



## “A COMPREHENSIVE REVIEW ON ORAL DISPERSIBLE TABLETS: INNOVATIONS, FORMULATION STRATEGIES AND FUTURE PROSPECTS”

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### ABSTRACT: -

Oral-dispersible tablets (ODTs) have emerged as an innovative dosage form that improves patient compliance and offers advantages over conventional tablets. These solid units rapidly disintegrate in the oral cavity, usually within one minute of contact with saliva, primarily due to the action of super-disintegrants. This makes ODTs particularly beneficial for pediatric and geriatric patients who experience swallowing difficulties. Various formulation approaches have been explored for ODT development, including direct compression, molding, melt granulation, phase-transition techniques, sublimation, lyophilization, and effervescent methods. Similar to conventional tablets, ODTs undergo evaluation for parameters such as hardness, friability, wetting time, moisture uptake, disintegration, and dissolution to ensure quality and performance.

**Keywords:** Disintegration, Drug delivery system, Oral dispersible tablets, Super-disintegrants, Patented technologies

### INTRODUCTION: -

Solid oral dosage forms are widely favored due to their low production cost, ease of administration, precise dosing, pain avoidance, and enhanced patient compliance. <sup>[1,2]</sup> Conventional tablets are commonly prescribed; however, certain patient populations—such as pediatric, geriatric, bedridden, mentally ill, or uncooperative patients—often face difficulties swallowing them, which can result in poor compliance and ineffective treatment. <sup>[3]</sup>

To address these challenges, pharmaceutical scientists have developed Oro-dispersible Tablets (ODTs), a novel oral dosage form designed to dissolve rapidly in the mouth, typically within seconds, without the need for water. Compared to conventional dosage forms, ODTs can offer improved solubility, faster absorption, quicker onset of action, and enhanced bioavailability. <sup>[4,5]</sup>

According to the European Pharmacopoeia, ODTs are solid dosage forms that rapidly dissolve in the mouth, generally within three minutes, before swallowing. <sup>[6]</sup> The United States Food and Drug Administration (FDA) defines ODTs as solid dosage forms containing an active ingredient that disintegrates almost instantly—usually within seconds—when placed on the tongue, with typical disintegration times ranging from a few seconds to about a minute. <sup>[7]</sup>

ODTs provide several advantages, including ease of administration for patients with swallowing difficulties, improved compliance, rapid onset of therapeutic action, enhanced bioavailability, and good stability. The formulation of ODTs often relies on superdisintegrants, such as cross-linked carmellose sodium, cross-linked polyvinylpyrrolidone (PVP), sodium starch glycolate, and others. <sup>[8]</sup>

Superdisintegrants play a critical role in promoting rapid tablet disintegration upon contact with saliva. [9]

ODTs can be prepared using various techniques, including direct compression, mass extrusion, sublimation, freeze-drying, and spray-drying. The primary aim of this review is to explore the recent advancements in ODT technology, requirements for active pharmaceutical ingredients, and the methods used for evaluating ODTs.

#### **IDEAL PROPERTIES OF ODTs: -** [10,11]

1. Minimal water requirement: Oro-dispersible tablets should disperse or dissolve rapidly in saliva, requiring little to no water for administration. The disintegration time should ideally be within a few seconds to minutes, ensuring faster onset of action and improved patient compliance.
2. Ease of transport and handling: The formulation should be sufficiently robust to withstand packaging, transportation, and normal handling without breakage.
3. Simple manufacturing process: An ideal ODT can be prepared using cost-effective and easily scalable manufacturing techniques without requiring complex technology.
4. Stability against environmental stress: ODTs should maintain their integrity and performance under normal storage conditions, showing minimal sensitivity to factors like pressure, temperature, and humidity.
5. High drug loading capacity: The dosage form should have the ability to incorporate adequate amounts of drug while maintaining rapid disintegration and palatability.

#### **LIMITATIONS OF ODTs: -** [12]

1. Many water-soluble diluents used in the preparation of ODTs are hygroscopic, which can lead to increased moisture uptake and may compromise the product's stability unless protective packaging is used.
2. If the formulation is not properly optimized, tablets may produce an unpleasant taste or gritty sensation in the oral cavity, reducing patient compliance.
3. Drugs that are light- or moisture-sensitive often require specialized packaging systems (e.g., aluminium-aluminium blisters), which increases manufacturing cost.
4. ODTs are generally sensitive to handling; therefore, they should be administered immediately after removal from the pack to maintain integrity.
5. Formulations should allow for rapid onset of therapeutic effect while ensuring they leave little to no residue in the mouth.
6. To improve acceptance, the dosage form must ensure a pleasant mouthfeel for the patient.

#### **DISADVANTAGES OF ODTs: -** [13]

1. Rapidly disintegrating tablets are often hygroscopic, so they require storage under controlled humidity and temperature conditions.
2. To ensure proper stability and protection, ODTs usually need specialized packaging systems.
3. These tablets generally exhibit low mechanical strength, which makes them fragile and requires careful handling.
4. If not carefully formulated, they may result in an unpleasant taste or gritty mouthfeel, reducing patient acceptability.

#### **ADVANTAGES OF ODTs: -**

1. Can be administered to patients who have difficulty swallowing conventional dosage forms, such as bedridden patients, elderly individuals, and patients with renal failure, thereby improving patient compliance. [14]
2. Suitable for bedridden, disabled, traveling, and busy individuals, as administration does not necessarily require water. [15]
3. Capable of accommodating high drug loading.
4. No chewing required, making it convenient for pediatric and geriatric patients. [16]

### ODT DRUG RELEASE MECHANISM: -

Orally disintegrating tablets (ODTs) release the drug with the help of superdisintegrants such as croscarmellose sodium, crospovidone, microcrystalline cellulose (MCC), and talc. These excipients act through different mechanisms once the dosage form comes in contact with saliva or aqueous medium.

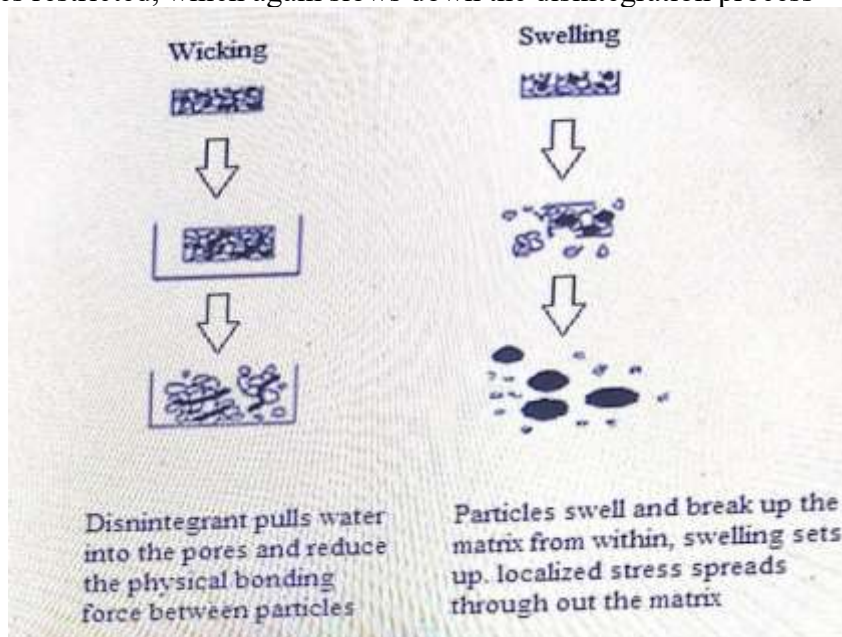
Mechanistic Approaches of Superdisintegrants:

A. Porosity and Capillary Action (Wicking):

- The capillary action reduces intermolecular bonding between drug particles.
- As a result, the tablet structure weakens and breaks into smaller fragments.

B. Swelling:

- Swelling of disintegrants is one of the most widely accepted mechanisms of tablet disintegration. When disintegrants come in contact with water, they absorb fluid and expand, creating pressure within the tablet structure that leads to its breaking apart. However, the efficiency of swelling depends on the tablet's porosity. Tablets with high porosity often show poor disintegration due to the lack of sufficient swelling force, as the pores allow water to escape without generating adequate pressure. Conversely, in tablets with lower porosity, the swelling force is strong enough to cause rapid disintegration. It is important to note that when the packing fraction is too high, fluid penetration into the tablet becomes restricted, which again slows down the disintegration process <sup>[17]</sup> (Figure No. 1).



**Figure No. 1: Drug release mechanism**

C. Deformation:

- During compression, disintegrant particles may become deformed.
- When exposed to water, they try to regain their original shape, exerting a disruptive force.
- In highly compacted tablets, deformation energy stored during compression is released, leading to tablet breakup.

D. Combination Mechanism:

- Some disintegrants (e.g., crospovidone) act through both swelling and wicking mechanisms, enhancing the rate of tablet disintegration. <sup>[18]</sup>

### METHOD OF PREPARATION: -

1. Melt Granulation:

In this method, a binder is melted and combined with the powder mixture to form granules, which are then cooled and compressed into tablets. This technique helps improve the solubility of drugs that

are poorly soluble and eliminates the need for organic solvents, resulting in a more efficient process.<sup>[19]</sup>

## 2. Wet Granulation:

The active pharmaceutical ingredient (API) and excipients are mixed with a binder solution to form granules, which are then dried and pressed into tablets. This method enhances the flow, compressibility, and consistency of the powder, making it ideal for APIs that cannot be compressed directly.<sup>[20]</sup>

## 3. Spray Drying:

Spray drying is widely used in the pharmaceutical industry to create highly porous and fine powders. Common ingredients in these formulations include gelatin (either hydrolyzed or not) as a matrix former, mannitol as a filler, and disintegrants such as croscarmellose sodium. Effervescent agents like citric acid and sodium bicarbonate may also be included to help the tablet disintegrate quickly. Tablets made using spray-dried powders often disintegrate within 20 seconds.<sup>[21-23]</sup>

## 4. Lyophilization (Freeze drying):

Lyophilization involves freezing a drug–excipient solution or suspension, followed by removal of water through sublimation under vacuum. This process creates a lightweight, porous matrix that enables saliva to penetrate quickly, causing very rapid disintegration in the oral cavity.<sup>[24]</sup> Such tablets are highly effective for patients needing fast onset of action. However, this method is expensive, time-consuming, and requires specialized equipment and packaging, which may limit large-scale commercial use.

## 5. Direct Compression:

Direct compression is considered the simplest and most economical technique for preparing fast/Oro-dispersible tablets. In this method, a blend of drug, superdisintegrants, and other excipients is directly compressed into tablets using conventional tableting machines.<sup>[25]</sup> The success of this approach mainly depends on the right choice of excipients (especially superdisintegrants and diluents) and optimization of compression parameters. Advantages include ease of scale-up, low cost, and fewer processing steps, but tablets may sometimes have limited mechanical strength.

## 6. Sublimation Method:

In sublimation, a volatile substance (such as camphor, menthol, or ammonium bicarbonate) is incorporated into the tablet formulation.<sup>[26]</sup> After compression, the tablets are exposed to heat or vacuum, which removes the volatile component by sublimation, leaving behind a porous structure. This increased porosity enhances saliva penetration and disintegration of the tablets. The method is relatively simple but requires careful handling of volatile agents to ensure safety and product uniformity.

## 7. Mass Extrusion:

This method involves softening the mixture of drug and excipients with solvents such as polyethylene glycol– methanol, then extruding it to form uniform cylindrical shapes. These shapes can be further processed into granules or coated particles to mask undesirable tastes.<sup>[27]</sup>

# EXCIPIENTS USED IN PREPARATION OF ODTs: -

## 1. Superdisintegrants:

- Function: Increase disintegration and dissolution rate.
- Examples: Crospovidone, MCC, Sodium starch glycolate, Croscarmellose sodium.

## 2. Sweeteners and Sugar-Based Excipients:

- Function: Act as bulking agents, provide sweetness, improve mouthfeel, and mask unpleasant taste.
- Examples: Aspartame, Dextrose, Fructose, Mannitol, Sorbitol, Maltose.

## 3. Flavors:

- Function: Enhance palatability, improve compliance and acceptability.
- Examples: Vanilla, Citrus oil, Fruit essence, Peppermint oil, Clove oil, Eucalyptus oil.

## 4. Surface-Active Agents:

- Function: Reduce interfacial tension, improve solubilization and wetting.

- Examples: Sodium lauryl sulfate (SLS), Sodium dodecyl sulfate.
5. Colorants:
- Function: Improve appearance and organoleptic properties.
  - Examples: Sunset yellow, Red iron oxide, Amaranth.
6. Lubricants:
- Function: Reduce friction during compression and prevent sticking.
  - Examples: Magnesium stearate, Stearic acid, Zinc stearate, Talc, PEG.
7. Fillers (Diluents):
- Function: Increase bulk of the dosage form, provide uniformity of weight and content.
  - Examples: Mannitol, Sorbitol, Xylitol, Calcium carbonate, Magnesium carbonate.

#### **PATENTED TECHNOLOGIES OF ODTs: -**

1. Zydis Technology (R.P. Scherer):
  - Method: Freeze-drying (lyophilization) of drug in gelatin matrix.
  - Key Feature: Dissolves in 2–3 seconds; very lightweight; self-preserving due to low water content.
  - Limitation: Fragile, needs special blister packaging. <sup>[28-30]</sup>
2. Orasolv Technology (CIMA Labs):
  - Method: Direct compression with effervescent disintegrating agents (18–27% w/w).
  - Key Feature: Taste masking + fast disintegration via effervescence.
  - Limitation: Tablets are soft/fragile, need special packaging. <sup>[28]</sup>
3. Durasolv Technology (CIMA Labs):
  - Method: Direct compression with high compaction pressure.
  - Key Feature: Stronger, durable tablets; can be packed in conventional blisters/vials.
  - Limitation: Not suitable for high-dose drugs (due to high compression). <sup>[28]</sup>
4. Wow Tab Technology (Yamanouchi Pharma):
  - Method: Combination of high and low moldable saccharides.
  - Key Feature: “WOW = Without Water”; can handle up to 50% drug loading; disintegrates in ~13 s.
  - Limitation: May require careful balance of saccharides for taste and hardness. <sup>[31]</sup>
5. Flashtab Technology (Prographarm Laboratories):
  - Method: Wet/dry granulation + compression; uses disintegrants (CMC, cross-PVP) & swelling agents (starch, MCC).
  - Key Feature: Good mechanical strength, disintegrates in <1 min.
  - Limitation: Slightly slower disintegration vs Zydis/Wow tab. <sup>[28]</sup>
6. Flash Dose Technology (Fuisz Corporation):
  - Method: Spinning mechanism forms “sugar floss” (cotton-candy like) matrix with drug.
  - Limitation: Fragile, requires careful packaging. <sup>[28]</sup>
7. Oraquick (KV Pharmaceuticals):
  - Method: Micromask™ taste-masking with microspheres.
  - Key Feature: Superior taste masking, strong tablets, rapid disintegration.
  - Limitation: Manufacturing process is relatively complex. <sup>[29]</sup>
8. NanoCrystal Technology (Elan Pharma):
  - Method: Patented wet milling to reduce drug particles (<1000 nm).
  - Key Feature: Higher surface area → improved dissolution & bioavailability.
  - Limitation: Needs specialized equipment & stabilization of nanosuspension. <sup>[28]</sup>
9. Pharmaburst Technology (SPI Pharma):
  - Method: Direct compression using co-processed excipients (mannitol-based).
  - Key Feature: Tablets dissolve in 30–40 s; simple and cost-effective.
  - Limitation: Not as rapid as lyophilized ODTs. <sup>[32]</sup>

## EVALUATION PARAMETERS OF ODTs:

### 1. Weight Variation Test: <sup>[33]</sup>

- This test ensures that each tablet in a batch contains a uniform amount of drug as per the label claim.

Acceptance criteria (IP/USP/BP):

- For tablets  $\leq 80$  mg:  $\pm 10\%$
- For tablets 80–250 mg:  $\pm 7.5\%$
- For tablets  $\geq 250$  mg:  $\pm 5\%$

### 2. Thickness: <sup>[34]</sup>

- It is usually measured using a Vernier caliper. Five tablets are randomly chosen and measured individually. Consistency in thickness indicates good process control.

### 3. Hardness Test: <sup>[35]</sup>

- Tablet hardness indicates mechanical strength and resistance to breakage during handling, transport, and storage. However, for ODTs, excessive hardness may reduce patient compliance and delay disintegration. The hardness is measured using instruments such as the Monsanto or Pfizer hardness tester.
- Acceptance range: Generally, 2–4 kg/cm<sup>2</sup> for ODTs.

### 4. Friability Test:

- Friability measures the ability of tablets to withstand mechanical stress during handling, packaging, and transportation. In this test, a specific number of tablets are accurately weighed and placed in a Roche friabilator. Acceptance criteria (IP/USP): Percentage weight loss should be  $\leq 1\%$ .

### 5. Wetting Time: <sup>[36]</sup>

- Wetting time reflects the ability of a tablet to absorb moisture, which is critical for rapid disintegration. A tablet is placed on folded tissue paper in a petri dish containing 6 mL of water, and the time taken for complete wetting is recorded.

### 6. Disintegration Test: <sup>[37]</sup>

- Disintegration is tested using the pharmacopoeial disintegration apparatus. Six tablets are placed in the apparatus tubes containing specified medium (e.g., water or buffer at  $37 \pm 2^\circ\text{C}$ ). The time taken for complete disintegration is recorded.
- Acceptance criteria (ODTs): Should disintegrate within  $\leq 30$  seconds (as per European Pharmacopoeia).

### 7. In Vitro Dissolution Studies: <sup>[38]</sup>

- Dissolution testing of ODTs can be performed similarly to conventional tablets. Typically, the USP Type II (paddle) apparatus is used at 50 rpm in suitable media such as:
- 0.1 N HCl (pH 1.2)
- Acetate buffer (pH 4.5)
- Phosphate buffer (pH 6.8)

## INDUSTRIAL APPLICATIONS: -

The industrial significance of ODT technology can be summarized as follows:

- **Formulation Development:** Enables the design and development of orally disintegrating dosage forms using existing and novel disintegrants.
- **Technology Advancement:** Provides opportunities to refine and improve current ODT technologies for better efficiency and patient acceptability.
- **Optimization of Excipients:** Focuses on optimizing the proportion of disintegrants and excipients to achieve rapid disintegration with adequate mechanical strength.
- **Packaging Innovation:** Encourages the selection and development of suitable, cost-effective packaging systems that enhance the stability and shelf life of ODTs.
- **Taste Masking Approaches:** Supports the exploration of taste-masking agents and techniques to improve palatability and patient compliance.

- Polymer Modification: Promotes research on modifying coating polymers to develop new disintegrants suitable for ODT formulations.

### **FUTURE PROSPECTS OF ODTs:**

Orally disintegrating dosage forms hold potential for the delivery of protein- and peptide-based therapeutics, which generally show poor bioavailability when given as conventional tablets.

- Since such molecules degrade rapidly in the stomach, traditional solid tablets may not remain suitable for their administration in the future.
- As next-generation drugs are expected to be largely protein- or peptide-based, alternative routes will be needed. Although injections are effective, they are often disliked by patients despite the availability of devices like auto-injectors.
- Inhalation systems provide another possible route, but research into biopharmaceuticals has mostly focused on small chemical entities with low molecular weight.
- The advancement of oral protein delivery technologies through ODTs, capable of releasing such drugs directly in the oral cavity, appears promising for improving the delivery of high molecular weight peptides and proteins.

### **CONCLUSION:**

Orally disintegrating tablets (ODTs) represent a novel and patient-friendly drug delivery system that addresses several limitations of conventional dosage forms. They provide advantages such as ease of administration, enhanced patient compliance, rapid onset of action, and in some cases, improved bioavailability. While significant progress has been made in their formulation and manufacturing technologies, further research is required to develop cost-effective processes, stronger mechanical properties, and effective taste-masking strategies. With the growing acceptance in the market and the availability of advanced technologies, ODTs hold great potential for product line extensions, lifecycle management, and first-to-market opportunities in the pharmaceutical industry.

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