

## Orodispersible Tablets: A Review on a Robust Invention

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**Abstract:** Orally disintegrating tablets (ODTs) are the great invention among solid dosage forms containing drugs. ODT disintegrate in the mouth cavity within less than 1 minute leaving an easily swallowable residue. The European Pharmacopeia choked to take up the term orally dispersible tablet is a tablet that disintegrates or disperses within less than 3 minutes in the mouth before swallowing. ODT is a right option of drug delivery for geriatric and paediatric patients because it overhaul the swallowing difficulty problem of dysphagia. The current article is focused on ideal characteristics, advantages and disadvantages, various technologies developed for ODT, evaluation methods along with recent research and future potential.<sup>1,2</sup>

**Key words:** Fast-disintegrating tablets, Fast-dissolving tablets, Mouth-dissolving tablets, Orally disintegrating tablets, Rapidly-dissolving tablets.

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### I. Introduction

Oral route is presently the gold standard in the pharmaceutical industry where it is regarded as the safest, most economical and most convenient method of drug delivery resulting in highest patient compliance. Solid dosage forms are popular because of the ease of administration, exact dosage, self-medication, avoidance of pain, and most importantly the patient compliance. And thereby it will also improve medication adherence.<sup>1</sup> Tablets and capsules are the most popular solid dosage forms. However, many people face difficulty in swallowing capsules and tablets. This difficulty in swallowing is known as dysphasia.<sup>2</sup> It has been found that this problem has been encountered in all groups of patient, but especially with paediatric and elderly populations. Thus, these conventional dosage forms result in high incidence of noncompliance and ineffective therapy with respect to swallowing specially in the case of paediatric, geriatric, or any mentally retarded persons. Orodispersible tablets are otherwise known as orally disintegrating tablets, mouth-dissolving tablets, rapidly-dissolving tablets, fast-disintegrating tablets, fast-dissolving tablets etc. The term orodispersible tablets may be defined as uncoated tablets intended to be placed in the mouth where they disperse readily within 3 min before swallowing.<sup>3</sup> United States Pharmacopoeia has also approved these dosage forms as orodispersible tablets. The European Pharmacopoeia has used the term orodispersible tablet for tablets that disperses readily within 3 minutes in the mouth before swallowing.

When put in the mouth, these dosage forms disintegrate instantly to release the drug, which dissolves or disperses in the saliva. Thereafter, the drug may get absorbed from the pharynx and oesophagus or from other sections of g.i.t as the saliva travels down. In that cases, bioavailability is significantly greater than that observed from conventional tablet dosage forms. Thus, ODTs are solid unit dosage forms like conventional tablets, but are composed of super disintegrants, which help them to dissolve the tablets immediately in the mouth in the presence of saliva without any difficulty of swallowing. It offers several advantages with respect to its stability, administration without water, easy manufacturing, dosing accuracy, small packaging size, and easy handling.<sup>4,5,6,7</sup> Its ease of administration in the population especially for geriatric, paediatric or any mentally retarded persons makes it a very popular dosage form. Due to the presence of super disintegrants, it gets dissolved quickly and it provides rapid onset of action.<sup>8</sup>

### Advantages Of ODTs

Drugs present in orodispersible tablets are also not be subjected to first pass metabolism. This type of drug delivery is becoming popular day by day due to its variety of advantages:

- Administration to the patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure and patients who refuse to swallow such as paediatric, geriatric and psychiatric patients.
- Rapid drug therapy intervention.

- Achieve increased bioavailability through pre-gastric absorption of drugs from mouth, pharynx and oesophagus as saliva passes down.
- Convenient for administration and patient compliant for disabled, bedridden patients and for travellers and busy people, who do not always have access to water.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in paediatric patients.

**Disadvantages of ODTs:**

- Hygroscopic in nature.
- Low amount of drug can be incorporated in each dose.
- Some time it possesses mouth feeling
- Highly fragile sometimes.
- ODT requires special packaging for stabilisation & safety of stable product.
- Eating and drinking may become restricted.<sup>8</sup>

**Ideal Properties of ODTs:**

**Compared with the same dose administered in a conventional dosages**

- a. Require no water for oral administration.
- b. Easily dissolve or disperse in saliva within a few seconds.
- c. Have a pleasing mouth feel.
- d. Leave negligible or no residue in the mouth when administered.
- e. Portable and easy to transport.
- f. Able to be manufactured in a simple conventional manner within low cost.
- g. Be less sensitive to environmental conditions like temperature, humidity etc.
- h. Permit the manufacture of tablet using conventional processing.
- i. It should be compatible with taste masking and other excipients.
- j. Leave minimal or no residue in the mouth after oral administration<sup>9</sup>

**Mechanism of Superdisintegrants:**

Superdisintegrants provide quick disintegration due to combined effect of swelling and water absorption by the formulation.<sup>9</sup> Due to swelling of superdisintegrants, the wetted surface of the carrier increases, this promotes the wettability and dispersibility of the system, thus enhancing the disintegration and dissolution. The optimum concentration of the superdisintegrant can be selected according to critical concentration of disintegrant. Below this concentration, the tablet disintegration time is inversely proportional to the concentration of the superdisintegrant, whereas if concentration of superdisintegrant is above critical concentration, the disintegration time remains almost constant or even increases .

**Challenges to develop ODTs**

- i. Rapid disintegration of tablet.
- ii. Avoid increase in tablet size
- iii. Have sufficient mechanical strength
- iv. Minimum or no residue in mouth
- v. Protection from moisture
- vi. Good package design
- vii. Compatible with taste masking technology
- viii. Not affected by drug properties<sup>10</sup>

**Excipients required in formulating ODTs:**

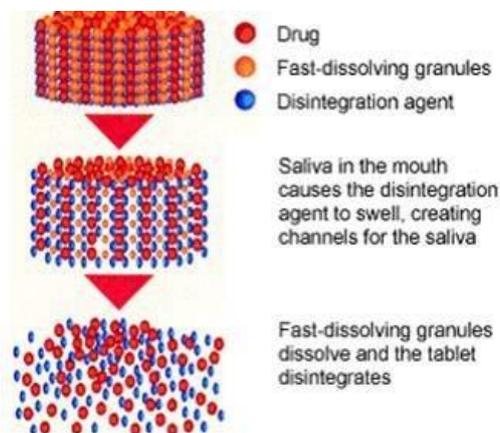
Excipients used in FDTs contain one superdisintegrant, a diluent, a lubricant and optionally swelling agent, a permeabilizing agent (depending upon drug nature), sweeteners and flavouring agents. Names of excipients classes and their percentages are given in Table 2.

Name of the excipients	Percentage used
Superdisintegrants	1–15
Binder	5–10
Antistatic agent	0–10
Diluents	0–85

**Table 2: Names And Weight Percentage Of Various Major Excipients<sup>12</sup>.**

**Superdisintegrants:**

In many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants principally affects the rate of disintegration and hence the dissolution. Disintegrants are substance or mixture of substances added to the drug formulations, which facilitate dispersion or breakup of tablet content of capsule in to smaller particles for quick dissolution. Superdisintegrant, are substances, which facilitate the faster disintegration with smaller quantity in contrast to disintegration.<sup>13</sup>

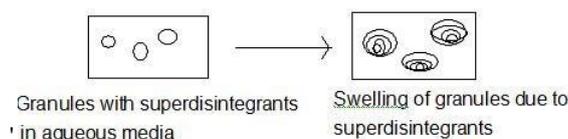


**Fig. 1 Basic mechanism of Superdisintegrant.**

**MECHANISMS of SUPERDISINTEGRANTS:**

There are four major mechanisms for tablet disintegration as follows:

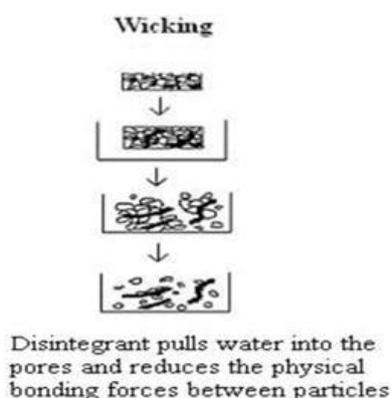
1) Swelling



**Fig. 2 Swelling mechanism**

2. Porosity and Capillary Action (Wicking)

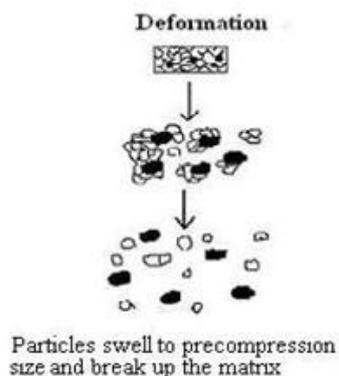
Disintegration by capillary action is always the first step. Effective disintegrants that do not swell are believed to impart their disintegrating action through porosity and capillary action. Tablet porosity provides pathways for the penetration of fluid into tablets.<sup>14</sup>



**Fig. 3 Wicking mechanism**

3. Deformation

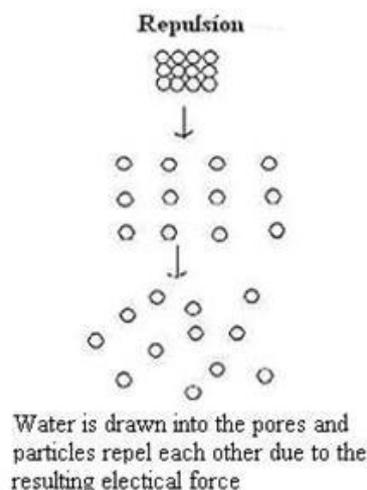
Hess had proved that during tablet compression, disintegrated particles get deformed and these deformed particles get into their normal structure when they come in contact with water or aqueous media.



**Fig. 5 Deformation mechanism.**

4. Due to disintegrating particle or particle repulsive forces

Guyot-Hermann has proposed a particle repulsion theory based on the observation that non-swelling particle also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it. Researchers found that repulsion is secondary to wicking. It is believed that no single mechanism is responsible for the action of most disintegrants.<sup>14</sup>



**Fig. 6 Repulsion mechanism.**

5. Heat of wetting

When disintegrants with another properties get wetted, localized stress is created due to capillary air expansion, which aids in disintegration of tablet.

6. Due to release of gases

Carbon dioxide released within tablets on wetting due to interaction between bicarbonate and carbonate with citric acid or tartaric acid. The tablet disintegrates due to generation of pressure within the tablet. This effervescent mixture is used when pharmacist needs to formulate very rapidly dissolving tablets or fast disintegrating tablet.

7. Combination action

In this mechanism, the combination of both wicking and swelling action facilitate disintegration. E.g. Crosspovidone

8. Enzymatic Reaction

Enzymes present in the body also act as disintegrants. These enzymes shortfalls the binding action of binder and helps in disintegration. Due to swelling, pressure is exerted in the outer direction that causes the tablet to burst or the accelerated absorption of water leads to an enormous increase in the volume of granules to promote disintegration.

## ROLE OF PHARMACISTS IN DISPENSING ODT:

Pharmacists are the drug experts and ideal persons to know about recent pharmaco therapeutic advances, thus have opportunity to educate the patient for effective treatment. It is responsibility of pharmacists to keep up-to-date on potential drug-drug and drug-food interactions of medications, that they may counsel properly to the patients. The majority of patients receiving ODT preparations have little knowledge of this novel dosage form.<sup>15</sup>

### Patient counselling in effective use of ODT :

ODT developed offers significant advantages for various group of patients, but the majority of patients receiving ODT have little apprehend of this novel dosage form. Patients receiving ODT may be amazed when tablets begin to disintegrate or dissolve in mouth. As pharmacists are ideal persons to know about the recent technologies, thus have opportunity to educate the patients for effective treatment.<sup>16</sup>

Counselling of patients about this dosage form can avoid any confusion and misunderstanding in taking ODT. Patient information that need to be provided include:

- Storage of this dosage form is important, as some of ODT developed may not have sufficient mechanical strength, which needs to be handled carefully.
- Patients with dryness of mouth or who take anticholinergic drugs may not be suitable candidates for administering ODT. Although no water is required to allow drug to disperse quickly and efficiently but decreased volume of saliva may slow the rate of disintegration or dissolution and may reduce the bioavailability of the drug.
- Patients need to be clearly counsel about the difference between effervescent and ODT. Some of technologies use effervescence, which encounters a pleasing tingling effect on the tongue.
- Although chewable tablets are available in market and patient need to be counselled about dissimilarities between chewable and ODT tablets. This ODT can be used easily in children who have lost their primary teeth and in geriatric patients who have lost their teeth permanently. With the pharmacists counselling, intervention and assistance about ODT, all patients on this novel dosage form could be more congruously and effectively treated with greater convenience.

### Future Perspectives:

Future challenges for many ODT manufacturers include reducing costs by finding ways to manufacture with conventional equipment, using versatile packaging, improving mechanical strength and taste-masking capabilities. ODTs may be suitable for the oral delivery of drugs such as protein and peptides.<sup>17</sup>

## II. Conclusion

In the last decade the evolution of orally disintegrating tablets (ODTs) and thin-film platforms has grown enormously in the field of pharmaceuticals. A wide variety of new masking methods combined with the aforementioned platforms have been developed in order to mask the bitter taste of drugs and achieve better patient compliance. The commercial success and viability of such products requires the development of robust formulations with excellent palatability, disintegration times, physicochemical stability and pharmacokinetic profiles. In this review, emerging trend of orodispersible tablets are summarized. A better understanding of these drug delivery approaches will help researchers to select the appropriate platform, or to develop innovative products with improved safety, patient compliance and clinical significance.<sup>18</sup>

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