Journal of Comprehensive Pharmaceutical Sciences
Online peer reviewed Journal | Published by COGNIX PRESS
Content available at www.cognixpress.in Online ISSN: 3139-5163

RESEARCH ARTICLE
OPEN ACCESS

FORMULATION, MANUFACTURING TECHNIQUES, AND EVALUATION OF ORALLY DISINTEGRATING TABLETS

DEEPTI DWIVEDI[1], ANKUR SRIVASTAVA*[2], DEEPIKA KUNWAR[3], BHARAT MISHRA[4]

[1,3,4]*Institute of Pharmacy-Dr Shakuntala Misra National Rehabilitation University, Lucknow.*
[2] *Institute of Pharmacy- Ram Manohar Lohia Awadh University, Ayodhya.*

Corresponding Author
Dr. Ankur Srivastava

Article History: 19.07.2026 Received: 06.08.2026 Revised: Accepted: 26.08.2026

ABSTRACT

The oral route of drug administration is widely considered the most preferred method due to its safety, ease of administration, cost-effectiveness, and high level of patient acceptance. Despite these advantages, conventional oral dosage forms may pose swallowing difficulties, particularly in pediatric, geriatric, and dysphagic patients, leading to poor compliance. To address these challenges, orally disintegrating tablets (ODTs) have emerged as a novel and patient-friendly dosage form. ODTs are designed to disintegrate rapidly in the oral cavity and dissolve in saliva without the need for water, thereby facilitating ease of administration. This feature makes them particularly suitable for patients experiencing conditions such as motion sickness, frequent vomiting, and neurological disorders. Additionally, ODTs can enhance the onset of action for drugs that are readily absorbed through the oral mucosa.

The increasing demand for such advanced drug delivery systems has led to the development of various formulation strategies and manufacturing techniques. This review provides an overview of the ideal properties, benefits and limitations, formulation components, preparation methods, and evaluation parameters of ODTs. Furthermore, it highlights commercially available products and recent advancements in this field, along with future perspectives in oral drug delivery technology.

Keywords: *Orally Disintegrating Tablets, Fast Dissolving Tablets, Oral Drug Delivery, Excipients, API.*

INTRODUCTION

Oral drug administration is the most widely preferred route due to its ease of use, non-invasive nature, versatility, and high patient compliance.(2,14) In addition, solid oral dosage forms are economical to manufacture as they do not require sterile conditions. Despite these advantages, conventional tablets and capsules may pose swallowing difficulties, particularly in pediatric, geriatric, and dysphagic patients, which can lead to poor therapeutic compliance [1-3].

To overcome these limitations, novel oral dosage forms such as orally disintegrating systems have been developed. These dosage forms rapidly disintegrate in the oral cavity without the need for water, thereby enhancing patient convenience and acceptance.(5-7) The oral cavity is an attractive site for drug delivery due to its rich blood supply, relatively high permeability, and reduced enzymatic activity compared to the gastrointestinal tract, which may improve drug absorption and onset of action [6,9].

Overview of Oral Mucosa

The oral cavity consists of the lips, cheeks, tongue, hard and soft palate, and the floor of the mouth. Its lining, known as the oral mucosa, includes buccal, sublingual, gingival, palatal, and labial regions. Among these, the buccal and sublingual areas contribute significantly to drug absorption due to their large surface area and permeability [10-12].

Structurally, the oral mucosa is composed of a stratified epithelium supported by a basement membrane, lamina propria, and submucosa. Its primary function is to protect underlying tissues while also serving as a potential route for systemic drug delivery. Based on function and location, oral mucosa is classified into lining mucosa, masticatory mucosa, and specialized mucosa [12].

Oral drug delivery

Oral drug delivery is the most widely accepted and commonly used route of administration due to its convenience, cost-effectiveness, and high patient compliance. However, conventional solid dosage forms such as tablets and capsules may be difficult to swallow, particularly for pediatric, geriatric, and dysphagic patients. This limitation often results in poor adherence to therapy and reduced treatment effectiveness [12-14].

To address these challenges, orally disintegrating dosage forms (ODDFs) have been developed. These formulations are designed to disintegrate rapidly in the oral cavity without the need for water, thereby improving patient compliance and convenience. Over the past decade, ODDFs have gained significant attention in pharmaceutical research and development due to their patient-friendly nature and potential for enhanced drug bioavailability.

Oral Mucosa as a Drug Delivery Site

The oral mucosa plays a vital role in drug delivery due to its unique anatomical and physiological characteristics. It consists of various regions such as buccal, sublingual, gingival, palatal, and labial mucosa. Among these, the buccal and sublingual regions are most commonly used for drug absorption due to their high permeability and rich blood supply [14)].

Advantages of Oral Mucosa

- Easy accessibility and self-administration
- Rapid drug absorption due to high vascularity
- Avoidance of hepatic first-pass metabolism
- Possibility of sustained and controlled drug delivery
- Reduced systemic side effects

Disadvantages

- Limited permeability for certain drugs
- Continuous saliva flow may wash away the drug
- Enzymatic degradation in the oral cavity
- Limited surface area for absorption
- Need for taste masking

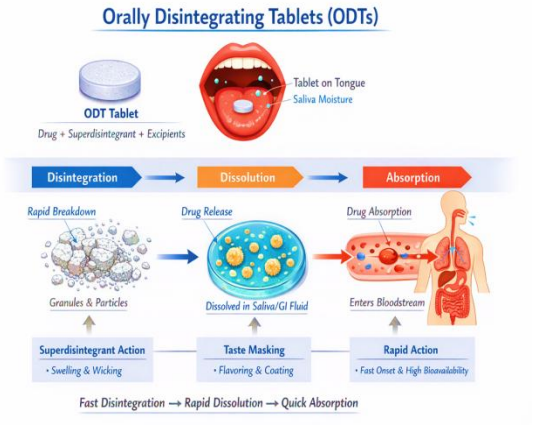

Figure 01: ODT Process Diagram

Need for Orally Disintegrating Dosage Forms

In conditions such as motion sickness, repeated vomiting, neurological disorders, and sudden coughing episodes, swallowing conventional dosage forms becomes difficult. ODDFs serve as an effective alternative in such cases. These formulations disintegrate quickly in the mouth, releasing the drug which dissolves or disperses in saliva and is subsequently absorbed through the oral mucosa or gastrointestinal tract [15].

The rapid disintegration and dissolution of ODDFs can lead to faster onset of action and, in some cases, improved bioavailability compared to conventional tablets.

Types of Orally Disintegrating Dosage Forms

1. Orally Disintegrating Tablets (ODTs)

ODTs are solid dosage forms that disintegrate rapidly in the oral cavity without the need for water. They are the most widely used ODDFs due to ease of manufacturing and patient acceptability.

2. Fast Dissolving Films

These are thin polymeric strips that dissolve quickly when placed on the tongue, releasing the drug rapidly. They combine the advantages of solid and liquid dosage forms.

3. Fast Dissolving Capsules (Fast Caps)

These are modified gelatin capsules designed to disintegrate quickly, offering high drug loading and improved stability.

4. Medicated Chewing Gums

These provide controlled drug release during chewing and are useful for conditions such as motion sickness, smoking cessation, and pain relief.

5. Freeze-Dried Wafers

These are porous and fragile dosage forms that disintegrate instantly in the oral cavity. They require specialized packaging due to their delicate nature.

Mechanism of Drug Release in ODDFs

The rapid disintegration of ODDFs is mainly due to:

- Quick penetration of saliva into the dosage form
- Swelling of superdisintegrants
- Capillary action (wicking effect)
- Increased porosity of the formulation

These mechanisms lead to the breakdown of the dosage form into smaller particles, facilitating rapid dissolution and absorption.(16)

Advantages of ODDFs

- Improved patient compliance
- No need for water during administration
- Rapid onset of action
- Reduced risk of choking
- Suitable for pediatric, geriatric, and bedridden patients
- Enhanced bioavailability in certain cases
- Convenient for travelers and emergency situations

Disadvantages of ODDFs

- Sensitivity to moisture (hygroscopic nature)
- Lower mechanical strength in some formulations
- Requirement of special packaging
- Limited drug loading for certain drugs

ORALLY DISINTEGRATING TABLETS (ODTs)

The performance of orally disintegrating tablets (ODTs) largely depends on the technology employed during their formulation and manufacturing. The rapid disintegration property of ODTs is primarily attributed to the quick penetration of saliva into the tablet matrix, which creates a porous structure and facilitates fast breakup of the tablet. Therefore, the development of ODTs mainly focuses on enhancing porosity, incorporating effective superdisintegrants, and utilizing highly water-soluble excipients [18-19].

Ideal Characteristics of ODTs

To distinguish ODTs from conventional dosage forms, they should possess the following characteristics:

1. Rapid disintegration in the oral cavity without the need for water, usually within a few seconds
2. Pleasant mouth feel without grittiness
3. Effective taste masking of bitter drugs
4. Adequate mechanical strength to withstand handling
5. Minimal or no residue remaining after administration
6. Stability under varying environmental conditions such as humidity and temperature
7. Capability to accommodate sufficient drug loading
8. Compatibility with conventional manufacturing and packaging processes at low cost

Advantages of ODTs

ODTs offer several advantages over conventional oral dosage forms:

- Suitable for patients who have difficulty swallowing, such as pediatric, geriatric, bedridden, and psychiatric patients
- Improved patient compliance and convenience
- Rapid onset of action due to quick disintegration and absorption
- Potential for enhanced bioavailability through pregastric absorption
- No requirement of water, making them ideal for travelers and emergency situations
- Reduced risk of choking compared to conventional tablets
- Improved patient acceptability due to pleasant taste and mouth feel
- Cost-effective manufacturing using conventional equipment
- Good chemical stability similar to traditional solid dosage forms
- Opportunity for product differentiation, patent extension, and lifecycle management
- Ability to provide the advantages of liquid formulations in a solid dosage form

Disadvantages of ODTs

Despite their benefits, ODTs also have certain limitations:

- Hygroscopic nature requiring storage in dry conditions
- Lower mechanical strength, making them fragile
- Possibility of unpleasant mouth feel in some formulations
- Requirement of specialized packaging to ensure stability and safety

Mechanism of Disintegration of ODTs

The rapid disintegration of ODTs is achieved through several mechanisms:

1. **Rapid Water Penetration:**
   Saliva quickly enters the porous tablet matrix, initiating disintegration.
2. **Use of Superdisintegrants:**
   Ingredients such as crospovidone and croscarmellose sodium swell upon contact with saliva, causing the tablet to break apart.
3. **Capillary Action (Wicking):**
   The porous structure facilitates the uptake of saliva into the tablet, leading to rapid breakup.
4. **Swelling Mechanism:**
   Certain excipients swell upon hydration, exerting pressure that breaks the tablet into smaller particles.
5. **Chemical Reaction:**
   Effervescent agents may react in the presence of saliva to produce gas, aiding in rapid disintegration.

FORMULATION CONSIDERATIONS FOR ORALLY DISINTEGRATING TABLETS (ODTs)

The design of orally disintegrating tablets requires a strategic combination of active pharmaceutical ingredients and excipients to ensure rapid disintegration, efficient drug release, and acceptable organoleptic properties. The formulation must be optimized to achieve quick breakdown in the oral cavity while maintaining sufficient mechanical integrity during handling and storage [20].

A. Drug Selection Criteria

Choosing an appropriate drug candidate is essential for the successful development of ODTs. The selected drug should exhibit physicochemical and pharmacokinetic properties that support rapid dissolution in saliva and, where applicable, absorption through the oral mucosa [21].

Preferred characteristics of a drug candidate include:

- Minimal or no inherent bitterness, or the ability to be effectively taste-masked
- Low therapeutic dose, typically below 20 mg

- Moderate molecular size to facilitate diffusion
- High aqueous solubility, particularly in saliva
- Favorable ionization profile at salivary pH
- Adequate lipophilicity to enable membrane permeation (log P generally >1)
- Capability to penetrate oral mucosal tissues

ODTs are particularly advantageous for drugs requiring a rapid onset of action. These include agents used in pain management, allergic conditions, neurological disorders, and infections [22].

Unsuitable Drug Candidates

Certain drugs are not ideal for ODT formulation, such as:

- Drugs with very short biological half-life requiring frequent administration
- Compounds with extremely unpleasant taste that cannot be masked effectively
- Drugs intended for sustained or controlled release delivery
- Drugs with poor permeability across oral mucosa

B. Role and Selection of Excipients

Excipients are critical in determining the performance characteristics of ODTs, including disintegration time, mechanical strength, and patient acceptability. A well-balanced formulation typically includes superdisintegrants, fillers, binders, lubricants, and optional additives for taste enhancement.(23)

Key Categories of Excipients

- **Disintegrating agents:** Facilitate rapid tablet breakup upon contact with saliva
- **Fillers:** Provide bulk and improve mouth feel
- **Binders:** Ensure structural integrity of the tablet
- **Lubricants:** Aid in manufacturing by reducing friction
- **Flavoring and sweetening agents:** Enhance palatability

Desired Properties of Excipients

For optimal performance in ODTs, excipients should:

- Rapidly dissolve or disperse in the oral cavity without leaving residue
- Mask any unpleasant taste of the drug effectively
- Support adequate drug loading without compromising tablet integrity
- Maintain stability under environmental stress conditions such as humidity and temperature variations

In addition, excipients with suitable thermal and hydration properties are preferred, as they contribute to faster disintegration and improved patient experience.

Role of Excipients in Orally Disintegrating Tablets (ODTs)

Excipients play a crucial role in the successful formulation of fast-melting or orally disintegrating tablets. They not only facilitate rapid disintegration and dissolution but also improve the overall stability, manufacturability, and patient acceptability of the dosage form. The selection of excipients must be done carefully to ensure compatibility with the drug and to achieve the desired performance [24].

For effective fast-melting behavior, excipients with suitable physicochemical properties are preferred. In general, excipients that soften or dissolve at or near body temperature (approximately 30–35°C) contribute to faster disintegration within the oral cavity. Additionally, excipients must provide a pleasant mouth feel and mask any undesirable taste of the active drug.

Category	Function	Examples
Superdisintegrants	Promote rapid disintegration of tablets by swelling and wicking mechanisms, thereby enhancing drug dissolution	Crospovidone, Croscarmellose sodium, Sodium starch glycolate, Microcrystalline cellulose, Pregelatinized starch
Flavoring Agents	Improve palatability and patient acceptability by masking unpleasant taste	Peppermint oil, Clove oil, Eucalyptus oil, Citrus oils, Vanilla, Fruit flavors
Sweeteners & Sugar-Based Excipients	Provide sweetness, improve mouth feel, and act as bulking agents	Aspartame, Mannitol, Sorbitol, Xylitol, Maltitol, Lactitol, Dextrose
Surfactants	Enhance solubility and dissolution by reducing surface tension	Sodium lauryl sulfate, Polysorbates (Tweens), Sorbitan esters (Spans)
Binders	Provide mechanical strength and maintain tablet integrity	Polyvinylpyrrolidone (PVP), Hydroxypropyl methylcellulose (HPMC), Polyvinyl alcohol (PVA)
Coloring Agents	Improve	Sunset yellow,

	appearance and product identification	Amaranth, Iron oxides
Lubricants	Reduce friction during tablet manufacturing and prevent sticking	Magnesium stearate, Stearic acid, Talc, Polyethylene glycol
Fillers/Diluents	Increase bulk and improve tablet structure	Mannitol, Calcium phosphate, Sorbitol, Xylitol, Pregelatinized starch

Superdisintegrant	**Chemical Nature**	**Disintegration Behavior**	**Functional Characteristics / Remarks**
Croscarmellose Sodium (Ac-Di-Sol®, Primellose®, Vivasol®)	Cross-linked cellulose derivative	Rapid hydration and expansion (4–8 times within seconds); acts through swelling and wicking	Suitable for both direct compression and wet granulation; exhibits multidirectional swelling; starch-free material
Crospovidone (Kollidon®, Polyplasdone®)	Cross-linked polyvinylpyrrolidone	Minimal swelling; primarily works via capillary (wicking) action	Highly porous and water-insoluble; produces tablets with excellent porosity and fast disintegration
Sodium Starch Glycolate (Explotab®, Primogel®)	Cross-linked starch derivative	Rapid and extensive swelling (up to 7–12 times within 30 seconds)	Swells in three dimensions; at higher concentrations may retard drug release due to gel formation
Alginic Acid Derivatives (e.g., Satialgine®)	Modified alginic acid	Rapid water uptake leading to swelling and wicking	Effective in both dry and wet granulation techniques; promotes quick tablet breakup
Soy Polysaccharides (Emcosoy®)	Natural polymeric material	Facilitates disintegration mainly by swelling and water absorption	Free from starch and sugars; suitable for nutraceutical and dietary formulations
Calcium Silicate	Inorganic porous material	Disintegration through capillary action (wicking)	Highly porous structure; used at relatively higher concentrations (20–40%) to enhance tablet porosity

MANUFACTURING APPROACHES AND EVALUATION OF ORALLY DISINTEGRATING TABLETS

Manufacturing Approaches

The preparation of orally disintegrating tablets (ODTs) involves multiple formulation strategies aimed at achieving rapid tablet disintegration upon contact with saliva. These approaches can be broadly divided into two groups: standard manufacturing methods and specialized proprietary techniques [25-28].

Table 01: Formulation Composition of Orally Disintegrating Tablets (ODTs)

S. No.	**Ingredient**	**Category**	**Quantity (mg)**
1	API (e.g., Paracetamol)	Active Drug	10
2	Mannitol	Diluent	60
3	Crospovidone	Superdisintegrant	5

4	Microcrystalline Cellulose	Binder	20
5	Aspartame	Sweetener	2
6	Flavor (Peppermint)	Flavoring agent	1
7	Magnesium Stearate	Lubricant	2
	Total		**100 mg**

A. Standard Manufacturing Methods

Conventional approaches focus on modifying the internal structure of tablets to allow quick penetration of saliva and rapid breakup. Some widely used methods include [29].

- **Lyophilization Technique:**
  In this method, the formulation is freeze-dried to produce a highly porous structure. This enhances water uptake and leads to extremely fast disintegration, although the resulting tablets tend to be fragile.
- **Atomization-Based Drying (Spray Drying):**
  A liquid mixture containing drug and excipients is converted into fine particles through rapid drying, resulting in a porous powder that facilitates quick disintegration.
- **Molding Process:**
  Tablets are formed by shaping a moist or semi-solid mixture. The resulting structure is less dense, allowing faster dissolution in the oral cavity.
- **Thermal Transition Method:**
  This technique utilizes excipients with different melting points. Controlled heating results in improved bonding and optimized disintegration behavior.
- **Melt-Based Granulation:**
  Binding is achieved using meltable substances, which enhance the integrity of the tablet while still allowing rapid breakdown.
- **Sublimation Approach:**
  Volatile components are incorporated into the tablet and later removed, leaving behind a porous matrix that promotes rapid fluid penetration.
- **Extrusion Technique:**
  A soft mass is extruded and processed to improve uniformity and taste masking properties.
- **Floss Formation Method (Cotton Candy Process):**
  This method creates a fibrous, highly porous structure that dissolves quickly when exposed to saliva.
- **Direct Compression:**
  The most straightforward and economical technique, where superdisintegrants and water-soluble excipients are directly compressed into tablets.

B. Advanced (Proprietary) Techniques

Modern ODT formulations often employ specialized technologies that are designed to optimize tablet performance. These methods are tailored to improve characteristics such as mechanical strength, taste masking, porosity, and dissolution rate. Such technologies typically involve unique processing steps or excipient combinations, resulting in improved patient acceptability and enhanced drug delivery. However, these approaches may require advanced equipment and higher production costs [30].

EVALUATION OF ORALLY DISINTEGRATING TABLETS

The quality assessment of ODTs involves evaluating both the powder blend (before compression) and the final tablet. These tests ensure proper flow, compressibility, and performance of the formulation [31-33].

A. Pre-Compression Parameters

1. Flow Behavior (Angle of Repose)

The flowability of the powder blend is determined by measuring the angle formed when the powder is allowed to flow freely and form a cone. It is calculated using the relation:

$$\tan\theta = \frac{h}{r}$$

Table 02: Classification of Powder Flow Based on Angle of Repose

S. No.	Angle of Repose (°)	Flow Behavior
1	≤ 25	Excellent flow
2	25 – 32	Good flow
3	32 – 38	Acceptable flow
4	> 38	Poor to very poor

Where h is the height and r is the radius of the cone. Lower values indicate better flow characteristics.

2. Bulk Density

Bulk density refers to the mass of powder occupying a given volume before compaction. It is calculated as:

$$\text{Bulk Density} = \frac{\text{Mass}}{\text{Initial Volume}}$$

This parameter helps in understanding packing properties.

Table 03: Flow Property Classification Using Compressibility Index

S. No.	Compressibility Index (%)	Flow Quality
1	5 – 10	Excellent
2	11 – 18	Good
3	19 – 25	Fair
4	26 – 32	Passable
5	33 – 40	Poor
6	> 40	Extremely poor

3. Tapped Density

Tapped density is determined after subjecting the powder to repeated tapping until a constant volume is achieved. It is calculated as:

$$\text{Tapped Density} = \frac{\text{Mass}}{\text{Final Volume}}$$

This value provides insight into the compressibility of the powder blend.

Table 04: Conventional Methods for Preparation of ODTs

S. No.	Technique	Process Description	Key Features / Outcomes
1	**Incorporation of Superdisintegrants**	Formulation includes optimized levels of disintegrating agents to promote rapid tablet breakup upon contact with saliva.	Produces tablets similar to conventional ones but with faster disintegration; may exhibit reduced hardness and increased friability.
2	**Lyophilization (Freeze Drying)**	Drug solution or suspension is frozen and subjected to sublimation to remove solvent, forming a porous matrix.	Extremely fast disintegration and enhanced bioavailability; however, tablets are fragile, moisture-sensitive, and expensive to produce.
3	**Molding Technique**	A moist blend is shaped under low pressure to form tablets with a porous structure.	Results in rapid dissolution due to low density; limited mechanical strength and stability concerns.
4	**Sublimation Method**	Volatile substances are incorporated into tablets and later removed by sublimation, leaving a porous structure.	Enhances dissolution rate; requires additional processing steps and careful handling of volatile components.
5	**Spray Drying**	A liquid formulation is spray-dried to produce porous particles, which are then compressed into tablets.	Produces tablets with rapid disintegration (typically within seconds); improves wettability and dissolution.
6	**Mass Extrusion**	A softened mass is extruded and cut into uniform segments; often used for taste masking.	Useful for coating bitter drugs; improves uniformity and palatability.
7	**Direct Compression**	Powder blend is directly compressed using standard equipment without prior granulation.	Economical and simple; suitable for moisture- and heat-sensitive drugs; dependent on flow properties of powder.
8	**Cotton Candy Process**	Formation of a fibrous matrix through flash melting and spinning, followed by milling and compression.	Produces highly porous tablets with good mechanical strength and high drug loading capacity.
9	**Melt Granulation / Phase Transition**	Uses meltable binders or excipients with varying melting points to	Enhances tablet strength while maintaining

		improve tablet structure and disintegration.	rapid disintegration; suitable for moisture-sensitive formulations.

Table 05: Advanced Techniques for ODT Preparation

S. No.	Technique	Process Overview	Key Features / Remarks
10	**Nanonization (Nanocrystal Technology)**	Drug particles are reduced to nanometer size using wet milling or similar techniques. Stabilizers are added to prevent aggregation, and the nanocrystals are incorporated into tablet formulations.	Particularly suitable for poorly soluble drugs; improves dissolution rate and bioavailability; enables dose reduction and offers good mechanical stability with conventional packaging.
11	**Fast Dissolving Films**	Drug is incorporated into a thin polymeric film that rapidly hydrates and dissolves when placed on the tongue.	Provides rapid onset of action and excellent patient compliance; useful for patients with swallowing difficulties; limited drug loading compared to tablets.
12	**Conventional Tableting (Non-effervescent)**	Tablets are prepared using standard compression methods without any special modification.	Cost-effective and easy to scale up; supports higher drug loading; however, disintegration rate depends on formulation variables such as hardness and particle size.
13	**Effervescent Tableting**	Incorporates acid-base components that react in the presence of saliva to release carbon dioxide, promoting rapid disintegration.	Produces a pleasant mouth feel due to effervescence; requires moisture-controlled processing and specialized packaging.
14	**Humidity-Assisted Tableting**	Tablets are exposed to controlled humidity after compression to modify internal structure and improve disintegration.	Enhances tablet strength and mouth feel; requires additional processing steps and may not be suitable for moisture-sensitive drugs.

Pre-Compression and Post-Compression Evaluation of ODTs

Pre-Compression Parameters

1. Compressibility Index (Carr's Index)

This parameter reflects the compressibility and flow behavior of the powder blend. It is calculated using bulk and tapped density values:

$$\text{Carr's Index (\%)} = \frac{(\text{Tapped Density} - \text{Bulk Density})}{\text{Tapped Density}} \times 100$$

Lower values indicate better flowability, whereas higher values suggest poor flow.

2. Hausner's Ratio

Hausner's ratio is another indicator of powder flow characteristics:

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

Interpretation:

- ≤ **1.25** → Good flow
- **> 1.25** → Poor flow

3. Void Volume

Void volume represents the empty spaces present within a powder bed:

$$V = V_b - V_p$$

Where:

- V_b = Bulk volume
- V_p = Packed (true) volume

4. Porosity

Porosity indicates the fraction of void space within the powder system:

$$\varepsilon = 1 - \frac{V_p}{V_b}$$

Percentage porosity is expressed as:

$$\%\varepsilon = \left(1 - \frac{V_p}{V_b}\right) \times 100$$

Porosity plays an important role in determining powder behavior during storage, handling, and compression.

Table 06: Pre-Compression Evaluation Data of Powder Blend

Parameter	Value	Interpretation
Angle of Repose	27°	Good flow
Bulk Density	0.45 g/cm³	—
Tapped Density	0.55 g/cm³	—
Carr's Index	18%	Good flow
Hausner Ratio	1.22	Acceptable

Post-Compression Evaluation of ODTs

1. Weight Variation Test

This test ensures uniformity in tablet weight within a batch. A sample of 20 tablets is weighed collectively, followed by individual weighing. The deviation from the average weight is compared with pharmacopoeial limits to ensure consistency **[**34].

Table 07: Acceptable Limits for Tablet Weight Variation

S. No.	Average Weight per Tablet (mg)	Allowed Variation (%)
1	Up to 150	±10%
2	150 – 300	±7.5%
3	Above 300	±5%

2. Tablet Hardness

Tablet hardness reflects the mechanical strength of the dosage form and its ability to withstand handling during manufacturing, packaging, and transportation. It is determined by measuring the force required to break a tablet diametrically using instruments such as hardness testers. For orally disintegrating tablets, moderate hardness is preferred to maintain a balance between structural integrity and rapid disintegration [35].

3. Friability

Friability evaluates the tendency of tablets to crumble or lose mass due to mechanical stress. It is assessed using a friabilator, where a pre-weighed sample of tablets is subjected to rotational motion. After the test, tablets are reweighed and the percentage weight loss is calculated:

$$\text{Friability (\%)} = \frac{W_{\text{initial}} - W_{\text{final}}}{W_{\text{initial}}} \times 100$$

A friability value below 1% is generally considered acceptable, indicating sufficient resistance to abrasion.

4. Disintegration Time

Disintegration time measures how quickly a tablet breaks down into smaller fragments under physiological conditions. Tablets are placed in a disintegration apparatus containing a suitable medium maintained at body temperature. ODTs are expected to disintegrate rapidly, usually within seconds to a minute.(36)

5. Mechanical Strength and Tensile Strength

Mechanical strength is essential for ensuring that tablets remain intact during processing and handling. It is commonly assessed through crushing strength and tensile strength. The tensile strength of a tablet can be calculated using the following relationship:

$$T = \frac{2F}{\pi dt}$$

Where:

- F = applied breaking force
- d = tablet diameter
- t = tablet thickness

Higher tensile strength indicates better mechanical resistance; however, excessively strong tablets may delay disintegration.

6. Uniformity of Dispersion

This test evaluates the ability of tablets to disperse uniformly in a liquid medium. Tablets are introduced into water and gently agitated. The dispersion is then passed through a sieve. Absence of residue indicates satisfactory dispersion behavior.

7. Wetting Time

Wetting time is an important parameter for ODTs as it correlates with the rate of disintegration. It is determined by placing a tablet on a moist absorbent surface and recording the time required for complete wetting. Shorter wetting time indicates faster tablet hydration.

8. Water Absorption Ratio

This parameter measures the capacity of a tablet to absorb water, whichdirectly influences disintegration. It is calculated using the equation:

$$R = \frac{W_a - W_b}{W_b} \times 100$$

Where:

- W_b = weight before absorption
- W_a = weight after absorption

Higher values indicate better water uptake ability.

9. Taste and Mouth Feel Evaluation

Patient acceptability of ODTs largely depends on taste and mouth sensation. Sensory evaluation is carried out using human volunteers who assess parameters such as bitterness, sweetness, and overall mouth feel. A scoring system is typically used to quantify the perception of taste over time.(37)

10. In-vitro Disintegration Study

This test is performed by placing tablets in a suitable buffer medium (commonly pH 6.8) and recording the time required for complete dispersion. It provides an estimate of how the tablet will behave in the oral cavity.

11. In-vivo Disintegration Study

In-vivo disintegration is assessed by placing the tablet on the tongue of volunteers and recording the time required for complete breakdown. This test reflects real-life performance and patient experience.

12. In-vitro Dissolution Study

Dissolution testing is conducted using standard apparatus (e.g., paddle type) in an appropriate dissolution medium maintained at physiological temperature. Samples are withdrawn at regular intervals and analyzed to determine the rate and extent of drug release.

13. Stability Studies

Stability testing is performed according to regulatory guidelines to evaluate the effect of environmental conditions such as temperature and humidity on the formulation. Parameters such as physical appearance, drug content, and dissolution profile are monitored over time [40].

Table 8: Post-Compression Evaluation Results of ODTs

Parameter	Result (Observed)	Standard Limit
Weight Variation	98–102 mg	±5%
Hardness	3.2 kg/cm²	2–4 kg/cm²
Friability	0.65%	< 1%
Disintegration Time	25 sec	< 60 sec
Wetting Time	18 sec	< 30 sec
Water Absorption Ratio	75%	50–100%
Drug Content	98.5%	95–105%

Table 09: Marketed Orally Disintegrating Tablets Categorized by Therapeutic Use

S. No.	Product Name	API (Drug)	Therapeutic Class	Manufacturer
1	Imodium Lingual	Loperamide HCl	Antidiarrheal	Janssen
2	Pepcid Rapid Tab	Famotidine	Anti-ulcer	—
3	Mosid-MT	Mosapride citrate	Prokinetic agent	Torrent
4	Claritin RediTabs	Loratadine	Antihistamine	Schering-Plough
5	Nimulid-MD	Nimesulide	NSAID	Panacea
6	Feldene Melt	Piroxicam	NSAID	Pfizer
7	Maxalt-MLT	Rizatriptan benzoate	Antimigraine	Merck
8	Zyprexa Zydis	Olanzapine	Antipsychotic	Eli Lilly
9	Zofran ODT	Ondansetron	Antiemetic	GSK
10	Remeron SolTab	Mirtazapine	Antidepressant	—
11	Romilast	Montelukast	Antiasthmatic	Ranbaxy
12	Olanex Instab	Olanzapine	Antipsychotic	Ranbaxy
13	Zomig Rapimelt	Zolmitriptan	Antimigraine	AstraZeneca
14	Zotacet-MD	Cetirizine HCl	Antihistamine	Zota Pharma
15	Nulev	Hyoscyamine sulfate	Antispasmodic	Schwarz Pharma
16	Klonopin Wafers	Clonazepam	Anticonvulsant	Roche
17	Kemstro	Baclofen	Muscle relaxant	Schwarz Pharma

18	Zelapar	Selegiline	Anti-Parkinson	Amarin Corp.
19	Tempra Quicklets	Acetaminophen	Analgesic/Antipyretic	BMS
20	Febrectol	Paracetamol	Analgesic	Prographarm
21	Benadryl Fast Melt	Diphenhydramine + Pseudoephedrine	Antiallergic/Decongestant	Warner-Lambert
22	Risperdal M-Tab	Risperidone	Antipsychotic	Janssen
23	Nurofen Flash Tab	Ibuprofen	NSAID	Ethypharm
24	Relivia Flash Dose	Tramadol HCl	Opioid analgesic	Fuisz Tech
25	Abilify Discmelt	Aripiprazole	Antipsychotic	Otsuka / BMS
26	Allegra ODT	Fexofenadine	Antihistamine	Sanofi
27	Aricept ODT	Donepezil	Anti-Alzheimer's	Eisai
28	Clarinex RediTabs	Desloratadine	Antihistamine	Schering-Plough
29	Alavert ODT	Loratadine	Antihistamine	Wyeth
30	FazaClo	Clozapine	Antipsychotic	Azur Pharma

CONCLUSION

Orally disintegrating tablets (ODTs) have emerged as a significant advancement in oral drug delivery systems, addressing many of the limitations associated with conventional solid dosage forms. Their ability to rapidly disintegrate in the oral cavity without the need for water makes them particularly advantageous for improving patient compliance, especially among pediatric, geriatric, bedridden, and dysphagic patients. This unique characteristic not only enhances convenience but also ensures better adherence to prescribed therapy, ultimately improving clinical outcomes.

In addition to patient convenience, ODTs provide faster onset of action due to rapid disintegration and dissolution, which facilitates quicker drug absorption. In certain cases, partial absorption through the oral mucosa may also contribute to improved bioavailability by bypassing the first-pass metabolism. These attributes make ODTs highly suitable for conditions requiring immediate therapeutic action, such as pain, allergies, and neurological disorders.

The successful formulation of ODTs depends on multiple critical factors, including the selection of appropriate drug candidates, optimization of excipients, and adoption of suitable manufacturing techniques. The creation of a highly porous tablet matrix, along with the incorporation of efficient superdisintegrants, plays a crucial role in achieving rapid disintegration. At the same time, challenges such as taste masking, mechanical strength, hygroscopicity, and stability must be carefully managed to ensure product quality and patient acceptability.

Advancements in formulation technologies—both conventional and patented—have significantly contributed to the development of robust ODT products with improved performance characteristics. Moreover, the availability of novel excipients and innovative processing techniques continues to expand the scope of ODTs, enabling their application across a broader range of drug categories, including poorly soluble and bitter drugs.

Despite these advancements, there is still ample scope for further research, particularly in enhancing stability, improving drug loading capacity, and developing cost-effective manufacturing processes. Future innovations are expected to integrate nanotechnology, novel drug carriers, and advanced taste-masking approaches, thereby further strengthening the potential of ODTs.

In conclusion, ODTs represent a promising and evolving drug delivery platform with substantial clinical and commercial significance. With ongoing research and technological progress, they are likely to play an increasingly important role in modern pharmaceutical development and patient-centric therapy.

REFERENCES

1. Uchegbu IF, Vyas SP. Niosomes as drug delivery systems. Int J Pharm. 1998;172:33–70.
2. Chang RK, Guo X, Burnside BA, Couch RA. Fast-dissolving tablets. Pharm Technol. 2000;24(6):52–58.
3. Kuchekar BS, Badhan AC, Mahajan HS. Mouth dissolving tablets: A novel drug delivery system. Pharma Times. 2003;35:7–10.
4. Seager H. Drug-delivery products and the Zydis fast-dissolving dosage form. J Pharm Pharmacol. 1998;50:375–382.

5. Dobetti L. Fast-melting tablets: Developments and technologies. Pharm Technol Eur. 2001;13:44–50.
6. Habib W, Khankari R, Hontz J. Fast-dissolve drug delivery systems. Crit Rev Ther Drug Carrier Syst. 2000;17:61–72.
7. Fu Y, Yang S, Jeong SH, Kimura S, Park K. Orally fast disintegrating tablets. Crit Rev Ther Drug Carrier Syst. 2004;21:433–475.
8. Shukla D, Chakraborty S, Singh S, Mishra B. Mouth dissolving tablets: An overview. Indian J Pharm Sci. 2009;71:335–341.
9. Bi Y, Sunada H, Yonezawa Y, Danjo K, Otsuka A, Iida K. Preparation and evaluation of compressed tablets rapidly disintegrating in oral cavity. Chem Pharm Bull. 1996;44:2121–2127.
10. Gohel M, Patel M, Amin A, Agrawal R, Dave R, Bariya N. Formulation design of mouth dissolving tablets. J Pharm Sci. 2004;7:1–6.
11. Kuno Y, Kojima M, Ando S, Nakagami H. Evaluation of rapidly disintegrating tablets. Int J Pharm. 2005;298:147–155.
12. Hirani JJ, Rathod DA, Vadalia KR. Orally disintegrating tablets: A review. Trop J Pharm Res. 2009;8:161–172.
13. Reddy LH, Ghosh B, Rajneesh. Fast dissolving drug delivery systems. Indian J Pharm Sci. 2002;64:331–336.
14. Sastry SV, Nyshadham JR, Fix JA. Recent technological advances in oral drug delivery. Pharm Sci Technol Today. 2000;3:138–145.
15. Allen LV. Pharmaceutical dosage forms and drug delivery systems. 8th ed. Lippincott Williams & Wilkins; 2005.
16. Banker GS, Anderson NR. Tablets. In: Lachman L, Lieberman HA, Kanig JL, editors. The Theory and Practice of Industrial Pharmacy. 3rd ed. 1987. p. 293–345.
17. Aulton ME. Pharmaceutics: The Science of Dosage Form Design. 2nd ed. Churchill Livingstone; 2002.
18. Indian Pharmacopoeia Commission. Indian Pharmacopoeia. Ghaziabad; 2018.
19. United States Pharmacopeia (USP). USP-NF. Rockville; 2020.
20. European Pharmacopoeia. Council of Europe; 2019.
21. Bhise SB, Rajkumar M. Effect of superdisintegrants in formulation of fast dissolving tablets. Int J Pharm Sci. 2010;2:66–72.
22. Desai PM, Er PXH, Liew CV, Heng PW. Review of disintegrants and superdisintegrants. J Pharm Sci. 2016;105:2545–2555.
23. Bandari S, Mittapalli RK, Gannu R, Rao YM. Orodispersible tablets: An overview. Asian J Pharm. 2008;2:2–11.
24. Sohi H, Sultana Y, Khar RK. Taste masking technologies in oral pharmaceuticals. Drug Dev Ind Pharm. 2004;30:429–448.
25. Jivraj M, Martini LG, Thomson CM. An overview of different excipients useful for direct compression. PSTT. 2000;3:58–63.
26. Shangraw RF. Direct compression tableting. J Pharm Sci. 1989;78:2–7.
27. Mizumoto T, Masuda Y, Yamamoto T, Yonemochi E, Terada K. Formulation design of fast disintegrating tablets. Int J Pharm. 2005;306:83–90.
28. Patil BS, Tate PM, Kulkarni U. Formulation and evaluation of mouth dissolving tablets. Int J Pharm Sci Rev Res. 2011;7:47–54.
29. Panigrahi R, Behera SP. Review on fast dissolving tablets. WebmedCentral Pharm Sci. 2010;1:WMC001146.
30. Nagar P, Singh K, Chauhan I, Verma M, Yasir M, Khan A. Orally disintegrating tablets: Formulation, preparation techniques. J Appl Pharm Sci. 2011;1:35–45.
31. Ghosh T, Ghosh A, Prasad D. A review on new generation orodispersible tablets. Int J Pharm Pharm Sci. 2011;3:1–7.
32. Abdelbary G, Eouani C, Prinderre P, Joachim J, Reynier JP, Piccerelle P. Determination of disintegration profile. Int J Pharm. 2005;292:29–41.
33. Suresh S, Pandit V, Joshi HP. Preparation and evaluation of mouth dissolving tablets. Indian Drugs. 2007;44:467–471.
34. Sharma D, Chopra R, Bedi N. Development and evaluation of paracetamol fast dissolving tablets. J Chem Pharm Res. 2012;4:435–441.
35. Yadav G, Kapoor A, Bhargava S. Fast dissolving tablets: A review. Int J Pharm Res Dev. 2012;4:1–8.
36. Kaur T, Gill B, Kumar S, Gupta GD. Mouth dissolving tablets: A novel approach. Int J Curr Pharm Res. 2011;3:1–7.
37. Mohanachandran PS, Sindhumol PG, Kiran TS. Superdisintegrants: An overview. Int J Pharm Sci Rev Res. 2011;6:105–109.
38. Gupta A, Mishra AK, Gupta V, Bansal P, Singh R. Recent trends of fast dissolving tablet. Int J Pharm Sci Res. 2010;1:1–10.
39. Mahajan HS, Kuchekar BS. Mouth dissolving tablets: A novel drug delivery system. Drug Dev Ind Pharm. 2009;35:114–122.
40. Patel DM, Patel NM, Patel MM. Fast dissolving tablets: An overview. J Pharm Sci. 2006;5:1–10.