Review Article

REVIEW ON: FAST DISSOLVING/DISINTEGRATING TABLETS

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ABSTRACT

An oral route of drug administration is the most popular route of administration. It have wide acceptance up to 50-60% of total dosage forms. Tablet is the most popular dosage forms existing today because of its convenience of self administration, compactness and easy manufacturing; however hand tremors, dysphasia in case of geriatric patients, the underdeveloped muscular and nervous systems in young individuals and case of uncooperative patients, the problem of swallowing is common phenomenon which leads to poor patient compliance. Mouth dissolving tablets (FDT) or fast dissolving tablets; (FDT) has emerged as alternative oral dosage forms. These are novel types of tablets that disintegrate/dissolve/disperse in saliva within few seconds. The basic approach used in development of FDT is the use of superdisintegrants like Cross linked carboxymelhylcellulose (Croscarmeliose), Sodium starch glycolate (Primogel, Explotab), Polyvinylpyrrolidone (Polyplasdone) etc.

Keywords: Fast dissolving tablet, Superdisintegrants, Drug delivery system, Patented Technology.

INTRODUCTION

Definition

A fast-dissolving drug delivery system (FDDS) in most cases is a tablet that dissolves or disintegrates in the oral cavity without the need of water or chewing. Most fast-dissolving delivery system films must include substances to mask the taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients.

According to European Pharmacopoeia, the fast dissolving tablets (FDT) should disperse/disintegrate in less than three minutes. The basic approach used in development of FDT is the use of superdisintegrants like Cross linked carboxymelhylcellulose (Croscarmeliose), Sodium starch glycolate (Primogel, Explotab). Polyvinylpyrrolidone (Polyplasdone) etc. which provide instantaneous disintegration of tablet after putting on tongue, thereby releasing the drug in saliva. Their growing importance was underlined recently when European pharmacopoeia adopted the term "Orodispersible tablet" as a tablet that to be placed in the mouth where it disperses rapidly before swallowing. The bioavailability of some drugs may be increased due to absorption of drug in oral cavity and also due to pregastric absorption of saliva containing dispersed drugs that pass down into the stomach. Morever, the amount of drug that is subjected to first pass metabolism is reduced as compared to standard tablet. The technologies used for manufacturing fast-dissolving tablets are freeze-drying, spray-drying, tablet molding, sublimation, sugar-based excipients, tablet compression. As a result of increased life expectancy, the elderly constitute a large portion of the worldwide population today. These people eventually will experience deterioration of their physiological and physical abilities.[1-3]

ADVANTAGES OF FDT

- Administration to the patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure and patients who refuse to swallow such as pediatric, geriatric and psychiatric patients.
- Rapid drug therapy intervention.
- Increased bioavailability/rapid absorption through pregastric absorption of drugs from mouth, pharynx and esophagus as saliva passes down.
- Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients.
- The risk of chocking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety.
- New business opportunity like product differentiation, product promotion, patent extension and life cycle management.[4-6]

CRITERIA FOR FDDS

- Free from bitter taste.
- Dose lower than 20 mg.
- Small to moderate molecular weight.
- Good solubility in water and saliva.
- Partially nonionized at the oral cavity's pH.

- Ability to diffuse and partition into the epithelium of the upper GIT.
- Ability to permeate oral mucosal tissue.

In contrast, the following characteristics may render a drug unsuitable for delivery as an orally disintegrating dosage form:

- Short half-life and frequent dosing.
- Very bitter or otherwise unacceptable taste because taste masking cannot be successfully achieved.
- Require controlled or sustained release.
- Combination with anticholinergics.[7,8]

SIGNIFICANCE OF FDTs

FDTs offer dual advantages of solid dosage forms and liquid dosage forms along with special features which include:

a. Accurate dosing

Being unit solid dosage forms, provide luxury of accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients.

b. Enhanced bioavailability

Bioavailability of drugs is enhanced due to absorption from mouth, pharynx and esophagus.

c. Rapid action

Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity.

d. Patient compliance

No need of water to swallow the dosage form. Hence, it is convenient for patients who are traveling and do not have immediate access to water.

e. Ease of administration

Convenient to administer specially for geriatric, pediatric, mentally disabled and bed ridden patients who have difficulty in swallowing.

f. Obstruction free

No risk of suffocation in airways due to physical obstruction when swallowed, thus providing improved safety and compliance.

g. Enhanced palatability

Good mouth feel, especially for pediatric patients as taste masking technique is used to avoid the bitter taste of drug.

h. Simple packaging

No specific packaging required. It can be packaged in push through blisters.

i. Business avenue

Provide new business opportunities in the form of product differentiation, line extension, uniqueness and life cycle management.

j. Cost effective

Conventional processing and packaging equipments allow the manufacturing of tablets at low cost.[9]

TECHNIQUES FOR PREPARING FDTs

Many techniques have been used for the formulation of Fast dissolving tablets.

1. Freeze drying / lyophilization
2. Tablet moulding
3. Spray drying
4. Sublimation
5. Direct compression
6. Mass extrusion
7. Cotton candy process
8. Phase transition
9. Melt granulation

1. Freeze-drying or lyophilization

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 FDT 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 lyophillization 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

Molding process is of two type i.e. solvent method and heat method. Solvent method involves moistening the powder blend with a hydroalcoholic 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 posses a porous structure that hastens dissolution. The

heat molding process involves preparation of a suspension that contains a drug, agar and sugar (For example, mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30ºC under vacuum. The mechanical strength of molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology.

The taste masked drug particles were prepared by spray congealing a molten mixture of hydrogenated Cottonseed oil, Sodium carbonate, Lecithin, Polyethylene glycol and an active ingredient into a Lactose based tablet triturate form. Compared to the lyophillization technique, tablets produced by the molding technique are easier to scale up for industrial manufacture.

3. Spray drying

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 Crospovidone are used as superdisintegrants. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. The formulation contained bulking agent like Mannitol and Lactose, a superdisintegrant like Sodium starch glycolate and Croscarmellose sodium and acidic ingredient (Citric acid) and/or alkaline ingredients (Example: Sodium bicarbonate). This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.

4. Sublimation

To generate a porous matrix, volatile ingredients are incorporated in the formulation that is later subjected to a process of sublimation. Highly volatile ingredients like Ammonium bicarbonate, Ammonium carbonate, Benzoic acid, Camphor, Naphthalene, Urea, Urethane and Phthalic anhydride may be compressed along with other excipients into a tablet. This volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique have reported to usually disintegrate in 10-20 sec.

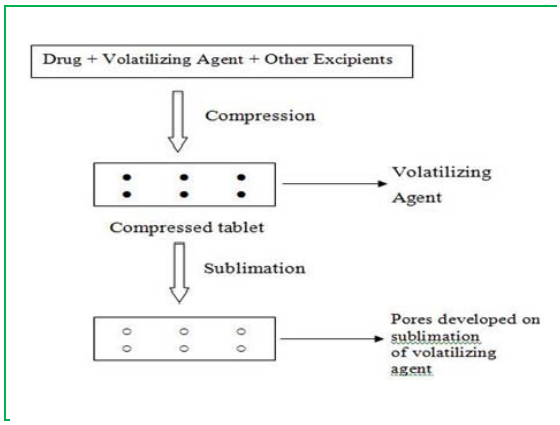

Figure 1: Steps Involved in sublimation

5. Direct compression

Direct compression represents the simplest and most cost effective tablet manufacturing technique. This technique can now be applied to preparation of FDT because of the availability of improved excipients especially superdisintegrants and sugar based excipients.

(a) Superdisintegrants

In many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants principally affects the rate of disintegration and hence the dissolution. The presence of other formulation ingredients such as water-soluble excipients and effervescent agents further hastens the process of disintegration.

(b) Sugar based excipients

This is another approach to manufacture FDT by direct compression. The use of sugar based excipients especially bulking agents like Dextrose, Fructose, Isomalt, Lactilol, Maltilol, Maltose, Mannitol, Sorbitol, Starch hydrolysate, Polydextrose and Xylitol, which display high aqueous solubility and sweetness and hence impart taste masking property and a pleasing mouthfeel. Mizumito *et al* have classified sugar-based excipients into two types on the basis of molding and dissolution rate.

Type 1: Saccharides (Lactose and Mannitol) exhibit low mouldability but high dissolution rate.

Type 2: Saccharides (Maltose and Maltilol) exhibit high mouldability and low dissolution rate.

6. Mass-extrusion

This technology involves softening the active blend using the solvent mixture of water-soluble Polyethylene glycol and Methanol and subsequent expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablet. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking.

7. Cotton candy process

This process is so named as it utilizes an inimitable spinning mechanism to produce floss like crystalline structure, which mimics cotton candy. This technique involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially recrystallized to have better flow properties and compressibility. This matrix is milled and blended with active ingredients as well as excipients and subsequently compressed to FDTs. This process can accommodate high doses of drug and offers improved mechanical strength. However, high process temperature limits the use of this process.

8. Phase transition

Kuno *et al* proposed a novel method to prepare FDTs with sufficient hardness by involving the phase transition of

sugar alcohol. In this technique, FDTs are produced by compressing and subsequently heating tablets that contain two sugar alcohols, one with high and other with a low melting point. Heating process enhances the bonding among particles leading to sufficient hardness of tablets which was otherwise lacking owing to low/little compactibility.

9. Melt granulation

Melt granulation is a process in which Pharmaceutical powders are efficiently agglomerated by the use of binder which can be a molten liquid, a solid or a solid that melts during the process.

For accomplishing this process, high shear mixers are utilized, where the product temperature is raised above the melting point of binder by a heating jacket or by the heat of friction generated by impeller blades. Perissutti *et al* prepared Carbamazepine fast-release tablets by melt granulation technique using polyethylene glycol 4000 as a melting binder and Lactose monohydrate as hydrophilic filler.[10-12]

SELECTION OF SUPERDISINTEGRANTS

Although superdisintegrants primarily affect the rate of disintegration, but when used at high levels it can also affect mouth feel, tablet hardness and friability. Hence, various ideal factors to be considered while selecting an appropriate superdisintegrants for a particular formulation should:

- Produce rapid disintegration, when tablet comes in contact with saliva in the mouth/oral cavity.
- Be compactable enough to produce less friable tablets.
- Produce good mouth feel to the patients. Thus, small particle size is preferred to achieve patient compliance.
- Have good flow, since it improves the flow characteristics of total blend.[13,14]

Table 1: List of super disintegrants[15]

Superdisintegrants	Example
Crosscarmellose® Ac-Di-Sol® Nymce ZSX® Primellose®Solutab®	Crosslinked Cellulose
Crosspovidone Crosspovidon M® Kollidon® Polyplasdone	Crosslinked PVP
Sodium starch glycolate Explotab®	Crosslinked Starch
Soy polysaccharides Emcosoy	Natural super Disintegrant
Alginic acid NF Satialgine	Crosslinked alginic acid

Table 2: List of commercially available fast dissolving tablets[15]

Trade Name	Active Drug	Manufacturer
Zoming-ZMT	Zolmitriptan	AstraZeneca, Wilmington, USA
Zyprexia	Olanzapine	Eli lilly, Indianapolis, USA
Felden fast melt	Piroxicam	Pfiser Inc., NY, USA
Maxalt MLT	Rizatriptan	Merck and Co., NJ, USA
Pepcid RPD	Famotidine	Merck and Co., NJ, USA
Nimulid FDT	Nimesulide	Panacea Biotech, New Delhi , India
Febrectol	Paracetamol	Prographarm, Chateauneuf, France
Relivia Flash dose	Tramadol HCl	Fuisz Technology, Ltd.
Cibalgina DueFast	Ibuprofen	Eurand International
Clarinex RediTabs	Desloratadine	Schering-Plough
Clonazepam FDT	Clonazepam	Par Pharmaceutical
Jr. Tylenol Meltaways	Acetaminophen	McNeil Consumer Healthcare

SOME OF PROMISING DRUG CANDIDATES FOR MOUTH DISSOLVING TABLETS

1. Antibacterial agents

Ciprofloxacin, Tetracycline, Erythromycin, Rifampicin, Penicillin, Doxycyclin, Nalidixic acid, Trimethoprim, Sulphacetamide, Sulphadiazine.

2. Anthelmintics

Albendazole, Mebendazole, Thiabendazole, Livermectin, Praziquantel, Pyrantel Embonate, Dichlorophen.

3. Antidepressants

Trimipramine Maleate, Nortriptyline HCl, Trazodone HCl, Amoxapine, Mianserin HCl.

4. Antidiabetics

Glibenclamide, Glipizide, Tolbutamide, Tolazamide, Gliclazide, Chlorpropamide.

5. Analgesics/anti-inflammatory agents

Diclofenac sodium, Ibuprofen, Ketoprofen, Mefenamic acid, Naproxen, Oxyphenbutazone, Indomethacin, Piroxicam, Phenylbutazone.

6. Antihypertensives

Amlodipine, Carvedilol, Diltiazem, Felodipine, Minoxidil, Nifedipine, Prazosin HCl, Nimodipine,Terazosin.

7. Antiarrhythmics

Disopyramide, Quinidine sulphate, Amiodarone HCl.

8. Antihistamines

Acrivastine, Cetrizine, Cinnarizine, Loratadine, Fexofenadine, Triprolidine.

9. Anxiolytics, sedatives hypnotics and neuroleptics

Alprazolam, Diazepam, Clozapine, Amylobarbitone, Lorazepam, Haloperidol, Nitrazepam, Midazolam phenobarbitone, Thioridazine, Oxazepam.

10. Diuretics

Acetazolamide, Clorthiazide, Amiloride, Furosemide, Spironolactone, Bumetanide, Ethacrynic acid.

11. Gastro-intestinal agents

Cimetidine, Ranitidine HCl, Famotidine, Domperidone, Omeprazole, Ondansetron HCl,Granisetron HCl.

12. Corticosteroids

Betamethasone, Beclomethasone, Hydrocortisone, Prednisone, Prednisolone, Methyl prednisolone.

13. Antiprotozoal agents

Metronidazole, Tinidazole, Omidazole, Benznidazole, Clioquinol, Decoquinate.[16]

PATENTED TECHNOLOGIES FOR FDTs

Rapid-dissolving characteristic of FDTs is generally attributed to quick penetration of water into tablet matrix resulting in its fast disintegration. Several technologies have been developed on the basis of formulation aspects and different processes. Resulting dosage forms vary on several parameters like mechanical strength, porosity, dose, stability, taste, mouth feel, dissolution rate and overall bioavailability. Table represents the list of unique patented technologies, their scientific basis and patent owner along with significant advantages.[17]

Table 3: Various patented technologies

Patented Technology	Basic Technology	Technology Developed by Company	Active ingredient (Brand Names)
Zydus	Lyophilization	R.P.Scherer,Inc.	Loratidine (Claritin Reditab and Dimetapp Quick Dissolve)
Quicksolv	Lyophilization	Janssen pharmaceutics	Cisapride monohydrate (Propulsid Quicksolv), Risperidone (Risperdal M-Tab)
Lyoc	Lyophilization	Farmalyoc	Phloroglucinol Hydrate (Spasfon Lyoc)
Flashtab	Direct Compression	Ethypharm	Ibuprofen (Nurofen FlashTab)
Orasolv	Direct Compression	Cima Labs,Inc.	Paracetamol (Tempra Quicklets), Zolmitriptan
Durasolv	Direct Compression	Cima Labs, Inc.	Hyoscyamine Sulfate (NuLev) Zolmitriptan (Zolmig ZMT)
Wowtab	Direct Compression	Yamanouchi Pharma Tech. Inc.	Famotidine (Gaster D)
Ziplets	Direct Compression	Eurand International	Ibuprofen (Cibalgina DueFast)
Advatab	Microcaps and Diffuscap CR Technology	Eurand International	AdvaTab cetrizine, AdvaTab Paracetamol
Flashdose	Cotton Candy Process	Fuisz Technology, Ltd.	Tramadol HCl (Relivia Flash dose)
Oraquick	Micromask Taste Masking	KV Pharm.Co.,Inc.	Hyoscyamine SulfateODT
Fuisz	Sugar based matrix known as Floss	Fuisz Pharmaceutical Ltd.	Diphenydramine & Pseudoeph

EVALUATION OF FAST DISSOLVING TABLET

Tablets from all the formulation were subjected to following quality control test.

1. General appearance

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

2. Size and Shape

The size and shape of the tablet can be dimensionally described, monitored and controlled.

3. 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

As per 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. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity.

Table 4: Uniformity of weight

Average weight of Tablets (mg)	Maximum percentage different allowed
130 or less	10
130-324	7.5
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. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation

and handling before usage depends on its hardness. Hardness of the tablet of each formulation was determined using Monsato Hardness tester.

6. Friability

It is the measurement of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. A preweighed tablet was placed in the friabilator. Friabilator 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 friabilator 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,

% Friability = Loss in weight / Initial weight x 100

7. *In- vivo* disintegration test

The test was carried out on 6 tablets using the apparatus specified in I.P.-1996 distilled water at 37°C ± 2°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.

8. Wetting time

The method reported by yunixia *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 were also determined.

9. *In vitro* dispersion time

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

10. Stability testing of drug (temperature dependent stability studies)

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 ± 1°C

(ii) 50 ± 1°c

(iii) 37 ±1°C and RH 75% ± 5%

The tablets were withdrawn after a period of 15 days and analyzed for physical characterization (Visual defects, Hardness, Friability, Disintegrations and 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°C.[18]

CONCLUSION

The development of a fast-dissolving tablet also provides an opportunity for a line extension in the marketplace; a wide range of drugs (For example, neuroleptics, cardiovascular drugs, analgesics, antihistamines, and drugs for erectile dysfunction) can be considered candidates for this dosage form. Pharmaceutical marketing is another reason for the increase in available fast dissolving/ disintegrating products. As a drug entity nears the end of its patent life, it is common for Pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity, while offering its patient population a more convenient dosage form or dosing regimen. In this regard, fast dissolving/ disintegrating tablet formulations are similar to many sustained release formulations that are now commonly available. An extension of market exclusivity, which can be provided by a fast-dissolving/disintegrating dosage form, leads to increased revenue, while also targeting underserved and under-treated patient populations. Although the cost to manufacture these specialized dosage forms exceeds that of traditional tablets, this additional cost is not being passed on to the consumer.

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