

A Review on Fast Dissolving Tablet

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Abstract

The convenience of administration and improved patient compliance are important in the design of oral drug delivery system which remains the preferred route of drug delivery inspite of various disadvantages. Fast disintegrating tablets (FDTs) have received ever-increasing demand during the last decade, and the field has become a rapidly growing area in the pharmaceutical industry. The popularity and usefulness of the formulation resulted in development of several FDT technologies. These techniques render the disintegration of tablet rapidly and dissolve in mouth in five seconds without chewing and the need of water which is advantageous mainly for pediatrics, geriatrics and patients having difficulty in swallowing tablets and capsules. Formulation of a convenient dosage form for administration, by considering swallowing difficulty and poor patient compliance, leads to development of orally disintegrating tablets. Conventional preparation methods are spray drying, freeze drying, direct compression, Molding, and sublimation while new technologies have been developed for the production of orodispersible tablets.

Keywords: Fast Dissolving Tablet, drug delivery system, fast disintegrating, fast melting.

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Introduction

Conventional dosage forms are pioneer of drug administration systems. The most widely used and accepted is the oral route of drug administrations. The oral dosage forms are widely used for ease of self-administration and low cost as compared to other dosage forms. [1]

It is however associated with some drawbacks such as dysphagia (difficulty in swallowing), low bioavailability and delayed onset of action. In order to overcome these issues researchers have long explored the “oral cavity” to harness its drawback to enhance the drug’s permeability as well as bioavailability. The “oral cavity” has a good permeability

because of mucosal lining being relatively less keratinized in the buccal mucosa. [2]

Drug absorbed via “oral cavity” directly enters into systemic circulation by a jugular vein ensuring, a rapid onset of action, avoidance of first pass metabolism, and drug degradation in gastric region and enzymatic hydrolysis in intestine [3]

Keeping in mind the advantages of the “oral cavity”, an Oral Dispersible Tablet, commonly known as the Fast Dissolving Tablets are a widely accepted formulations. According to European pharmacopoeia “ODT (Oral Dispersible Tablet) should disperse or disintegrate in less than 3 minute when placed on

tongue". Fast dissolving drug delivery system (FDDDS) is a newer concept which combines the advantages of both liquid and solid formulations and at the same time, offer advantages over the traditional dosage forms.

Fast dissolving tablets are novel drug delivery system that dissolves, disintegrate or disperse the API in saliva within few seconds with or without intake of water. The faster the dissolution of drug into the solution, quicker is the absorption and onset of clinical effect. The bioavailability of some drugs may increase due to absorption of drugs in oral cavity or also due to pregastric absorption of drug from saliva that pass down into the stomach. Natural and synthetic Superdisintegrants like mucilage, cross linked carboxymethyl cellulose (croscarmellose) and sodium starch glycolate (primogel), poly vinyl pyrrolidone provide immediate disintegration of tablets and facilitate the design of delivery system with desirable characteristics. These types of formulations are widely recommended for the drugs used in emergency. e.g., Cardiac agents, Asthama, Brain stroke, Anti-hyperlipidemic etc. [4]

Advantages of FDTs

Improved compliance/added convenient new business opportunities product differentiation, line extension and lifecycle management, exclusivity of product promotion, and patent-life extension.

- 1) No water needed.
- 2) No chewing needed.
- 3) Better taste.
- 4) Improved stability.
- 5) Suitable for controlled/sustained release actives.
- 6) Allows high drug loading
- 7) Ability to provide advantages of liquid medication in the form of solid preparation.
- 8) Cost- effective.
- 9) Rapid drug therapy intervention.
- 10) High drug loading is possible.

- 11) Have acceptable taste and pleasant mouth feeling. [5]

Limitations of FDTs

The major disadvantages of FDTs are related to the mechanical strength of tablets.

FDT are very porous and soft molded metrics or compressed in a tablet with low compression, which makes tablet friable and brittle which difficult to handle.

Bad tastes drugs are difficult to formulate as FDT; special precaution should have to be taken before formulate such kind of drug.

Several FDT are hygroscopic cannot maintain physical integrity under normal condition from humidity which requires specialized package.

Dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.

Rate of absorption from the saliva solution and overall bioavailability.

Drug and dosage form stability. [6, 7]

Salient Feature of Fast Dissolving Drug Delivery System:

Patient Compliance is easy and the administration of tablet especially for patients suffering from dysphagia, cardiac and renal complications/victims, bedridden patients, and patient who refuse to swallow the dosage form such as pediatric, geriatric & psychiatric patients [8].

Oral disintegration of tablet eliminates the use of water which is suitable for patients who are traveling and cannot access water easily.

Quick onset of action due to rapid disintegration followed by dissolution.

Increased Bioavailability, due to absorption via mouth buccal mucosa which has better permeability properties.

- a. Pregastric absorption if any will result in improved bioavailability reduced dose and side effects, improving clinical efficiency [9].
- b. The FDT will give a good mouth feel, especially in pediatric patients due more emphasis on organoleptic proper- ties.
- c. FDT will be safer than conventional dosage forms as it eliminates choking, or airway obstruction.
- d. Better business opportunities like, product differentiation, product endorsement, patent extensions and life cycle management [10].
- e. Favorable in cases which require an immediate and rapid onset of action e.g. motion sickness, sudden episodes of allergic attack or coughing.

Techniques in Preparation of FDTs

The various methods have been attempts for formulation of FDTs;

Freeze drying

Lyophilization means drying at low temperature under condition that involves the removal of water by sublimation. Drug in a water soluble matrix which is then freeze dried to give highly porous structure. The tablets prepared by lyophilization disintegrate rapidly in less than 5 seconds due to quick penetration of saliva in pores when placed in the oral cavity. Lyophilization is useful for heat sensitive drugs i.e. thermo-labile substances. [11]

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 hydroalcoholic 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 increases dissolution. [12]

Tablet Molding

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 possess a porous structure that hastens 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. Masking of taste is an added problem to this technology and the masked drug particles are prepared by spray congealing a molten mixture of hydrogenated polyethylene glycol, cottonseed oil, lecithin, and sodium carbonate an active ingredient into a lactose based tablet triturate form. Tablets produced by the moulding technique are easy to scale up for industrial manufacturer, compared to the lyophilisation technique. [13]

Direct Compression:

Direct compression represents the most cost effective and simplest tablet manufacturing technique. Because of the accessibility of improved excipients especially super disintegrants and sugar based excipients, this technique can now be utilized for preparation of Fast Dissolving Tablets.

Spray drying

Spray drying can produce highly porous and fine powders that dissolve rapidly. This technique is based on a particulate support matrix, which is prepared by spray drying an aqueous composition containing support matrix and other components to form a highly porous and fine powder. This then mixed with active ingredients and compressed into tablets. The formulations are incorporated by hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or crosscarmellos sodium as disintegrating and an acidic material (e.g. citric acid) and / or alkali material (e.g. sodium

bicarbonate) to enhance disintegration and dissolution. Tablet compressed from the spray dried powder disintegrated within 20 seconds when immersed in an aqueous medium.

Evaluations [14, 15, 16, 17]

Organoleptic properties:

The size and shape of the tablet can be dimensionally described, monitored and controlled. 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. Hardness: A significant strength of ODT is difficult to achieve due to the specialized processes and ingredients used in the manufacturing. The limit of hardness for the ODT is usually kept in a lower range to facilitate early disintegration in the mouth. The hardness of the tablet may be measured using conventional hardness testers.

Friability:

To achieve % friability within limits for an ODT is a challenge for a formulator since all methods of manufacturing of ODT are responsible for increasing the % friability values. Thus, it is necessary that this parameter should be evaluated and the results are within bound limits (0.1-0.9%)

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. In-Vivo Disintegration test²³⁻²⁵: 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

Dissolution test:

Commonly the drugs may have dissolution conditions as in USP monograph. Other media such as 0.1 N HCl, pH 4.5 and pH 6.8 buffers should be used for evaluation of ODT in the same way as their ordinary tablet counterparts. Experience has indicated that USP 2 paddle apparatus is most suitable and common choice for dissolution test of ODT tablets, where a paddle speed of 50 rpm is commonly used. Typically the dissolution of ODTs is very fast when using USP monograph conditions. Hence slower paddle speeds may be utilized to obtain a comparative profile. Large tablets approaching or exceeding one gram and containing relatively dense particles may produce a mound in the dissolution vessel, which can be prevented by using higher paddle speeds. These two situations expand the suitable range of stirring to 25-75 rpm.

Conclusion

Fast-dissolving tablets are innovative dosage forms developed and specially designed to overcome some of the problems that seen in conventional solid dosage form i.e. difficulty in swallowing of the tablet in geriatric and pediatric patients. Fast-dissolving tablets are designed to dissolve or disintegrate quickly in the saliva generally within less than 60 seconds (range of 5-60 seconds). Fast dissolving tablets have better patient compliance and acceptance may improve biopharmaceutical properties, bioavailability improved efficacy, convenience, and better safety compared with conventional oral dosage forms. The popularity of FDTs has increased fabulously over the last decade. FDTs need to be formulated for psychotic patients, bedridden, geriatric, and pediatric patients,

for those patients who may not have access to water, patients who are busy in traveling. FDTs formulations formulated by some of these conventional and patent technologies and FDTs have sufficient mechanical strength, quick

disintegration/dissolution in the buccal cavity without water. The newer technologies utilized for the formulation of the FDTs that provide more effective dosage forms with more advantages and minimal disadvantages.

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