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Orally Disintegrating Tablets: A Short Review

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Abstract: *Mouth dissolving tablets are well established dosage forms available in the market. The numerous advantages that they offer to the patients in terms of compliance as well as to the manufacturers in terms of huge revenues by line extension of products are well known. In spite of such popularity, there seems to be lack of a standardized system to characterize these dosage forms. Enormous work has been done in this field, wherein some of the researchers have developed their own methods of evaluation. This article attempts to present a detailed review regarding technological advances made so far in the area of evaluation of mouth dissolving tablets with respect to special characteristics of these unique dosage forms. In the absence of any available standardized method, the author's recommendation on critical issues in the field may be considered.*

Keywords: Mouth dissolving ,Evaluation technique , Disintegration test , Taste masking , E-tongue.

I. INTRODUCTION

Mouth dissolving drug delivery systems (MDDDS) are a new generation of formulations which combine the advantages of both liquid and conventional tablet formulations, and at the same time, offer added advantages over both the traditional dosage forms. They provide the convenience of a tablet formulation and also allow the ease of swallowing provided by a liquid formulation. MDDDS offer the luxury of much more accurate dosing than the primary alternative, oral liquids. This segment of formulation is especially designed for dysphagic, geriatric, pediatric, bed-ridden, travelling and psychotic patients who are unable to swallow or refuse to swallow conventional oral formulations [1–3]. As they dissolve/disintegrate very fast when placed in the mouth, MDDDS are the most convenient dosage forms for dysphagic, pediatric and geriatric patients with swallowing problem. They do not require water for administration, thus are good alternative for travellers and for bed ridden patients. They simply vanish when placed in the mouth, so cannot be hidden in mouth by psychotic patients. These products not only increase the patient's compliance but also fetch large revenues to manufacturers due to line extension of the existing formulation.

In the recent past, several new advanced technologies have been introduced for the formulation of mouth dissolving tablets (MDTs) with very interesting features, like extremely low disintegration time, exceptional taste masking ability, pleasant mouth feel and sugar free tablets for diabetic patients.

The technologies utilized for fabrication of MDDDS include lyophilization [4], moulding [5], direct compression [6], cotton candy process [7], spray drying [8], sublimation [9], mass extrusion [10], nanonization [11] and quick dissolve film formation [12]. These techniques are based on the principles of increasing porosity and/or addition of superdis integrants and water soluble excipients in the tablets. The formulations prepared from these techniques differ from each other on the basis of the factors like mechanical strength of final product, drug and dosage form stability, mouth feel, taste, rate of dissolution of the formulation in saliva, rate of absorption from saliva and overall drug bioavailability. Although, numerous technologies had been developed for the fabrication of these uniques dosage forms in last two decades, but so far, no standardized technique has been designed or mentioned in pharmacopoeias for their evaluation except in European Pharmacopoeia (EP), which defines orodispersible tablets as "uncoated tablets intended to be placed in the mouth where they disperse rapidly before being swallowed". EP also specifies that the orodispersible tablets should disintegrate within 3 minutes when subjected to conventional disintegration test used for tablets and capsules [13]. This article presents a detailed review regarding the evaluation measures available in literature to characterize the MDTs, which have been designed keeping in view the special features of these novel drug delivery systems.

Descriptions of Orally Disintegrating Dosage Forms ODTs are distinguished from conventional sublingual tablets, buccal tablets, and lozenges, which require more than a minute to dissolve in oral cavity. In the literature, ODTs also are called orodisperse, mouth-dissolving, quick-dissolve, fast-melt, and freeze-dried wafers. A freeze-dried wafer is a

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quick-dissolving, thin matrix that contains a medicinal agent that does not need water for swallowing. This fragile dosage form requires unit-dose packaging to ensure physical stability. The wafer disintegrates instantaneously in the oral cavity and releases drug, which dissolves or disperses in the saliva. The saliva is swallowed and the drug is absorbed across the gastrointestinal tract (GIT)[14]

- An orally disintegrating tablet (ODT) is a solid dosage form that contains medicinal substances and disintegrates rapidly (within seconds) without water when placed on the tongue. The drug is released, dissolved, or dispersed in the saliva, and then swallowed and absorbed across the GIT[15]

A quick-dissolving tablet (also known as a fast-dissolving, fast-dissolving multi particulate, rapid-dissolving, mouth-dissolving, fast melting, or oro dispersing tablets) is an oral tablet that does not require water for swallowing. The tablet dissolves within 60 seconds when placed in the mouth. The active ingredients are absorbed through mucous membranes in the mouth and GIT and enter the blood stream. A fraction of pre gastric drug absorption may bypass the digestive system and metabolism by the stomach acids and enzymes. In general, the tablets are physically robust and can be packaged in multi dose containers[16].

Ideal properties of ODTs

The performance of ODTs depends on the technology used during their manufacture. The necessary property of such tablets is the ability to disintegrate rapidly and disperse or dissolve in saliva, thereby obviating the need for water. Various technologies have been developed that enable ODT to perform this unique function.

An ideal ODT should meet the following criteria:

- does not require water for oral administration yet disintegrates and dissolves in oral cavity within a few seconds
- has sufficient strength to withstand the rigors of the manufacturing process and post-manufacturing handling • allow high drug loading
- has a pleasant mouth feel
- is insensitive to environmental conditions such as humidity and temperature
- is adaptable and amenable to existing processing and packaging machineries
- is cost-effective.

The Need for Development of ODTS The need for non-invasive delivery systems persists due to patients' poor acceptance of, and compliance with, existing delivery regimes, limited market size for drug companies and drug uses, coupled with high cost of disease management. [17]

II. MECHANISMS OF ODTs

ODTs involve the following mechanisms to achieve the desired fast dissolving characteristics

1. 1.Water must quickly enter into the tablet matrix to cause rapid disintegration and instantaneous dissolution of the tablet
2. Incorporation of an appropriate disintegrating agent or highly water soluble excipients in the tablet formulation.
3. There are some under mentioned mechanisms by which the tablet is broken down into the smaller particles and then subsequently result a solution or suspension of the drug. The mechanisms are-

- High swellability of disintegration
- Chemical reaction
- Capillary action(18)

III. FORMULATION ASPECTS OF ODTs

Important ingredients that are used in the formulation of ODTs should allow quick release of the drug, resulting in faster dissolution. This includes both the pharmacologically active ingredients (drug) and the excipients (additives). A. Selection of drug candidate: Several factors may be considered while selecting an appropriate drug candidate for development of orally disintegrating tablets.

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The ultimate characteristics of a drug for dissolution in mouth and pregastric absorption from fast dissolving tablets include (19)

1. Free from bitter taste
2. Dose lower than 20mg
3. Small to moderate molecular weight
4. Good solubility in water and saliva
5. Partially unionized at oral cavity pH
6. Ability to diffuse and partition in to the epithelium of upper GIT(log >1,or preferably>2)
7. Ability to permeate oral mucosal tissue.

There are no particular limitations as long as it is a substance which is used as a pharmaceutical active ingredient. Researchers have formulated ODT for various categories of drugs used for therapy in which rapid peak plasma concentration is required to achieve the desired pharmacological response. These include neuroleptics, cardiovascular agents, analgesics, antiallergic, anti-epileptics, anxiolytics, sedatives, hypnotics, diuretics, anti-parkinsonism agents, anti-bacterial agents and drugs used for erectile dysfunction (20)

In contrast, the following characteristics may render unsuitable for delivery as an orally disintegrating tablet:-

1. Short half life and frequent dosing.
2. Very bitter or otherwise unacceptable taste because taste masking cannot be successfully achieved.
3. Require controlled or sustained release.
4. Combination with anticholinergics.

B. Selection of excipients

Mainly seen excipients in ODT are as follows at least one disintegrant, a diluent, a lubricant, and optionally, a swelling agent, sweeteners, and flavoring agents etc. Ideal bulk excipients for orally disintegrating dosage forms should have the following properties (Bansal et al, 2003):

1. Disperses and dissolves in the mouth within a few seconds without leaving any residue.
2. Masks the drug's offensive taste and offers a pleasant mouth feel.
3. Enables sufficient drug loading and remains relatively unaffected by changes in humidity or temperature.(21)

IV. TECHNIQUES FOR PREPARATION OF ODTs

The techniques used to manufacture ODTs can be classified as:-

1) Conventional techniques

2) Patented techniques Conventional Techniques

The various conventional technologies are developed for the preparation of Orally Disintegrating drug delivery system that are Freeze drying, Spray drying, Molding , Phase transition process, Melt granulation, Sublimation, Mass Extrusion, Cotton Candy Process, Direct compression(22,23)

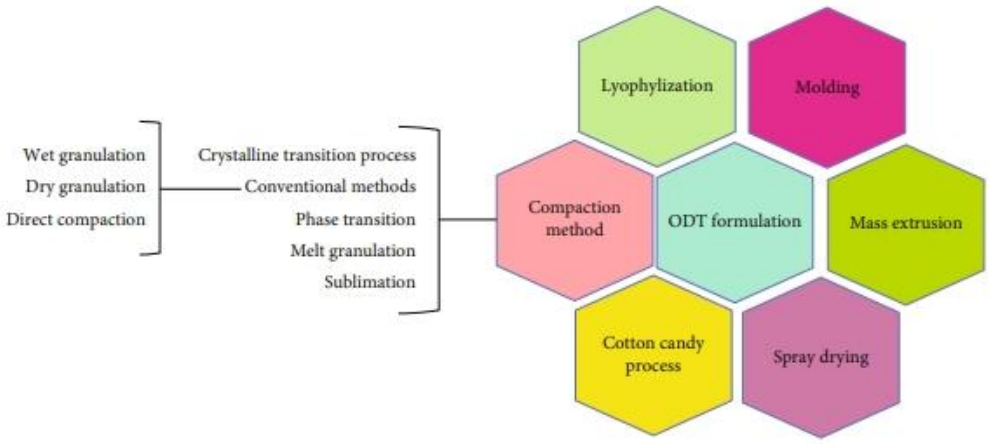

Fig 1. ODT formulation techniques (24)

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Patented Techniques

Rapid-dissolving characteristic of ODTs is generally attributed to fast penetration of water into tablet matrix resulting in its fast disintegration. Several technologies have been developed on the basis of formulation aspects and different processes and resulting dosage forms vary on several parameters like mechanical strength, porosity, dose, stability, taste, mouth feel, dissolution rate and overall bioavailability.(18)

ODT Evaluation of Special Concern

Crushing strength and friability can be assessed as stated in pharmacopoeias. But some tests are of special concern and these include the following

Wetting time

Wetting time of dosage form is related to the contact angle. It needs to be assessed to give an insight into the disintegration properties of the tablets; a lower wetting time implies a quicker disintegration of the tablet. For this purpose, a tablet is placed on a piece of tissue paper folded twice and kept in a small Petri dish (ID = 6.5 cm) containing 6 ml of water, and the time for complete wetting is measured [25]

Disintegration test

The time for disintegration of ODTs is generally less than one minute and actual disintegration time that patient can experience ranges from 5-30 seconds. The standard procedure of performing disintegration test for these dosage forms has several limitations and they are not suitable for the measurement of very short disintegration times. The method needs to be modified for ODTs as disintegration is required without water; thus the test should mimic disintegration in salivary contents. A modified dissolution apparatus is applied to an ODT with a disintegration time that is too fast to distinguish differences between tablets when the compendial method is used. A basket sinker containing the tablets is placed just below the water surface in a container with 900 mL of water at 37 0C, and a paddle rotating at 100 rpm is used. The disintegration time is determined when the tablet has completely disintegrated and passed through the screen of the sinker[26] .

Various scientists41 have developed new in vitro methods that allow an accurate determination of disintegration test. The disintegration test is performed using a texture analyzer instrument. In this test, a flat-ended cylindrical probe penetrates into the disintegrating tablet immersed in water. As the tablet disintegrates, the instrument is set to maintain a small force for a determined period of time. The plots of some distance traveled by the probe generated with the instrument's software provide disintegration profile of the tablets as a function of time The plot facilitates calculation of the start and end-point of the tablet disintegration.[27]

Dissolution test

The development of dissolution methods for ODTs is comparable to the approach taken for conventional tablets, and is practically identical. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent ODT. Other media such as 0.1 M HCl and buffer (pH 4.5 and 6.8) should be evaluated for ODT much in the same way as their ordinary tablet counterparts [28]

Advantages of ODTs

The major advantage of the ODT formulation is that it combines

the advantages of both liquid and conventional tablet formulations. It provides the convenience of a tablet formulation, and also allows the ease of swallowing as the liquid formulation. Others are:

- Not requirement of water or other liquid to swallow.
- Easily dissolution or disintegration in saliva within a few seconds.
- Pleasing taste.
- Leave in trace amount or no residue in the mouth when administered.
- Being portable and easy to transport.
- Being able to be manufactured by direct compression method with low cost.
- Can be easily administered to children, old and mentally disabled patients.

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• Accurate dosing as compared to liquids.
• Dissolution and absorption of drug is fast, offering rapid onset of action.
• Bioavailability of drug is increased as some drugs are absorbed from mouth, pharynx and esophagus through saliva transferring down into the stomach
• First pass metabolism is reduced, thus offering improved bioavailability and thus reduced dose and side effects.
• Free from risk of suffocation due to physical obstruction when swallowed, thus offering improved safety.
• Suitable for sustained/controlled release actives.
• Allows high drug loading (29,30)

Challenges and Limitations for ODTs

Drugs with relatively larger doses are difficult to formulate into ODTs e.g. antibiotics like ciprofloxacin with adult dose tablet containing about 500 mg of the drug [31].

The application for technologies used for ODTs is limited by the amount of drug into each unit dose. The drug dose must be lowerthan 400mg for insoluble drugs and 60mg for soluble drugs [32].

However Flashdose technology can accommodate larger drug doses and offers improved mechanical strength. Orasolv® technology can accommodate a wide range of active pharmaceutical ingredient from 1 mg to 500 mg [33].

Mechanical strength - ODTs are made of porous or soft molded matrices in order to allow its disintegration in mouth. This makes tablet friable and handling becomes difficult.

Orodispersible tablets with highly porous structure and good mechanical strength have been developed by sublimation method. Also Durasolv® has much higher mechanical strength than Orasolv due to the use of higher compaction pressures duringcompression.

Palatability - ODTs are intended to be dissolved in mouth. Most of the drugs have bitter taste. Bitter taste can be masked with enough sweetener and flavors.

Specifically, methods of taste masking include lipophilic vehicles, coating with polymers, carbohydrates, lipids or proteins complexation with cyclodextrins or ion-exchange resins, formation of salts, use of salting out layers and solid dispersions [34].

OraQuick utilizes its own patented taste masking technology i.e. MicroMask®. In MicroMask® technology, taste-masking processis done by incorporating drug into matrix microsphere [35].

Drugs in form of ODTs are hygroscopic in nature and hence need to be protected from humidity [36].

To overcome humidity
problem special working facilities can be designed by simple methods and special air-conditioning systems can be set up.

Size of tablet 7 and 8 mm are easy to swallow while tablets of size 8mm are easy to handle. Hence, tablet sizes which are both easyto handle and swallow are difficult to achieve. For the patient compliance, to make the swallowing easier, round shape punches having optimum dimensions can be used.

Drug candidates should be stable both in water and in saliva, should not ionize at oral cavity pH and should be able to permeateoral mucosal tissue to diffuse and partition in upper GI epithelium (logP > 1, or preferably > 2, not have short half-life). To optimize solubility problem of the active pharmaceutical ingredient some solid buffers and surfactants can also be chosen.

Future of ODTs

ODT technology is applicable to a wide range of therapeutic agents including generics, thereby adding value, i.e. "supergenerics" for veterinary or human application .

Some new quality control methods can be developed to determine the technological aspects of orally disintegrating tablets to define the characteristics of ODTs

Protein and peptide–based therapeutics that used via oral route, have limited bioavailability when administered by immediate release tablets. Those kinds of products usually degrade immediately in gastrointestinal system. The developments of improved oral protein delivery Technology by ODTs, that dispersed and/or dissolved in the saliva, are very promising for the delivery of high molecular weight protein and peptide

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It would be an innovative improvement in the ODT technology when development of ODTs with controlled release properties that can deliver drugs which has short half-lives like 12–24 hours. The added convenience and compliance of such formulations will be used more immensely

In addition, the ability to formulate drugs in large doses will bring another important technological advance. In general, the ODT formulations require large amounts of excipients, and having large doses of drug will only make the final formulation too big to handle. ODT formulations that require fewer excipients than the drug itself will be a break through

ODT technologies are in progress, but development of formulation of ODTs that contains lipophilic active pharmaceutical ingredients is a challenge. New ODT technology should be developed to find a solution for this problem As far as seen in the literature there is not much delayed release ODTs in the market. Controlled release ODTs and/or in line with the purpose system and/or fixed dose combination ODT technologies can be developed as a next generation(37)

V. FUTURE POTENTIAL

These dosage forms may be suitable for the oral delivery of drugs such as protein and peptide-based therapeutics that have limited bioavailability when administered by conventional tablets. These products usually degrade rapidly in the stomach. Should next generation drugs are predominantly protein or peptide based, tablets may no longer be the dominant format for dosing such moieties. Injections generally are not favored for use by patients unless facilitated by sophisticated auto-injectors. Inhalation is one good alternative system to deliver these drugs, but the increased research into biopharmaceuticals so far has generated predominantly chemical entities with low molecular weights. The developments of enhanced oral protein delivery technology by ODTs which may release these drugs in the oral cavity are very promising for the delivery of high molecular weight protein and peptid (18)

Sr no	Name of the Product API	Name of company
1	Imodium Lingual	Imodium Janssen
2	Pepcidin Rapitab Pepcide	
3	Mosid – MT Mosapride citrate	Torrent
4	Calritin Reditabs Micronized Loratadine	Schering plough Corp., USA
5	Nimulid – MD Nimesulide	Panaceas

Table no .1 Marketed Preparations of ODTs(18)

VI. CONCLUSION

The ODTs have potential advantages over conventional oral dosage forms as they improved patient compliance; convenience, rapid onset of action and bioavailability which drawn the attention of many manufactures. The pediatric and geriatric populations are the primary ones whose problems are easily targets by ODTs, as both the groups found it difficult to swallow conventional tablets. ODTs are to maximize the porous structure of the tablet matrix and incorporate super disintegrating agents in optimum concentration so as to achieve rapid disintegration and instantaneous dissolution of the tablet along with good taste masking properties and excellent mechanical strength. Many drugs can be incorporated in ODT especially unpalatable drugs. The research is still going on. More products need to becommercialized to use this technology properly. Thus ODT may be developed for most of the available drugs in near future.

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