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(REVIEW ARTICLE)

Fast dissolving tablet: An updated review

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Abstract

Improved patient management and patient tracking are essential to the development of an oral drug delivery system that remains a popular drug delivery route despite various maladies. Fast-dispersing pills (FDTs) have found growing demand over the past decade, and the field has become a fast-growing area in the pharmaceutical industry. The popularity and usefulness of the construction has led to the development of many FDT technologies. These are ways to make the tablet dissolve faster and spill in the mouth for five seconds without chewing and the need for beneficial water especially for children, the elderly and patients with difficulty swallowing pills and pills. The development of a simple dose form, taking into account the difficulty of swallowing and the adherence of the patient, leads to the formation of oral contraceptive pills. Typical methods for spray drying, ice drying, direct mixing, molding, and sublimation while new technologies have been developed to produce orodispersible tablets.

Keywords: Fast dissolving tablets; Freeze drying; Spray drying; Taste masking

1. Introduction

Despite the amazing development of drug delivery, oral route remains the preferred method of treating medical agents due to accurate dosage, inexpensive treatment, self-medication, unusual approach and ease of administration leading to a high level of patient compliance. . Pediatric patients may suffer from seizure due to musculoskeletal disorders. In addition, patients with little or no fluid, reduce the use of contraceptives or pills [1-3].

Extensive drug research is focused on creating new dosage forms. Many of these efforts have focused on developing new drug delivery systems or on increasing patient compliance. The fast translator tablet (FDT) is a very popular commercial product. Oral drug delivery is the most popular and acceptable form of patient use. The most popular form of dosage pills and pills, the main disadvantage of these methods of measuring swallowing weight. Dysphagia is also associated with a wide range of health conditions, including stroke, Parkinson's disease, AIDS, radiation treatment of the head and neck and other neurological disorders, including cerebral palsy. A fast-acting tablet has major benefits such as no need for water treatment, early onset of action, reducing the risk of constipation, preventing hepatic first pass metabolism [4]. A skilled secretion system is needed to hide this bitterness as a form of implantation. Complex, polymer coating, resin frame [5-6].

Remember the benefits of the "oral zone", Disposable Oral Tablets, known as Disperse Tablets, just widely accepted forms. According to the European Pharmacopoeia "ODT (Oral Dispersible Tablet) should be dispersed or dispersed in less than 3 minutes if placed on the tongue". The Immediate Drug Delivery System (FDDDS) is a new concept that combines the advantages of liquid and solid formulas and, at the same time, offers advantages over traditional dosage forms [7-10]. The benefits of the immediate elimination pills are improving patient compliance, faster onset of action,

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greater bioavailability and better stability that make these pills popular as the standard of choice in the current market [11-13]. This review has provided a brief overview of the fast-depleting tablet (FDT).

2. Criteria for Fast dissolving Drug Delivery System

- The tablets should not require water to swallow, but it should dissolve or disintegrate in the mouth as it comes in contact with saliva in seconds.
- Be compatible with taste masking.
- Be portable without fragility concern.
- Have a pleasant mouth feel.
- Leave minimum or no residue in the mouth after oral administration.
- Exhibit low sensitive to environmental condition as temperature and humidity.

2.1. Salient Feature of Fast Dissolving Drug Delivery System

- 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 & psychiatric patients.
- No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
- Rapid dissolution and absorption of the drug, which will produce quick onset of action.
- Some 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 can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
- The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
- New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra-rapid onset of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- 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.

2.2. Benefits of fast dissolving tablets

- Administered without 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.
- Beneficial in cases such as motion sickness, suede episodes of allergic attack or coughing, where an ultra-rapid onset of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
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2.3. Limitations of Mouth Dissolving Tablets

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

3. Technologies used for manufacturing of MDTs

In the recent 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 another one is nonpatented technologies.

3.1. Lyophilization or Freeze-drying

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 Rapid disintegration and dissolution when placed on the tongue and the freeze-dried unit dissolves instantly to release the drug. However, the MDTs formed by lyophilization have low mechanical strength, poor stability at higher temperature, and humidity [8].

3.2. Molding

In this method, molded tablets are prepared by using water-soluble ingredients so that the tablets dissolve completely and rapidly. The powder blend is moistened with a hydro alcoholic solvent and is molded into tablets under pressure lower than that used in conventional tablet compression. The solvent is then removed by air-drying. Molded tablets are very less compact than compressed tablets. These possess porous structure that increase dissolution [9].

3.3. Cotton candy process

This process is so named as it utilizes a unique spinning mechanism to produce floss-like crystalline structure, which mimic cotton candy. Cotton candy process [10] 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.

3.4. Spray drying

This technology produces highly porous and fine powders as the processing solvent is evaporated during the process [11]. In 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 [12-13].

3.5. 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].

3.6. Melt granulation

In 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 [15].

3.7. Phase transition process

Kuno et. al., [16] investigated 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 containing 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 sufficient 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.

3.8. Sublimation

The presence of a highly porous structure in the tablet matrix is the key factor 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 [17]. 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.

3.9. Direct compression methods

This technique is easy 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 method [18]. The disintegration and dissolution of directly compressed tablets depends on single or combined effect of disintegrants, water soluble excipients and effervescing agents. Disintegrants efficacy is strongly affected by tablet size and hardness. Disintegration properties can 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 disintegrants to ensure fast disintegration and high dissolution rates [19]. The addition of water soluble excipients or effervescent agent can further increase dissolution or disintegration properties. Super disintegrants provide fast disintegration due to combine effect of swelling and water absorption.

As an effect of swelling of super disintegrants the wetted surface of the carrier increase, which promotes wettability and dispersibility of the system and thereby increase the disintegration and dissolution [20-22]. The optimum concentration of superdisintegrant can be selected according to critical concentration of disintegrants. Below this concentration the tablet disintegration time is inversely proportional to the concentration of superdisintegrant, where as if concentration of superdisintegrant incorporated in tablet is above the critical concentration, the disintegration time remains approximately constant or even increases [23].

4. Patented Technologies for Fast Dissolving Tablets

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 [24]. 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, 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 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 [25].

4.1. 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 tabletting 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 [26].

4.2. 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 [27].

4.3. 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-binding shear form matrix termed as "floss". Shear form matrices are prepared by flash heat processing [28].

4.4. Wow tab Technology

Wow tab technology is 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 (e.g. lactose, glucose, and mannitol) and granulated with a high mouldability saccharide (e.g. Maltose, oligosaccharides) and compressed into table [29].

4.5. 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 tableting technology [30].

5. Evaluation of mouth dissolving tablet

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

5.1. Size and Shape

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

5.2. Tablet thickness

Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets were taken and their thickness was recorded using micrometer [31].

5.3. Uniformity of weight

I.P. procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. 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 [32].

5.4. Tablet hardness

Hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. 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 [33].

5.5. Friability

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 [34]. 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;

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

5.6. *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 is taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds [35].

5.7. 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 [36].

5.8. *In vitro* dispersion time

In vitro dispersion time was measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH 6.8. Three tablets from each formulation were randomly selected and in vitro dispersion time was performed [37].

6. Conclusion

The MDTs have potential advantages over conventional dosage forms, with their improved patient compliance, convenience, bioavailability and rapid onset of action had drawn the attention of many manufactures over a decade [38] 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 easily in children who have lost their primary teeth and in geriatric patients who have lost their teeth permanently [39] 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 have significant advantages as both solid and liquid dosage forms, MDTs may be developed for most of the available drugs in near future [40].

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare no conflicts of interest, financial or otherwise.

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