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A REVIEW ON FAST DISSOLVING TABLET

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Abstract: Oral drug delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, most convenient and most economical method of drug delivery having the highest patient compliance. Fast dissolving tablets (FDTs) have received ever-increasing demand during the last decade, and the field has become a rapidly growing area in the pharmaceutical industry. Fast dissolving tablets are solid dosage forms containing drugs that disintegrate in the oral cavity within less than one minute leaving an easy-to-swallow residue. These dosage forms are placed in the mouth, allowed to disperse or dissolve in the saliva. The release the drug as soon as they come in contact with the saliva, thus obviating the need for water during administration.

Keywords: Fast dissolving tablets, Superdisintegrants, Patient compliance.



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INTRODUCTION

The oral route of administration is considered as the most widely accepted route because of its convenience of self-medication, accurate dose, safest and economical route. Approximately one-third of the population, primarily the geriatric and pediatric population, has swallowing difficulties, resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness.

This problem led to the development of novel type of dosage form known as fast dissolving tablet, which rapidly disintegrate and dissolve in saliva. Fast dissolving tablets are ideal for all types of people, including the people who have swallowing difficulties (dysphasia), pediatric, geriatrics and bedridden patients. It also use for active patients who are busy, travelling and may not have access water. Fast dissolving tablets are novel drug delivery system that dissolve or disintegrates in saliva within few seconds with or without intake of water. The faster the drug dissolve into solution, quicker the absorption and onset of clinical effect. 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.

Fast dissolving drug delivery systems were initially developed in the late 1970s as an alternative to tablets, capsules and syrups for pediatrics and geriatrics patients who experience difficulties in swallowing traditional oral solid dosage forms.

FDTs: DEFINITION:

Fast Dissolving Tablet (FDT) is defined as "A solid dosage form containing medicinal substance, which disintegrates rapidly, usually within matter of seconds, when placed upon the tongue". The disintegration time for fast dissolving tablets varies from a few seconds to more than a minute depending on the formulation and the size of the tablet.

Advantages of fast dissolving tablet

- **Accurate dosing:** Being unit solid dosage forms, provide accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients.
- **Enhanced bioavailability:** Bioavailability of drug can be enhanced due to absorption from mouth, pharynx and esophagus.
- **Rapid action:** Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity.

- **Patient compliance:** No need of water to swallow the dosage form. Hence, it is convenient for patient who are travelling and do not have immediate access to water.
- **Ease of administration:** Convenient to administer specially for geriatrics, pediatrics, mentally disabled and bed bidden patients who have immediate access to water.
- **Obstruction free:** No risk of suffocation in air ways due to physical obstruction when swallowed, thus providing improved safety and compliance.
- **Cost effective:** Conventional processing and packaging equipment allow the manufacturing of tablets at low cost.
- **Enhanced palatability:** Good mouth feel, especially for pediatric patients as taste masking technique is used to avoid the bitter taste of drug.
- **Simple packaging:** No specific packaging required. It can be packaged in push through blister.

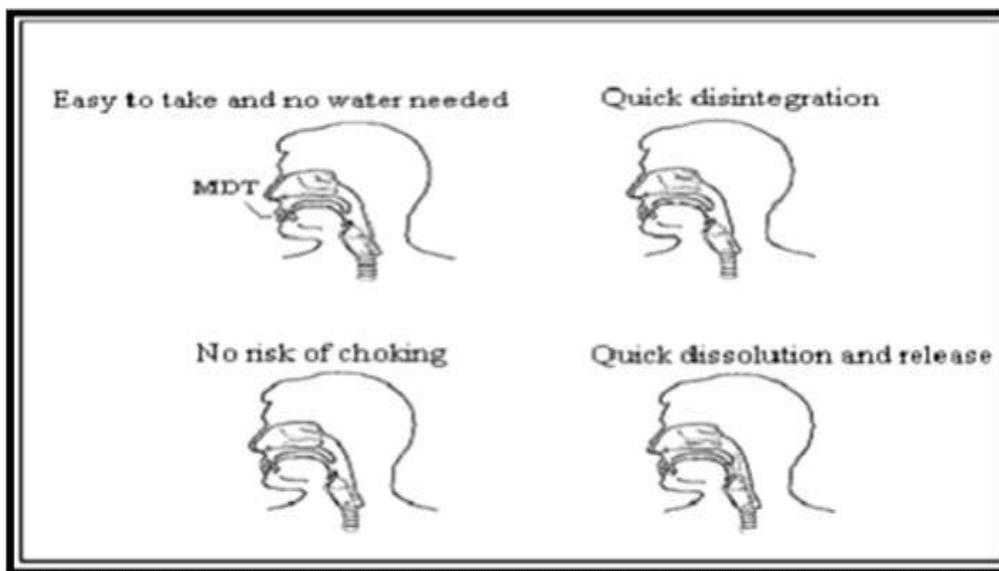


Fig. 1: Advantages of FDT

Ideal Characteristic of the drug for fast dissolving dosage form

- Ability to permeate the oral mucosa.
- Small to moderate molecular weight.
- Good stability in water and saliva.
- Partially unionizes at oral cavity pH.

- Dose should be low as possible.
- Poor solubility of drug suitable candidate for the proposed work.

Limitation

- Drugs with relatively larger doses are difficult to formulate into MDT e.g. antibiotics like amoxicillin with adult dose tablet containing about 500 mg of the drug.
- Patients who concurrently take anticholinergic medications may not be the best candidates for FDT.
- Similarly patients with Sjogren's syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.
- 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.

The need for development of fast dissolving tablet

Patient's factors: Fast dissolving dosage form is suitable for those patients (particularly pediatrics and geriatrics patients) who are not be able to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following:

- Patients in compliance due to fear of choking.
- Geriatrics patients mainly suffering from condition like hand tremors and dysphasia.
- Very elderly patients of depression who may not be able to swallow the solid dosage form.
- Travelling patients suffering from motion sickness and diarrhea because they do not have easy access to water.
- Pediatric patients who are unable to swallow easily because their nervous system and internal muscles are not completely developed.

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

Challenges for development of fast dissolving tablet

Mechanical strength : In order to allow FDTs to disintegrate in the oral cavity, they are made of either very porous and soft-molded matrices or compressed into tablets with very low compression force, which makes the tablet friable and brittle, difficult to handle and often requiring specialized peel-off blister packaging that may add to the cost.

Amount of drug: The application of technologies used for FDTs is limited by the amount of drug that can be incorporated into each unit dose.

Size of tablet: It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was larger than 8mm. Therefore, the tablet size that is both easy take and easy to handle is difficult to achieve.

Mouth feel: FDTs should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the FDTs should be as small as possible. Moreover addition of flavor and cooling agents like menthol improve the mouth feel.

Sensitivity to environmental conditions: FDTs should exhibit low environmental conditions such as humidity and temperature as most of the materials used in FDTs are meant to dissolve in minimum quantity of water.

Role of superdisintegrants

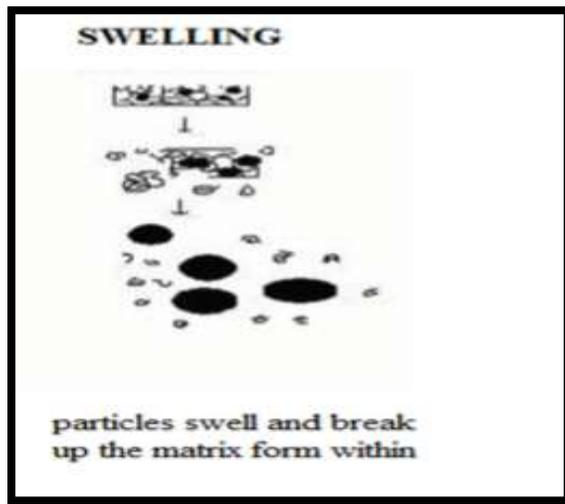
Superdisintegrants will promote the breakup of the tablet and capsule into smaller fragments in an aqueous environment to by promoting moisture penetration and dispersion of the tablet matrix. This will increase the surface area and promote a more rapid release of the active drug substance into saliva. Besides it interact strongly with water. They will enhance the disintegration process which the solid dosage forms will break in an aqueous environment and enhance the dissolution rate. Dissolution can cause the drug to be absorbed through the cell membranes into systemic circulation for therapeutic efficacy and enhance in bioavailability thereby enhance the therapeutic effectiveness. They are effective at low concentration and have greater disintegrating efficiency and mechanical strength.

Mechanism of Superdisintegrants

Swelling

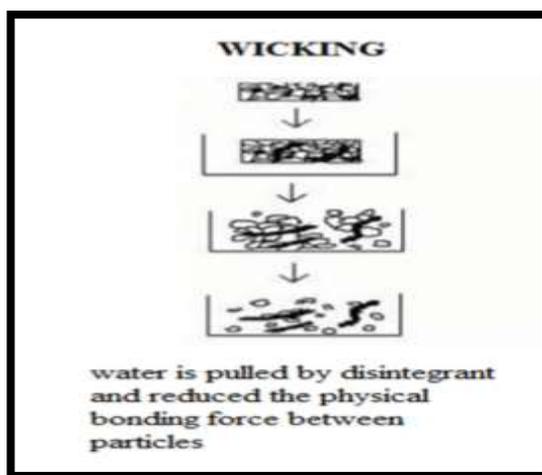
Perhaps the most widely accepted mechanism of action for tablet disintegration is swelling. Tablets with high porosity show poor disintegration due to lack of adequate swelling force. Sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that

if the packing fraction is very high, fluid is unable to penetrate in the tablet and disintegration is again slows down.



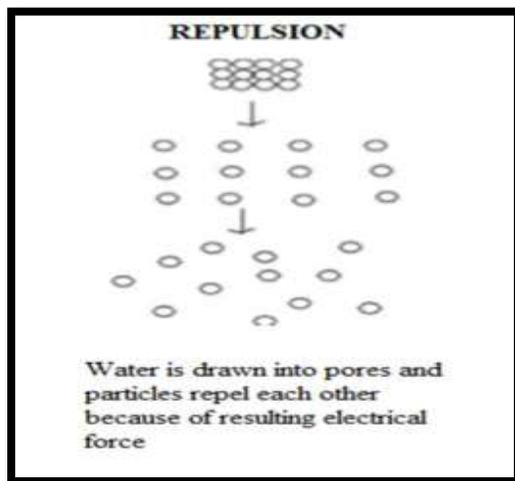
Porosity and capillary action (Wicking)

Disintegration by capillary action is always the first step. When we put the tablet into suitable aqueous medium, the medium penetrates into the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bond and breaks the tablet in to fine particles. Water uptake by tablet depends upon hydrophilicity of the and on tableting conditions. For these types of disintegrants maintenance of porous structure and low interfacial tension towards aqueous fluid is necessary which helps in disintegration by creating a hydrophilic network around the drug particle.



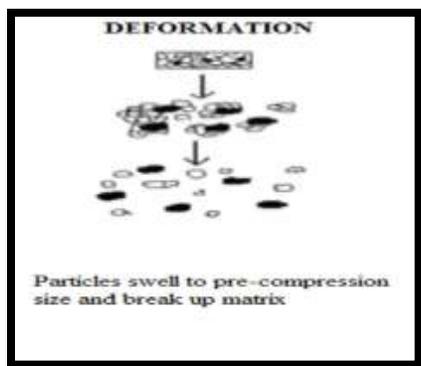
Due to disintegrating particle/particle repulsive forces

Another mechanism of disintegration attempts to explain the swelling of tablet made with 'nonswellable' disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that nonswelling particle also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it. Researchers found that repulsion is secondary to wicking.



Due to deformation

During tablet compression, disintegrant particles get deformed and these deformed particles get into their normal structure when they come in contact with aqueous media or water. Occasionally, the swelling capacity of starch was improved when granules were extensively deformed during compression. This increase in size of the deformed particles produces a breakup of the tablet. This may be a mechanism of starch and has only recently begun to be studied.



Techniques for preparing fast dissolving tablet Conventional technologies

- Freeze Drying or Lyophilization
- Sublimation
- Spray drying
- Melt Granulation
- Mass extrusion
- Tablet molding
- Direct compression method
- Nanonization
- Cotton candy process

Freeze Drying or Lyophilization

The drug is dissolved or dispersed in an aqueous solution of a carrier. The mixture is poured into the wells of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution. Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze-drying. Finally the blisters are packaged and shipped.

Sublimation

Inert solid ingredients that volatilize rapidly like urea, camphor, ammonium carbonate, ammonium bicarbonate, and hexamethylenetetramine were added to the other tablet ingredients and the mixture is compressed into tablets. The volatile materials were then removed via sublimation, which generates porous structure. Porous structure that enhances dissolution by using volatile material or solvent e.g. cyclohexane, benzene etc.

Spray-Drying

Spray drying technique produces highly porous and fine powders as the processing solvent is evaporated during this process. The formulations contained hydrolyzed and unhydrolyzed gelatin as a supporting agent for the matrix, mannitol as a bulking agent and sodium starch Glycolate/croscarmellose as a disintegrants. Disintegration and dissolution were further enhanced by adding an acid (e.g., citric acid) or an alkali (e.g., sodium bicarbonate). The

suspension of above excipients was spray-dried to yield a porous powder which was compressed into tablets.

Melt granulation

It prepared by incorporating a hydrophilic waxy binder (super polystate) PEG-6-stearate. Super polystate not only acts as binder and increase physical resistance of tablet but also helps the disintegration of tablet. It melts in the mouth and solubilizes rapidly leaving no residue.

Mass-Extrusion

In this technology the active blend is soften using the solvent mixture of water-soluble methanol and polyethylene glycol. Subsequent expulsion of softened mass through the extruder or syringe to get a cylinder product and is divided into even segments using heated blade to form tablet.

Tablet Moulding

Molding process is of two type's i.e. solvent method and heat method. The tablets manufactured by solvent method are less compact than compressed tablets and posses a porous structure that increase dissolution. The mechanical strength of moulded tablets is a matter of great concern. Binding agents, which improve the mechanical strength of the tablets, need to be incorporated. Tablets produced by the moulding technique are easy to scale up for industrial manufacturer, compared to the lyophilisation technique.

Direct Compression

In this method, tablets are compressed directly from the mixture of the drug and excipients without any preliminary treatment. It is most cost effective tablet manufacturing technique. The conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression.

Superdisintegrants: Superdisintegrants are the principally affecting disintegration and ultimately dissolution of the fast dissolving tab- lets, mainly for direct compression techniques. The presence of other ingredients such as water-soluble excipients and effervescent agents further hastens the disintegration process.

Sugar Based Excipients: This is another route to approach the direct compression technique. The use of sugar based excipients especially bulking agents like lactilol, dextrose, isomalt, fructose, maltitol, maltose, mannitol, sorbitol, polydextrose, xylitol, and starch hydrolysate which display high aqueous solubility and sweetness, and hence impart taste masking property

and a pleasant mouth feel. It have categorized sugar-based excipients into two types on the basis of molding and dissolution rate.

Type 1: saccharides (mannitol and lactose) exhibit low mould-ability but high dissolution rate.

Type 2: saccharides (maltitol and maltose) exhibit high mould-ability and low dissolution rate

Nanonization

It involves size reduction of drug to nanosize by milling the drug using a proprietary wet-milling technique. The nanocrystals of the drug are stabilized against agglomeration by surface adsorption on selected stabilizers, which are then incorporated into FDTs.

Cotton candy process

It involves the formation of matrix of polysaccharides by simultaneous action of flash melting and spinning. This candy floss matrix is then milled and blended with active ingredients and excipients after re-crystallization and subsequently compressed to FDT.

Patented technologies:

- Zydis technology
- Wowtab technology
- Orasolv technology
- Durasolv technology
- Flashdose technology
- Flashtab technology
- Oraquick technology
- Ziplets/Advatab technology
- Lyoc technology

Zydis technology

Zydis® was first marketed technology and introduced by R. P. Scherer Corporation (Cardinal Health, Inc.) in 1986. It is a unique freeze-dried oral solid dosage form, that can be administered without water and it dissolves instantly on tongue in less than 3 seconds.

Wowtab technology

Wowtab technology was developed and patented by Yamanouchi Pharma Technologies. 'Wow' means 'without water'. The active ingredients may constitute up to 50 % w/w of the tablet.

Orasolv technology

Orasolv® is Cima Lab's first orally disintegrating dosage form. This technology is based on the direct compression of effervescent agent and taste masked drug at low compression force in order to minimize oral disintegration and dissolution time.

Durasolv technology

Durasolv® is Cima's second-generation fast- dissolving/ disintegrating tablet formulation. Durasolv® has much higher mechanical strength than Orasolv due to the use of higher compaction pressures during tableting. Durasolv® product is thus produced in a faster and more cost-effective manner.

Flashdose technology

This technology is patented by Fuisz Technologies, Ltd. This technology utilized 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.

Flashtab technology

Flashtab technology was developed by Prographarm. A disintegrating agent and a swelling agent are used in combination with coated taste-masked microgranules of drug.

OraQuick technology

OraQuick utilizes its own patented taste masking technology i.e. MicroMask®. In MicroMask® technology, taste-making process is done by incorporating drug into matrix microsphere.

ZiPLETS/Advatab technology

In this technology, microencapsulation process is used for coating the drug particles with gastro soluble polymer to mask the taste along with restriction of drug dissolution in mouth cavity.

Lyoc Technology

Lyoc technique was owned by Cephalon Corporation. Lyoc utilizes a freeze-drying process but differ from Zydis in that the product is frozen on the freeze dryer shelves.

Ingredients used in fast dissolving tablet

Superdisintegrants: Super disintegrant provide quick disintegration due to combined effect of swelling and water absorption by the formulation.

Swelling Index = $[(\text{Final volume} - \text{Initial volume})/\text{initial volume}] \times 100$

Example: croscarmellose sodium, crospovidone, carmellose, carmellose calcium, sodium starch glycolate, ion exchange resins (e.g. Indion 414), etc. Sodium starch glycollate has good flowability than croscarmellose sodium. Cross povidone is fibrous nature and highly compactable.

Antistatic agent: An antistatic agent is a compound used for treatment of materials or their surfaces in order to reduce or eliminate buildup of static electricity generally caused by the triboelectric effect. Example: colloidal silica (Aerosil), precipitated silica (Sylod.FP244), talc, maltodextrins, beta-cyclodextrin etc.

Lubricants: Lubricants remove grittiness and assist in the drug transport mechanism from the mouth down into the stomach. Example: Magnesium stearate, stearic acid, leucine, sodium benzoate, talc, magnesium lauryl sulphate, liquid paraffin etc.

Flavours: Example: Peppermint flavour, clove oil, anise oil, eucalyptus oil. Flavoring agents include, vanilla, citrus oils, fruit essences etc.

Sweeteners: Example: Sorbitol, Mannitol, Maltitol solution, Maltitol, Xylitol, Erythritol, Sucrose, Fructose, Maltose, aspartame, sugars derivatives etc.

Fillers: Example: Directly compressible spray dried Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, pregelatinized starch, magnesium trisilicate, aluminium hydroxide etc.

Evaluation parameter for fast dissolving tablet

1. Pre-compression

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 Vb is the bulk volume of the powder.

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

$$Dt = M / Vt$$

Where, M is the mass of powder, Vt is the tapped volume of the powder.

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

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

Where, θ is the angle of repose. h is the height in cms. r is the 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.

Carr's index (or) % compressibility: It indicates powder flow properties.

$$I = (Dt - Db) / Dt * 100$$

Dt is the tapped density of the powder. Db is the bulk density of the powder.

Hausner ratio: Hausner ratio is an indirect index of ease of powder flow.

$$\text{Hausner ratio} = Dt / Db$$

Dt is the tapped density. Db is the bulk density.

Lower hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25).

2. Post-compression:

General Appearance:

The general appearance of a tablet, its visual identity and over all "elegance" is essential for consumer acceptance and tablet's size, shape, colour, presence or absence of an odour, taste, surface texture, physical flaws and consistency and legibility of any identifying marking.

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.

Weight variation:

20 tablets were selected randomly from the lot and weighted individually to check for weight variation.

Table: weight variation and accepted % deviation

Average Weight of Tablet	% Deviation
80 mg or less	10.0
More than 80 mg but less than 250 mg	7.5
250 mg or more	5.0

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 should be lesser than conventional tablet falling in the range of 3-4kg/cm². Hardness of the tablet of each formulation was determined using Monsanto Hardness tester.

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 height of 6 inches in each revolution. Pre -weighted sample of tablets was placed in

the friabilator and were subjected to the 100 revolutions. Friability should be within the range of 0.1-0.9%. The friability (F) is given by the formula.

$$\text{Friability} = (I.W - F.W)/I.W \times 100$$

Wetting Time:

Wetting time of dosage form is related to the contact angle. It needs to be assessed to give an insight into the disintegration properties of the tablets; a lower wetting time implies a quicker disintegration of the tablet. For this purpose, a tablet is placed on a piece of tissue paper folded twice and kept in a small Petri dish (ID = 6.5 cm) containing 6 ml of water, and the time for complete wetting is measured.

Water absorption Ratio:

A piece of tissue paper folded twice was placed in a small Petridish 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,

$$R = 10 (w_a/w_b).$$

Where, w_a is weight of tablet before water absorption & w_b is weight of tablet after water absorption.

Disintegration test:

The time for disintegration of FDTs is generally less than 1 min and actual disintegration time that patient can experience ranges from 5 to 30s. The disintegration test for FDT should mimic disintegration in mouth within saliva.

***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.

Stability testing of drug (temperature dependent stability studies):

The fast disintegrating tablets are packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines for accelerated studies.

(1) $40 \pm 1^\circ\text{C}$ (2) $50 \pm 1^\circ\text{C}$ (3) $37 \pm 1^\circ\text{C}$ 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 .

Conclusion

The main aim of fast dissolving tablets is to constitute an innovative dosage form, which overcomes the problem of swallowing and provides a quick onset of action. These dosage forms and their route of administration results in better efficacy, rapid onset of action, enhanced bioavailability, and improved patient compliance. This system allows easy self administration without the need of water to swallow. It has provided new area for research and development both for industries and academics.

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