid and extensive swelling with minimal gelling	Explotab Primogel Glycolys
07	Ion exchange resin	-	Resins	-	Amberlite (IPR 88)
08	L-HPC	-	Low hydroxyl propyl cellulose	Both swelling and wicking	-
09	Acrylic acid derivatives	-	Poly (Acrylic acid) Superporoushydrogel	Wicking action	-
10	Sodium Alginate	-	Sodium salt of Alginic acid	Rapid swelling in aqueous medium or wicking action	-
11	Effervescent mixture	-	Citric acid, tartaric acid and sodium bicarbonate	Effervescence	-
12	Karaya gum	-	Natural disintegrant	-	-
13	<i>Hibiscus rosasinensis</i> Linn Mucilage	6 % w/w	Natural disintegrant	-	-
14	<i>Isapghula</i> Husk Mucilage (Plantagoovata	8 % w/w	Natural disintegrant	-	-
15	<i>Cucurbitamaxima</i> pulp powder	2.5 % w/w	Natural disintegrant	-	-
16	<i>Lepidiumsativum</i> Seed Mucilage	10% w/w	Natural disintegrant	-	-
17	Fenugreek Seed Mucilage	4 % w/w	Natural disintegrant	-	-
18	Chitosan	3 % w/w	-	-	-
19	<i>Ocimumgratissimum</i> Mucilage powder and seed powder	5 % w/w	Natural disintegrant	-	-
20	Guar Gum	2-10% w/w	Natural disintegrant	-	-

21	Gellan Gum	4 % w/w	-	-	-
22	Agar	1-10% w/w	-	-	-
23	Starch 1500	5-10%	Natural disintegrant	-	-
24	Microcrystalline Cellulose	10-20%	-	-	-
25	Alginates	Alginic acid is used as disintegrant at 1-5% concentration while sodium alginate at 2.5 - 10% concentration.	-	-	-
26	Chitin	-	-	-	-

OTHER EXCIPIENTS USED IN FDTs FORMULATION^[8]

Criteria for excipients

The ideal characteristics of excipients for oral dispersible tablets include:

- It must be able to disintegrate quickly.
- Their individual properties should not affect the ODTs.
- It should not have any interaction with drug and other excipients.
- It should not interfere in the efficacy and organoleptic properties of the product.
- When selecting binder (a single or combination of binders) care must be taken in the final integrity and stability of the product.
- The melting point of the excipients used should be in the range of 30-35°C.
- The binder may be in liquid, semi solid, solid or polymeric in nature.

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 state, calcium state, talc, polyethylene glycol, liquid paraffin, magnesium lauryl sulfate, colloidal silicon dioxide.

CONVENTIONAL TECHNIQUES

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 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.

4) Sublimation

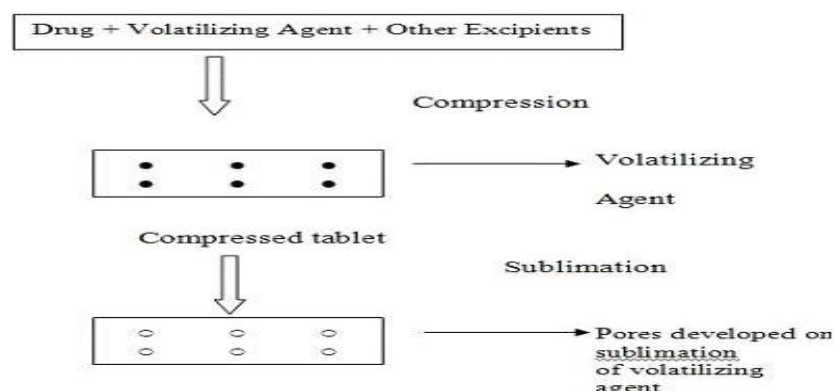


Figure 1: Steps Involved in Sublimation

5) 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 croscarmellose sodium as disintegrating and an acidic material (e.g. citric acid) and/or alkali material (e.g. sodium bicarbonate) to enhance disintegration and dissolution.

6) 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.

7) 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 and the directly compressed tablets disintegration and solubilization depends on single or combined action of disintegrants, water soluble excipients and effervescent agent.

8) 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.

9) 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^[1,7]

1) Zydis technology.

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

Table 2 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
Zipleths/ advatab	Furand	Molding
Nanocrystal	Flan Crop.	Lyophilization
Lyoc	Pharmalyoc Inc.	Freeze drying
Flashtab	Ethypharm Inc.	Compressed tablet

EVALUATION TESTS^[8-17]**1. 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.

3. 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 3 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

4. 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.

5. Friability

The friability was determined using Roche friabilator and expressed in percentage (%). 20 tablets from each batch were weighed separately (W_{initial}) and placed in the friabilator, which was then operated for 100 revolutions at 25 rpm. The tablets were reweighed (W_{final}) and the percentage friability (F) was calculated for each batch by using the following formula. After completion of rotations, the tablets were dedusted by using camel hair brush and weighed (w). The percent loss in weight or friability (f) was calculated by the formula

$$f = \left(1 - \frac{w}{w_0} \right) \times 100$$

6. 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 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.

7. Wetting time

The method 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.

8. *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.

9. *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.

10. *In Vitro* release studies

The *In Vitro* drug release studies of the prepared fast dissolving tablets with semi synthetic and natural super disintegrants were performed, in triplicate, in a USP Dissolution Apparatus. The dissolution test was performed using Phosphate buffer pH 6.8 at $37 \pm 0.5^{\circ}\text{C}$. The speed of rotation of paddle was set at 50 rpm. Aliquots of 1 mL were withdrawn from the dissolution apparatus at different time intervals and filtered through a cellulose acetate membrane (0.45 μm) and fresh dissolution medium was replenished immediately. Absorbance of solution was checked by UV spectrophotometer at a wavelength and drug release was determined from standard curve.

Table 4 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	Mitrazepine

CONCLUSION

The recent advancement of a quick dissolving dosage forms give a decent chance to a line expansion in the commercial center; drugs (e.g. neuroleptics, cardiovascular medications, analgesics, antihistamines and medications for erectile brokenness) can be considered contender for this dose structure. They have potential advantages over conventional solid oral dosage form because this drug delivery system helps to overcome some of the challenges associated with conventional solid dosage form such as difficulty in swallowing of tablet in paediatric and geriatric patients. This drug delivery is one of the great inventions of all the novel drug delivery systems. They have improved patient compliance, convenience, bioavailability, rapid onset of action. However, common people are not much aware of this delivery system.

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