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Research Article

FAST DISSOLVING TABLETS: NOVEL APPROACH TO DRUG DELIVERY

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ABSTRACT

Fast dissolving tablets (FDTs) have received ever-increasing demand during the last decade, and the field has become a rapidly growing area in the pharmaceutical industry. Fast dissolving drug delivery systems (FDDDSs) are the system which disintegrate and release the active ingredient quickly and that do not require water to aid swallowing. In the conditions (pediatric and geriatric patients, difficulty in swallowing, uncooperative patients), where the traditional tablets and capsules administration is inconvenient, the fast dissolving/ disintegrating tablets are perfect alternative. Regardless of different advancements in drug delivery, the oral route remains the perfect route for the administration of therapeutic agents because the low cost of therapy and ease of administration lead to high levels of patient compliance. Recently, Fast dissolving drug delivery systems have started gaining popularity and receiving as one such example with amplified consumer choice, for the reason of speedy disintegration or dissolution, self administration even without water or chewing. This can be achieved by various conventional methods like direct compression, wet granulation, moulding, spray drying, freeze drying, and sublimation. Some patented technologies are also there to formulate this dosage form such as Zydis technology, Wowtab technology, Orasolv technology, Durasolv technology, and Flash Dose technology etc. Taste of the drug is one of the most important parameters which should be taken in account for the development of FDTs. Oral administration of bitter drugs with an acceptable degree of palatability can be achieved by taste masking approach. For masking the obnoxious taste of the drug different polymers bring into play for coating, different resins utilize for complex formation, sweeteners and flavors draw on in direct compression while formulating this form of delivery system. This communication reviews the applications and technologies involved in formulation of FDDDS specially focused on FDTs (fast dissolving tablets).

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INTRODUCTION

The conventional dosage forms (tablet and capsule) have wide acceptance up to 50-60% of total dosage forms. Tablet is still most popular conventional dosage forms existing today because of ease of self administration, compact in nature, easy to manufacture and it can be deliver in accurate dose. Traditional tablets and capsules administered with an 8-oz. (One glass) of water may be inconvenient or impractical for some patients. However, some patients, particularly pediatric and geriatric patients, have difficulty swallowing or chewing solid dosage forms. Many pediatric and geriatric patients are unwilling to take these solid preparations due to fear of choking. For example, a very elderly patient may not be able to swallow a daily dose of antidepressant in the form of a Caplet shaped Tablet. 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. Pharmaceutical technologists have put in their best efforts to develop a fast dissolving/ disintegrating drug delivery system (FDDTs) to overcome these problems.[1, 2] The Center for Drug Evaluation and Research(CDER), US FDA defined Fast-dissolving/disintegrating tablets (FDDTs) are "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue". European Pharmacopoeia also adopted the term "Oro Dispersible Tablet" defined as "uncovered tablet for buccal cavity, where it disperses before ingestion". Fast disintegrating tablets (FDTs) are solid dosage forms which dissolve rapidly in saliva without chewing and additional 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. These are also called melt-in-mouth tablets; repi-melts, porous tablets, oro-dispersible, quick dissolving or rapid disintegrating tablets. Different types of technologies have been employed for the formulation of fast dissolving tablets viz freeze-drying, Tablet Molding, Direct Compression Method, Spray drying, Sublimation, Cotton candy process, etc.[3]

Requirements of Fast Dissolving Tablet

A. Not require water to swallow because it should dissolve or disintegrate in the mouth within a few seconds.
B. Allow high drug loading
C. Have a pleasing mouth feel
D. Leave minimal or no residue in the mouth after oral administration
E. Exhibit low sensitivity to environmental conditions such as humidity and temperature
F. Rapid dissolution of drug and absorption which may produce rapid onset of action
G. Some drugs are absorbed form the mouth, pharynx and oesophagus as the saliva passes down into the stomach in such cases bioavailability of drugs is increased.

Advantages of Fast Dissolving Tablet

A. Accurate dosing: Being unit solid dosage forms, provide 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 drug is enhanced due to absorption form 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. Ease of administration: Convenient to administer specifically for geriatric, pediatric and mentally patients who are travelling and do not have immediate access to water.
E. Patient compliance: No need of water to swallow the dosage form. Hence it is

convenient for patients who are travelling and do not have immediate access to water.

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 moth feels, especially for pediatric patients as taste masking technique is used to avoiding the taste of drug.

H. Cost effective: Conventional processing and packaging equipment allow the manufacturing of tablets at low cost.[3, 4]

Limitation of Fast Dissolving Tablet[5]

A. The tablets usually have insufficient mechanical strength. Hence, careful handling is required during manufacturing process.

B. The tablets may leave unpleasant taste and/or grittiness in oral cavity if not formulated properly.

C. Drugs with larger doses are difficult to formulate into fast dissolving tablet.

Need For Development of Fast Dissolving Table

A. Patient factors: Orally disintegrating dosage forms are particularly suitable for patients (particularly pediatric and geriatric patients) who are not able to swallow traditional and capsules with an 8 oz glass of water.

B. Effectiveness factor: Increased bioavailability and faster onset of action are major claim of these formulations. Dispersion in saliva in oral cavity cause pregastric absorption forms some formulations in those cases where drug dissolves quickly. Buccal pharyngeal and gastric regions are absorption for many drugs. Any pregastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo a great deal of hepatic metabolism.

C. Manufacturing and marketing factors: As a drug 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, unique product differentiation, value-added product line extension, and extend patent protection, while offering its patient population a more convenient dosage form. This leads to increased revenue, while also targeting underserved and undertreated patient populations.[6, 7]

Table 1: Ingredients and Technologies Used for Formulating FDT

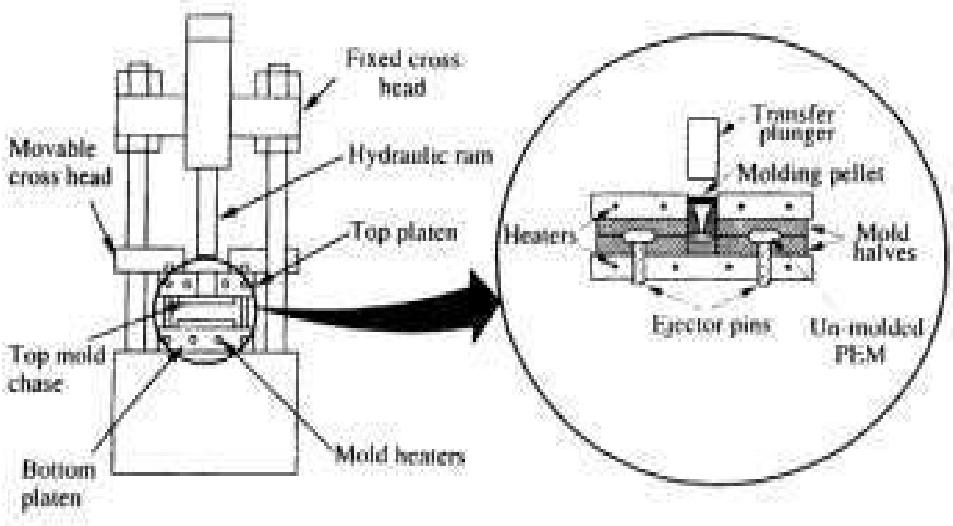
Drug(s)	Ingredients Used	Technologies used	Disintegration time (sec)
Rizatriptan benzoate	Primogel, Ac-di-sol, Kollidon, Avicel PH102, Orocell, Talc, Aerosil and Magnesium stearate, Aspartame and Sucralose.	Direct compression	85
Capecitabie	Crospovidone, HPMC, Mannitol, MCC.	Direct compression	50
Aceclofenac	SSG, Mannitol, MCC.	Direct compression	12.2 - 27.5
Resperidone	Mannitol, Aspartame, PEG 400 &4000, MCC (Ph 200), Gelucire 44/14.	Spray drying and compression	Below 30
Famotidine	Mannitol, PVP K30, Dextran, Sucralose, Sugar, Lactose.	Freeze drying	2-6
Ondansetron	SSG, Polacrillin potassium, MCC, Colloidal SiO2, Aspartame, Talc.	Direct Compression	10-15sec
Ascorbic acid, Cimetidine	Erythritol, D-mannitol, MCC, Corn starch, Pregelatinized starch.	Molding, Direct Compression	31-37

In this method, water-soluble ingredients are used so that tablet disintegrate and dissolve rapidly. The powder blend is moistened with a hydro alcoholic solvent and is molded in to tablet using compression pressure lower than used in conventional tablets compression. The solvent is then removed by air-drying. Molded tablets have a porous structure that enhances dissolution. Two problems commonly encountered are mechanical strength and poor taste masking characteristics. Moulding process is of two types: i) Solvent method and ii) Heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass. The solvent is then removed by air drying. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 300C under vacuum.[8]

2. Spray drying

Spray drying can produce highly porous and fine powders that dissolve rapidly. This technique is based on a particulate support matrix, which is prepared by spray drying an aqueous composition containing support matrix and other components to form a highly porous and fine powder. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 sec in aqueous medium. The formulation contained bulking agent like mannitol and lactose, a superdisintegrant like sodium starch glycolate & Crosscarmellose sodium and acidic ingredient (citric acid) and/or alkaline ingredients (sodium bicarbonate).[9, 10]

Figure 1. Tablet Moulding Technique



3. Lyophilization /Freeze drying

Lyophilization means drying at low temperature under condition that involves the removal of water by sublimation. Drug in a water soluble matrix which is then freeze dried to give highly porous structure. Lyophilization is useful for heat sensitive drugs i.e. thermo-labile substances. Freeze drying process normally consists of three steps:

i) Material is frozen to bring it below the eutectic point.

ii) Primary drying to reduce the moisture around 4% w/w of dry product.

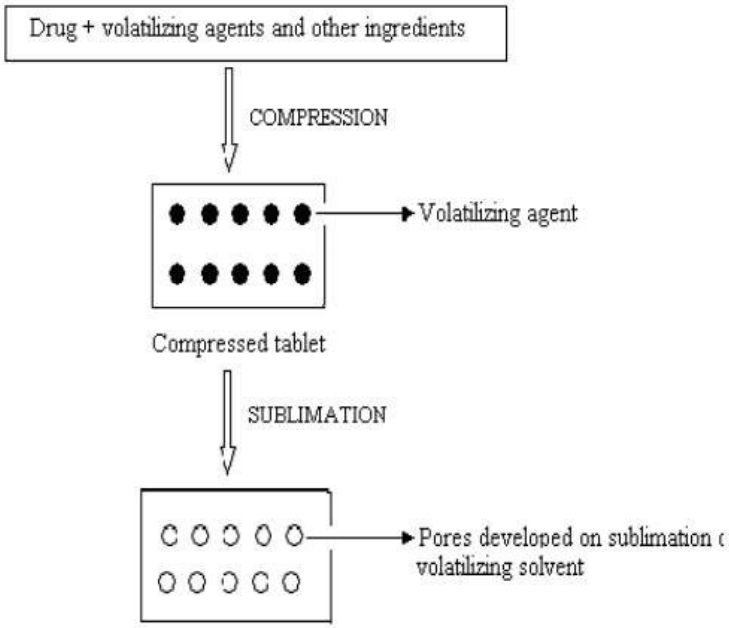
iii) Secondary drying to reduce the bound moisture up to required final volume.ZYDIS®

(R.P. Scherer, Swindon, UK), using freeze drying processes, is one of the first generations of fast disintegrating dosage form. There are approximately 12 marketed ZYDIS® products, including Lorazepam, Piroxicam, Loperamide, Loratidine, and Enalapril.[2, 10]

4. Sublimation

In this method a subliming material or volatile substance like camphor, is removed by sublimation from compressed tablets and high porosity is achieved due to the formation of many pores where camphor particles previously existed in the compressed tablets prior to sublimation of the camphor. A high porosity was achieved due to the formation of many pores where camphor particles previously existed in the compressed mannitol tablets prior to sublimation of the camphor. Camphor was sublimed from the dried granules by vacuum exposure.[8]

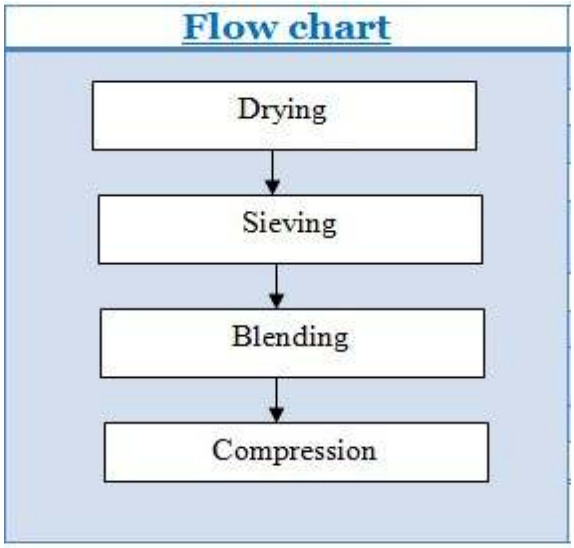
Figure 2. Sublimation Technique



5. Direct compression method

Direct compression is the most popular technique because of its easiness and cost effectiveness. In this method, tablets are compressed directly from the mixture of the drug and excipients without any preliminary treatment. The mixture to be compressed must have adequate flow properties and cohere under pressure thus making pretreatment as wet granulation unnecessary. Few drugs can be directly compressed into tablets of acceptable quality. A type of disintegrant and its proportion are of prime importance. The other factors to be considered are particle size distribution, contact angle, pore size distribution, tablet hardness and water absorption capacity. All these factors determine the disintegration. The disintegrant addition technology is cost effective and easy to implement at industrial level.[11-13]

Figure 3. Direct Compression Technique



This technique can now be applied to Fast disintegrating tablets because of the availability of improved tablet excipients, especially tablet disintegrants, effervescent agent and sugar-based excipients.

6. 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. FDT were produced by compressing powder containing erythritol (melting point: 122°C) and xylitol (melting point: 93-95°C), and then heating at about 93°C for 15 min. After heating, the median pore size of the tablets was increased and tablet hardness was also increased. Tablet did not have sufficient hardness because of low compatibility but after heating, increase in inter-particular bonding or binding surface area occurs which then increased tablet hardness.

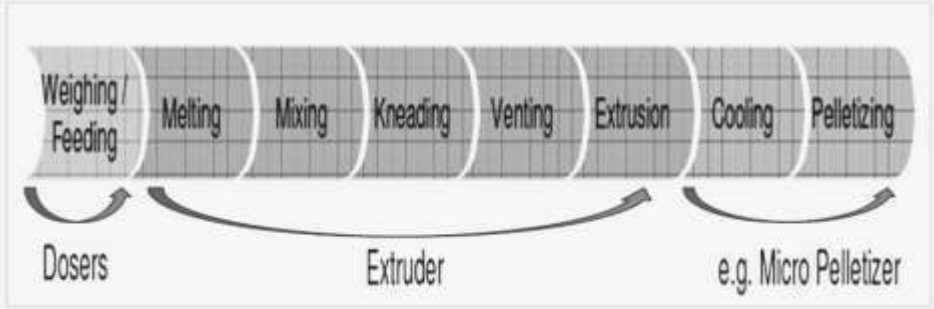
7. Melt granulation

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.[14-18]

8. Mass extrusion

This technology involves softening of the active blend using the solvent mixture of water soluble polyethylene glycol and methanol and expulsion of softened mass through the extruder or syringe to get a cylindrical shaped extrude which are finally cut into even segments using heated blade to form tablets. This process can also be used to coat granules of bitter drugs to mask their taste.

Figure 4. Mass Extrusion Technique



9. Cotton candy process

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 ODTs. This process can accommodate high doses of drug and offers improved mechanical strength. However, high process temperature limits the use of this process. This process is so named as it utilizes an inimitable spinning mechanism to produce floss like crystalline structure, which mimics cotton candy. The manufacturing process can be divided into four steps as detailed below.

A) Floss Blend

In this step, 80% sucrose in combination with mannitol/dextrose and 1% surfactant is blended to form the floss mix. The surfactant acts as a crystallization enhancer in maintaining the structural integrity of the floss fibers. It also helps in the conversion of amorphous sugar into crystalline form from an outer portion of amorphous sugar mass and subsequently converting the remaining portion of the mass to complete crystalline structure. This process helps to retain the dispersed drug in the matrix, thereby minimizing migration out of the mixture.

B) Floss Processing

The floss formation machine uses flash heat and flash flow processes to produce matrix from the carrier material. The machine is similar to that used in „cotton-candy" formation which consists of a spinning head and heating elements. In the flash heat process, the heat induces an internal flow condition of the carrier material. This is followed by its exit through the spinning head (2000–3600 rpm) that flings the floss under centrifugal force and draws into long and thin floss fibers, which are usually amorphous in nature.

C) Floss Chopping and Conditioning

This step involves the conversion of fibers into smaller particles in a high shear mixer granulator. The conditioning is performed by partial crystallization through an ethanol treatment (1%) which is sprayed onto the floss and subsequently evaporated to impart improved flow and cohesive properties to the floss.

D) Blending and Compression

Finally, the chopped and conditioned floss fibers are blended with the drug alongwith other required excipients and compressed into tablets. In order to improve the mechanical strength of the tablets, a curing step is also carried out which involves the exposure of the dosage forms to elevated temperature and humidity conditions, (40 °C and 85% RH for 15 min). This is expected to cause crystallization of the floss material that results in binding and bridging to improve the structural strength of the dosage form.

10. Nanoionization

Nanomelt technology involves reduction in the particle size of drug to nano size by wet- milling technique. Surface adsorption of the nano-crystals of the drug is done on selected

stabilizers for stabilizing them against agglomeration, which are then incorporated into MDTs. This technique is mainly advantageous for poor water soluble drugs and also for a wide range of doses (up to 200 mg of drug per unit).[19-24]

11. Oral disintegrating thin film

In FDT that provides a very convenient means of taking medications and supplements. In this technique, a non-aqueous solution is prepared containing water soluble film forming polymer (Pullulan, carboxy methylcellulose, hydroxypropyl methylcellulose, hydroxyl ethylcellulose, hydroxyl propylcellulose, polyvinyl pyrrolidone, polyvinyl alcohol or sodium alginate, etc.), drug and other taste masking ingredients, which is allowed to form a film after evaporation of solvent. In case of a bitter drug, resin adsorbate or coated microparticles of the drug can be incorporated into the film. This film, when placed in mouth, melts or dissolves rapidly, releasing the drug in solution or suspension form. The features of this system include paper thin films of size less than 2X2 inches, dissolution in 5 sec, instant drug delivery and flavored
after taste.[11]

Patented Technologies for Fast Dissolving Tablet

Several technologies are available for preparing FDTs. But some commercially useful technologies are:

1. Zydis technology

Zydis formulation is a unique freeze dried tablet in which drug is physically entrapped or dissolved within the matrix of fast-dissolving carrier material. When zydis units are put into the mouth, the freeze dried structure disintegrates instantaneously and does not require water to aid swallowing. To impart strength during handling, polymers such as gelatin, dextran or alginates are incorporated. These form a glossy amorphous structure, which imparts strength. To obtain crystallinity, elegance and hardness, saccharides such as mannitol or sorbitol are incorporated. Water is used in the manufacturing process to ensure production of porous units to achieve rapid disintegration. Various gums are used to prevent sedimentation of dispersed drug particles in the manufacturing process. Collapse protectant, glycines prevent the shrinkage of zydis units during freeze drying process or long term storage. Zydis products are packed in blister packs to protect the formulation from moisture in the environment.

2. Durasolv technology

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of drug, filler and a lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packaged into conventional packaging system like blisters. Durasolv is an appropriate technology for product requiring low amounts of active ingredients.

3. 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. The tablets produced are soft and friable and packaged in specially designed pick and place system.

4. Lyoc technology

This is patented technology of Laboratories L. Lafon, Maisons Alfort, France .It utilizes a freeze drying process but differ from Zydis in that the product is frozen on the freeze dryer shelves. These formulations require a large proportion of undissolved inert filler (mannitol), to prevent in homogeneity by sedimentation during this process and to increase the viscosity of the in process suspension.

5. Flashtab technology

Prographarm laboratories have patented the Flashtab technology. Tablet prepared by this system consists of an active ingredient in the form of micro crystals. Drug micro granules

may be prepared by using the conventional techniques like Coacervation, micro encapsulation and extrusion spheronization.

6. Wowtab technology

Wowtab Technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water". The combination of high and low mouldability is used to produce tablets of adequate hardness. Active ingredients are mixed with low mouldability saccharides and then granulated with high mouldability saccharides and then compressed into tablet.

7. Oraquick technology

The Oraquick fast dissolving/disintegrating tablets formulation utilizes a patented taste masking technology. This taste masking process does not utilize solvents of any kind, so leads to faster and more efficient production. During processing low-heat is produced so this technique is suitable for heat sensitive drugs. KV pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particle is more pliable. This technique gives tablets with good taste masking and quick dissolution in matter of seconds.

8. Flashdose technology

Flash dose technology has been patented by Fuisz. Nurofen meltlet is a new form of Ibuprofen as melt-in-mouth tablets. Flash dose tablets consist of self binding shear form matrix termed as "floss". Shear form matrices are prepared by flash heat processing.

9. Frosta technology

Akina patents this technology. It utilizes the concept of formulating plastic granules and compressing them at low pressure to produce strong tablets with high porosity. Plastic granules composed of porous and plastic material, water penetration enhancer, and binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to
30 sec depending on size of tablet.

10. Sheaform technology

In this technology, a shearform matrix, „Floss" is prepared. Feedstock prepared with a sugar carrier is subjected to flash heat processing. In this process, the sugar is simultaneously subjected to centrifugal force and to a temperature gradient, which raises the temperature of the mass to create an internal, flow condition, which permits part of it to move with respect of the mass. The floss so produced is amorphous in nature so it is further chopped and recrystallized by various techniques to provide aciform flow properties and this facilitate blending the recrystallized matrix is then blended with other tablet excipients and an active ingredient. The resulting mixture is compressed into tablet.[12, 25-27]

Table 2. Some patented technologies for fast dissolving tablets

Technology	Company's Name	Technology Base
Durasolv, Orasolv	CIMA Lab Inc.	Moulding
Flash Tab	Ethypharm	Moulding
Wow Tab	Yamanouchi Pharma	Moulding
Zydis	R.P. Scherer Inc.	Freeze dried Wafers
Flash Dose	Fuisz Technology Ltd.	Cotton-candy Process
Ziplets	Eurand	Moulding
Fast Melt	Elan Corp.	Moulding

Evaluation Parameter of Fast Dissolving Tablets Dosage Form

1. Evaluation of Blend

The prepared blend is evaluated by following tests:

A. Bulk density

It is the ratio of total mass of powder to the bulk volume of powder. It was determined by pouring a weighed quantity of tablet blend into graduated cylinder and measuring the height.

Bulk density is the ratio of mass of tablet blend to bulk volume.

$$\text{Bulk Density} = \frac{\text{Mass}}{\text{Apparent volume}}$$

B. Tapped density

It is the ratio of the total mass of the powder to the tapped volume of the powder. Accurately weighed amount of tablet blend poured in graduated cylinder and height is measured. Then cylinder was allowed to 100tap under its own weight onto a hard surface. The tapping was continued until no further change in height was noted.

$$\text{Tapped Density} = \frac{\text{Mass}}{\text{Tapped volume}}$$

C. Carr's index

Compressibility is the ability of powder to decrease in volume under pressure using bulk density and tapped density the percentage compressibility of powder were determined, which is given as Carr"s compressibility index. It is indirectly related to the relative flow rate. Carr"s compressibility index was determined by the given formula.

$$\text{Carr's Index} = \frac{\text{Tapped Density} - \text{Bulk Dens}}{\text{Tapped Density}}$$

D. Hausner's ratio

Hausner"s ratio indicates the flow properties of powder and measured by the ratio of tapped density to bulk density. Hausner"s ratio was determined by the given formula.

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

E. Angle of repose

Angle of repose was determined by using funnel method. The accurately weighed blend was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap of blend. The drug excipient blend was allowed to flow through the funnel freely on to the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation.

$\theta = \tan^{-1}(h/r)$

Here;

h = Height of pile

r = Radius of pile

θ = Angle of repose

2. Evaluation of Tablet

The tablets quality control tests following:

A. Weight Variation

According to I.P. procedure for uniformity of weight, twenty tablets are taken and their weight is determined individually and collectively on an electronic 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.

Average weight of Tablets (mg)	Maximum % deviation
80 mg or less	±10
More than 80 mg but less than 250 mg	±7.5
250 mg or more	±5

B. Thickness

Thickness of tablets is determined using Vernier caliper. An average value is calculated by using tablets in triplicate and then the mean ± standard deviation values of thickness are notified.

C. 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 in case of MDTs is kept low to allow rapid disintegration in mouth. It is done by using hardness tester like Pfizer hardness tester or Monsanto tablet hardness tester.

D. Friability

Friability is measured of mechanical strength of tablets. Roche Friabilator is used to

determine the friability by following procedure. A preweighed tablet is placed in the friabilator. Friabilator consist of a plastic chamber that revolves at 25 rpm, dropping the tablets at a distance of 6 inches with each revolution. The tablets are rotated in the friabilator for 4 minutes for 100 revolutions. At the end of test, tablets are reweighed; the loss in the weight of tablet is the measure of friability and is expressed in percentage as;

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

E. Disintegration Time

The test is carried out using the disintegration apparatus. Phosphate buffer (pH 6.8) maintained at 37ºC ± 2ºC is used as a disintegration media and the time taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus is measured.

F. Wetting Time

A piece of tissue paper folded twice is placed in a small petridish containing 6ml. of distilled water. A tablet is carefully placed on the surface of the paper and the time required for water to reach the upper surface of the tablet is noted as the wetting time. Less is the wetting time, indicates more porous the tablet.

G. Water Absorption Ratio

A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of water. A tablet was put on the paper & the time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio (R), was determined using following equation,

$R = 100 * (Wa - Wb / Wb)$

Here,

Wb is weight of tablet before water absorption

Wa is weight of tablet after water absorption.

H. In vitro Drug Release Studies

The in vitro drug release is studied using USP dissolution apparatus II (paddle type) at 50 rpm in 900 ml of phosphate buffer (pH 6.8) at37±0.5ºC. At different time intervals, 10 ml of sample is withdrawn and filtered. An equal volume of the medium is introduced into the container after each withdrawal to maintain a constant volume. The absorbance of the samples is determined by UV Spectrophotometer at given max. The mean values of drug released are plotted as cumulative % drug release vs. time.[14, 15]

MARKETED PRODUCTS OF FAST DISSOLVING TABLETS (FDTs)

Table 3. Marketed product of FDTs

Brand/ Trade name	Active Drug	Manufacturer Company
Benadryl Fastmelt	Diphenhydramine	Pfizer
Cibalginadue FAST	Ibuprofen	Novartis Consumer Health
Olanex Instab	Olanzepine	Ranbaxy
Torrox MT	Rofecoxib	Torrent pharmaceuticals, India
Romilast	Montelukast	Ranbaxy
Nimulid MDT	Nimesulide	Panacea Biotech
Zyprexa	Olanzapine	Eli Lilly
Maxalt-MLT	Rizatriptan Benzoate	Merck
Acivir DT	Acyclovir	Cipla
Pepcid RPD	Famotidine	Merck
Zotacet MD	Cetrizine HCl	Zota pharma
Orthoref MD	Rofecoxib	Biochem
Romilast	Montelukast	Ranbaxy lab. Ltd
Valus	Valdecoxib	Glenmark
Nulev	Hyoscymine sulfate	Schwarz pharma

Felden fast melt	Piroxicam	Pfiser Inc., USA
Febrectol	Paracetamol	Prographarm, France
Zofran ODT	Ondansetron	Glaxo Wellcome, UK
Fazaclo	Clozapine	Azurpharma
Risperdal M-Tab	Risperidone	Janssen

CONCLUSION

Fast dissolving tablet is an innovative dosage forms for all age groups, specifically pediatric, geriatric patients and patients with swallowing difficulties. The development of a fast- dissolving tablet also provides an opportunity for a line extension in the marketplace; a wide range of drugs (e.g., neuroleptics, cardiovascular drugs, analgesics, antihistamines, and drugs for erectile dysfunction) can be considered candidates for this dosage form. 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. The fast dissolving tablet has been developed which offers the combined advantages of ease of dosing and convenience of dosing in the absence of water or fluid. These tablets are designed to dissolve or disintegrate rapidly in the saliva generally within <60 seconds. Fast dissolving tablet acts like solid dosage form when outside the body & solution when administered. Fast dissolving tablet overcomes the problems of swallowing and provides a quick onset of action. Considering the many benefits of fast dissolving tablet, it is only a matter of time until a majority of oral formulations are prepared in fast dissolving tablet forms. 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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