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Review Article

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MOUTH DISSOLVING TABLE: A REVIEW

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ABSTRACTS

MDT is ever-increasing demand in the formulation department since the last decade. The popularity and utility of the formulation resulted in development of several MDT technologies. These techniques provide the disintegration of tablet rapidly and dissolve in mouth in few seconds with the help of mouth saliva. 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. This review gives an idea of formulating MDT and its, evaluation parameters.

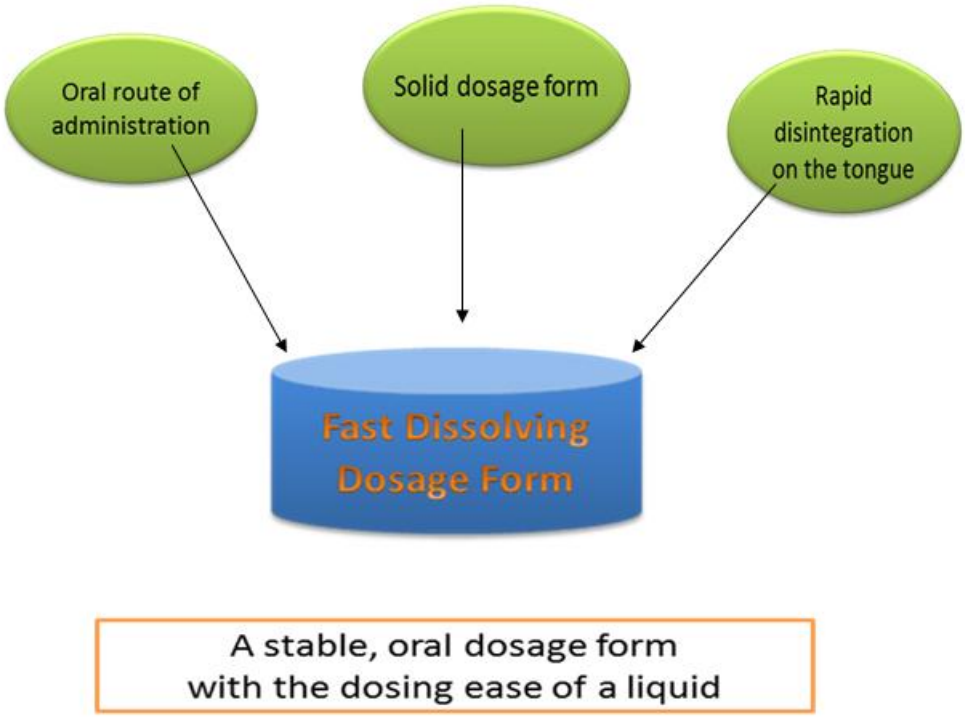
KEYWORDS: Fast Dissolving Tablet, delivery system, fast disintegrating, evaluation.

INTRODUCTION

MDT were developed in the late 1970s as an alternative to conventional dosage forms for pediatric and geriatric patients. Mouth dissolving tablets (MDT) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. MDT make a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly. Drug delivery systems are becoming increasingly sophisticated as scientists acquire a better understanding of the physicochemical parameters pertinent to their performance. Despite of tremendous advancements in drug delivery, the oral route remains the perfect route for the administration of therapeutic agents because of low cost of therapy, ease of administration. Tablets and capsule are the mostly used in the MDT.[1] It is a tablet that disintegrates and dissolves rapidly in the saliva within a few seconds without the need of drinking water or chewing. A mouth dissolving tablet usually dissolves in the oral cavity within 15 s to 3 min. Most of the MDTs include certain super disintegrants[2] and taste masking agent. According to European pharmacopoeia, these MDTs should dissolve/disintegrate in less than three minutes. US FDA defined MDTs as "A solid dosage form containing medicinal substances or active.

IDEAL PROPERTIES OF MDTS[3]

1. It does not require any water or liquid for the dissolving the tablet.
2. It takes few seconds in saliva to dissolve.
3. Have a pleasing taste.
4. Leave negligible or no residue in the mouth when administered.
5. Easy to transport production is very able to be manufactured in a conventional manner with low cost.
6. Be less sensitive to environmental conditions like temperature and humidity.



Advantages of MDT

No need of water to swallow the tablet.[4]

1. Can be easily administered to pediatric, elderly and mentally disabled patients.
2. Accurate dosing as compared to liquids.
3. Excellent mouths feel property produced by use of flavours and sweetners.
4. Convenient to administer during travelling without need of water. Fast disintegration of tablets.

NECESSITATE OF MTD[5]

1. Orally disintegrating dosage forms are particularly suitable for patients find it inconvenient to swallow traditional tablets and capsules with glass of water.
2. Patients who are unwilling to take solid preparation due to fear of choking
3. A patient with persistent nausea, who may be in journey, or has little or no access to water
4. Increased bioavailability.

Some drugs formulated as MDT[6]

Therapeutic Category	Drugs
Anti-fungal	Griseofulvin, Miconazole
Anti-bacterial	Doxycycline, Erythromycin, Rifampin,
Anti--Malarial	Chloroquine, Amodiaquine
Anti-hypertensive	Amlodipine, Nifedipine, Prazocin23
Ant-ithyroid	Carbimazole
Analgesic/Anti-inflammatory	Ibuprofen, Mefenamic acid, Piroxicam

FORMULATION OF MDT

Superdisintegrants[7]

Disintegrants play a major role in the disintegration and dissolution of MDTs. Super disintegrants provide quick disintegration due to combined effect of swelling and water absorption by the formulation.

Eg.1. Croscarmelose sodium, Crospovidone, Sodium starch glycolate

BULKINESS[8]

Bulkiness are important in the development of fast dissolving tablets. Bulking agents improve the texture of the tablets that consequently enhances the disintegration in the mouth, besides adding volume and reducing the concentration of the active in the formulation. The bulking agents for this dosage form should be more sugar-based such as mannitol.

EMULSIFYING

Emulsifying agents are significant for formulating fast dissolving tablets as they help in quick disintegration and drug release without the need for chewing, swallowing.

DRINKING WATER[9]

A variety of emulsifying agents for fast dissolving tablet formulations include alkyl Sulfates, propylene glycol esters, lecithin, sucrose esters and others. These can be added in the range of 0.05% to about 15% by weight of the final formulation.

Lubricants[10]
Excipients, these can aid in making the tablets more palatable after they disintegrate in the mouth.[11]

Flavours and taste masking agents make the products more palatable and pleasing for patients.

A wide range of sweeteners including sugar, dextrose and fructose, as well as nonnutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols are available.

CHALLENGES IN FORMULATION OF FDT[12]

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.[13]

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.[14]

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.[15]

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.[16]

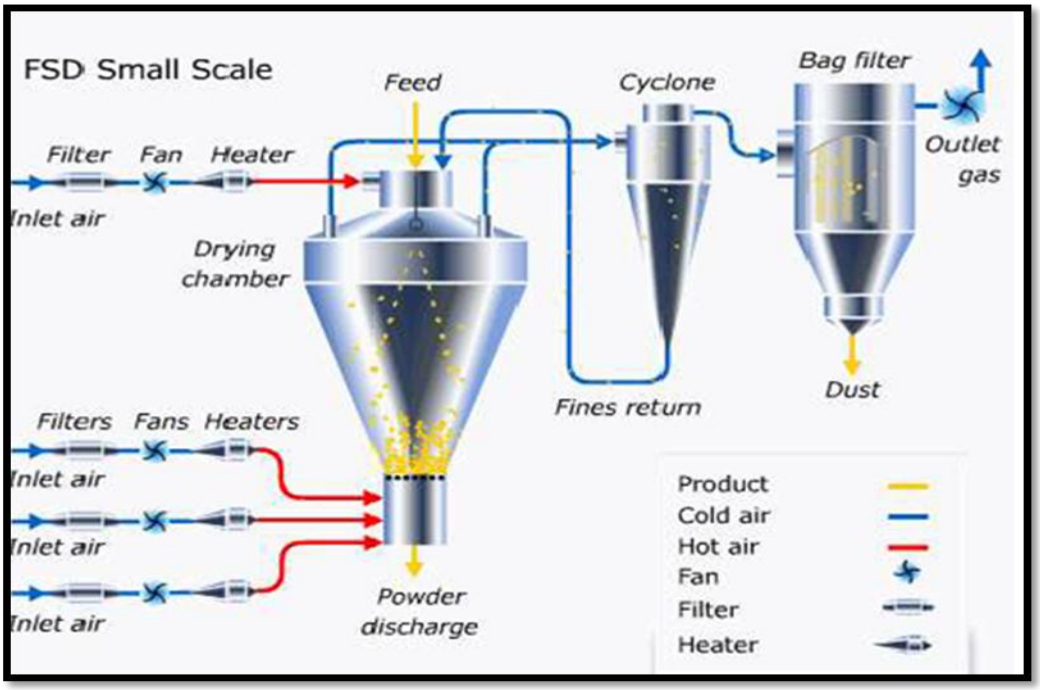
Size of tablet
It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was one larger than 8 mm.[17]

METHOD FOR THE SOLID DISPERSION

1. Freeze drying or Lyophilization
2. Spray drying.
3. Molding
4. Tablet Molding

1. Freeze drying or Lyophilization
Lyophilization means drying at low temperature under condition that involves the removal of water by sublimation.[18] 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. Example - Antacids

2. Spray drying
Spray drying can produce highly porous and fine powders that dissolve rapidly. It is based on support matrix, which is prepared to form a highly porous powder, then mix with active Ingredients and compressed.[19]



3. 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.[20]

4. 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. 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.[21]

EVALUATIONS PARAMETERS[22]

Organoleptic properties[20]

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[19]

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[18]

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[19]

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

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

Dissolution test conducted in 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. 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. which can be prevented by using higher paddle speeds. These two situations expand the suitable range of stirring to 25-75 rpm.

MARKETED PRODUCTS[23]

Brand name	Active ingredient	Application	Company
ClaritinR RediTabs	Loratadine	Antihistamine	Scherig corporation
Childrens Dimetapp	Loratadine[24]	Allergy	Wyeth consumer Healthcare
Imodium Istant Melts	Loperamide HCL	Antidiarrheal	Janssen
Triaminic [27]	Various combination	Pediatric cold cough,Allergy	Novartis consumer Health
Rapimelt	Zolmitriptan [25]	Anti-migraine	AstraZeneca Alaver
Gaster D	Famotidine	Anti-ulcer	Yamanouchi
Kemstro [28]	Baclofen	Anti-spastic[26] Analgesic	Schwarz Pharma

FUTURE SCOPE

Various products are available commercially in market which produced by fast dissolving tablet technologies. Still there is wide area for research on this technology. Some of the challenges like formulating a drug of bitter taste and moisture absorbing nature create problems for formulation scientist.

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