Fast Dissolving Tablets

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ABSTRACT: Fast-dissolving tablets are designed to rapidly disintegrate or dissolve in the saliva without the need for water. Some of these tablets dissolve almost instantly, in just a few seconds, while others, known as fast-disintegrating tablets, may take up to a minute to completely break down in the mouth. These formulations are particularly beneficial in situations where oral administration is preferred, as they are convenient, safe, and economical, leading to better patient compliance.
The ability to dissolve or disintegrate in the mouth without the need for water makes these tablets ideal for patients who may have difficulty swallowing conventional oral dosage forms. This includes young children, the elderly, bedridden individuals, or those with conditions such as dysphagia, hand tremors, or impaired motor skills. Additionally, people who are mentally ill, developmentally disabled, or uncooperative, as well as patients on restricted liquid diets or experiencing nausea, can also benefit from these formulations.

Fast-dissolving tablets are especially helpful for individuals who are active, traveling, or in situations where water may not be readily available, such as during motion sickness, allergic attacks, or coughing. Moreover, these tablets offer an opportunity for pharmaceutical companies to expand their product lines to meet the needs of a variety of patient groups who require an easier, more accessible means of medication administration.

INTRODUCTION

Oral drug administration is widely accepted, accounting for 50-60% of total dosage forms. Solid dosage forms, such as tablets and capsules, are especially popular due to their ease of administration, accurate dosing, suitability for self-medication, pain-free intake, and, most importantly, high patient compliance. However, a significant drawback for some patients is the difficulty in swallowing these dosage forms. Drinking water is essential for swallowing oral medications, and many people experience discomfort when trying to swallow conventional dosage forms like tablets, especially when water is not available or in conditions such as motion sickness (kinetosis) and sudden episodes of coughing associated with colds, allergies, or bronchitis. To address these challenges, fast-dissolving tablets (FDTs), also known as mouth-dissolving tablets, melt-in-mouth tablets, or orodispersible tablets, have gained considerable attention. These tablets are designed to dissolve or disintegrate rapidly upon contact with saliva, allowing the drug to be released almost instantly. The faster a drug dissolves, the quicker it is absorbed, leading to a faster onset of clinical effects. Some drugs can even be absorbed directly from the mouth, pharynx, and esophagus, enhancing bioavailability compared to conventional tablets.

The advantages of mouth-dissolving tablets are increasingly recognized in both the pharmaceutical industry and academia. Their significance was highlighted when the European Pharmacopoeia adopted the term "Orodispersible tablet" to describe tablets that rapidly disperse in the mouth before swallowing, typically within three minutes. To achieve this rapid disintegration, fast-dissolving tablets often incorporate superdisintegrants such as crosslinked carboxymethyl cellulose (croscarmellose), sodium starch glycolate (primogel, explotab), or polyvinylpyrrolidone (polyplasdone), which facilitate immediate disintegration upon placing the tablet on the tongue, thereby releasing the drug into the saliva. This not only increases the bioavailability of certain drugs but also reduces the amount of the drug exposed to first-pass metabolism compared to conventional tablets. Technologies used in the manufacture of fast-dissolving tablets include freeze-drying, spray-drying, tablet molding, sublimation, and the use of sugar-based excipients, in addition to compression and disintegration techniques. As life expectancy continues to rise, the elderly population represents a significant and growing portion of the global population. With aging, individuals often experience a decline in their physiological and physical abilities, making fast-dissolving tablets an increasingly important option for improving drug administration in this demographic.

CRITERIA FOR FAST DISSOLVING DRUG DELIVERY SYSTEM:

The tablets should:

- Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of 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.
- Allow the manufacture of the tablet using conventional processing and packaging equipments at low cost.

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 Un-Cooperative, 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 On Set 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.

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.

EXISTING TECHNIQUES FOR PREPARING FAST DISOLVING TABLETS

Many techniques have been reported for the formulation of Fast dissolving tablets or Orodispersible tablets.

1. Freeze drying / lyophilization
2. Tablet Moulding
3. Spray drying

1. Freeze-Drying or Lyophilization:

Freeze drying is the process in which water is sublimed from the product after it is frozen. This technique creates an amorphous porous structure that can dissolve rapidly. A typical procedure involved in the manufacturing of ODT using this technique is mentioned here. The active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer. The mixture is done by weight and poured in the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion. Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze-drying. After freeze-drying the aluminum foil backing is applied on a blister-sealing machine. Finally the blisters are packaged and shipped. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability. The major disadvantages of lyophillization technique are that it is expensive and time consuming; fragility makes conventional packaging unsuitable for these products and poor stability under stressed conditions.

2. Tablet Molding:

Molding process is of two types i.e. solvent method and 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 (compression molding). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and posses a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30°C

under vacuum. The mechanical strength of molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology.

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

3. Spray Drying :

In this technique, gelatin can be used as a supporting agent and as a matrix, mannitol as a bulking agent and sodium starch glycolate or crosscarmellose or crospovidone are used as superdisintegrants. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. The formulation contained bulking agent like mannitol and lactose, a superdisintegrant like sodium starch glycolate & 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.

IMPORTANT PATENTED TECHNOLOGIES FOR FAST DISSOLVING TABLETS

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.

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.

3. 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 (eg. lactose, glucose, and mannitol) and granulatedwith a high mouldability saccharide (eg. Maltose, oligosaccharides) and compressed into table

PREFORMULATION STUDIES FAST DISSOLVING TABLET

Preformulation study relates to pharmaceutical and analytical investigation carried out proceeding and supporting formulation development efforts of the dosage form of the drug substance. Preformulation yields basic knowledge necessary to develop suitable formulation for the toxicological use. It gives information needed to define the nature of the drug substance and provide frame work for the drug combination with pharmaceutical excipients in the dosage form. Hence, the following preformulation studies were performed on the obtained sample of drug.

1. Bulk Density (Db):

It is the ratio of total mass of powder to the bulk volume of powder. It was measured by pouring the weight powder (passed through standard sieve # 20) into a measuring cylinder and initial weight was noted. This initial volume is called the bulk volume. From this the bulk density is calculated according to the formula mentioned below. It is expressed in g/ml and is given by

$$D_b = M / V_b$$

Where, M is the mass of powder

V_b is the bulk volume of the powder.

2. Tapped Density (Dt):

It is the ratio of total mass of the powder to the tapped volume of the powder. Volume was measured by tapping the powder for 750 times and the tapped volume was noted if the difference

between these two volumes is less than 2%. If it is more than 2%, tapping is continued for 1250 times and tapped volume was noted. Tapping was continued until the difference between successive volumes is less than 2 % (in a bulk density apparatus). It is expressed in g/ml and is given by

$$D_t = M / V_t$$

Where, M is the mass of powder

V_t is the tapped volume of the powder.

3. Angle of Repose (θ):

The friction forces in a loose powder can be measured by the angle of repose (θ). It is an indicative of the flow properties of the powder.

It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane

$$\tan(\theta) = h / r$$

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

Where, θ is angle of repose

h is height in cms

r is radius in cms

The powder mixture was allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of powder formed. Care was taken to see that the powder particles slip and roll over each other through the sides of the funnel. Relationship between angle of repose and powder flow property.

Angle of Repose as an Indication of Powder Flow Properties

Sr. No.	Angle of Repose (°)	Type of Flow
1	< 20	Excellent
2	20 – 30	Good
3	30 – 34	Passable
4	> 34	Very Poor

4. Carr's index (or) % compressibility:

It indicates powder flow properties. It is expressed in percentage and is give

$$I = \frac{D_t - D_b}{D_t} \times 100$$

Where,

D_t is the tapped density of the powder

D_b is the bulk density of the powder.

Relationship between % compressibility and flow ability

% Compressibility	Flow ability
5 – 12	Excellent
12 – 16	Good
18 – 21	Fair Passable
23 – 35	Poor
33 – 38	Very Poor
< 40	Very Very Poor

5. Friability (F):

Friability of the tablet determined using Roche friabilator. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at I height of 6 inches in each revolution. Preweighted sample of tablets was placed in the friabilator and were subjected to the 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F) is given by the formula.

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

IN-VITRO DRUG RELEASE:

Release of the drug *in vitro*, was determined by estimating the dissolution profile.

1. Crushing Strength:

It is the force required to break a tablet by compression in the radial direction, it is an important parameter in formulation of mouth dissolve tablets because excessive crushing strength significantly reduces the disintegration time.

In the present study the crushing strength of the tablet was measured using Pfizer hardness testers. An average of three observations is reported.

2. Friability testing:

The crushing test may not be the best measure of potential behavior during handling and packaging. The resistance to surface abrasion may be a more relevant parameter. Friability of each batch was measure in “Electro lab friabilator”. Ten preweighed tablets were rotated at 25 rpm for 4 min, the tablets were then re weighed and the percentage of weight loss was calculated.

3. Modified disintegration test:

The standard procedure of performing disintegration test for these dosage forms has several limitations and they do not suffice the measurement of very short disintegration times. The disintegration time for ODT needs to be modified as disintegration is required without water, thus the test should mimic disintegration in salivary contents. For this purpose, a petridish (10 cm diameter) was filled with 10 ml of water. The tablet was carefully put in the center of petridish and the time for the tablet to completely disintegrate into fine particles was noted.

4. 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,

$$R=10(wa/wb)$$

where,

Wb is weight of tablet before water absorption

wa is weight of tablet after water absorption.

IN-VITRO DISPERSION TIME-

Tablet was added to 10 ml of phosphate buffer solution, ph 6.8 at 37+0.5ºc, Time required for complete dispersion of a Tablet was measured.

CONCLUSION

The development of a novel, cost-effective one-step Fast Dissolving Drug Tablet (FDDT) manufacturing process using conventional tabletting technology aims to produce robust tablets suitable for standard packaging. This proprietary technology can be applied to a wide range of therapeutic agents, including generics, creating value through "supergenerics" for both human and veterinary applications. The market segment for these products offers significant potential for new and enhanced oral therapies.

Swallowing difficulties affect approximately one-third of the population, especially in geriatric and pediatric groups, leading to poor compliance with oral tablet medication and, consequently, reduced therapy effectiveness. To address this, fast-dissolving tablets (FDDTs) have been developed, offering a convenient and easy-to-dose alternative that does not require water. These tablets are designed to dissolve or disintegrate rapidly in the saliva, typically within 5 to 60 seconds.

However, current FDDT technologies face limitations in terms of mechanical strength, making handling and packaging challenging, and production costs remain higher compared to conventional tablets. There is a clear need for improved manufacturing processes that create fast-dissolving tablets that are both strong and cost-effective, comparable to traditional tablet production. This would fulfill a critical medical need, particularly for drugs used by populations with difficulty swallowing.

The development of fast-dissolving tablets also offers the opportunity for market expansion. Many drugs, including neuroleptics, cardiovascular drugs, analgesics, antihistamines, and erectile dysfunction treatments, could benefit from this new dosage form. Moreover, as patents for certain drugs near expiration, pharmaceutical companies often look to reformulate them into more convenient dosage forms, like fast-dissolving tablets. This allows for extended market exclusivity, providing manufacturers with a competitive advantage while also offering improved options for patients. Despite the higher production cost of these specialized tablets, the price to the consumer remains comparable to traditional tablets.

REFERENCES

[1]. Lailla, J.K., Sharma, A.H., Freeze-drying and its applications, Indian Drugs, 1993, 31, 503-513.

[2]. Seager, H., Drug delivery products and zydis fast dissolving dosage form, J. Pharm. Phamacol., 1998, 50, 375-382.

[3]. Renon, J.P., Corveleyn, S., Freeze-dried

rapidly disintegrating tablets, US Patent No. 6,010,719, 2000.

[4]. Masaki, K., Intrabuccaly disintegrating preparation and production there of, US Patent No.5,466,464, 1995.

[5]. Pebley, W.S., Jager, N.E., Thompson, S.J., Rapidly disintegrating tablets, US Patent No. 5,298,261, 1994.

[6]. Allen, L.V, Wang, B., Method of making a rapidly dissolving tablet. US Patent No. 5,635,210, 1997.

[7]. Bhupendra GP, Satish NP. Formulation, evaluation and optimization of orally disintegrating tablet of cinnarizine. J Sci Technol. 2010;5:9–21. [Google Scholar]

[8]. Reynolds JE, editor. 31st ed. London: Pharmaceutical Press; 1996. Martindale: The Extra Pharmacopoeia; p. 406. [Google Scholar]

[9]. Chang RK, Guo X, Burnside BA, Couch RA. Fast dissolving tablets. Pharm Tech. 2000;24:52. [Google Scholar]

[10]. 14th ed. New Delhi: The controller of publications; 1996. Indian Pharmacopoeia, Ministry of Health and Family Welfare, Govt. of India; p. A-54. [Google Scholar]

[11]. Lachman L, Lieberman A, Kinig JL. 4th ed. Bombay: Varghese Publishing House; 1991. The Theory and Practice of Industrial Pharmacy; pp. 67–8. [Google Scholar].