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Oral Disintegration Tablets: Bridging the Gap between Rapid Dissolution and Patient Compliance

Patil Payal K.*, Dhankani Mansi A., Dhankani Amitkumar R., Pawar Sunil P.

Department of Pharmaceutics, P.S.G.V.P. Mandal's College of Pharmacy, Shahada, Dist. :-Nandurbar,425409 India.

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ABSTRACT

A novel dose type called oral disintegrating tablets (ODTs) dissolves quickly in the mouth without the need for water. ODTs gained a widespread acceptance as a dosage form because of their convenience, ease of administration, and potential to improve patient compliance, particularly in populations like children, the elderly, those with swallowing difficulties and people with dysphagia. Pharmaceutical technology has advanced significantly with ODTs, which provide a more convenient option than traditional tablets and capsules. ODTs are formulated with specialized excipients that enable them to disintegrate quickly upon contact with saliva, often within seconds. The manufacturing process requires precise control to prevent premature disintegration, while also ensuring the tablets remain intact during handling and packaging. Recent advances in ODT technology have introduced techniques such as freeze-drying, direct compression, and spray-drying, which help to improve the mouthfeel, disintegration time, and stability of these tablets. Furthermore, the application of various taste-masking strategies is crucial for improving the palatability of bitter APIs. ODTs have found applications in a wide range of therapeutic areas, including pain management, central nervous system disorders, and gastrointestinal diseases, where rapid onset of action and ease of use are critical. The growing demand for patient-centric drug delivery systems is driving further research into the formulation and commercialization of ODTs, promising an innovative solution to enhance therapeutic efficacy and patient satisfaction. This review attempts to give a thorough overview of oral disintegrating tablets (ODTs), focusing on their formulation, mechanisms of disintegration, advantages, challenges, and current applications in various therapeutic areas.

Keywords: ODT, drug delivery systems, patient compliance, bioavailability, taste masking

INTRODUCTION:-

The solid dose forms known as oral disintegrating tablets (ODTs), fast-dissolving tablets (FDTs), or fast-melt tablets dissolve and dissolve quickly in the mouth without the need for water. For individuals who have trouble swallowing regular tablets or capsules, these tablets provide a useful alternative that enhances overall medication adherence.[1]

One kind of solid dose form called an oral disintegration tablet (ODT) dissolves and dissolves rapidly in the mouth without the need for water. Patients can conveniently take their medications thanks to this special formulation, especially those who have trouble swallowing pills (such as youngsters, the elderly, or people with dysphagia). When patients require rapid drug absorption, ODTs may also be the best option. Oral disintegration tablets (ODTs) are a particular kind of tablet that dissolves or disintegrates rapidly in the mouth without the need for water. For those who have trouble swallowing ordinary pills or capsules, such as children, the elderly, or those who have dysphagia, this makes it convenient.[2]

The ODT market has seen exponential growth in recent years due to their convenience, ease of administration, and faster onset of action. According to a report by Markets, the global market for ODTs is projected to reach USD 28.8 billion by 2026, driven by advances in formulation technology and the rising demand for patient-centric dosage forms.[2]

OBJECTIVES:

- **Enhance Patient Compliance:**

ODTs are designed to improve patient adherence to medication by providing a more convenient and user-friendly dosage form, especially for individuals who have difficulty swallowing traditional tablets or capsules.

- **Rapid Onset of Action:**

The primary objective of ODTs is to facilitate the rapid disintegration and dissolution of the active pharmaceutical ingredient (API) in the mouth, enabling faster absorption and quicker onset of therapeutic effects.

- **Improved Patient Convenience:**

ODTs are designed to be taken without water, making them more convenient for patients in situations where water is not readily available, such as while traveling or in emergencies.

- **Minimize the Need for Swallowing Pills:**

ODTs provide an ideal alternative for pediatric, geriatric, and dysphagic patients who have difficulty swallowing traditional dosage forms.

- **Masking of Bitter Taste:**

One of the key objectives of ODTs is to effectively mask the unpleasant taste of bitter or unpalatable drugs, improving the overall patient experience.

- **Enhanced Bioavailability:**

ODTs are formulated to improve the solubility and bioavailability of poorly soluble drugs by increasing the surface area available for absorption in the gastrointestinal tract.

- **Cost-Effective and Scalable Production:**

The development and manufacturing of ODTs aim to achieve cost-effective production methods such as direct compression, which can be scaled up for mass production while maintaining product quality and consistency.

- **Stability and Shelf-life:**

Ensuring the stability of both the active ingredient and the formulation as a whole, while maintaining the desired disintegration properties, is crucial for achieving an acceptable shelf-life.

- **Customization for Specific Therapeutic Areas:**

ODTs can be customized for various drug classes, including those used for central nervous system disorders, pain management, gastrointestinal issues, and more, to meet the specific needs of each therapeutic indication.[12]

- **Non-invasive and Easy Administration:**

ODTs are designed for quick and easy administration without the need for external tools like water or a glass, which enhances the ease of use and patient satisfaction, particularly in individuals with physical or cognitive limitations. [3]

Advantages:-

- The taste of drugs should be covered up.
- Useful for pediatric and geriatric patients.
- Due to their inability to swallow significant amounts of water, patients with mental illnesses, motion sickness, dysphasia, and frequent emesis prefer this dose form.

- ODTs are easy to carry and can be taken discretely, making them suitable for patients on the go.
- Ideal for patients who are traveling or do not have easy access to water.
- No residue in the oral cavity after administration.
- Because the oral or buccal mucosa is highly vascularized, drugs that first pass hepatic processing have an advantage over them. As a result, the drugs are absorbed straight into the systemic circulation.
- Allow high drug loading.
- ODTs are suitable for sustained and controlled release actives. [4,5,6]

Limitations of Oral Disintegration Tablets: - [7,8,9]

- Typically, the tablets' mechanical strength is inadequate. Therefore, handling must be done carefully.
- Unpleasant taste and grittiness in the tongue may result from poorly made designed tablets.
- Drugs that are susceptible to light or moisture must be packaged specifically.
- Administering precautions to be implemented shortly after removal from the pack
- Because there is no choice for film coating, ODTs may not be suitable for light-sensitive drugs.

Ideal Properties[10,11]**:-**

- It can be taken orally without the need for water.
- It must possess sufficient taste-masking capabilities.
- It should be sufficiently firm and have a pleasing mouthfeel.
- When used orally, it should leave little to no residue in the mouth.
- Taste masking should work with it.
- High drug loading is permitted.
- It should be less sensitive to external factors like humidity and temperature.
- The dosage of the medication should be minimal.
- The first pass metabolism of the material is vast and high.

Fig No. 1: Oral Disintegrating Tablet Technology

FORMULATION OF ODTs:-

The formulation of ODTs is a delicate balance of excipients, active ingredients, and processing techniques. Key components include:

1. Active Pharmaceutical Ingredient (API):-

Role: Produces the intended therapeutic effects.

Examples of APIs and Their Impact on Disintegration Time

✓ **Water-soluble APIs:** These APIs (e.g., paracetamol, loratadine) tend to disintegrate quickly, reducing the time for the tablet to dissolve in the mouth.

✓ **Poorly soluble APIs:** APIs like Ibuprofen or some other poorly soluble drugs may need additional excipients like superdisintegrants to help break the tablet apart faster.

Example: Tylenol (Acetaminophen) and Panadol, Ibuprofen, Amoxicillin, Diphenhydramine, Loratadine, Guaifenesin, Bacitracin, Famotidine, Omeprazole, Levothyroxine, Atorvastatin, Gabapentin, Amlodipine, Fluoxetine, Ibuterols.[12]

2. Colour:-

Role: It enhances appearance and organoleptic properties of dosage form.

Impact Disintegration Time in ODTs

✓ **Tablet Matrix and Composition**: The impact on disintegration time is minimal unless the concentration of the coloring agent is excessively high, which could change the tablet's hardness or porosity.

✓ **Effect on Wetting and Moisture Penetration**: Water-soluble coloring agents might have a slight effect on moisture penetration into the tablet.

Example: Sunset yellow, Red iron oxide, Amaranth, etc.[12]

3. Fillers:-

Role: Mannitol or microcrystalline cellulose for tablet bulk.

Enhances bulk of dosage form. It enhances bulk of dosage form.

Impact Disintegration Time in ODTs

Fillers in ODTs, like mannitol (water-soluble) or microcrystalline cellulose (insoluble), affect disintegration time. Water-soluble fillers speed up disintegration, while insoluble fillers help maintain tablet structure but may slow disintegration.

Example: Mannitol, Lactose, Microcrystalline cellulose, Crosspovidone, Sodium Starch Glycolate.[13]

4. Lubricants:-

Role: Used to improve the flow of the powder and prevent sticking during manufacturing. It helps reduces friction and wear by introducing a lubricating film.

Lubricants minimize friction and wear by providing a lubricating layer between the moving mechanical components of a tablet punching machine.

Impact of Lubricants on Disintegration Time:-

Lubricants in ODTs, like magnesium stearate, are used to prevent friction during tablet compression. While they typically don't affect disintegration time directly, excessive amounts can slow disintegration by creating a hydrophobic layer that reduces water absorption, making the tablet break down more slowly.

Example: Gum Orthodontic Wax, Silicone-Based Gels, Water-Based Lubricants.[13]

5. Surface Active Agents:-

Role: Enhance the solubilization of ODTs.

Lowers interfacial tension and consequently improves the solubilization of FDT.

Impact on Disintegration Time

✓ Surface-active agents (surfactants) in ODTs, such as polysorbates or sodium lauryl sulfate, improve disintegration by reducing surface tension and enhancing water absorption. This helps the tablet break apart more quickly in the mouth, leading to faster disintegration and a quicker onset of action.

Example: Sodium lauryl sulfate, Sodium-doecylsulfate, Polyoxyethylene sorbitan, fatty acid esters, Polyoxyethylene steartes, etc.[13]

6. Sweeteners and sugar based excipients:-

Role: Hence impart taste masking property and a pleasing mouth feel. Sugar based excipients act as bulking agents. They exhibit high aqueous solubility and sweetness and impart taste masking property.

Impact of Sweeteners and Sugar-Based Excipients on Disintegration Time

✓ **Sugar-based excipients** like mannitol or sorbitol are hydrophilic and help the tablet dissolve faster by absorbing moisture, which can speed up disintegration.

✓ **Sweeteners** (like aspartame or sucralose) typically do not affect disintegration time but are used to mask the bitterness of the active ingredient.

Example: Artificial sweeteners like Aspartame, Sugars derivatives. Bulking agents like dextrose, fructose, isomalt, lactilol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol.[13]

7. Binder:-

Role: Maintains integrity of dosage form.

Binders are divided into two categories based on how they are used: solution binders, which are used in wet granulation and dry binders, which are added to the powder mixture for direct compression formula or to the powder mix after the wet granulation process is finished.

Impact of Binders on Disintegration Time in ODTs:-

✓ **Fast-dissolving binders:** Binders like hydroxypropyl cellulose can dissolve quickly and facilitate faster disintegration, enhancing the breakdown of the tablet in the mouth.

✓ **Stronger binders:** Some binders provide more cohesive bonding, which might slightly slow disintegration if they are too strong or used in high amounts, as they can resist moisture absorption.

Example: Polyvinyl pyrrolidone (PVP), Polyvinyl alcohol (PVA), Hydroxypropyl methylcellulose (HPMC)[13]

8. Superdisintegrants:-

Role: Burst disintegration facilitator.

Superdisintegrants aid in the rapid breakdown of orally disintegrating tablets when positioned on the tongue.

The following properties should be considered when selecting the superdisintegrant(s).

• Ability to flow and to be compressed • Poor gel formation • Poor water solubility

• Good hydration • Inability to form complexes with drugs

Impact of Superdisintegrants on Disintegration Time:

They help the tablet break apart quickly when exposed to moisture by rapidly absorbing water and swelling, which leads to faster breakdown in the mouth.

Example: Crospovidone, croscarmellose sodium, sodium starch glycolate, sodium carboxymethyl cellulose, microcrystalline cellulose, spray-dried lactose, acrylic acid, alginic acid, sodium alginate, soy polysaccharides.[14]

9. Bulking material:-

Role: Textural properties (disintegration time) improver.

Impact of Bulking Materials on Disintegration Time in ODTs

✓ **Water-soluble bulking agents** (e.g., mannitol or sorbitol) help speed up disintegration by attracting moisture, which promotes faster breakdown of the tablet in the mouth.

✓ **Insoluble bulking agents** (e.g., microcrystalline cellulose) provide structural integrity but do not significantly affect disintegration time, as they do not absorb water as quickly.

Example: Sugar and sugar-based derivatives (dextrose, fructose, isomalt, lactilol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose, and xylitol).[15]

10. Emulsifier:-

Role: Disintegration accelerator

Impact of Emulsifiers on Disintegration Time in ODTs

Emulsifiers in Oral Disintegration Tablets (ODTs), such as polysorbates or lecithin, help improve the wetting properties of the tablet by reducing surface tension. This aids in faster moisture absorption, which can accelerate disintegration.

Example: Alkyl sulfates, propylene glycol, lecithin, sucrose esters.[16]

11. Sweetener:-

Role: Bitter taste mask

Impact of Sweeteners on Disintegration Time

The impact on disintegration time is minimal compared to excipients like superdisintegrants, which are specifically designed to enhance disintegration.

Example: Sodium saccharin, sugar alcohols, natural sugars (sugar, dextrose, fructose).[17]

12. Flavor:-

Role: Patient compliance and acceptability improver

Impact of Flavor on Disintegration Time

Flavors in Oral Disintegration Tablets (ODTs) are mainly used to improve taste and mask any bitterness of the active ingredients. Some water-soluble flavors might slightly aid in moisture absorption, which can have a very minor effect on the disintegration process.

Example: Peppermint flavor, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, oil of bitter almonds, vanilla, citrus oils, fruit essences.[18]

Table No.1: List of Formulation Ingredients of ODTs

SR. NO.	INGREDIENTS	ROLE	EXAMPLE	REFERENCES
1	Active Pharmaceutical Ingredient (API)	Produces the therapeutic effect	Tylenol, Panadol, Ibuprofen, Amoxicillin,etc	Shweta Kalyan et.al.[12]
2	Colour	It enhances appearance and organoleptic properties of dosage form.	Sunset yellow, Red iron oxide, Amaranth3.	Mayank Bansal et.al. [12]
3	Fillers	Improve Flowability	Mannitol, Lactose, Microcrystalline cellulose, Crosspovidone, Sodium Starch Glycolate	Mohd Yasir et.al. [13]
4	Lubricants	Designed to minimize the friction that exists between the wall of tablet and the die cavity at the time of tablet ejection.	Various stearic acid salts and derivatives e.g. Magnesium stearate Gum Orthodontic Wax, Silicone-Based Gels, Water-Based Lubricants	Madhu Verma et.al. [13]
5	Surface Active agents	Enhance the solubilization of ODTs.	Sodiumlaurlysulfate, Sodium-doecylsulfate, Polyoxyethylene sorbitan fatty acid esters, Polyoxyethylene steartes etc	Priyanka Nagar et.al. [113]
6	Sweeteners and sugar based excipients	Hence impart taste masking property and a pleasing mouth feel.	Artificial sweeteners like Aspartame, Sugars derivatives. Bulking agents like dextrose, fructose, isomalt, lactilol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol	Kusum Singh et.al. [13]
7	Binder	Maintains integrity of dosage form.	Polyvinylpyrrolidone(PVP), Polyvinylalcohl(PVA), Hydroxy propyl methylcellulose(HPMC)	Iti Chauhan et.al. [13]
8	Superdisintegrant	i) Ensure Rapid Disintegration ii)Burst disintegration facilitator iii) Allow for Lower Concentrations iv) Enhance Patient Compliance v) Improve Tablet Texture and Mouthfeel vi) Burst disintegration facilitator	Crospovidone, croscarmellose sodium, sodium starch glycolate, sodium carboxymethyl cellulose, microcrystalline cellulose, spray-dried lactose, acrylic acid, alginic acid, sodium alginate, soy polysaccharides, Isphagula husk pregelatinized starch, modified corn starch, ion exchange resins, gas evolving disintegrants, polacrilin potassium etc.	Gupta S, et.al. [14]
9	Bulking material	Textural properties (disintegration time) improver	Sugar and sugar-based derivatives (dextrose, fructose, isomalt, lactilol, maltitol, maltose,	Nagar P. et.al. [15]

			mannitol, sorbitol, starch hydrolysate, polydextrose, and xylitol)	
10	Emulsifier	(i) Disintegration accelerator (ii)Bioavailability enhancer of immiscible substances	Alkyl sulfates, propylene glycol, lecithin, sucrose esters, sodiumdoecylsulfate, sodium lauryl sulfate, polyoxyethylene sorbitan fatty acid esters (Tweens)	Dhakane J. P. et.al.[16]
11	Sweetener	(i) Bitter taste mask (ii) Tablets' acceptability enhancer	Sodium saccharin, sugar alcohols, natural sugars (sugar, dextrose, fructose), sugars derivatives, aspartame, vanilla, bubble gum, grapefruit	Chowdary K. et.al.[17]
12	Flavor	Patient compliance and acceptability improver	Peppermint flavor, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, oil of bitter almonds, vanilla, citrus oils, fruit essences	Liang A. C. et.al.[18]

Evaluation of ODTs:-

➢ **Bulk density:-** Prior to tapping, the bulk density was calculated by dividing the powder's weight by its volume. [19]

Bulk density = weight of powder\volume of packing

➢ **Thickness:-** The consistency of tablet size depended on tablet thickness. Three randomly chosen samples were assessed for thickness using venire callipers.[19]

➢ **Tablet hardness:-** A tablet's strength can be determined by its hardness. The force needed to shatter the tablet during testing is measured.[19]

➢ **Tapped density:-** After tapping, the weight of the powder divided by its volume was used to calculate the taped density. [19]

Tapped density = weight of powder\tapped volume of packing

➢ **Carr's index (Compressibility):-** This parameter measures how compressible the powder mixture is and is determined using the following formula. [20]

Carr's index (%) = (tapped density- bulk density) ×100/ tapped density

➢ **Hausner's ratio:-** This is another parameter for powder characterization which measures the flowability of the Pow der and granules. [20]

Hausner's ratio = bulk density\ tapped density

➢ **Weight variation test:-**

Weighing: The individual weight of each tablet is recorded.

Calculation: The average weight of the 20 tablets is calculated.

Comparison: The weight of each individual tablet is compared to the average, and the variation is calculated as a percentage of the average weight. [21]

➢ **Tablet Friability:-** Tablets should undergo a friability test to determine whether or not they are abrasion-resistant. The Roche friabilator is used to test friability. Twenty tablets are weighed and put into the machine's plastic drum, which rotates 100 times at 25 rpm. Tablets are then wiped down with a cloth and weighed once more. The following formula is used to determine percentage friability.[22]

% Friability = (W0-W)/ W0*100

Where, W0 = Initial weight of 20 tablets

W = Weight after 100 revolutions

The weight loss should not be more than 1% w/w.

➢ **In vivo disintegration time:-**In-vivo disintegration time is determined by placing the tablet in the mouth of healthy human volunteers.[22]

Pharmaceutical Uses:- [23]

✓ **Pain Relief:-** Certain analgesics, such as Ibuprofen or Acetaminophen, may be available in ODT form.

✓ **Antidepressants and Antianxiety Medications**:- Drugs like ondansetron (used for nausea) or certain antidepressants may be formulated as ODTs.

✓ **Allergy Medications:-** Some antihistamines are available as ODTs to make them easier to take on the go.

Mechanisms of Disintegrant in ODTs:- [24,25,26]

The key characteristic of ODTs is their ability to disintegrate rapidly in the mouth. This process typically involves:

Hydration:- Upon contact with saliva, the tablet absorbs moisture, which initiates the disintegration process. Superdisintegrants play a key role in facilitating this step. The superdisintegrants present in the formulation begin to swell and initiate the breakdown of the tablet.

Swelling:- The superdisintegrants cause the tablet to swell, leading to the break-up of the solid tablet into smaller particles. The absorbed moisture causes the superdisintegrants to swell, which facilitates the tablet's disintegration into smaller particles.

Dispersion:- After disintegration, the API is dispersed in the saliva, where it begins to dissolve and can be absorbed through the oral mucosa or swallowed for gastrointestinal absorption. The particles of the active ingredient are then dispersed in the saliva, making the drug available for absorption. The dissolved particles may either be absorbed through the oral mucosa (bypassing the gastrointestinal tract) or swallowed and absorbed in the stomach.

Mouthfeel and Taste:- The tablet may dissolve in a few seconds, offering a smooth mouthfeel. However, the taste profile of the tablet is a crucial consideration for patient compliance, especially for pediatric or geriatric populations.

Manufacturing Techniques:- [27,28,29,30]

ODTs are typically manufactured using one of the following methods:

✓ **Direct Compression:-** The disintegration and solubilization of directly compressed tablets depend on single or combination action of disintegrants, water soluble excipients and effervescent agents utilized. This is a simple method where the API and excipients are mixed and compressed directly into a tablet form. This method involves compressing a blend of the drug and excipients directly into tablets without the need for a liquid phase. Direct compression is advantageous because it is a simple and cost-effective process, but it requires careful selection of excipients to ensure the tablet disintegrates quickly.

API degradation, moisture sensitivity, and maintaining consistent quality, while regulatory constraints include strict process validation, excipient control, and stability testing. Stability, material variability, and regulatory requirements for consistent quality and process validation.

Table No. 2: Advantage and Limitation of Direct Compression Method.

Advantage	Limitation
Cost-Effective: Fewer processing steps and equipment requirements reduce production costs.	Limited Control Over Release Rate: For some formulations, achieving controlled or sustained release may be difficult with direct compression alone.

✓ **Lyophilization (Freeze Drying):-** In this process, a solution or suspension of the drug is frozen and then dried under vacuum, resulting in a porous structure that rapidly disintegrates when placed in the mouth. In this technique, a drug formulation is frozen and then dried under vacuum. The result is a porous, lightweight tablet that disintegrates rapidly when placed in the mouth. An example of this technology is the Zydis system, which is widely used in the development of ODTs.

Maintaining product stability during freezing and drying, and ensuring consistent quality, while regulatory constraints include strict process validation, batch uniformity, and stability testing requirements. Process consistency, and meeting regulatory requirements for validation and quality control.

Table No. 3: Advantage and Limitation of Lyophilization (Freeze Drying) Method

Advantage	Limitation
More rapid dissolution than other available Solid products. No need for water.	Time-consuming: Lyophilization is a slow process, taking several hours to days to complete.

✓ **Spray Drying:-** This technique is used to create solid particles of the drug that dissolve quickly in the mouth. Maintaining product stability, consistency, and meeting regulatory requirements for process validation and quality control.

Table No. 4: Advantage and Limitation of Spray Drying Method

Advantage	Limitation
Spray drying is a fast process, making it ideal for large-scale production of ODTs.	The efficiency of the process can be low in terms of yield, and some material may be lost during the drying process.

✓ **Melt Granulation:-** It is a helpful method for increasing the pace at which medications that are not very soluble in water, like I griseofulvin, dissolve. Temperature sensitivity, maintaining batch uniformity, and meeting regulatory requirements for process validation and stability.

Table No. 5: Advantage and Limitation of Melt Granulation Method.

Advantage	Limitation
Melt granulation uses heat to melt the binder, eliminating the need for solvents, which simplifies the process and reduces costs.	Excessive heat may degrade heat-sensitive APIs, limiting its applicability for certain compounds.

✓ **Molding:** In the molding technique, the drug is dissolved in a solvent, and the resulting mixture is poured into molds. After evaporation of the solvent, the molded tablets are formed. This method often produces highly porous tablets with rapid disintegration rates. Challenges with material consistency, mold precision, and meeting regulatory requirements for product stability and quality control.

Table No. 6: Advantage and Limitation of Molding.

Advantage	Limitation
Disintegrate more rapidly and offer improved taste because the dispersion matrix is, in general, made from water-soluble sugars	Molded tablets tend to be softer and more fragile, which can make handling, packaging, and transport more difficult.

✓ **Mass Extrusion:-** Using a solvent mixture of methanol and water-soluble polyethylene glycol, the method softens the active blend. To create a tablet, the heated blade is used to cut the softened material into even segments after it has been extruded through a syringe to create a cylinder. To achieve taste masking, the dried cylinder can also be used to coat bitter medicine grains. In order to create tablets, a blend of active chemicals and other substances is softened using a combination of ethanol and polyethylene glycol. The soft mass is then expelled through a syringe or extruder to create a cylindrical shape. [31,32] Challenges with controlling uniformity, maintaining stability of sensitive APIs, and meeting regulatory requirements for process validation and product quality.

Table No. 7: Advantage and Limitation of Mass Extrusion Method

Advantage	Limitation
To mask the bitter taste	Mass extrusion requires specialized equipment, which can be expensive to set up and maintain.

✓ **Cotton Candy or Sublimation Method:** A relatively new technique, the sublimation method involves the use of volatile compounds like ammonium bicarbonate or camphor, which are removed after tablet formation, leaving a porous structure. This increases the disintegration rate of the final tablet. Polysaccharides or saccharides spin and melt quickly to form a matrix known as a floss. To enhance sustainability and flow characteristics, the resultant matrix undergoes partial recrystallization. The floss matrix is ground, combined with the excipients and active ingredient, and then compacted. The cotton candy technique is described in numerous patents. [33,34]

Challenges with maintaining product stability, controlling consistency, and meeting regulatory requirements for process validation and quality control.

Table No. 8: Advantage and Limitation of Cotton Candy or Sublimation Method

Advantage	Limitation
Creates highly porous tablets that disintegrate quickly when placed in the mouth, enhancing patient compliance, especially for those who have difficulty swallowing.	The resulting tablets are often very soft and fragile due to their porous nature, which can lead to breakage during handling, packaging, or transport.

Table No. 9: Comparison between various ODT Formulation Technique

Sr. No.	Method	Description	Advantage	Limitations
1	Direct Compression	Powder blends of API and excipients are directly compressed into tablets without prior granulation.	Fast, cost-effective, and simple; no need for moisture or heat, preserving the integrity of heat-sensitive drugs.	Only suitable for drugs that have good flowability and compressibility. Achieving uniformity can be challenging for certain formulations.
2	Lyophilization (Freeze Drying)	The drug formulation is frozen, and water is removed by sublimation, creating a porous structure ideal for fast dissolution.	Ideal for heat-sensitive drugs, producing highly porous tablets with rapid disintegration.	Expensive, time-consuming, and low tablet mechanical strength
3	Spray Drying	A liquid solution or suspension of API and excipients is atomized & dried into fine particles.	Creates uniform, fine particles that enhance dissolution rates.	High energy consumption, potential drug degradation due to heat, and complex equipment requirements.
4	Melt Granulation	A molten binder is used to bind powder particles, and the mixture is then cooled and compressed into tablets.	Efficient for moisture-sensitive drugs and improves flow properties of powders.	Heat-sensitive drugs may degrade, and the process requires specialized equipment.
5	Molding	Involves creating a slurry or paste of the drug and excipients, which is poured into molds and dried to form tablets.	High porosity, suitable for poor compressibility drugs	Requires drying time Slow production time
6	Mass Extrusion	Involves mixing the drug with excipients and extruding the mixture to form a uniform mass that is then cut into tablets.	Mass extrusion produces highly uniform tablets, ensuring accurate and consistent dosing.	Mass extrusion requires specialized equipment, which can be costly to acquire and maintain.
7	Cotton Candy or Sublimation Method	This method is often used for creating light, airy tablets that dissolve almost instantaneously upon contact with moisture.	Enhancing palatability and patient compliance Extremely fast disintegration, low cost	Scaling the process for large-scale production can be difficult.

Marketed formulations of Oral Disintegration Tablet :-[35,36]

- **Ondansetron (Zofran ODT):-** A medication used for preventing nausea and vomiting associated with chemotherapy, radiation therapy, and surgery.

- **Clozapine (Fazaclo):-** Clozapine is mainly prescribed for treatment-resistant schizophrenia and Severe, Suicidal behavior in schizophrenia patients.

- **Allegra ODT (Fexofenadine):-** Allergic rhinitis and chronic idiopathic urticaria.

- **Claritin RediTabs (Loratadine):-** Allergic rhinitis and other allergic conditions.

- **Tramadol HCL (Rybix):-** Tramadol is an opioid analgesic that works by altering how the brain and nervous system respond to pain.

- **Risperdal M-Tab (Risperidone):-** Treatment of schizophrenia, bipolar disorder, and irritability associated with autistic disorder.

- **Torrox MT (Rofecoxib):-** Treatment of Nausea and Vomiting, Gastroesophageal reflux disease(GERD), Dyspepsia, Gastric acid-related disorders.

- **Gaster D (Gaster D):-** Treatment of Gastroesophageal reflux disease(GERD), Indigestion(Dyspepsia).

- **Zontec (Cetrizine):-** Allergic Rhinitis(Hay fever), Seasonal Allergies, Other Allergic Conditions.

- **Olanzapine (Zyprexa Zydis):-** Olanzapine is primarily used for the treatment of Schizophrenia. Olanzapine is an atypical antipsychotic.

- **Nexium ODT (Esomeprazole):-** Treatment of gastroesophageal reflux disease (GERD) and peptic ulcers.

Challenges In ODT Development :- [37,38,39]

While ODTs offer numerous advantages, their formulation presents several challenges:

- **Hygroscopicity:-** Under typical temperature and humidity circumstances, a number of oral disintegrating dosage forms lose their physical integrity due to their hygroscopic nature. As a result, they require humidity protection, necessitating the use of specialist product packaging.

- **Aqueous solubility:-** Due to the creation of eutectic mixtures, which induce freezing-point depression and the formation of a glassy solid that may collapse upon drying due to the loss of supporting structure during the sublimation process, water-soluble pharmaceuticals present a number of formulation issues. By employing different matrix-forming excipients, like mannitol, which can cause crystallinity and give the amorphous composite stiffness, such collapse can occasionally be avoided.

- **Mechanical strength:-** ODTs need to be robust enough for handling, packaging, and transportation, but also fragile enough to disintegrate rapidly in the mouth. Achieving the right balance between hardness and disintegration time is challenging.

- **Mouth Feel:-** When ODT is broken up, the particles should be small and have a pleasant mouth rather than larger ones.

- **Taste Masking:-** The need to mask the taste of APIs without affecting the tablet's disintegration and dissolution characteristics can complicate formulation. The bitter taste of certain drugs can be difficult to mask effectively, which may affect patient compliance. The selection of appropriate flavoring agents and taste-masking technologies is crucial.

- **Good Packaging Design:-** As a first step, package design should be enhanced to shield ODTs from moisture and the environment.

- **Limited Drug Loading:-** ODTs may have limited capacity for high-dose drugs, which can be a challenge for some therapeutic areas (e.g., oncology or pain management).

- **Scalability:-** While some manufacturing techniques are cost-effective, scaling up the production of ODTs can be difficult, especially for complex formulation processes like lyophilization.

- **Size of tablet:-** The size of a pill determines how easy it is to take. According to reports, tablets larger than 8 mm were the simplest to manage, while those smaller than 7-8 mm were the easiest to swallow. As a result, it is challenging to find a tablet size that is convenient to carry and manage.

- **Cost of Production:-** The advanced excipients and specialized equipment required for the production of ODTs may increase the overall cost compared to traditional tablets, Certain manufacturing techniques, particularly freeze-drying and molding, can be expensive, potentially making ODTs less economically viable for certain drug formulations.

Applications of ODTS :-

ODTs are used in a wide range of therapeutic areas:

- **Pain Management:-** Drugs such as Acetaminophen, Ibuprofen, and Triptans (for migraine) have been formulated as ODTs for rapid relief of symptoms. ODTs are often used for the delivery of analgesics, such as nonsteroidal anti-inflammatory drugs (NSAIDs), where rapid onset of action is desirable.

ODTs are often used to deliver analgesics such as Acetaminophen, Ibuprofen, and more specialized drugs like triptans for migraine relief. Their rapid disintegration facilitates quick relief from acute pain conditions.[40]

- **Psychiatric Disorders:-** Antidepressants, antipsychotics, and anxiolytics are frequently developed as ODTs to enhance patient adherence, particularly in patients with depression, anxiety, or schizophrenia. For patients with psychiatric disorders, particularly those with conditions like schizophrenia, bipolar disorder, or depression, ODTs improve adherence to medications like antipsychotics and antidepressants, reducing the stigma associated with treatment and enhancing the patient experience.[41]

- **Nausea and Vomiting:-** Anti-emetic drugs like ondansetron are formulated as ODTs to provide fast relief for patients undergoing chemotherapy or those with motion sickness.[42,43]

- **Pediatric and Geriatric Populations:-** ODTs are often preferred for children and elderly patients, who may have difficulty swallowing conventional tablets. ODTs are particularly useful for pediatric and geriatric patients who may struggle with swallowing conventional tablets or capsules. The ease of use and improved patient compliance make ODTs an attractive option in these populations. ODTs are particularly beneficial for young children who may have difficulty swallowing tablets or capsules, and elderly patients with swallowing difficulties.[44]

- **Anti-emetic Drugs:-**ODTs are often employed in delivering anti-emetic drugs like ondansetron for the prevention of nausea and vomiting, particularly in chemotherapy patients. ODTs are also commonly used for nausea and vomiting treatments, especially in patients undergoing chemotherapy.[45]

- **Mental health treatments:-** Many psychiatric medications, such as those used for depression and anxiety, are formulated as ODTs to improve patient adherence.[46]

- **Treatment of Conditions Requiring Quick Relief**: ODTs are ideal for conditions requiring rapid relief, such as pain relief (analgesics), nausea, migraine, and anxiety (e.g., anti-anxiety medications like lorazepam or alprazolam. [47]

- **Convenience and Portability:** ODTs are highly portable and do not require water to be ingested, which appeals to patients with busy lifestyles. The ability to take a dose anywhere—whether in a car, on a plane, or during work—has led to the rising popularity of ODTs in the over-the-counter (OTC) market.

- **Consumer Healthcare and OTC Market Growth:** The consumer healthcare market is increasingly adopting ODT formulations for over-the-counter (OTC) products, including vitamins, minerals, cold and allergy medications, and dietary supplements.

- **Market Expansion in Prescription Drugs:** The market for prescription ODTs is also expanding, particularly in therapeutic areas such as pain management, neurology, psychiatry, and cardiology.

- **Innovative Drug Delivery Systems**: ODTs provide a platform for developing innovative drug delivery technologies, such as bioenhancers or novel excipients that can enhance the solubility and stability of poorly soluble drugs.

- **Global Market Potential:** The ease of use, combined with growing healthcare awareness, further increases the potential for ODT adoption on a global scale.

Future Trends and Advancements:- [48-49]

Recent advancements in ODT technology focus on:

- **Novel Superdisintegrants:-** New generations of superdisintegrants are being developed to enhance the speed and efficiency of tablet disintegration.

- **Taste Masking Technologies:-** Advanced methods like polymer-based taste-masking systems are being explored to overcome the challenges of bitter APIs.

- **High-Throughput Screening:-** New manufacturing technologies are improving the quality and reproducibility of ODT production, reducing costs, and increasing scalability.

- **Personalized Medicine:-** ODTs are increasingly being tailored to the specific needs of patients, with adjustable doses or combinations of drugs in a single tablet for optimized therapy.

Conclusion

Orally disintegrating tablets represent a significant advancement in pharmaceutical dosage forms, providing a patient-friendly alternative to conventional oral tablets. The ability to dissolve rapidly in the mouth without the +need for water enhances medication adherence, especially for those with swallowing difficulties. Despite challenges in formulation, such as stability and taste masking, advances in technology continue to improve the development of ODTs. Their growing popularity across various therapeutic indications highlights their importance in modern medicine.

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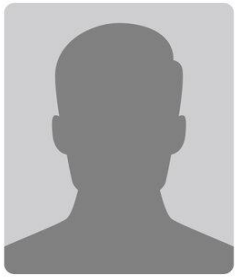
	Author Name: Patil Payal K. Author Affiliation:- Department of Pharmaceutics, P.S.G.V.P.M's College of Pharmacy, Shahada. Author Address/Institute Address: P.S.G.V.P.M's College of Pharmacy, Shahada.
	Author Name: Dhankani Mansi A. Author Affiliation:- Department of Pharmaceutics, P.S.G.V.P.M's College of Pharmacy, Shahada. Author Address/Institute Address: P.S.G.V.P.M's College of Pharmacy, Shahada.

	Author Name: Dhankani Amitkumar R. Author Affiliation:- Department of Pharmaceutics, P.S.G.V.P.M's College of Pharmacy, Shahada. Author Address/Institute Address: P.S.G.V.P.M's College of Pharmacy, Shahada.
	Author Name: Pawar Sunil P. Author Affiliation:- Department of Pharmaceutics, P.S.G.V.P.M's College of Pharmacy, Shahada. Author Address/Institute Address: P.S.G.V.P.M's College of Pharmacy, Shahada.