IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Review Article
August 2023 Vol.:28, Issue:1

An Approach for Oro Dispersible Tablet: An Overview

IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
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Submitted: 25 July 2023
Accepted: 18 August 2023
Published: 30 August 2023

Keywords: Fast dissolving tablets, mouth dissolving tablets, super disintegrants, patented technology

ABSTRACT

The most prescribable and appropriate route in terms of patient compliance is the delivery of drugs by the oral route. Improving patient compliance always presents a challenge for developing an oral drug delivery system. Over the last decade, fast-disintegrating tablets (FDTs) have received ever-increasing demand, and the field has become a rapidly rising pharmaceutical industry. FDTs are disintegrating and dissolve rapidly in the saliva without the need for water. Such tablets readily in the saliva dissolve or disintegrate in the saliva generally < 60 seconds. Generally, super disintegrants are used in the solid dosage form at a low concentration, typically 1-10% by weight relative to the total dosage unit weight, Different types of super disintegrants such as synthetic, semi-synthetic, natural, and co-processed blends, etc., have been used to establish successful mouth dissolving tablets and to resolve the limitations of traditional methods of tablet dosing. FDTs have benefits such as accurate dosing, easy portability, and manufacturing good physical and chemical stability and an ideal alternative for pediatric and geriatric patients. In addition to these benefits, dysphagia is the most common disadvantage of FDTs benefits associated with numerous conditions such as sudden allergy exposure, mental disability, motion sickness, unconsciousness, water unavailability, etc. To get rid of these problems several innovative drug delivery systems have been developed like mouth dissolving tablets (MDTs). This article aims to address ideal properties, advantages, disadvantages, need for the formulation, super disintegrants, patented technologies, and evaluation and FDTs.

INTRODUCTION

The oral route of delivery of drugs remains to be most acceptable and best route for administration. This route of administration has two main challenges such as odynophagiaand unpalatable drugs. To overcome these problems innovative new drug delivery systems have been developed. Among the novel approaches mouth dissolving drug delivery systemplays an important role. The oral route of delivery of drugs remains to be most acceptable and best route for administration. This route of administration has two main challenges such as odynophagia and unpalatable drugs. To overcome these problems innovative new drug delivery systems have been developed. Among the novel approaches mouth dissolving drugdelivery system plays an important role. [1]

The accentuation on the availability of drugs highlights the importance of the relatively rapid disintegration of a tablet as a criterion for ascertaining uninhibited drug dissolution behavior. A number of factors affects the disintegration replace of tablets.[2]

These are novel types of tablets that disintegrate/disperse/dissolve in saliva within few seconds without water. According to European Pharmacopoeia, these mouth-dissolving tablets should dissolve/disintegrate in less than three minutes. [3]

According to European Pharmacopoeia, “the Fast-Dissolving Tablets should disperse/disintegrate in less than three minutes 1,Fast dissolving tablets are also called as mouth-dissolving tablets, melt-in mouth tablets Oro dispersible tablets, Rapid melts, porous tablets, quick dissolving etc. [4]

Definition:

The Centre for Drug Evaluation and Research (CDER), US FDA defined Oral Disintegrating Tablets (ODT) as “A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.” A rapid-dissolvingtablet can be defined as a solid dosage form that can disintegrate into smaller granules that slowly dissolve in the mouth. The disintegration time for a rapid dissolving tablet varies from a few seconds to more than a minute depending on the formulation and the size of the tablet.[5]

However, of all the above terms United States Pharmacopoeia (USP) approved these dosage forms as ODTs. United States Food and Drug Administration (FDA) defined ODTs as Mouth dissolving tablets formulated mainly by two techniques first use of super disintegrants like croscarmellose sodium, sodium starch glycolate and cross povidone [6]

Oral Disintegrating Tablets:

The Centre for Drug Evaluation and Research defines orally disintegrating tablets asa dosage form – "A solid dosage form which disintegrates rapidly within a matter of seconds when placed under the tongue". The disintegrating time for orally disintegrating tablet varies from seconds to minutes, depending upon the size of tablet and formulation. European pharmacopeia orally disintegrating tablets as- "Uncovered tablet which disperse before ingestion in the buccal cavity". Different technological techniques such as freeze drying or moulding or direct compression etc. are used to prepare the formulation of this type in the pharmaceutical market. [7] There are different approaches reported inthe literature in which the efficacy of Metronidazole was improved using different carrier systems for the treatmentof buccal cavities.[8]

According to European Pharmacopoeia, the ODT should disperse/disintegrate in less than three minutes. The basic approach used in development of MDT is the use of super disintegrants like Cross-linked carboxymethyl cellulose (Croscarmellose), Sodium starch glycolate (Primo gel, Exploitable). Polyvinylpyrrolidone (Polycladose) etc. which provide instantaneous disintegration of the tablet after putting on tongue, thereby releasing the drug in saliva.[9]

Advantages of oral dispersing tablets (ODTs)

- Compatible with taste masking and has a pleasing mouth feel.
- Can be easily administered to pediatric, elderly, and mentally disabled patients.
- No need for water to swallow the tablet.
- No residue in the oral cavity after administration.
- Manufacturing of the tablets can be done using conventional processing andpacking equipment at minimum cost.[3]

- Dissolution and absorption of drugs are fast, offering a rapid onset of action.

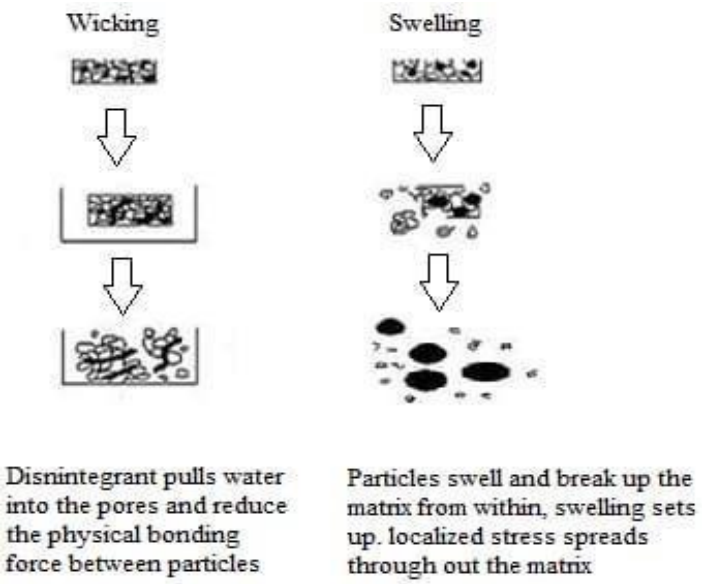
- The bioavailability of drugs is increased as some drugs are absorbed from the mouth, pharynx and exophages through saliva passing down into the stomach. [10]

Mechanism of Super disintegrants:

There are four major mechanisms for tablet disintegration as follows:

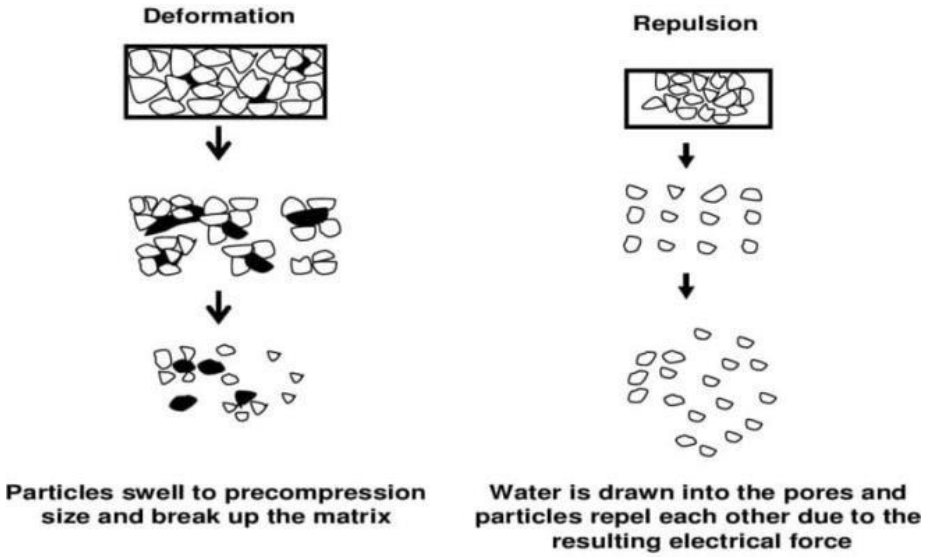
1. Swelling: Perhaps the most widely accepted general mechanism of action for tablet disintegration is swelling. Tablets with high porosity show poor disintegration due to lack of adequate swelling force. On the other hand, sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that if the packing fraction is very high, fluid is unable to penetrate in the tablet and disintegration is again slows down.

2. Porosity and capillary action (Wicking): Disintegration by capillary action is always the first step. When we put the tablet into a suitable aqueous medium, the medium penetrates into the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bond and breaks the tablet into fine particles. Water uptake by tablet depends upon the hydrophilicity of the drug /excipient and on tableting conditions.[10]



3. Due to disintegrating particle/particle repulsive: Forces Another mechanism of disintegration attempts to explain the swelling of tablet made with 'non swellable' disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that no swelling particle also cause disintegration of tablets.[4]

4. Deformation: When the pressure applied to the starch grains they deformed and when pressure removed, they will come into original shape. But when they compressed into tablets, they deformed permanently which release their energy when coming in contact with water.[4]



Limitation of ODTs

- Dryness of the mouth due to decreased saliva production may not be good candidatesfor these tablet formulations.
- Rate absorption from saliva solution and overall bioavailability.
- Drug and dosage form stability.
- Mouth feels.[3]

Criteria for Fast Dissolving Drug Delivery System:

The criterion for FDT is underlined in table 1: [11]

parameters		**Acceptance/rejection**
Water required for swallowing		No
Compatible with taste masking		Yes
Portable		Yes
Fragility concern		No
Good mouth feel		Yes
Patient compliance		Yes
cavity/grittiness		No
Sensitive to environment factors(humidity, temperature)	No	
Suitable for conventional tablet processing and packing	Yes	
Economic	Yes	
Leave residue in oral		

Salient Features of Fast Dissolving Drug Delivery System

➢ Ease of administration to patients who refuse to swallow a tablet, such as pediatrics and geriatric patients and, psychiatric patients.

➢ Convenience of administration and accurate dosing as compared to liquids.

➢ No need of water to swallow the dosage, which is highly convenient feature for patients who are traveling and do not have immediate access to water.[12]

NEWER MANUFACTURING TECHNOLOGIES USED NOW DAYS FOR FAST-DISSOLVING TABLETS

1. Freeze drying/Lyophilization
2. Moulding
3. Sublimation

4. Spray drying

5. Direct compression

6. Mass extrusion

7. Nanonization

8. Fast dissolving film.[3]

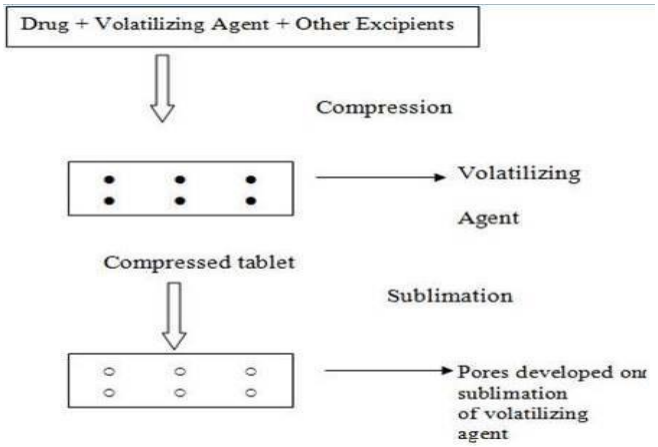
1. Freeze drying/Lyophilization: It is a pharmaceutical process that allows the drying of heat sensitive drugs and biological under low temperature by the application of vacuum to remove water by sublimation. Drugs are dissolved or dispersed in aqueous solution of a carrier, transferred to preformed blister packs and subjected to nitrogen flush to freeze out, then placed in the refrigerator to complete the process. Characteristics of lyophilization techniques are, they possess high porosity and specific surface area, and dissolve rapidly in mouth presenting high drug bioavailability. The major drawback of this system is high cost, time-consuming procedure and fragility, making conventional packing inappropriate for packing this dosage form and stability issues under stress conditions.[13]

2. Moulding: The molding process is of two types i.e., solvent method and heat method. Solvent method involves moistening the powder blend with a hydro-alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and possess a porous structure that hastens dissolution. The heat molding process involves the preparation of a suspension that contains a drug, agar and sugar (e.g., mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at room temperature to form a jelly and drying at 30○C under vacuum. The mechanical strength of molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology.

Compared to the lyophilization technique, tablets produced by the molding technique are easier to scale up for industrial manufacture.[14]

3. Sublimation: The incorporation of volatile ingredients to generate a porous mixture is subjected to a process of sublimation. Highly volatile ingredients like benzoic acid,

ammonium bicarbonate, ammonium carbonate, camphor, naphthalene, urea, phthalic anhydride and urethane may be compressed along with other excipients into a tablet. By process of sublimation, this volatile material is then removed, leaving behind a highly porous matrix. Tablets manufactured by this technique are reported to usually disintegrate within 10-20 sec. Solvents like benzene; cyclohexane can be used as pore forming agents. [11]



4. Spray-Drying: Spray-drying is a process that produces highly porous and fine powders that dissolve quickly. The formulations are prepared by incorporating hydrolysed and non-hydrolyzed gelatins as supporting agents, mannitol as a bulking agent, sodium starch glycolate or croscarmellose sodium as disintegrating and an acidic material (e.g. citric acid) and or alkalimaterial (e.g. sodium bicarbonate) to increase disintegration and dissolution. The formulationis spray dried to give a porous powder. The active drug is dissolved or dispersed in an aqueoussolution of a carrier/polymer.[15]

5. Direct compression: Direct compression represents the simplest and most cost-effective tablet manufacturing technique. MDT can be prepared by using these techniques because of the availability of improved excipients, especially super-disintegrates and sugar-based excipients. (a)Super-disintegrates (b) Sugar based excipients.[3]

MILLING → SIEVING → MIXING → COMPRESSION

6. Mass Extrusion: This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol and methanol and expulsion of softened mass through the extruder or syringe to get a cylindrical shaped extrude which are finally cut into

even segments using heated blade to form tablets. This process can also be used to coat granules of bitter drugs to mask their taste. [16]

7. Nanonization: A recently developed Nano melt technology involves a reduction in the particle size of the drug to nanosized by milling the drug using a proprietary wet-milling technique. The nanocrystals of the drug are stabilized against agglomeration by surface adsorption on selected stabilizers, which are then incorporated into MDTs. This technique is especially advantageous for poor water-soluble drugs. Other advantages of this technology include fast disintegration/dissolution of nanoparticles leading to increased absorption and hence higher bioavailability and reduction in dose, cost-effective manufacturing process, conventional packaging due to exceptional durability and wide range of doses (up to 200 mg of drug per unit).[9]

8. Fast Dissolving Films: It is a new frontier in MDDS that provides a very convenient means of taking medications and supplements. In this technique, a non-aqueous solution is prepared containing water-soluble film-forming polymer (pullulan, carboxy methylcellulose, hydroxypropyl methylcellulose, hydroxyl ethyl cellulose, hydroxyl propyl cellulose, polyvinyl pyrrolidone, polyvinyl alcohol or sodium alginate, etc.), drug and other taste masking ingredients, which is allowed to form a film after evaporation of solvent. In case of a bitter drug, resin adsorbate or coated microparticles of the drug can be incorporated into the film [63]. This film, when placed in the mouth, melts or dissolves rapidly, releasing the drug in solution or suspension form. The features of this system include paper-thin films of size less than 2X2 inches, dissolution in 5 sec, instant drug delivery and flavored after taste. [17]

EVALUATION OF ORAL FAST DISINTEGRATING TABLET

A) PRE-FORMULATION STUDIES.

1) Bulk density: Bulk density was determined by pouring the 5gm of powder in to a 100ml graduated cylinder. The bulk volume (v) was noted. Bulk density was noted by using the following formula,

Bulk density=m/vb m= mass of the powder

vb= bulk volume of the powder [18]

2) Tapped density: The measuring cylinder containing measured amount of the powder

was tapped for specified number of taps and time. The volume occupied by the powder after tappingand mass was noted.

Tapped density =

m/Vt m = mass of the powder

Vt = tapped volume of the powder [3]

3) Carr's index (or) % compressibility: It indicates powder flow properties. It is expressed in percentage and is given:

$$I = \frac{Dt - Db}{Dt} \times 100$$

Where Dt is the tapped density of the powder andDb is the bulk density of the powder.[18]

% Compressibility	Flow property
5-12	Excellent
12-16	Good
18-21	Fair Passable
23-35	Poor
33-38	Very Poor
<40	Very Very Poor

4) Hausner ratio: The hausner ratio is an indirect index of ease of powder flow. It is calculatedby the following

Formula.

$$\text{Hausner ratio} = \frac{Dt}{Db}$$

Where Dt is the tapped density.Db is the bulk density.

Lower Hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25).[14]

5) Angle of repose: It is used to determine the flow properties of powders, pellets, granules.

Itis defined as the maximum angle possible between the surface of the pile of powder and the horizontal plane.

$$\theta = \tan^{-1}h/r$$

where,

θ = angle of repose

h = height of the pile in cmr = radius of the pile in cm

The powder mixture was allowed to flow through the funnel fixed to a stand at definite height. The angle of repose was then calculated by measuring the height and radius of the heap of powder formed.[1]

SL. NO.	Angle of repose	Type pf flow
1	<20	Excellent
2	20-30	Good
3	30-34	Passable
4	>34	Very Poor

B) POST-FORMULATION STUDIES

1) Tablet thickness: 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. [6]

2) Hardness: The limit of hardness for the FDT 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 (Monsanto tablet hardness tester). It is expressed in kg or pound.[19]

3) Uniformity of weight: Randomly select 20 tablets and weigh individually and together in a single pan balance. Note the average weight and calculate the standard deviation. United StatesPharmacopoeia (USP- 29) limit for weight variation in case of tablets is as follows: for

weight130mg or less, ± 10%,for130 mg through 324 mg, ± 7.5% and more than 324 mg, ± 5%.23.

$$PD= [(Wavg–Wind) / Wavg] \times 100$$

Where PD= Percentage deviation, Wavg= Average weight of tablet, Wind = Individual weightof tablet[15]

4) Friability: Friability test is performed to assess the effect of friction and shocks upon transportation and handling, which may often cause tablet to chip, cap or break. Roche friabilitywas used for the purpose. Pre-weighed sample of ten tablets should be placed in the friabilator,then operate for 100 revolutions. After 100 revolutions dedust the tablets and re-weigh. Calculate the percentage loss in weight as follows.

Calculation % Friability = [(A-B)/A] x 100

Where, A = Initial weight of 20 tablets, B = Final weight of 20 tablets. Compressed tablets should not lose more than 1% of their initial weight**.**[15]

5) Wetting time: The wetting time of the mouth-dissolving tablets is very considerable because when we place MDT in the mouth it gets dissolve within a few seconds. Lower wetting time gives very fast disintegration of the MDT, So, it plays an important role in the manufacturing of mouth-dissolving tablets. For the assessment of wetting time 10 ml of distilled water containing eosin, a water-soluble dye was placed in a Petri dish of 10 cm diameter. Tablets were carefully placed in the centre of the Petri dish and the time vital for water to touch the higher superficiality of the tablet was noted. This is called wetting time.[18]

6) Disintegration test: The time for disintegration of FDTs is generally less than 1 min and actual disintegration time that the patient can experience ranges from 5 to 30s. The disintegration test for FDT should mimic disintegration in the mouth within saliva.[19]

7) Dissolution test: The dissolution methods for FDT are practically identical to conventional tablet when FDT does not utilize taste masking. Commonly the drugs may have dissolutionconditions as in the USP monograph. 0.1N HCl, pH 4.5 and pH 6.8 buffers should be used for evaluation of FDT in the same way as their ordinary tablet counterparts. USP 2 paddle apparatus is the most suitable and common choice for dissolution test of FDT tablets as compared to the USP1 (basket) apparatus due to

specific physical properties of tablets. Inpaddle apparatus the paddle speed of 25-75 rpm is commonly used. Since the dissolution ofFDTs is very fast when using USP monograph conditions hence slower paddle speeds may beutilized to obtain a comparative profile. Large tablets (≥1gram) may produce a mound in the dissolution vessel which can be prevented by using higher paddle speeds 36. [19]

8) List of recent research work reported on orodispersable tablets:

Sl no.	**Author name**	**Method of preparation**	**Drug**	**Components**	**Report**
01.	Kumar RS et al (2019)[20]	Direct compression	Ibuprofen	Starchphthalate, croscarmellose sodium,crospovidone	Concluded that in combination with crospovidone,starch phthalate enhanced the dissolution efficiency of the drug.
02.	Mohini Ket al (2009)[21]	Direct compression	Amlodipine Besylate	Camphor, microcrystalline cellulose	Amlodipine is a dihydropyridine ca^{2+}antagonist that inhibits the transmembrane influx of ca^{2+}ions into vascular smooth muscle.
03.	Shukla Aet al (2010)[22]	Direct compression	Meloxicam	Crospovidone, colloidal silica dioxide	Meloxicam- dependent disintegration was observed in batches prepared using camphor as a sublimation agent.

04.	Jain V etal (2010)[23]	Granulation	Aceclofenac	Microcrystalline cellulose,sodium starch glycolate	The mode of actionof aceclofenac is based on the inhibition of prostaglandin synthesis.
05.	Patel B etal (2009)[24]	Direct compression	Glipizide	Crospovidone, croscarmellose sodium	Concluded, the tablets disintegratedrapidly in oral cavity&had acceptable hardness &friability
06	Gohel Met al (2005)[25]	Vaccum drying technique	Nimesulide	Camphor, crospovidone	Thus concluded that,an optimum point can be reachedin the shortest time with minimum efforts.

CONCLUSION

FDT concept evolved to overcome some of the problems that existed in conventional solid dosage form i.e., difficulty in swallowing tablets in pediatric and geriatric patients who constitute a large proportion of the world's population. FDT may lead to improve efficacy, Bioavailability, rapid onset of action, and better patient compliance due to its quick absorptionfrom mouth to GIT as the saliva passes. Fast-dissolving tablet acts like solid dosage form whenoutside the body and solution when administered. The basic approach followed by all the currently available technologies engaged in the formulation of Fast dissolving tablets is 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 The availability of the various technologies and manifold advantages of Fast dissolving tablets willsurely increase its popularity in the near future.

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