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A Short Review on Mouth Dissolving Tablets

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Review Article

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ABSTRACT

The main aim of floating drug delivery system is to develop a new dosage form which is convenient in administration and manufacturing, should free from side effects and should exhibit immediate release with better patient compliance and enhanced bioavailability. Tablets are the most widely accepted dosage forms in oral drug delivery system due to its numerous advantages. But beside the advantages there a few disadvantages like sudden exposure of allergies, mental disability, motion sickness, unconsciousness, lack of water etc. In order to overcome such difficulties new drug delivery systems like fast dissolving tablets were developed. As this dosage form shows a very rapid rate of disintegration when they placed over the tongue without aid of water they became most popular and convenient dosage forms for geriatrics and paediatrics with improved patient compliance.

INTRODUCTION

Most commonly used conventional dosage forms are tablets and capsules. Compressed tablets are the most widely used dosage forms due to its numerous advantages. They are convenient, easy to administer, economic, tamper-proof, easy to packing and transport and more stable than other oral dosage forms [4]. Also tablets have certain special release profile products such as enteric or delayed release patterns.

Definition: Fast dissolving tablets FDT's are defined as solid unit dosage forms placed over the tongue and dispersed in saliva, releases the drug with a rapid disintegration rate which is intended for oral administration [2-5]. There are few medicines which are absorbed from the mouth, pharynx and oesophagus as they pass down in to the stomach. The main disadvantage with the traditional dosage forms is that they have to be administered with water. Geriatrics and pediatrics finds it difficult to swallow tablets. Due to this dysphagic condition, they do not comply with prescription resulting in patient non-compliance. Sudden attacks of allergic attacks, motion sickness, coughing and unavailability of water etc [6,7]. Are the other major causes for patient non-compliance? Such complications can be overcome by fast dissolving tablets.

"Fast Dissolving tablets" also referred as, 'Quick Dissolve', 'Rapid Melt', 'Quick Disintegrating', 'Mouth Dissolving', 'Orally Disintegrating', 'Oro Dispersible', 'Melt-in Mouth' etc. Recently Orally Disintegrating (OD) Tablet technology has been approved by United States Pharmacopoeia (USP), Centre for Drug Evaluation and Research (CDER). USFDA defined OD tablet as "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed over the tongue"[8-15]. Recently European Pharmacopoeia also adopted the term "Oro Dispersible tablet" as a tablet that disperses rapidly before swallowing when it is placed in the mouth. These dosage forms dissolve or disintegrate within 15 sec to 3 mins without the need of water. Despite various terminologies used, Oro Dispersible tablets are here to offer unique form of drug delivery with many advantages over the conventional oral solid dosage forms [16,18].

ADVANTAGES OF FAST MOUTH DISSOLVING TABLETS

Ease of swallowing

Dysphagic population constitute 35% of the general population, since this disorder is associated with a number of medical conditions such as Stroke, Parkinson's disease, AIDS, Head and Neck Radiation Therapy and other neurological disorders [19].

No water needed

These fast dissolve dosage forms don't require water for its administration unlike conventional dosage forms. This is very convenient for patients who are travelling.

Superior taste

Mostly fast dissolving dosage forms were coated with sweetening agent and a flavor.

Accurate dose

The fast dissolve dosage forms have the added advantages of convenience and accurate dosing as compared to liquids.

e) It shows pre-gastric absorption from the mouth, pharynx and esophagus hence it has a rapid rate of drug absorption.

f) Intervention in rapid drug therapy is possible.

g) New business opportunities like product differentiation, line extension and life cycle management, exclusivity of product promotion [20-27].

Table 1: Therapeutic applications of fast-dissolve dosage forms target population therapeutic areas.

Paediatric	Antibiotics
	Anti-asthmatics
	Cough/Cold/Allergy
	Anti-epileptics
	Analgesics/Anti pyretic
	Anti-depressants
Adult and Elderly	Parkinson's
	Anti-migraine
	Alzheimer's
	Anti-asthmatics
	Anti-emetics
	Cancer
	Diabetes
	AIDS
	Gastric Relief
	Psychotherapeutics
	Cardiovascular
	Cough/Cold/Allergy
	Analgesics /NSAIDs

IDEAL CHARACTERISTICS OF FAST DISSOLVING TABLETS

They should not require water for administration, yet dissolve or disintegrate in the mouth within a few seconds [28,29]

- Should compatible with sweetening agents for masking of taste
- Should have acceptable taste
- Should leave minimal residue in the mouth after its administration
- Should compatible for high drug loading
- Should withstand to humidity and temperature
- Manufacturing and packaging should be economic

To attain the tablet's fast dissolving character, water should quickly egress into the tablet matrix to cause rapid disintegration and instant dissolution of the tablet [30]. Increase in the porous structure of the tablet matrix and incorporating appropriate disintegrating agents or extremely water soluble agents in the tablet formulation are the fundamental approaches employed in current fast dissolving tablet technologies. Basically, the disintegrates major activity is to oppose the affectivity of the tablet binder and therefore the physical forces that act under compression to make the tablet [31]. The mechanism by which tablet disintegrates into smaller particles and then produces a homogeneous suspension or solution is based on:

- I) Capillary action
- II) High swell ability of disintegrates
- III) Capillary action and high swell ability
- IV) Chemical reaction (Release of Gases).

By capillary action

First step of disintegration is always done by capillary action. Once the tablet comes in contact with the aqueous medium it replaces the air adsorbed on the tablet by penetration of aqueous medium into the tablet. There by it weakens the intermolecular bonding and breaks the tablet into fine particles. Hydrophilicity of the drug /excipient decides the water uptake by the tablet [32]. For these types of disintegrates 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 particles.

By swelling

Disintegration of tablets can be achieved by swelling mechanism. Tablets show poor disintegration with less swelling force and high porosity. On the other hand, sufficient swelling force is exerted in the tablet with low porosity [33-39]. 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.

Because of heat of wetting (air expansion)

Wetting of disintegrates with exothermic properties exhibits localized stress due to capillary air expansion, which helps in disintegration of tablet. This explanation, however, is limited to only a few types of disintegrates and cannot describe the action of most recent disintegrating agents [40].

Due to disintegrating particle/particle repulsive forces

Guyot-Hermann has proposed that non-swelling particle also cause disintegration of tablets by particle repulsion theory [41]. 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

Hess had proved that disintegrated particles gets deformed during tablet compression and these deformed particles when they come in contact with aqueous media or water they get into their normal structure. Moreover, when granules were extensively deformed during compression the swelling capacity of starch also improved. Thus increased deformed particles produce a breakup of the tablet [42-47]. This may be a mechanism of starch and has only recently begun to be studied. (Figure 1 & 2).

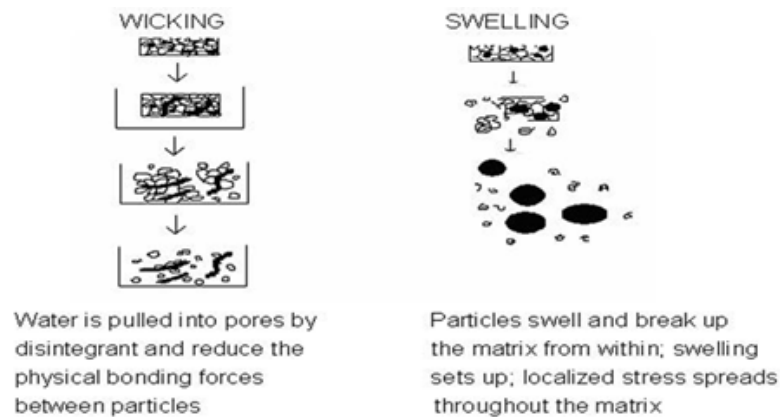


Figure 1: Mechanism of disintegration by wicking and swelling.

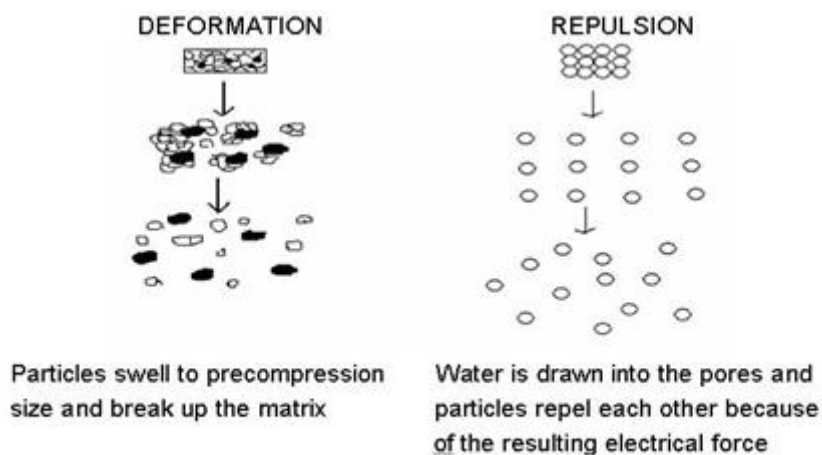


Figure 2: Mechanism of disintegration by deformation and repulsion.

Due to release of gases

Upon wetting Carbon dioxide released within tablets, due to interaction between bicarbonate and carbonate with citric acid or tartaric acid [48]. Disintegration of tablet takes place due to generation of pressure within the tablet. Such an effervescent mixture is used when there is a need to formulate very rapidly dissolving tablets or fast disintegrating tablet. As these disintegrates are highly sensitive to small changes in humidity level and temperature, manufacturing of the tablets should be done with appropriate environmental conditions. The effervescent blend is either added before compression or can be added in to two separate fraction of formulation [49,50].

By enzymatic reaction

Here, enzymes presents in the body act as disintegrates and destroys/inhibits binders thereby facilitate disintegration [51].

The technologies used to manufacture mouth dissolving tablets can be classified as:

- 1) Conventional technologies
- 2) Patented technologies

Table: 2: Technologies used to manufacture mouth dissolving tablets

CONVENTIONAL	PATENTED TECHNOLOGIES
Freeze Drying.	Zydis Technology.
Tablet Moulding.	Durasolv Technology.
Sublimation	Orasolv Technology.
Spray Drying.	Flash dose Technology.
Mass extrusion	Wow tab Technology.
Direct Compression	Flash tab Technology
Shea form Technology.	

CONVENTIONAL TECHNOLOGIES FOR PREPARING MOUTH DISSOLVING TABLETS

Freeze drying

Freeze drying is a process of sublimation of water content from the product through freezing. Thus formed freeze dried forms shows more rapid dissolution compared to other conventional dosage forms. Glossy amorphous structural appearance is due to lyophilisation of the drug; thereby enhancing the dissolution characteristics of the formulation. Due to its high economic equipment the usage of freeze drying became limited [52]. Other major disadvantages of the final dosage forms include lack of physical resistance in standard blister packs. The matrix is partially dried below the equilibrium freezing point of the matrix. Vacuum drying of the tablet above its collapse temperature rather than freeze drying below its collapse temperature provides a method for manufacturing tablets with increased structural integrity, which disintegrates rapidly in saliva [53-57].

Moulding

Solid dispersions are the tablets which are produced by moulding technique. Extent or amount of the drug it dissolves in the molten carrier depends on the physical form of the drug [58]. The drug can exist as discrete particles or micro particles dispersed in the matrix. It may dissolve completely/ partially in the molten carrier to form solid solution and the remaining particles stay undissolved and dispersed in the matrix [59]. Disintegration time, drug dissolution rate will depend on the type of dispersion or dissolution. Moulded tablets generally made from water-soluble sugars thus offers rapid disintegration and improved taste. These moulded tablets were subjected to erosion and breakage during handling and opening of blister packs because of its lesser mechanical strength [60-64].

Sublimation

Tablets containing highly water soluble excipients as a matrix material show slow dissolution in water because of its low porosity. Tablets with high porosity and rapid dissolution have been developed by adding inert solid volatile substances (urea, urethane, ammonium carbonate, camphor, naphthalene) to other excipients of the tablet and this blend was subjected to tableting. Porosity of the tablet can be achieved by removal of solid volatile substance through sublimation [65]. Compressed tablets containing mannitol and camphor have been prepared by sublimation technique. Thus formed tablets exhibits good mechanical strength and also shows a rapid dissolution i.e, 10-20 seconds.

Spray drying

Highly porous and fine powders may be made by spray drying, as the processing solvent is gaseous phase throughout spray drying process [66]. Spray drying technique is based upon a particulate support matrix and other components to form a highly porous and fine powder. This is then mixed with above ingredients and compressed to tablet. The fast dissolving tablets prepared form Spray drying technique disintegrated within 20 seconds [67].

Mass extrusion

This technology involves softening the active blend with the solvent mixture of soluble synthetic resin glycol, methanol and expulsion of softened mass through the extruder or syringe to induce a cylinder of the merchandise into even segments with heated blade to create tablets. The dried cylinder may be accustomed to coat granules of bitter tasting medicine and thereby masking their bitter taste [68].

Direct compression

Direct compression is the easiest and simplest for the manufacturing of tablets. Simple and economical equipment utilization, commonly available excipients and a limited number of processing steps [69] are concerned in direct compression. Conjointly high doses can be accommodated and final weight of tablet will simply exceed that of different production strategies. Directly compressed tablet's disintegration and solubilization depends on single or combined action of disintegrates, soluble excipients and effervescent agent Disintegrant efficacy is strongly affected by tablet size and hardness. Large and hard tablets have disintegration time more than that usually required [70-73]. As consequences, product with best disintegration properties usually have medium to tiny size and/or high crumbliness and low hardness. Breakage of tablet edges throughout handling and tablet rupture throughout the gap of blister alveolus, all result from meager physical resistance [74]. **Table 3**

Table 3: Various commercially available superdisintegrants along with their properties.

s.no	Name	Type	Properties	Brand name
1	Crospovidone	Polyvinyl- pyrrolidone	Crossed linked Poly vinyl pyrrolidone Rapidly disperses and swells in water	Polyplasdone XL, Kollidon CL
2	Croscarmellose Sodium.	Modified cellulose	Cross linked sodium carboxy methyl cellulose.Excellent swelling and water wicking properties.	Ac-di-sol, Primellose, Solutab.
3	Sodium starch Glycolate	Modified starch	Sodium salt of carboxy methyl ether of starch. High swelling capacity and rapid water uptake	Primogel, Explotab glycilyls

PATENTED TECHNOLOGIES FOR OR DISPERSIBLE OR MOUTH DISSOLVING TABLETS

Zydis technology

Zydis formulation may be a distinctive freeze dried pill within which drug is physically entrapped or dissolved inside the matrix of fast-dissolving carrier material. Once Zydis units square measure place into the mouth, the freeze-dried structure disintegrates outright and doesn't need water to assist swallowing [75]. The Zydis matrix is composed of many materials designed to achieve a number of objectives. To impart strength throughout handling, polymers like gelatin, dextran or alginates square measure incorporated. This kind a glossy amorphous structure that imparts strength.

To obtain crystallinity, magnificence and hardness, saccharides like water pill or sorbitol square measure incorporated. Water is employed within the producing method to confirm production of porous units to achieve speedy disintegration. Various gums are used to prevent sedimentation of dispersed drug particles in the manufacturing process [76]. Collapse protectants such as glycine prevent the shrinkage of Zydis units during freeze drying process or long term storage. As these Zydis products are moist sensitive they should be packed in blister packs to protect the formulation from moisture [77-80].

Durasolv technology

Durasolv is that the proprietary technology of CIMA labs. The tablet created by this technology comprises a drug, fillers and a lubricating substance. Tablets are prepared by using conventional tableting equipment and have good rigidity [80,81]. These can be packaged into conventional packaging system like blisters. Durasolv is an appropriate and best suited technology for products requiring small amounts of active ingredients.

Orasolv technology

CIMA labs have developed Orasolv Technology. In this system active medicament is style covert. It additionally contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time [82]. Conventional blenders and tablet machine is used to prepare the tablets. The tablets ready square measure soft and friable and packed in specially designed decide and place system.

Flash dose technology

This technology is based on the preparation of sugar based matrix known as floss, which is made from a combination of excipients either alone or in combination of drugs [83]. Two platform fuisz technologies called Shea form or Ceform are currently being utilized in preparation of wide range of oral disintegrating product. Nurofen meltlet, a brand new sort of no steroidal anti-inflammatory as melt-in-mouth tablets; ready mistreatment flash dose technology is that the initial industrial product launched by Biovail Corporation [84-91]. Flash dose tablets consist of self-binding shear form matrix termed as "Floss". Shear form matrices are prepared by flash heat processing.

Wowtab technology

Wow tab Technology is proprietary by Yamanouchi company WOW means that "Without Water". During this method, combination of low mouldability saccharides and high mouldability saccharides is employed to get a apace melting robust pill [92]. The active ingredient is mixed with an occasional mouldability super molecule and coarse with a high mouldability super molecule and compressed into tablet [93].

Flashtab technology

Tablets prepared by this technology consists microcrystals as active ingredients [94]. Drug micro granules may be prepared by using the conventional techniques like coacervation, microencapsulation, and extrusion-spheronisation. All the processing utilized conventional tableting technology.

Ceform technology

Initially microspheres containing active ingredient are prepared. The manufacturing involves keeping a dry powder containing pure drug or a blend of drug and other ingredients into precision engineered, and rapidly spinning

machine. The centrifugal force throws dry blend at high speed through small, heated openings. The resultant microburst of heat liquefies the drug blend to form sphere [95-101]. The microspheres are blended or compressed into preselected oral delivery dosage form. The microspheres area unit alloyed or compressed into preselected oral delivery dose type. The microspheres are often incorporated into a good vary of quick dissolving dose forms like flash dose, or spoon dose, EZ chew.

Shear form technology

Shear type technology is predicated on preparation of floss that's additionally called "Shear type Matrix", that is made by subjecting a feedstock containing a sugar carrier to flash heat processing [102]. During this method, the sugar is at the same time subjected to force and to a gradient that raises the temperature of the mass to make an enclosed flow condition, which allows a part of it to maneuver with respect of the mass. The flowing mass exits through the spinning head that flings the floss. The floss so produced is amorphous in nature so it is further cropped and recrystallized by various techniques to provide uniform flow properties and then facilitates blending [103]. The recrystallized matrix is then integrated with different pill excipients and an energetic ingredient. The resulting mixture is compressed into tablet [104-107]. The active ingredient and different excipients will be integrated with floss before closing recrystallization. The Shear type floss, once integrated with the coated or uncoated microspheres, is compressed into tablets or EZ tender tablets from commonplace tableting equipment [107-111].

Cotton candy

Cotton candy process also referred as candy floss process .this technique forms the basis of flash dose (Fuss technologies, Chantilly, VA) in this technology. Simultaneous action of flash melting and centrifugal force, saccharides or polysaccharides are processed into amorphous floss. Thus formed floss is then subjected to recrystallization to impart a good flow properties and compressibility. Now this is milled and blended with active ingredient and other excipients and finally compressed to tablet. Tablets processed by this method avails good mechanical strength and can accommodate high doses too. [112-119]. As the candy floss are hygroscopic, their manufacturing requires controlled humidity [120]. (Tables 4 & 5).

Table 4: Comparison of some patented technologies for mouth dissolving tablets [121-127].

Technology	Novelty	Handling /storage	Drug release /bio availability
Zydis (R.P Scherer, Inc.)	First to market. Freeze Dried	Do not push tablet through foil. Do not use dosage form from Damaged package. Sensitive to degradation at humidities >65%	Dissolves in 2 to 10 seconds. May allow for pre gastric absorption leading to enhanced bio availability

Orasolv (CIMA labs,inc)	Unique taste Masking. Lightly compressed	Packaged in patented foil packs	Disintegrates in 5 to 45seconds depending upon the size of the tablet. No significant Change drug bioavailability
Durasolv (CIMA Labs, Inc.)	Similar to Orasolv, but with better mechanical strength	Packaged in foil or bottles packaged in bottles, avoid exposure to moisture or humidity	Disintegrates in 5 to 45 seconds dependi ng upon the size of the tablet. No significant change in drug bioavailability
Wowtab(YAMANOUCHI Pharma Technologies, Inc.)	Compressed dosage form. Proprietary taste masking. Smooth melt action gives superior mouth feel.	Package in bottles. Avoid exposure to moisture or humidity	Disintegrates in 5 to 45seconds up on the size of the tablet. No significant change in drug bio availability

Table 5: List of commercially available or dispersible tablets [128-133].

Trade Name	Active Drug	Manufacturer
Feldene Fast Melt	Piroxicam	Pfizer Inc., USA
Calritin Redi Tab	Loratidine	Schering Plugh Corp, USA
Maxalt MLT	Rizatriptan	Merck & Co. USA
Zyprexia	Olanzapne	Eli Lilly, Indianapolis, USA
Pepcid RPD	Famotidine	Merck & Co., NJ, USA
Zofran ODT	Ondansetron	Glaxo Wellcome, Middlesex, UK
Zoming-ZMT	Zolmitriptan	AstraZeneca, Wilmington, USA
Tempra Quiclets	Acetaminophen	Bristol Myers Squibb, NY, USA
Febrectol	Paracetamol	Prographarm, Chateauneuf, France

Nimulid MDT	Nimesulide	Panacea Biotech, New Delhi, India
Romilast	Montelukast	Ranbaxy Labs Ltd., New Delhi, India
Benadryl Fastmelt	Diphenhydramine and pseudoephedrine	Warner Lambert, USA

CONCLUSION

Fast dissolving tablets are the inventive dosage forms which are designed for rapid disintegration in saliva without water. Due to its rapid onset of action FDT's offer improved patient compliance. FDT's is growing in an exceedingly positive manner because of its several potential advantages over conventional dosage forms and its usage by geriatrics and pediatrics. They show higher bioavailability over conventional dosage forms. Hence fast dissolving tablets became the most popular choice over conventional dosage forms around the world.

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