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A Comprehensive Review on Fast (Mouth) Dissolving Tablets (FDTS)



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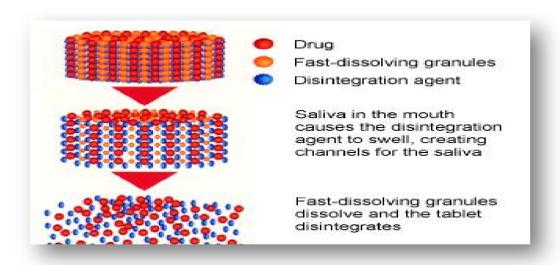
ABSTRACT

This review unfolds the comprehensive knowledge on the formulations of fast (mouth) dissolving tablets. Across the globe, 1/3 population has difficulty swallowing tablets. Fast Dissolving Tablets (FDTs) have gotten always expanding requests during the last decade, and the field has become a quickly developing region in the drug business. US Food and Drug Administration (USFDA) characterized dissolving tablet (FDT) as "the structure of a strong measurement containing a therapeutic substance or dynamic fixing which deteriorate quickly ordinarily inside merely seconds when put upon the tongue. Mouth dissolving tablets are strong dose structures that, when put in the mouth, break down, disintegrate and discharge dynamic specialist inside a couple of moments without the requirement for water. Geriatric and pediatric patients experience trouble in swallowing tablets, which prompts poor patient compliance. Fast Dissolving tablets have numerous impacts on better drug delivery with ultra-short action capacity. These dosage forms allow to delivery of the specific drug rapidly in the systemic circulation. For the ideal fast dissolving tablet, many drug properties could potentially affect the behavior of formulations. A disintegrant is an excipient, which is added to a tablet or capsule to support the separation of the compacted mass when it is placed into a liquid climate. Some commonly used disintegrants are such as sodium starch glycolate, crosslinked povidone, Low-substituted hydroxyl propyl cellulose, microcrystalline cellulose, Cross-carmellose sodium and pregelatinized starch. Lyophilization, Sublimation, Spray-Drying, and Addition of disintegrants are some useful techniques for formulating mouth dissolving tablets. In conclusion, Oral Dissolving Tablets may be a highly demanding dosage form in the coming years due to their ultra-short action.

INTRODUCTION

Across the globe, 1/3 population has difficulty swallowing tablets (Madan et al. 2009). The comfort of organization and further developed patient consistency are significant in the designing of an oral drug delivery system that stays the preferred route of drug administration. Fast Dissolving Tablets (FDTs) have gotten always expanding requests during the last decade, and the field has become a quickly developing region in the drug business. These procedures render the disintegration of the tablet quickly and disintegrate in the mouth within five seconds without biting and the need for water. This technique is profitable fundamentally for pediatrics, geriatrics, and patients experiencing issues in swallowing tablets and cases (Rahane & Ruchh, 2018). The formulation is more useful for the hospitalized patients who have the problem in swallowing (Gupta et al. 2012).

US Food and Drug Administration (USFDA) characterized quick-dissolving tablet (FDT) as "the structure of a strong measurement containing a therapeutic substance or dynamic fixing which deteriorate quickly ordinarily inside merely seconds when put upon the tongue (Masih et al. 2017). Mouth dissolving tablets are strong dose structures that, when put in the mouth, break down, disintegrate and discharge dynamic specialist inside a couple of moments without the requirement for water. It has more importance to geriatric, Pediatric, disabled patients since they have an issue in gulping and the patient with dysphasia. It is more helpful for the voyager and occupied patients who don't have simple admittance to water. Mouth dissolving tablets are ready by different advances with the guide of superdisintegrants. Mouth dissolving tablets are more solid than ordinary dose structures like tablets, cases as a result of better persistent consistency (Joshi et al. 2020).



 $\textbf{Fig 1:} \ \textbf{Mechanism of disintegration of mouth dissolving tablets}$

The bioavailability of certain medications might be expanded due to retention of medications in the oral pit and due to pre-gastric retention of salivation containing scattered medications that pass down into the stomach. Besides, the measure of medication that is exposed to first pass digestion is diminished when contrasted with standard tablets. The following figure depicts the disintegration mechanism of fast dissolving tablets (Masih et al. 2017).

Conventional tablets and containers directed with an 8-oz. glass of water might be awkward or unfeasible for a few patients. For instance, an older patient may not be ready to swallow a day-by-day portion of the upper. An eight-year-old with sensitivities could utilize the structure of a more advantageous measurement than an antihistamine syrup. A mid-life lady going through radiation treatment for breast malignancy might be too queasy to even consider gulping her H2-blocker. Quick dissolving/breaking down tablets (FDDTs) are an ideal fit for such patients (Prajapati & Ratnakar, 2009).

Geriatric and pediatric patients experience trouble in swallowing tablets, which prompts poor patient compliance. To beat this shortcoming, researchers have created inventive medication conveyance frameworks known as "soften in the mouth" or "mouth dissolve (MD)" tablets. These are novel kinds of tablets that break down/disintegrate/scatter in spit/saliva (Basu et al. 2011).

Fast dissolving drug conveyance framework can be acquired by the different strategies for example direct pressure, tablet shaping, freeze-drying, shower drying nanonization. Oral quick-dissolving tablets are an instance of a couple of existing technologies with the possibility to oblige different physicochemical, pharmacokinetic, and pharmacodynamic characteristics for drugs (Yadav et al. 2012).

Ideal drug properties

For the ideal fast dissolving tablet, many drug properties could potentially affect the behavior of formulations. The properties include the solubility, crystal morphology, particle size, hygroscopicity, compressibility, and bulk density of a drug that can significantly modify the final tablet's characteristics, such as its strength and disintegration. The drugs having poor solubility and high permeability are the best suitable molecules for mouth dissolving tablets in a dose of 125mg & 250mg. For example, Ibuprofen, Promethazine, prednisone, Indomethacin, Fentanyl citrate, Griseofulvin, Hydrochlorothiazide, and Crystallized Paracetamol are drugs that have been incorporated as FDTs system (Parkash et al. 2011).

Some super-disintegrants used in FDTs (Panigrahi et al. 2010; Garg & Gupta, 2013)

A disintegrant is an excipient, which is added to a tablet or capsule to support the separation of the compacted mass when it is placed into a liquid climate.

Some super-disintegrants are as follows-

1. Sodium Starch Glycolate

It is utilized in the convergence of 2-8 % and ideal is 4%. Component of Action: Rapid and broad expanding with negligible gelling. Microcrystalline cellulose is utilized in a convergence of 2-15% of tablet weight.

2. Cross-linked Povidone

It is used in a concentration of 2-5% as of the weight of the tablet. It is insoluble in water. It acts by water wicking and swelling.

3. Low-substituted hydroxyl propyl cellulose

It rapidly swells in water. LH-11 and LH-21 grades exhibit the highest degree of swelling. Certain grades can also show some binding properties while having disintegration capacity. It is used in the concentration of 1-5%.

4. Microcrystalline cellulose

It is one of the best disintegrants used in the development of fast dissolving tablets. It is used with a concentration of 2-15%. It is utilized in formulation due to its water-wicking property.

5. Cross-carmellose sodium

It is used as a potent disintegrant agent for a long time. It is suitable for all the properties required while the formulation of oral dissolving tablets. It is used in 1-3% in the case of direct compression and 2-5% while used in the wet compression technique. It acts by both the mechanism- wicking and swelling.

6. Pregelatinized starch

It is available in the market with the brand name Starch 1500. It is utilized in the concentration of 1-20%. It serves as a powerful swelling agent in mouth dissolving tablets.

Methods of preparation of FDTs

\Delta Lyophilization or Freeze-Drying

The development of permeable items in freeze-drying measures is taken advantage of by informing MDTs. Lyophilization is a cycle, which incorporates the expulsion of dissolvable from a frozen suspension or arrangement of medication with structure-framing added substances. Freeze-drying of medication alongside added substances gives shiny shapeless construction coming about in profoundly permeable and lightweight items (Gupta et al. 2012).

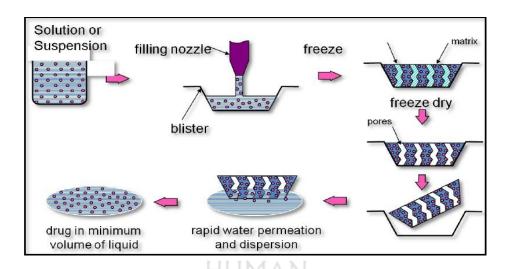


Figure No. 2: Lyophilization technique in FDTs formulation (Garg & Gupta 2013)

Spray-Drying method

The preparations contained hydrolyzed and unhydrolyzed gelatin as a supporting specialist for the framework, mannitol as a building specialist, and sodium starch glycolate/cross-carmellose as a disintegrant. Breaking down and disintegration were additionally upgraded by adding a corrosive (e.g., citrus extract) or a soluble base (e.g., sodium bicarbonate). The suspension of the above excipients was splash dried to yield a permeable powder which was packed into tablets. Tablets made by this strategy deteriorated in < 20 secs in a fluid medium (Garg & Gupta 2013).

❖ Super-disintegrant addition method

In the super-disintegrant addition method, specified quantities of active pharmaceutical ingredients and additives are weighed accurately and passed through 60 Sieve. All the materials are transferred to a mortar and triturated till it was uniform. The obtained powder

blend is evaluated for angle of repose, bulk & tap density, and compressibility index. The blend is compressed into tablets using a single tablet punching machine (Patel et al. 2010).

❖ Zydis Technology

Zydis method is a patent process. It uses a freeze-drying cycle to make completed measurement units which essentially contrast from regular oral frameworks. In this innovation, the arrangement or suspension of medication in water is poured in preformed rankles and passing them to an extraordinarily planned cryogenic freezing interaction to control the size of ice precious stones which guarantees that the tablet is having a permeable network for fast crumbling. Then, at that point, these frozen units are then moved to enormous scope freeze dryers for the sublimation cycle, where most of the excess dampness is eliminated from the tablets and open rankles are pressed utilizing a warmth seal measure (Parkash et al. 2011).

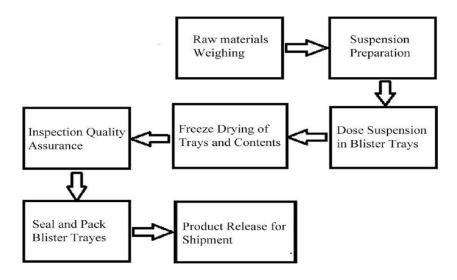


Figure No. 3: Zydis Technology Process

Sublimation

The inert solid ingredients that volatilize rapidly such as urea, camphor ammonium carbonate, are added to the active pharmaceutical ingredients & additives and the mixture is compressed into tablets. The volatile materials are then removed via sublimation, which formulates a porous structure. The porous structure enhances dissolution rate by using volatile material e.g. cyclohexane, benzene, etc. (Siddiqui et al. 2010).

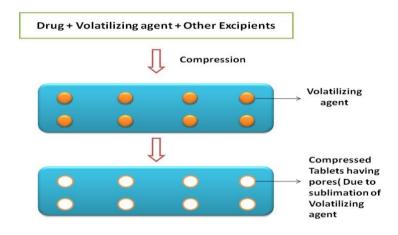


Figure No. 4: Sublimation process (Garg & Gupta, 2013)

Ideal properties of FDTs (Ratnaparkhi et al. 2008)

The following points are considered for ideal FDTs-

- Having a taste masking property
- Showing enough hardness less friable
- Leaving no residue in the buccal cavity after oral administration
- Manufactured by conventional processing methods

Advantages of fast dissolving tablets (Masih et al. 2017; Yadav et al. 2012).

The followings are the advantages of fast dissolving tablets-

- 1. No water is required.
- 2. No chewing is needed.
- 3. Enhanced stability
- 4. Facilitated absorption and bioavailability
- 5. Palatable (Non-irritating)
- 6. Not costly
- 7. Fast onset of action
- 8. Risk of choking is avoided; improved safety

- 9. Prevents sudden episodes of allergic attacks due to ultra-short action
- 10. High drug loading facility
- 11. Low sensitivity to humidity and temperature
- 12. Easily administered in pediatric, elderly, and mentally disturbed patients
- 13. Convenient for sustained or controlled release dosage forms
- 14. Avoided First Pass/ Presystemic Metabolism

Disadvantages of FDTs (Bahrainian et al. 2017)

- 1. High hygroscopicity
- 2. Not easy for bitter taste drugs
- 3. Inefficiency for high drug loading in films/ nanofibres

CONCLUSION

FDTs idea was developed to beat a portion of the issues that existed in customary strong measurement structure for example trouble in gulping of tablets in pediatric and geriatric patients who comprise an enormous extent of the total populace. FDT might prompt further development adequacy, bioavailability, the fast beginning of the activity, better understanding consistency because of its speedy assimilation from mouth to GIT as the salivation passes. Quick dissolving tablet behaves like a strong measurement structure when outside the body and arrangement when directed. In the future FDT might be generally worthy and recommended dose structure because of its fast activity (Siddiqui et al. 2010). Oral Dissolving Tablets may be a highly demanding dosage form in the coming years due to their ultra-short action. It might be used for commercial purposes with a low cost of production as well.

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Nil

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