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Fast Dissolving Tablets-A Review

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Abstract: Fast dissolving tablets dissolve rapidly in the saliva without the need for water. Some tablets are designed to dissolve in saliva remarkably fast, within a few seconds and are true fast-dissolving tablets. This tablet format is designed to allow administration of an oral solid dose form in the absence of water or fluid intake. Such tablets readily dissolve or disintegrate in the saliva generally within <60 seconds. Tablet is the most popular among all dosage forms existing today because of its convenience of self administration, compactness and easy manufacturing however hand tremors, dysphasia in case of geriatric patients, under developed muscular and nervous systems in young individuals and in case of uncooperative patients the problem of swallowing is common phenomenon which leads to poor patient compliance.

Key words: Fast Dissolving Tablet • Antibacterials • Antihypertensives • Superdisintegrants • Mouth Dissolving Tablets

INTRODUCTION

A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintergrates in the oral cavity without the need of water or chewing. Most fast-dissolving delivery system 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. These are also called melt-in-mouth tablets, porous tablets, oro-dispersible, quick dissolving or rapid disintegrating tablets. [1] Fast dissolving tablets are used in patients, like pediatric, geriatric, bedridden, or mentally disabled, who may face difficulty in swallowing conventional tablets or capsules leading to ineffective therapy, with persistent nausea, sudden episodes of allergic attacks, or coughing for those who have an active life style. Fast dissolving tablets are also suitable when local action in the mouth is desirable such as local anaesthetic for oral ulcers, toothaches, cold sores, or teething and to those who cannot swallow intact sustained action tablets [2-3].

Salient Feature of Fast Dissolving Tablets [4]:

- No need of water to swallow the dosage form, which is high convenient feature for patients who are travelling and do not have immediate access to water.
- Rapid dissolution and absorption of the drug, which will produce quickly onset of action.
- Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric and psychiatric patients.
- Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
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- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.

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

Advantage of Fast Dissolving Tablets [5-6]:

- Does not require water for oral administration.
- Insensitive to environmental conditions such as humidity and temperature.
- Have a pleasant mouth feel.
- FDT passes all the advantages of solid dosage forms like good stability, easy manufacturing, unit and accurate dosing, easy handling etc.
- Provides rapid drug therapy intervention.
- There is no risk of physical obstruction due to dosage form.
- The possibility of an improved bioavailability due to rapid absorption and faster onset of action.
- Ease of administration to patients who are unable or refuses to swallow a tablet, such as pediatric, geriatric and psychiatric and disabled patient.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Can be designed to leave minimal or no residue in the mouth after administration and also to provide a pleasant mouth feel.
- Allows high capacity of drug loading.
- FDTs helps avoids hepatic metabolism by allowing pregastric drug absorption thus reducing the dose of drug required.
- Adaptable to existing processing and packaging machinery.
- Cost effective.
- Mark potential faster onset of action than conventional oral dosage forms.

Criteria of Drug for Formulating as Fast Dissolving Tablets [7,8]:

- Dose lower than 20 mg.
- Free from bitter taste.
- Drug should have good solubility in water and saliva.
- Small to moderate molecular weight.
- Ability to permeate oral mucosa.
- At least partially non-ionized at the oral cavity.
- Ability to diffuse and partition into the epithelium of the upper GIT.

• Short half-life and frequent dosing drugs are unsuitable for FDT

Limitations of Fast Dissolving Tablets [9]:

- The tablets usually have insufficient mechanical strength. Hence, careful handling required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.

Techniques for Preparing Fast Dissolving Tablets

Freeze drying/Lyophilization: It is one of the first generation techniques for preparing FDT, in which sublimation of water takes place from the product after freezing. Lyophilization is a pharmaceutical technology which allows drying of heat sensitive drugs and biologicals at low temperature under conditions that allow removal of water by sublimation.

Freeze Drying Process Normally Consists of Three Steps:

- Material is frozen to bring it below the eutectic point.
- Primary drying to reduce the moisture around 4% w/w of dry product.
- Secondary drying to reduce the bound moisture up to required final volume.

Due to lyophilization, bulking agent and sometimes drug acquire glossy amorphous structure and thus dissolution is enhanced. The tablets prepared by freeze drying or lyophilisation are very porous in nature and disintegrate or dissolve rapidly when it comes in contact with saliva [10].

Moulding: There are two types of molding process:

Solvent Method Heat Method

- Solvent method: Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressure in molded plates to form a wetted mass. Air drying is done to remove the solvent. Such tablets are less compact than compressed tablets and possess a powder structure that hastens dissolution.
- Heat method: In the heat molding process a suspension is prepared that contains a drug, agar and sugar (mannitol or lactose). This suspension is

poured in the blister packaging wells and then agar is solidified at the room temperature to form a jelly and dried at 30°C under vacuum. The main concern about these molded tablets is their mechanical strength, which can be achieved by using binding agents [11].

Spray Drying: In this technique, gelatin can be used as a supporting agent and as a, mannitol, matrix as a bulking agent and sodium starch glycolate or crosscarmellose or crospovidone are used as superdisintegrants. Tablets manufacture from the spray-dried powder has 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 (e.g. sodium bicarbonate). This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.

Sublimation Method: 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. Even solvents like cyclohexane benzene can be used as pore forming agents [12].

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. This technique can now be applied to fast dissolving tablets because of the availability of improved tablet excipients, especially tablet disintegrates and sugar-based excipients [13].

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 blade to form tablets. The dried cylinder can also be used to coat granules of bitter tasting drugs and there by masking their bitter taste [14].

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.

Phase Transition: 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 compatibility.

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. Prepared Carbamazepine fast-release tablets by melt granulation technique using polyethylene glycol as a melting binder and Lactose monohydrate as hydrophilic filler [15].

Patented Technologies for Fdt (Fast Dissolving Tablet):

- Zydis Technology
- Orasolv Technology
- Durasolv Technology
- Flash Dose Technology
- Flash tab Technology
- Wow tab Technology

Zydis Technology: Zydis formulation is a unique freeze dried technique 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. The zydis matrix is composed of many material designed to achieve a number of objectives. To impart strength and resilience during handling, polymers such as gelatin, dextrin 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 while various gums are used to prevent sedimentation of dispersed drug particles in the manufacturing process. Collapse protectants such as glycine 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.

Orasolv Technology: CIMA labs have developed Orasolv Technology. 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.

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 tablet equipment and have good rigidity. These can be packaged into conventional packaging system like blisters. Durasolv is an appropriate technology for product requiring low amount of active ingredients.

Flash Dose Technology: Flash dose technology has been patented by Fuisz. Nurofen Meltlet, a new form of ibuprofen as melt in mouth tablets prepared using flash dose technology is the first commercial product launched by Biovail Corporation. Flash dose tablets consist of self flash heat processing [16].

Flash Tab Technology: Prographarm laboratories have patented the Flash tab technology. Tablets prepared by this system consist of an active ingredient in the form of

micro crystals. Drug micro granules may be prepared by using the conventional techniques like Co-acervation, micron-capsulation and extrusions pheronisation. All the processing utilized conventional tableting technology [17].

Wow Tab Technology: Wow tab technology patented by Yamanouchi Pharmaceutical co. wow means "Without Water". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide (eg. lactose, glucose and mannitol) and granulated with a high mouldability saccharide (eg. Maltose, oligosaccharides) compressed into table.

Some of Promising Drug Category for Fast Dissolving Tablets [18]

Antibacterial agents: Ciprofloxacin, Erythromycin, Tetracycline, Rifampicin, Penicillin, Doxycyclin, Nalidixic acid, Trimethoprim, Sulphadiazine, Sulphacetamide,

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

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

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

Analgesics/Anti-Inflammatory Agents: Ibuprofen, Diclofenac sodium, Ketoprofen, Mefenamic acid, Naproxen, Indomethacin, Oxyphenbutazone, Piroxicam, Phenylbutazone.

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

Antiarrhythmics: Disopyramide, Quinidine sulphate, Amiodarone HCl.

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

Anxiolytics, Sedatives Hypnotics and Neuroleptics: Alprazolam, Diazepam, Amylobarbitone, Clozapine, Haloperidol, Lorazepam, Nitrazepam, Thioridazine, phenobarbitone, Oxazepam, Midazolam.

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Table 1: List of commercially ava	ilable fast dissolving tablets [18]
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Trade name	Active drug	Manufacturer
Jr. Tylenol		
Meltaways	Acetaminophen	McNeil Consumer
Healthcare		
Febrectol	Paracetamol	Prographarm,
Chateauneuf, France		
Pepcid RPD	Famotidine	Merck and Co., NJ, USA
Felden fast melt	Piroxicam	Pfiser Inc., NY, USA
Zyprexia	Olanzapine	Eli lilly, Indianapolis, USA
Zoming-ZMT	Zolmitriptan	AstraZeneca,
Wilmington, USA		
Maxalt MLT	Rizatriptan	Merck and Co., NJ, USA
Claritin redi TAB	Loratidine	Schering plough Corp., USA
Nimulid FDT	Nimesulide	Panacea Biotech,
New Delhi, India		
Cibalgina DueFast	Ibuprofen	Eurand International
Clonazepam FDT	Clonazepam	Par Pharmaceutical
Relivia Flash dose	Tramadol HCl	Fuisz Technology, Ltd
Romilast	Montenlukast	Ranbaxy lab. ltd. New- Delhi, India

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

Gastro-Intestinal Agents: Ranitidine HCl, Cimetidine, Famotidine, Domperidone, Omeprazole, Granisetron HCl, Ondansetron HCl.

Corticosteroids: Beclomethasone, Betamethasone, Hydrocortisone, Prednisolone, Methyl prednisolone.

Antiprotozoal Agents: Tinidazole, Metronidazole, Ornidazole, Benznidazole, Clioquinol, Decoquinate.

Evaluation of Fast Disintegrating Tablets: FDTs formulations have to be evaluated for the following evaluation test.

General Appearance: The general appearance of a tablet, its visual identity and over all elegance is essential for consumer acceptance. It includes tablets size, shape, colour, presence or absence of an odour, taste, surface texture, physical flaws and consistency and eligibility of any identifying marking.

Size and Shape: The size and shape of the tablet can be dimensionally described controlled and monitored.

Tablet Thickness: Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets were taken and their thickness was recorded using micrometer [19].

Uniformity of Weight: IP Procedure, 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 [20].

Average weight of tablets	Maximum percentage difference allowed
130 or less	10
130-324	7.5
More than 324	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 Monsanto Hardness tester.

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 plasticchamber 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

In- vivo **Disintegration Test:** The test was carried out on 6 tablets using the apparatus specified in I.P.-1996 distilled water at $37^{\circ}C \pm 2^{\circ}C$ was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no pal able mass remaining in the apparatus was measured in seconds [21].

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 Petri dish (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 [22].

In-vitro **Dispersion Time:** Tablet was added to 10 ml of phosphate buffer solution, pH 6.8 at 37+0.5°c, Time required for complete dispersion of a Tablet was measured [23].

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.

- $40 \pm 1 \,^{\circ}\text{C}$
- $50 \pm 1^{\circ}C$
- $37 \pm 1^{\circ} \text{ C}$ 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 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.

In vitro **Dissolution Test:** The development of dissolution methods for FDTs is comparable to the

approach taken for conventional tablets and is practically identical. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent FDT. Other media such as 0.1 M HCl and buffer (pH 4.5 and 6.8) should be evaluated for FDT much in the same way as their ordinary tablet counterparts. It has been suggested that USP 2 paddle apparatus is the most suitable and common choice for orally disintegrating tablets, with a paddle speed of 50 rpm commonly used [24].

CONCLUSION

The development of a fast-dissolving tablet constitutes an innovative dosage form, which overcomes the problem of swallowing and provides a quick onset of action. The paediatric and geriatric population are the primary, targets, as both the groups found it difficult to swallow conventional tablets. The basic approach followed by all the currently available technologies engaged in the formulation of Fast dissolving tablets is to maximize the porous structure of the tablet matrix and incorporate super disintegrating agents in optimum concentration so as to achieve rapid disintegration and instantaneous dissolution of the tablet along with good taste masking properties and excellent mechanical strength The availability of the various technologies and manifold advantages of Fast dissolving tablets will surely increase its popularity in the near future.

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