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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

Despite of tremendous innovations in drug delivery, the oral route remains the preferred route for administration of therapeutic agents because of accurate dosage, low cost therapy, self medication, non invasive method and ease of administration leading to high level of patient compliance. Pediatric patients may suffer from ingestion problems as a result of underdeveloped muscular and nervous control. Moreover, patients traveling with little or no access to water, limit utility of orally administered conventional tablets or capsules[1, 2, 3]

A wide variety of pharmaceutical research is directed at developing new dosage forms. Most of these efforts have focused on either formulating novel drug delivery systems or increasing the patient compliance. Fast dissolving tablet (FDT) is the most widely preferred commercial products. Drug delivery through oral route is the most preferred and accepted way of application by the patients.[1] The most popular dosage form being tablets and capsules, one important disadvantage of these dosage forms is the difficulty to swallow. Dysphagia is also associated with a number of medical conditions including stroke, Parkinson's disease, AIDS, head and neck radiation therapy and other neurological disorders including cerebral palsy. Fast dissolving tablet have major advantages that is there is no need of water for administration, rapid onset of action, reduce risk of suffocation, avoid hepatic first pass metabolism.[4]The one of the most significant issue with FDT is the bitterness of the drug that can be exposed to taste bud as the tablet breaks apart in the oral cavity. Skillful taste masking technique is needed to hide this bitterness like

formation of inclusion complex, polymer coating, resin complex.[5, 6]

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.[7-10]

The benefits of Fast dissolving tablets are to improve patients' compliance, rapid onset of action, increased bioavailability and good stability which make these tablets popular as a dosage form of choice in the current market [11-13]. This review presented the concise information about the Fast dissolving tablet (FDT).

CHARACTERISTICS OF FDTs

Rapid-breakdown or fast disintegrating tablet of the type of those intended to undergo disaggregation in the mouth in contact with the saliva in less than 60 seconds, preferably in less than 40 seconds, forming a suspension which is easy to swallow. It is better known by the phrase "orodispersible tablets". It is estimated that 50% of the population has difficulties in swallowing tablets or capsules. This problem results in the prescribed medicament not being taken and hence in the efficacy of the treatment being severely affected [14]. So orodispersible tablets are easy administration for patients who have problems of deglutition or for those persons who would like to take their treatment without simultaneous ingestion of liquid.[15, 16]

Recent advances in novel drug delivery (NDDS) aims to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for ease of administration and to achieve better patient compliance. One such approach is oral disintegrating tablets (ODTs). ODTs are solid unit dosage forms, which disintegrates or dissolves rapidly in the mouth without the general requirement for swallowing, the chewing and water. Developments in the dosage form designing the ODTs fulfill the requirement of patient needs without compromising its efficacy. The ODTs satisfies the patient's requirements that are difficulty in the swallowing of the conventional tablets or capsules.[17,18] Basic properties are listed in following table;

Table 1: Ideal properties of FDT[19]

Properties	Yes/No
Suitable for Conventional tablet processing and packaging	Yes
Portable	Yes
Fragility Concern	No
Good Mouth Feel	Yes
Sensitive to Environmental factors (humidity, temperature)	No
Water required for swallowing	No
Patient Compliance	YES
Economic	YES
Leave Residue in oral cavity/Grittiness	No
Compatible with Taste Masking	Yes

ADVANTAGES OF FDTs [14]

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

2. No water needed.

3. No chewing needed.

4. Better taste.

5. Improved stability.

6. Suitable for controlled/sustained release actives.

7. Allows high drug loading.

8. Ability to provide advantages of liquid medication in the form of solid preparation.

9. Cost- effective.

10. Rapid drug therapy intervention.

11. High drug loading is possible.

12. Have acceptable taste and pleasant mouth feeling

DRUGs FORMULATED AS FDTs

The eligibility criteria for drugs to be formulated as Fast Dissolving Tablets are low dose, good stability in aqueous media, good mechanical strength [20] and compatibility with excipients [21, 22]

Table 2: Some drugs formulated as FDTs

Therapeutic Category	Drugs
Anti-fungal	Griseofulvin, Miconazole
Anti-bacterial	Doxycycline, Erythromycin, Rifampin, Tetracycline
Anti--Malarial	Chloroquine, Amodiaquine
Anti-hypertensive	Amlodipine, Nifedipine, Prazocin[23]
Ant-ithyroid	Carbimazole
Analgesic/Anti-inflammatory	Ibuprofen, Mefenamic acid, Piroxicam
Anticancer	Acyclovir[24]
Antiemetic	Ondensatron[25]

EXCIPIENTS COMMONLY USED FOR FDTs PREPARATION

Mainly seen excipients in FDT are as follows at least one disintegrant, diluent, lubricant, and swelling agent, permeabilizing agent, sweeteners, and flavoring[26]

Table 3: Name and weight percentage of different excipients[26]

Name of the excipients	Percentage Used
Disintegrants	1 to15%
Diluents	0 to 85%
Binder	5 to 10%
Antistatic Agent	0 to 10%

Table 4: Challenges in formulation of FDTs [27-30]

Challenges	**Description**
Mechanical strength and disintegration time	MDTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. Many MDTs are fragile and there are many chances that such fragile tablet will break during packing, transport or handling by the patients.. It is very natural that increasing the mechanical strength will delay the disintegration time.
Taste masking	Many drugs are bitter in taste. So effective taste masking of the bitter drugs must be done so that the taste of the drug is not felt in the oral cavity.
Mouth feel	Tablet should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the Tablet should be as small as possible. Tablet should leave minimal or no residue in mouth after oral administration.
Sensitivity to environment	Tablet generally should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in a Tablet are meant to dissolve in minimum quantity of water.
Palatability	As most drugs are unpalatable, tablets should contain the medicament in a taste-masked form.
Mechanical strength	In order to allow ODTs 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 tablets friable and/or brittle, difficult to handle, and often requiring specialized peel-off blister packing that may add to the cost.
Hygroscopic property	Several orally disintegrating dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging.
Aqueous solubility	Water-soluble drugs pose various formulation challenges because they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process.
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 one larger than 8 mm.
Fast Disintegration	FDTs should disintegrate in the mouth without additional water or with a very small amount (e.g., 1–2 mL) of water.

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.[31]

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 posses porous structure that increase dissolution [32] .

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 posses 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[33]. 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 lyophillisation technique [34]

Direct Compression:

Direct compression represents the most cost effective and simplest tablet manufacturing technique. Because of the accessibility of improved excipients especially superdisintegrants and sugar based excipients, this technique can now be utilized for preparation of Fast Dissolving Tablets [35].

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 crosscarmellose 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. [36, 37]

Mass Extrusion

In this technique, a blend of active drug and other ingredients is softened using solvent mixture of water soluble polyethylene glycol, using methanol and then softened mass is extruded through the extruder or syringe to get a cylinder of product, which is finally cut into even segments with the help of heated blades to get tablets. The dried cylinder can be used to coat the granules of bitter tasting drugs and thereby masked their bitter taste[38, 39].

EVALUATION OF FAST DISSOLVING TABLETS [23, 24, 25, 40]

Organoleptic properties:

The size and shape of the tablet can be dimensionally described, monitored and controlled. Tablet 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[23,25]:

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 test[23-25]:

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. [40].

CONCLUSION

FDTs are dosage forms which are formulated to dissolve/disintegrate rapidly in the saliva generally within few seconds. FDTs offer lot of advantages over conventional dosage forms such as improved efficacy, bioavailability, rapid onset of action, better patient compliance. Particularly FDTs provide more comfort to pediatric and geriatric patients. FDTs can be prepared by several methods based on the drug and additives used. Usually FDTs possess less mechanical strength. But by applying some new technologies and additives FDTs with sufficient mechanical strength can be prepared[41].

The basic fundamental used in the development of the fast-dissolving tablet is to maximize its pore structure. Vacuumdrying and freeze-drying techniques have been tried by researchers to maximize the pore structure of tablet matrix. Freeze drying is cumbersome and yields a fragile and hygroscopic product. Therefore, a vacuum-drying technique was adopted in the present investigation after addition of a subliming agent to increase porosity of the tablets. Even bitter drugs can be incorporated in FDTs by using taste masking agents. The research for FDTs is still going on. FDTs provide wide marketing also which makes the dosage form successful in the market. Many drugs will be formulated as FDTs in future for its market potential[42].

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