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Fast-Disintegrating Tablets: A Short Review

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ABSTRACT

The convenience of administration along with improved patient compliance is important in the development of oral drug delivery system that remains the favored route of drug delivery inspite of a range of disadvantages. One among problem can be solved in this novel drug delivery system by formulating "mouth dissolving tablets" (MDTs) that disintegrates or dissolves quickly without water within few seconds inside the mouth due to the act of superdisintegrant or maximizing pore structure in the formulation. These mouth dissolving tablets are advantageous mainly for pediatric, geriatric and mentally ill patients who have complexity in swallowing conventional tablets and capsules units. This review describes the various formulation aspects, superdisintegrants engaged and technologies developed for MDTs, along with various excipients, evaluation tests..

Keywords: Fast-disintegrating tablet, Sublimation, Mouth Dissolving Tablets, MDT.

INTRODUCTION

Regardless of incredible innovations in drug delivery system, the oral route keeps on the preferred route for administration of therapeutic agents for the reason that of accurate dosage, low cost therapy, self-medication, non- invasive method and ease of administration leading to elevated level of patient compliance. Pediatric patients may undergo from ingestion problems as a result of under- developed muscular and nervous control. Furthermore patients traveling with little or no access to water, limit utility of orally administered conventional tablets or capsules. (12, 13, 16)

The tablet is one of the most widely used dosage form which existing today because of its convenience in terms of self-administration, compactness and easiness in manufacturing. On the other hand, geriatric, pediatric and mentally ill patients experiences difficulty in swallowing conventional tablets, which leads to poor patient compliance. To conquer these problems, scientists have developed innovative drug delivery system known as mouth dissolving or disintegrating tablets (MDTs). These are the novel types of tablets that dissolve or disintegrate or disperse in saliva within few seconds without water. According to the European pharmacopoeia, these MDTs should dissolve/disintegrate in less than three minutes. This formulation is more helpful for the bed-ridden and patients who have the swallowing problem. The profit of MDTs is to improve patients compliance, rapid onset of action, improved bioavailability and good stability

which make these tablets popular as a dosage form of choice in the current market.7, 9, 31.

Mouth dissolving tablets are also named as oro-dispersible tablets or fast disintegrating tablets or orally disintegrating tablets or quick disintegrating tablets or fast dissolving tablets or rapid dissolving tablets or porous tablets or quick melt tablets and rapid melt tablets. Though of all the beyond terms are United States Pharmacopoeia (USP) approved these dosage forms as ODTs. United States Food and Drug Administration (FDA) defined the ODTs as "A solid dosage form that containing medicinal substances or active ingredients which disintegrates very rapidly within a few seconds when placed up on tongue". (10, 37)

The Mouth dissolving tablets are prepared mainly by two techniques in which first use of super disintegrants like crosscarmellose sodium, sodium starch glycolate and crosspovidone. But in another method maximize the pore structure of the tablets by freeze drying and vacuum-drying. The bioavailability of a number of drugs may be increased due to absorption of drugs in oral cavity and also due to pre- gastric absorption of saliva containing dispersed drugs that pass down in to the stomach. In addition the amount of drug that is subjected to the first pass metabolism that reduced as compared to standard tablets. (14, 30)

Standard characteristics of fdts

Quick-breakdown or fast disintegrating tablet are one type of those intended to go through disaggregation in the mouth in contact with the saliva in less than 1 minute, preferably in less than 45 seconds, that forming a suspension which is easy to swallow. It is better known by the phrase "orodispersible tablets". It is estimated that 50% of the peoples has difficulties in swallowing tablets or capsules. This problem results in the prescribed medicament not being in use and hence in the efficacy of the treatment being severely affected. (6) Thus orodispersible tablets are easy to administration for patients who have problems of deglutition or for those persons who would like to take their treatment without simultaneous ingestion of liquid.(1, 23)

Current advances in novel drug delivery (NDDS) aims to improve safety and efficacy of drug molecule by formulating a suitable dosage form for ease of administration and to achieve better patient compliance. One such approach is oral disintegrating tablets (ODTs). ODTs are solid unit dosage forms, which disintegrates or dissolves rapidly in the mouth without the general requirement for swallowing, the chewing and water. New Developments in the dosage form designing the ODTs accomplish the requirement of patient needs without compromising its efficacy. The ODTs satisfies the patient's necessities that are difficulty in the swallowing of the conventional tablets or capsules.(21,33)

Ideal Properties Fdt (15,18, 26, 25,36)

- Suitable for Conventional tablet processing and packaging
- Fragility Concern
- Good Mouth Feel
- Patient Compliance
- Economic
- Compatible with Taste Masking

Advantages of Fdts (36)

1. Enhanced compliance/added convenient, new business opportunities product differentiation, line extension and lifecycle management, exclusivity of product promotion, and patent life extension.
2. No water required.
3. No chewing required.
4. Improved taste.
5. Enhanced stability.
6. Appropriate for controlled/sustained release actives.
7. Allows high drug load.
8. Ability to give advantages of liquid medication in the form of solid preparation.
9. Cost effective.
10. Rapid drug therapy interference.
11. High drug loading is possible.
12. Have satisfactory taste and pleasant mouth feeling

Drugs formulated as Fdts

The eligibility criterion for drugs that to be formulated as Fast Dissolving Tablets is low dose, good stability in aqueous media, good mechanical strength and compatibility with excipients. (11, 27)

Common excipients used for Fdts preparation

Generally seen excipients in FDT are as follows and at least one disintegrant, diluent, lubricant, and swelling agent, permeabilizing agent, sweeteners, and flavors. **(22)**

Name of the excipients	Percentage Used
Disintegrants	1 to15%
Diluents/fillers	0 to 85%
Binder	5 to 10%
Antistatic Agent	0 to 10%

Formulation challenges of fdts

Challenges	Brief Description
Mechanical strength & disintegration time	MDTs are formulated to get disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. A lot of MDTs are easily broken and there are many chances that such fragile tablet will break during packing, transport or handling by the patients.. It is very natural that increasing the mechanical strength will delay the disintegration time.
Masking of Taste	Numerous drugs are bitter in taste. So effective taste masking of the bitter drugs must be done so that the taste of the drug is not felt in the oral cavity.
The Mouth feel	Tablet should not disintegrate into bigger particles in the oral cavity. The particles generated after disintegration of the Tablet should be as small as possible. Tablet should leave minimal or no residue in mouth after oral administration.
Environmental Sensitivity	Tablet usually should show low sensitivity to environment conditions such as humidity and temperature as most of the materials used in a Tablet are meant to dissolve in minimum quantity of water.
Palatability	As the majority of drugs are unpalatable, tablets should contain the medicament in a taste-masked form.
Mechanical strength to withstand sock	In order to allow ODTs to disintegrate in the oral void, they are made of either very porous and soft-molded matrices or compressed into tablets with very little compression force, which makes the tablets friable and/or brittle, difficult to handle, and often requiring specialized peel-off blister packing that may add to the cost.

Hygroscopical property	Numerous orally disintegrating dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Therefore they require protection from humidity which calls for specialized product packaging.
Aqueous solubility	Water-soluble drugs pose various formulation challenges since they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process.
Tablet Size	It has been reported that the most easiest size of tablet to swallow is 7-9 mm even as the easiest size to handle was one larger than 8 mm.
Fast Disintegration	FDTs be supposed to disintegrate in the mouth with no additional water or with a very small amount (e.g., 1–2 Ml) of water.

Fast dissolving drug delivery system criteria

The tablets must

- Not need water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Be well-matched with taste masking.
- Be moveable without fragility concern.
- Have a pleasing mouth feel.
- Leave smallest amount or no residue in the mouth after oral administration.
- Exhibit low sensitive to environmental condition as temperature and humidity.

Fast dissolving drug delivery system's salient feature

- Simplicity of Administration to the patient who cannot swallow, such as the elderly, stroke victims, confined to bed patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric & psychiatric patients.
- No require of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have instant access to water.
- Fast dissolution and absorption of the drug, which will make quick onset of action.
- A number of drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is increased.
- Pre-gastric absorption be able to result in improved bioavailability and as a result of abridged dosage; get better clinical performance through a reduction of unwanted effects.
- Superior mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
- The threat of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, therefore providing improved safety.
- Fresh business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- Helpful in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra fast on set of action required.
- An greater bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to quick disintegration and dissolution of these tablets.
- Constancy for longer period 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.

Fast dissolving tablets's benefits

- Administered with no water, anywhere, any time.
- Suitability for geriatric and pediatric patients, who experience difficulties in swallowing and for the other groups that may experience problems using conventional oral dosage form, due to being mentally ill, the developmentally disable and the patients who are uncooperative, or are on reduced liquid intake plans or are nauseated.
- Helpful in cases such as motion sickness, suede episodes of allergic attack or coughing, where an ultra rapid onset of action required.
- An improved bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to fast disintegration and dissolution of these tablets.
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Mouth dissolving tablets's limitations

- The tablets typically have inadequate mechanical strength. Therefore careful handling is required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.

Different technologies used for manufacturing of mdts

In the current past, several new advanced technologies have been introduced for the

manufacturing of MDTs with ideal properties like less disintegration time, pleasant mouth feel, exceptional taste masking and sugar free tablets for diabetic patients. The technologies used for manufacturing of MDTs broadly classified in two category one is patented and other one is non-patented technologies.

Lyophilization or freeze-drying

The formation of porous product in freeze-drying process is exploited in formulating MDTs. Lyophilization is a process, which includes the removal of solvent from a frozen suspension or solution of drug with structure-forming additives. Freeze-drying of drug along with additives imparts glossy amorphous structure resulting in highly porous and lightweight product. The resulting tablet has quick disintegration and dissolution when placed on the tongue and the freeze-dried unit dissolves instantly to release the drug. Though, the MDTs formed by lyophilization have low mechanical strength, poor stability at higher temperature, and humidity. (15)

Molding

In this method, the molded tablets are prepared by using water-soluble ingredients so the tablets dissolve completely and rapidly. The powder blend is moistened with a hydroalcoholic solvent and is molded into tablets under pressure lesser than that used in conventional tablet compression. The solvent is then removed by air-drying .Molded tablets are very less compact than compressed tablets. These posses porous structure that increase dissolution.(38)

Cotton candy process

This process is thus named as it utilizes a sole spinning mechanism to produce floss-like crystalline structure, which mimic cotton candy. Cotton candy process involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially re-crystallized to have improved flow properties and compressibility. This candy floss matrix is then milled and blended with active ingredients and excipients and subsequently compressed to MDTs. (29)

Spray drying

This technology produces extremely porous and fine powders as the processing solvent is evaporated during the process. (5) By this method to prepare MDTs hydrolyzed and nonhydrolyzed gelatin were used as supporting matrix, mannitol as bulking agent and sodium starch glycolate or crosscarmellose sodium as superdisintegrant. Disintegration and dissolution were further increased by adding acidic substances like citric acid or alkali substance like sodium bicarbonate. This formulation technique gives porous powder and disintegration time < 20 sec. (3,4)

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 tablets 14.

Melt granulation

By this process, MDTs can be prepared by incorporating a hydrophilic waxy binder (super polystate) PEG-6-stearate. Super polystate is a waxy material with an m. pt. of 33- 37°C and a hydrophilic-lipophilic balance of 9. It not only acts as a binder and increases the physical resistance of tablets, but also helps in the disintegration of tablets as it melts in the mouth and solubilizes rapidly leaving no residue. Super polystate was incorporated in the formulation of MDTs by melt granulation method where granules are formed by the molten form of this material. (1)

Phase transition process

In this processes for the disintegration of MDTs by phase transition of sugar alcohols using erythritol (m. pt. 122°C), xylitol (m. pt. 93-95°C), trehalose (97°C), and mannitol (166°C). Tablets were produced by compressing a powder having two sugar alcohols with high and low melting points and subsequent heating at a temperature between their melting points. Before heating process, the tablets do not have enough hardness because of low compatibility. The tablet hardness was increased after heating process, due to the increase of inter particle bonds or the bonding surface area in tablets induced by phase transition of lower melting point sugar alcohol. (38)

Sublimation

The existence of a highly porous structure in the tablet matrix is the key thing for rapid disintegration of MDTs. Even though the conventional tablets contain highly water- soluble ingredients, they often fail to disintegrate rapidly because of low porosity. To improve the porosity, volatile substances such as camphor can be used in tableting process, which sublimated from the formed tablet. Developed MDTs utilizing camphor, a subliming material that is removed from compressed tablets prepared using a mixture of mannitol and camphor. Camphor was sublimated in vacuum at 80°C for 30 min after preparation of

tablets.(21)

Direct compression methods

This technique is simple way to formulate MDTs since limited number of processing steps, low manufacturing cost and also accommodate high dose the final weight of tablet can easily exceed that of other production technique. The disintegration and dissolution of directly compressed tablets depends on single or joint effect of disintegrant, water soluble excipients and effervescing agents. Disintegrant efficacy is strongly affected by tablet size and hardness. Disintegration properties be able to be optimized by medium or low tablet size, low hardness and low physical resistance. It is essential to choose a suitable and an optimum concentration of disintegrant to ensure fast disintegration and high dissolution rates.(33, 28).

The adding up of water soluble excipients or effervescent agent can additional increase dissolution or disintegration properties. Super disintegrants provide fast disintegration due to combine effect of swelling and water absorption. As an result of swelling of super disintegrant the wetted surface of the carrier enlarge, which promotes wettability and dispersibility of the system and thereby increase the disintegration and dissolution. (8, 20, 17). The best concentration of superdisintegrant can be chosen according to critical concentration of disintegrant. Under this concentration the tablet disintegration time is inversely proportional to the concentration of superdisintegrant, where as if concentration of superdisintegrants incorporated in tablet is above the critical concentration, the disintegration time remains approximately constant or even increases.

Patented technologies for fast dissolving tablets: Zydis technology

Zydis formulation is a exclusive freeze dried tablet in which drug is physically entrapped or dissolved inside the matrix of fast dissolving carrier material. When zydis units are put into the mouth, the freeze-dried structure disintegrates instantaneously and does not need water to aid swallowing. The zydis matrix is composed of numerous material designed to achieve a number of objectives. To impart strength and resilience during handling, polymers such as gelatin, dextran or alginates are incorporated. These form a shiny amorphous structure, which imparts strength. To attain 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 quick 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.

Durasolv technology

Durasolv is the one of 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 tabletting equipment and have good rigidity. These be able to be packaged into conventional packaging system like blisters. Durasolv is an suitable technology for product requiring low amounts of active ingredients.

Orasolv technology

CIMA labs developed Orasolv Technology. In this system active medicament is taste masked. It also hold 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 create the tablets. The tablets produced are soft and friable.

Flash dose technology

Flash dose technology was patented by fuisz. Nurofen meltlet, a novel 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 binding shear form matrix termed as “floss”. Shear form matrices are prepared by flash heat processing.

Wow tab technology

Wow tab technology has patented by Yamanouchi Pharmaceutical Co. WOW means “Without Water”. In this development, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a quickly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide (e.g. lactose, glucose, and mannitol) and granulated with a high mouldability saccharide (e.g. Maltose, oligosaccharides) and compressed into table.

Flash tab technology

Prographarm laboratories have patented the Flash tab 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 spheronisation. All the processing utilized conventional tabletting technology.

Evaluation of the mouth dissolving tablet

MDTs formulations have to be evaluated for the following evaluation test parameters.

Organoleptic properties

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

Tablet thickness

Tablet thickness is a very important characteristic in reproducing appearance and also in including 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.

Uniformity of weight

I.P. procedure for homogeny 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 group weight. The weight variation test would be a satisfactory method of determining the drug content uniformity.

Average weight of Tablet (mg)	Permissible difference (%)
130 or less	10
130-324	7.5
More than 324	5

Tablet hardness

A important strength of ODT is hard to achieve due to the specialized processes and ingredients used in the manufacturing. The boundary of hardness for the ODT is usually kept in a lower range to facilitate early disintegration in the mouth. The hardness of the tablet may be measured using conventional hardness testers. 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

To achieve % friability inside limits for an ODT is a challenge for a formulator since all methods of manufacturing of ODT are responsible for rising the % friability values. Thus, it is necessary that this parameter should be evaluated and the results are within bound limits (0.1-0.9%) It is measured of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. A pre weighed 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;

$$\%\text{Friability} = \text{loss in weight} / \text{Initial weight} \times 100$$

In-Vivo Disintegration test

The test was carried out on 6 tablets using the apparatus particular in I.P.-1996 distilled water at 37°C ± 2°C was used as a disintegration media and the time in second is taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds.

Wetting time

The method reported by Yunixia et al., was followed to evaluate 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. 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.

In vitro dispersion time: (2,24, 34)

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 is taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds. 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.

Dissolution test

Usually the drugs those may have dissolution conditions as in USP monograph. Other media such as 0.1 N Hcl, pH 4.5 and pH 6.8 buffers should be used for evaluation of ODT in the same way as their ordinary tablet counterparts. Experience has indicated that USP 2 paddle apparatus is most suitable and common choice for dissolution test of ODT tablets, where a paddle speed of 50 rpm is commonly used. Typically the dissolution of ODTs is extremely fast when using USP monograph conditions. Hence slower paddle speeds may be utilized to obtain a comparative profile. Large tablets approaching or exceeding one gram and containing relatively dense particles may produce a mound in the dissolution vessel, which can be prevented by using higher paddle speeds. These two situations expand the suitable range of stirring to 25-75 rpm. (19)

CONCLUSIONS

The MDTs contain potential advantages above conventional dosage forms, by means of their better patient compliance, convenience, bioavailability and fast onset of action had drawn the notice of many manufactures over a decade. MDTs formulations obtained by some of these technologies have sufficient mechanical strength, quick disintegration/dissolution in the mouth without water. These MDTs can be used without difficulty in children who have vanished their primary teeth and in geriatric patients who have lost their teeth permanently. They remain solid during storage, which aid in stability of dosage forms and transform into liquid form within few seconds after its administration. As they contain important advantages as both solid and liquid dosage forms, MDTs may be developed for most of the available drugs in near future.

FDTs are the dosage forms which are formulated to dissolve/disintegrate quickly in the saliva usually within few seconds. FDTs offer bunch of advantages over conventional dosage forms such as improved efficacy, bioavailability, rapid onset of action, better patient compliance. Particularly FDTs provide more comfort to pediatric and geriatric patients. FDTs can be prepared by several methods based on the drug and additives used. Typically FDTs possess fewer mechanical strength. But by applying some new technologies and additives FDTs with sufficient mechanical strength can be prepared. (32)

For maximize pore structure an essential fundamental used in the development of the fast-dissolving tablet. Vacuum drying and freeze-drying techniques have been tried by researchers to maximize the pore structure of tablet matrix. Freeze drying is unwieldy and yields a fragile and hygroscopic product. Therefore, a vacuum-drying technique was adopted in the present investigation subsequent to addition of a subliming agent to increase porosity of the tablets. Even bitter drugs can be incorporated in FDTs by using taste masking agents. The research for FDTs is still going on. FDTs offer wide marketing also which makes the dosage form successful in the market. Many drugs will be formulated as FDTs in future for its market potential.(35)

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