ORODISPERSIBLE TABLETS: A COMPREHENSIVE REVIEW OF FORMULATION STRATEGIES, TECHNOLOGIES AND RECENT ADVANCES

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Abstract

Orodispersible tablets (ODTs) are solid dosage forms designed to rapidly disintegrate in the oral cavity without the need for water, offering significant advantages in terms of patient compliance, convenience, and rapid onset of action, particularly for pediatric, geriatric, and dysphagic patients. This review provides a comprehensive overview of ODTs, including formulation considerations, development strategies such as direct compression, freeze-drying, sublimation, and moulding techniques, as well as key technologies like Zydis, Orasolv, Durasolv, Wowtab, and FlashTab systems. The underlying mechanisms of disintegration, including swelling, wicking action, porosity, and the role of saliva, are also discussed in detail. In addition, critical evaluation parameters such as pre-compression properties, mechanical strength, disintegration time, wetting behavior, and dissolution studies are highlighted to ensure product quality and performance. Recent advancements including 3D printing, nanotechnology-based systems, and co-processed excipients are also explored, emphasizing the evolution of ODTs toward more efficient and patient-centric drug delivery systems. Despite their advantages, challenges such as moisture sensitivity, taste masking limitations, and scale-up issues persist, but ongoing innovations continue to expand their therapeutic and commercial potential in modern pharmaceutics.

Keywords: *Orodispersible tablets, fast dissolving tablets, superdisintegrants, taste masking, lyophilization, direct compression, 3D printing, nanotechnology, patient compliance, oral drug delivery.*

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1. INTRODUCTION

Orodispersible tablets (ODTs) are solid dosage forms designed to disintegrate rapidly in the oral cavity without the need for water, typically within seconds, resulting in a suspension or solution that can be easily swallowed. According to the United States Pharmacopeia, ODTs are defined as tablets that disintegrate rapidly within 30 seconds to 3 minutes when placed on the tongue. This dosage form has gained significant attention in modern drug delivery due to its ability to improve patient compliance and provide rapid therapeutic action (Kuchekar et al., 2003; Bandari et al., 2008).

ODTs were developed primarily to address the limitations associated with conventional oral dosage forms, particularly swallowing difficulties (dysphagia), which are common among pediatric, geriatric, psychiatric, and bedridden patients. Additionally, they are beneficial for patients experiencing nausea, vomiting, or conditions requiring rapid onset of action. The ease of administration without water also makes ODTs highly suitable for emergency situations and for patients with restricted access to fluids (Siddiqui et al., 2018).

From a formulation perspective, ODTs represent a complex balance between mechanical strength and rapid disintegration. The inclusion of superdisintegrants, porous structures, and taste-masked drug systems plays a crucial role in achieving desired performance characteristics. Over the past two decades, significant advancements in formulation technologies such as freeze-drying, sublimation, and direct compression have enabled the successful commercialization of ODT products across multiple therapeutic categories.

ODTs offer several advantages, including improved patient compliance, enhanced bioavailability for certain drugs, rapid onset of action, and increased convenience. However, they also present challenges such as moisture sensitivity, limited drug loading capacity, and the need for effective taste masking. These factors necessitate careful formulation design and selection of appropriate excipients and manufacturing techniques (Dobetti, 2001; Rathbone et al., 2015).

With continuous advancements in pharmaceutical technology, including nanotechnology-based systems and 3D printing, ODTs are evolving into more sophisticated and patient-centric drug delivery platforms. As a result, they are expected to play an increasingly important role in modern pharmacotherapy and personalized medicine.

2. Formulation Considerations

The formulation of orodispersible tablets (ODTs) requires careful consideration of drug-related and excipient-related factors to ensure rapid disintegration, acceptable taste, mechanical strength, and adequate bioavailability. Since ODTs are designed to disintegrate in

the oral cavity without water, formulation design becomes more critical than conventional tablets, particularly for dose uniformity, palatability, and stability.

2.1 Drug selection criteria for ODTs

The selection of a suitable drug candidate is a key determinant of successful ODT formulation. Ideal drugs for ODTs generally possess low to moderate dose, as high-dose drugs may lead to large tablet size and poor mouthfeel. Drugs should have good aqueous solubility or at least moderate permeability to ensure rapid dissolution once disintegrated in saliva. The taste of the drug is also a critical factor, as bitter drugs require effective taste masking strategies.

Additionally, drugs with short biological half-life, those requiring rapid onset of action, and drugs used in pediatric, geriatric, psychiatric, or dysphagic patients are preferred candidates. Drugs such as antihistamines, antiemetics, analgesics, and CNS-active agents are commonly formulated as ODTs due to their need for fast therapeutic action and ease of administration (Reddy et al., 2020; Siddiqui et al., 2018).

Physicochemical properties such as particle size, hygroscopicity, and stability in saliva must also be considered. Highly moisture-sensitive drugs may require protective formulation strategies, as ODTs are inherently porous and sensitive to humidity (Bhatt & Sharma, 2019).

2.2 Role of excipients in ODTs

Excipients play a crucial role in determining the performance of ODTs, particularly in achieving rapid disintegration, adequate mechanical strength, and improved palatability. Unlike conventional tablets, ODTs require a delicate balance between hardness and rapid break-up, which is achieved through carefully selected functional excipients.

Fillers and diluents such as mannitol, microcrystalline cellulose, and lactose are widely used to provide bulk and improve mouthfeel. Mannitol is especially preferred due to its cooling sensation and high aqueous solubility, which enhances patient acceptability (Khan et al., 2021).

Binders ensure tablet integrity during handling and packaging, while lubricants and glidants improve powder flow and compression characteristics. However, excessive use of lubricants may delay disintegration time.

Flavouring agents, sweeteners (such as aspartame, sucralose), and colouring agents are used to improve organoleptic properties, which is particularly important for bitter drugs. Overall, the excipient system must support both fast disintegration and acceptable mechanical strength, which remains one of the major formulation challenges in ODT development (Bandari et al., 2008; Gupta et al., 2019).

2.3 Superdisintegrants and their mechanism

Superdisintegrants are the most critical excipients in ODT formulations, as they directly influence the disintegration time and drug release rate. Commonly used superdisintegrants include crospovidone, croscarmellose sodium, and sodium starch glycolate.

These agents act through different mechanisms:

- **Swelling mechanism:** Sodium starch glycolate rapidly absorbs water and swells, causing tablet breakup.
- **Wicking action:** Croscarmellose sodium facilitates capillary water uptake into the tablet matrix.
- **Shape recovery and porous structure formation:** Crospovidone promotes rapid disintegration by elastic recovery and capillary action without significant swelling (Rathore et al., 2019).

The efficiency of superdisintegrants depends on their concentration, particle size, and mode of incorporation (intra-granular or extra-granular). Excess concentration may lead to gelling or delayed disintegration, whereas optimal levels significantly enhance oral dispersion within seconds (Kumar et al., 2020).

2.4 Taste masking strategies

Taste masking is a critical requirement in ODT formulation, as the drug is released directly in the oral cavity, making palatability a key determinant of patient compliance. Bitter drugs require specialized strategies to prevent interaction with taste receptors during disintegration.

One of the most widely used approaches is flavoring and sweetening agents, which help in masking mild bitterness. However, for highly bitter drugs, more advanced techniques are required.

Coating techniques, such as polymer coating (ethyl cellulose, Eudragit polymers), are commonly used to prevent drug dissolution in saliva while allowing release in gastric fluid. Another effective method is complexation with cyclodextrins, where drug molecules are encapsulated within a hydrophilic cavity, reducing taste perception.

Additionally, solid dispersion techniques, ion-exchange resins (resinate formation), and microencapsulation are widely employed for effective taste masking (Rawat et al., 2019; Pahwa & Gupta, 2011).

The selection of a taste masking strategy depends on drug solubility, dose, and release profile requirements. An ideal system should mask bitterness completely without affecting disintegration time or bioavailability.

3. Formulation Strategies for ODT Development

The development of orodispersible tablets (ODTs) relies on several formulation strategies designed to achieve rapid disintegration, acceptable mechanical strength, and improved patient compliance. These techniques are selected based on drug properties, required disintegration time, manufacturing feasibility, and scale-up considerations. Among the most widely used approaches are direct compression, freeze drying, sublimation, and moulding/effervescence-based systems.

3.1 Direct compression technique

Direct compression is the most widely used and cost-effective method for ODT formulation due to its simplicity, reduced processing steps, and suitability for moisture- and heat-sensitive drugs. In this technique, drug and excipients are blended and directly compressed into tablets without prior granulation.

The success of this method depends heavily on the use of **specially designed excipients**, such as directly compressible fillers (mannitol, microcrystalline cellulose) and **superdisintegrants** (crospovidone, croscarmellose sodium). These excipients ensure rapid water uptake and tablet breakup upon contact with saliva.

However, this method may face limitations such as poor flow properties, segregation of blend components, and difficulty in achieving optimal mechanical strength at very high disintegrant levels. Despite these challenges, direct compression remains the most preferred industrial technique due to its scalability and low production cost (Gohel et al., 2004; Bandari et al., 2008).

3.2 Freeze drying (lyophilization)

Freeze drying, also known as lyophilization, is a highly effective technique used to produce porous, highly friable tablets that rapidly disintegrate in the oral cavity. In this process, a drug solution or suspension is first filled into blister packs or moulds, frozen, and then subjected to sublimation under vacuum to remove ice directly as vapor.

The resulting tablets have high porosity, low density, and extremely fast disintegration time (often within seconds) due to rapid penetration of saliva. This technology is commonly used in commercial products like Zydis-based formulations.

Despite its advantages, lyophilization has limitations such as high production cost, complex manufacturing process, fragility of final dosage form, and requirement of specialized packaging to protect against moisture and mechanical stress (Seager, 1998; Kuno et al., 2005).

3.3 Sublimation technique

The sublimation technique involves the incorporation of volatile substances (such as camphor, ammonium bicarbonate, or menthol) into the tablet matrix, which are later removed by sublimation under reduced pressure or heat. This process creates a highly porous structure within the tablet, facilitating rapid water penetration and disintegration.

After compression, tablets are subjected to conditions that allow the subliming agent to evaporate, leaving behind a porous network. This significantly reduces disintegration time and improves drug release rate.

However, careful selection of sublimating agents is essential to ensure safety, stability, and uniform pore formation. Additionally, this method may involve extra processing steps compared to direct compression (Patel et al., 2009; Mohanachandran et al., 2011).

3.4 Moulding and effervescence-based systems

Moulding is a technique in which drug and excipients are moistened and molded into tablet-shaped units, followed by drying. Molded tablets are highly porous and dissolve quickly in the oral cavity due to weak interparticle bonding and increased wettability. However, they often suffer from poor mechanical strength and require careful handling and packaging.

Effervescence-based systems incorporate acid-base combinations (such as citric acid and sodium bicarbonate) that release carbon dioxide upon contact with saliva or water. The generated gas enhances tablet disintegration and promotes rapid drug dispersion.

These systems are particularly useful for achieving very fast disintegration; however, they require protection from moisture during storage, and taste masking may still be necessary due to the acidic components used (Dobetti, 2001; Bi et al., 1996).

Table 1: Comparison of Formulation Techniques for ODTs

Technique	Principle	Advantages	Limitations	Suitable Drugs
Direct compression	Compression of powder blend using superdisintegrants	Simple, low cost, scalable	Poor flow, limited dose flexibility	Low–moderate dose drugs
Freeze drying (lyophilization)	Sublimation of frozen drug solution	Very fast disintegration, high porosity	Fragile, costly, moisture sensitive	Potent low-dose drugs
Sublimation	Removal of volatile components to create pores	Improved porosity and disintegration	Additional processing step	Moisture-stable drugs

Moulding	Tablets formed using moist mass and drying	Rapid disintegration, good taste	Low mechanical strength	Water-soluble drugs
Effervescence system	CO_2 generation for breakup	Very fast disintegration	Moisture sensitive, stability issues	Acid–base compatible drugs

4. Technologies Used in ODTs

Several proprietary and non-proprietary technologies have been developed to manufacture orodispersible tablets (ODTs) with improved disintegration characteristics, mechanical strength, and patient acceptability. These technologies primarily focus on optimizing porosity, taste masking, and rapid drug release while maintaining acceptable stability and handling properties.

4.1 Zydis technology

Zydis technology is one of the most widely recognized freeze-dried (lyophilized) ODT systems, in which the drug is dispersed in a water-based matrix containing polymers such as gelatin, mannitol, and sugars. The formulation is filled into pre-formed blister packs and subjected to freeze-drying, resulting in a highly porous, lightweight structure.

Upon contact with saliva, Zydis tablets rapidly disintegrate within seconds due to their **extremely high porosity and rapid water uptake**, without requiring chewing or water intake. This technology is particularly suitable for low-dose, highly potent, and water-insoluble drugs. However, tablets produced using Zydis technology are mechanically fragile and require specialized packaging to prevent breakage and moisture exposure (Seager, 1998; Klancke, 2003).

4.2 Orasolv and Durasolv systems

Orasolv technology is based on an effervescent disintegration system, where an acid–base combination (typically citric acid and sodium bicarbonate) generates carbon dioxide upon contact with saliva, promoting rapid tablet disintegration. It also incorporates taste-masking by coating drug particles with a solvent-based system. However, Orasolv tablets have relatively low mechanical strength and require special handling.

Durasolv technology was developed to overcome the mechanical weakness of Orasolv tablets. It uses conventional direct compression techniques with stronger binding agents, resulting in tablets with improved hardness and better mechanical integrity. Durasolv tablets do not require special packaging and are suitable for moderately high drug loads, although they may have slightly longer disintegration times compared to Orasolv systems (Dobetti, 2001; Liang & Chen, 2001).

4.3 Wowtab technology

Wowtab (Without Water Tablet) technology utilizes a combination of saccharides with high moldability and compressibility, such as mannitol, lactose, and maltose, to produce tablets that rapidly dissolve in the mouth. The key principle involves achieving a balance between tablet hardness and rapid disintegration through the use of saccharide-based excipients.

Wowtab formulations exhibit good mechanical strength and are suitable for large-scale manufacturing using conventional tablet compression equipment. The technology is particularly useful for drugs requiring moderate to high doses and provides better stability compared to freeze-dried systems (Makino et al., 1998; Dobetti, 2001).

4.4 FlashTab technology

FlashTab technology is a multi-layered system that combines rapidly disintegrating excipients, effervescent agents, and coated drug particles to achieve fast dissolution and improved taste masking. The formulation typically involves a dual approach where one layer ensures rapid tablet disintegration while the other provides mechanical strength and controlled release characteristics.

This technology offers a good balance between fast disintegration, taste masking, and manufacturability, making it suitable for a wide range of therapeutic agents. However, formulation complexity and cost may be higher compared to conventional direct compression methods (Bi et al., 1996; Bandari et al., 2008).

4.5 Comparative overview of technologies

ODT technologies differ significantly in terms of disintegration time, mechanical strength, cost, scalability, and drug suitability. Freeze-dried systems like Zydis provide extremely rapid disintegration but suffer from poor mechanical strength and high production cost. In contrast, compression-based technologies such as Durasolv and Wowtab offer better mechanical integrity and scalability but may have slightly longer disintegration times.

Effervescent systems like Orasolv provide rapid disintegration but require careful packaging due to moisture sensitivity. Overall, the selection of technology depends on drug properties, dose requirements, manufacturing feasibility, and target patient population. A balanced approach between rapid disintegration and tablet robustness is essential for successful ODT development (Dobetti, 2001; Klancke, 2003).

Table 2: Comparison of Major ODT Technologies

Technology	Mechanism	Key Feature	Advantages	Limitations
Zydis	Freeze-dried matrix	Highly porous structure	Ultra-fast disintegration, excellent mouthfeel	Fragile, high cost

Orasolv	Effervescence + taste masking	Effervescent disintegration	Good taste masking, rapid action	Low mechanical strength
Durasolv	Direct compression	Stronger binding system	Better hardness, no special packaging	Slower disintegration vs Orasolv
Wowtab	Saccharide-based compression	High compressibility excipients	Good mechanical strength	Limited for high-dose drugs
FlashTab	Multi-layer system	Combined rapid + strength design	Balanced properties	Complex formulation

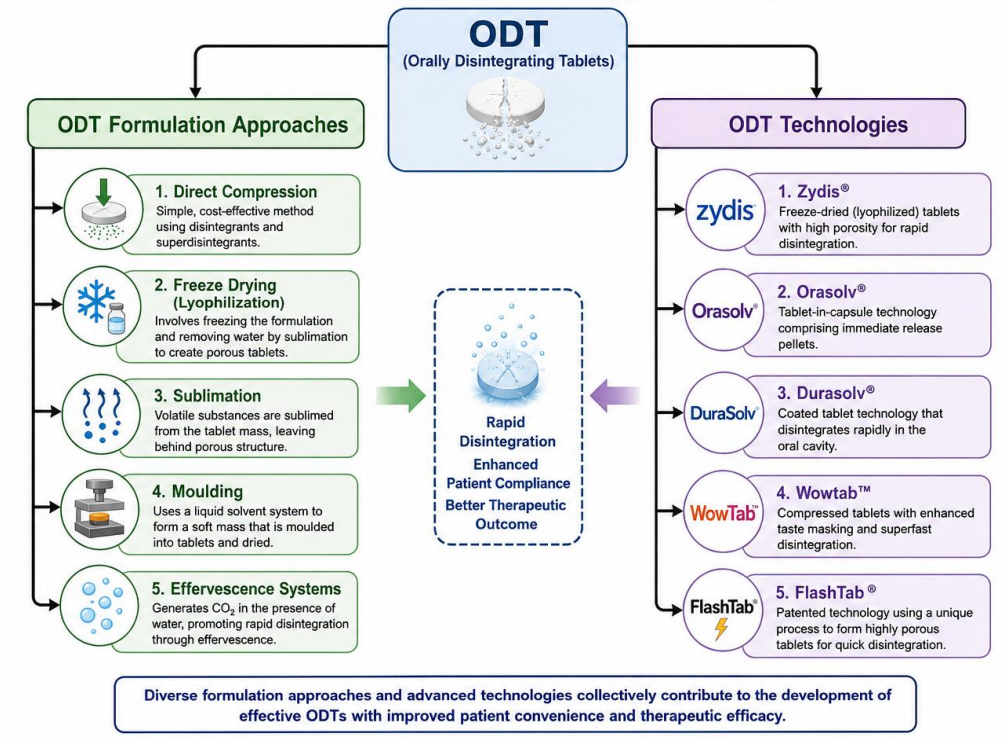

Figure 1: Flowchart of ODT Formulation Strategies and Technologies

5. Mechanism of Disintegration

The rapid disintegration of orodispersible tablets (ODTs) is governed by a combination of physicochemical processes that facilitate water uptake, tablet breakup, and subsequent drug dissolution in the oral cavity. These mechanisms act synergistically and are strongly influenced by formulation composition, porosity, and the presence of superdisintegrants.

5.1 Swelling mechanism

The swelling mechanism is one of the primary pathways involved in ODT disintegration. In this process, superdisintegrants such as sodium starch glycolate and croscarmellose sodium absorb saliva rapidly and undergo significant volumetric expansion. This swelling generates internal stress within the tablet matrix, leading to the rupture of interparticle bonds and subsequent disintegration.

The efficiency of swelling depends on the type and concentration of disintegrant, as well as the tablet porosity. Excessive swelling agents, however, may form a gel-like barrier that can delay complete disintegration if not properly optimized. Overall, swelling creates a mechanical force that facilitates rapid tablet breakup in the oral cavity (Reddy et al., 2020; Kumar et al., 2020).

5.2 Wicking action

Wicking, also known as capillary action, involves the penetration of liquid into the tablet matrix through pores formed during compression. This mechanism does not rely on swelling but rather on the ability of porous structures and hydrophilic excipients to draw saliva into the tablet.

Superdisintegrants such as crospovidone are particularly effective in promoting wicking due to their highly porous structure. As liquid enters the tablet, it reduces the cohesive forces between particles, leading to faster disintegration. Wicking is especially important in formulations where minimal swelling is desired to avoid gel formation (Bandari et al., 2008; Rathore et al., 2019).

5.3 Porosity and capillary action

Porosity plays a crucial role in enhancing the disintegration of ODTs by increasing the surface area available for fluid penetration. Tablets with higher porosity allow rapid ingress of saliva, which accelerates both wicking and swelling processes.

Capillary action occurs when liquid is drawn into the interstitial spaces within the tablet due to surface tension forces. This phenomenon significantly reduces disintegration time by promoting internal hydration of excipients and drug particles. Techniques such as sublimation and freeze-drying are specifically designed to increase porosity and thereby enhance capillary-driven disintegration (Patel et al., 2009; Dobetti, 2001).

5.4 Role of saliva in tablet disintegration

Saliva is the primary medium responsible for initiating disintegration of ODTs in the oral cavity. It provides the necessary aqueous environment for hydration, swelling, and dissolution processes. The volume, composition, and viscosity of saliva directly influence disintegration efficiency.

Saliva contains electrolytes and enzymes that may interact with tablet excipients, further enhancing breakdown. Additionally, continuous movement of saliva within the oral cavity facilitates uniform wetting and dispersion of drug particles. However, variations in salivary flow rate among individuals—such as in elderly or xerostomic patients—can affect

disintegration performance and drug release behavior (Siddiqui et al., 2018; Kaur et al., 2019).

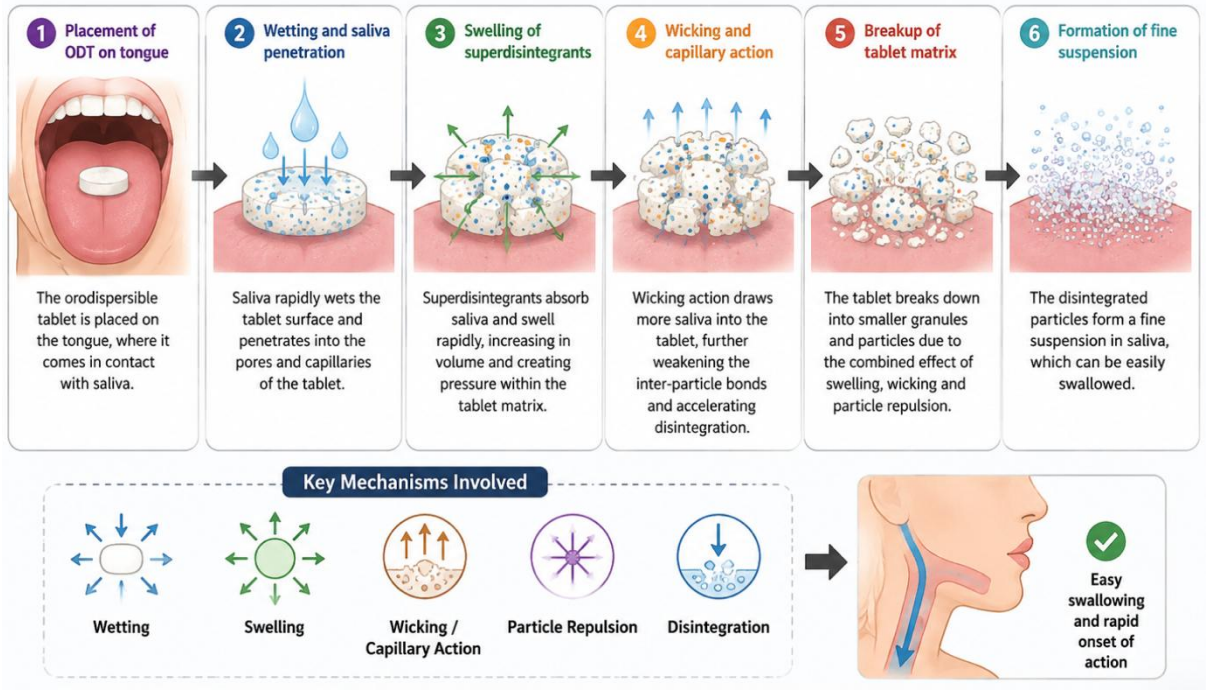

Figure 2: Mechanism of Orodispersible Tablet Disintegration in the Oral Cavity

6. Evaluation of Orodispersible Tablets

The evaluation of orodispersible tablets (ODTs) is essential to ensure product quality, performance, and patient acceptability. Since ODTs are designed for rapid disintegration in the oral cavity, special emphasis is placed on parameters such as mechanical strength, disintegration behavior, and drug release characteristics. Both pre-compression and post-compression evaluations are performed to ensure reproducibility and consistency of the final dosage form.

6.1 Pre-compression parameters

Pre-compression studies are carried out to evaluate the flow and compressibility characteristics of powder blends prior to tablet formation. These parameters are critical for ensuring uniform die filling and consistent tablet weight.

Commonly evaluated parameters include angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio. A lower angle of repose indicates good flowability, while Carr's index and Hausner's ratio provide insights into compressibility and packing behavior of the powder blend.

Good flow properties are essential in ODT formulation, especially in direct compression techniques, where poor flow can lead to weight variation, content non-uniformity, and poor tablet integrity. Optimization of excipient ratios, particularly glidants and diluents, is often

required to improve powder flow characteristics (Aulton & Taylor, 2013; Lachman et al., 2017).

6.2 Mechanical strength (hardness, friability)

Mechanical strength is a critical quality attribute for ODTs, as tablets must withstand handling, packaging, and transportation while still disintegrating rapidly in the oral cavity.

Hardness (crushing strength) is measured to assess tablet integrity, while friability testing evaluates the tendency of tablets to break or crumble under mechanical stress. Ideally, ODTs should possess sufficient hardness to resist physical damage but should not be so hard that disintegration is delayed.

A friability value of less than 1% is generally considered acceptable for conventional tablets; however, in ODTs, achieving this limit while maintaining rapid disintegration remains a formulation challenge. The balance between mechanical strength and rapid disintegration is largely controlled by the selection and concentration of binders and superdisintegrants (Banker & Anderson, 2016; Gohel et al., 2004).

6.3 Disintegration time and wetting behavior

Disintegration time is one of the most important evaluation parameters for ODTs, as it directly reflects the performance of the dosage form in the oral cavity. According to pharmacopeial standards, ODTs should typically disintegrate within seconds to a few minutes without the need for water.

The disintegration process is influenced by tablet porosity, type of superdisintegrant, and compression force. Lower compression force generally results in faster disintegration but may reduce mechanical strength.

Wetting time is also evaluated to determine the time required for water (or simulated saliva) to reach the upper surface of the tablet. A shorter wetting time indicates faster hydration and better disintegration efficiency. The water absorption ratio is often used alongside wetting time to quantify liquid uptake capacity (Nagar et al., 2011; Reddy et al., 2020).

6.4 Dissolution and drug release studies

Dissolution testing is performed to evaluate the rate and extent of drug release from ODTs after disintegration. Although ODTs disintegrate rapidly in the oral cavity, complete drug dissolution is required for systemic absorption.

Standard USP dissolution apparatus (I or II) is commonly used with appropriate media to simulate gastrointestinal conditions. The dissolution profile is influenced by drug solubility, particle size, excipient composition, and disintegration behavior.

Rapid dissolution is often correlated with enhanced bioavailability, especially for poorly soluble drugs formulated using solid dispersion or nano-based techniques. Comparative dissolution studies are also performed to evaluate the performance of ODTs against conventional tablet formulations (Sharma et al., 2018; Klancke, 2003).

7. Recent Advances in ODT Technology

Recent years have witnessed significant advancements in orodispersible tablet (ODT) technology driven by innovations in additive manufacturing, nanotechnology, multifunctional excipients, and patented drug delivery platforms. These developments aim to overcome classical limitations of ODTs such as low drug loading, moisture sensitivity, taste masking challenges, and mechanical fragility while improving patient-centric performance.

7.1 3D printed ODTs

Three-dimensional (3D) printing has emerged as a revolutionary approach in ODT fabrication, enabling precise control over tablet geometry, porosity, and drug distribution. Techniques such as fused deposition modeling (FDM), selective laser sintering (SLS), and inkjet printing allow customization of dose, shape, and disintegration behavior.

3D-printed ODTs can be engineered with high internal porosity, facilitating ultra-rapid disintegration and improved dissolution rates. Additionally, this technology supports personalized medicine, particularly useful in pediatrics and geriatrics where dose flexibility is critical. Despite these advantages, limitations include high production cost, limited large-scale manufacturing capability, and regulatory challenges related to reproducibility and validation (Alomari et al., 2015; Trenfield et al., 2019).

7.2 Nanotechnology-based ODT systems

Nanotechnology has significantly enhanced the performance of ODTs by improving solubility, bioavailability, and dissolution rate of poorly water-soluble drugs. Nanoformulations such as nanosuspensions, solid lipid nanoparticles (SLNs), nanostructured lipid carriers (NLCs), and polymeric nanoparticles are commonly incorporated into ODT matrices.

These systems increase surface area and improve drug dispersion upon disintegration, resulting in faster onset of action. Nanoparticle-loaded ODTs are particularly useful for BCS Class II and IV drugs, where dissolution is the rate-limiting step. However, challenges include stability issues, scale-up complexity, and potential aggregation of nanoparticles during storage (Sahoo & Labhasetwar, 2003; Date et al., 2010).

7.3 Co-processed excipients and novel carriers

Co-processed excipients represent a major advancement in ODT formulation technology. These are multifunctional excipient systems engineered by combining two or more excipients at a sub-particle level to improve flowability, compressibility, and disintegration performance without chemical modification.

Common examples include co-processed mannitol–microcrystalline cellulose systems and lactose-based multifunctional excipients. These materials enhance tablet robustness while maintaining rapid disintegration, thereby overcoming the traditional trade-off between mechanical strength and fast dissolution.

Novel carriers such as spray-dried excipients, porous silica-based systems, and sugar alcohol blends have further improved mouthfeel, stability, and manufacturability of ODTs (Gohel & Jogani, 2005; Pabari & Ramtoola, 2012).

7.4 Patented and commercial innovations

Several patented technologies have significantly contributed to the commercialization of ODTs. Systems such as Zydis, Orasolv, Durasolv, Wowtab, and FlashTab have been widely adopted in pharmaceutical industries for developing fast-dissolving dosage forms.

Modern commercial innovations focus on enhanced taste masking, high drug loading capacity, and improved mechanical strength. Additionally, orally disintegrating films and hybrid ODT systems have expanded the scope of rapid-dissolving oral delivery platforms.

Pharmaceutical companies are also increasingly investing in orally disintegrating combination therapies and fixed-dose ODT formulations, improving patient adherence in chronic diseases. Despite advancements, intellectual property constraints and manufacturing costs remain key limiting factors for widespread adoption (Dobetti, 2001; Klancke, 2003).

8. Challenges and Future Perspectives

Despite significant advancements in orodispersible tablet (ODT) technology, several formulation, stability, and manufacturing challenges still limit their universal application. At the same time, rapid progress in material science, nanotechnology, and digital manufacturing is opening new opportunities for next-generation patient-centric ODT systems.

8.1 Stability and moisture sensitivity

One of the major limitations of ODTs is their high sensitivity to moisture, primarily due to their porous structure and the presence of hydrophilic excipients. This porosity, although essential for rapid disintegration, also increases the risk of hygroscopicity, physical instability, and degradation of moisture-sensitive drugs.

Exposure to humidity can lead to softening, loss of mechanical strength, and changes in disintegration time. Therefore, ODTs often require specialized packaging such as alu-alu

blisters or desiccant-containing packs to maintain stability throughout shelf life. Additionally, environmental conditions during storage and transportation play a critical role in product performance (Dobetti, 2001; Kaur et al., 2019).

8.2 Taste masking limitations

Taste masking remains a persistent challenge in ODT formulation, especially for drugs with high bitterness, low dose tolerance, or rapid salivary solubility. Although techniques such as polymer coating, ion-exchange resins, and complexation with cyclodextrins are widely used, complete taste masking without affecting drug release is difficult to achieve.

Many taste-masking strategies may delay disintegration or reduce bioavailability if not properly optimized. Furthermore, patient perception of taste is subjective, making standardization of palatability testing complex. Hence, achieving a balance between effective taste masking and rapid drug release continues to be a formulation challenge (Rawat et al., 2019; Pahwa & Gupta, 2011).

8.3 Manufacturing and scale-up issues

Although direct compression and other techniques enable ODT production, industrial scale-up remains challenging due to sensitivity in formulation parameters such as compression force, excipient ratio, and environmental humidity control.

Freeze-dried systems, in particular, suffer from high production cost, longer processing time, and fragility, making large-scale manufacturing less feasible. Even in compression-based systems, achieving consistent tablet hardness and disintegration time across batches requires strict process control and advanced quality systems.

Additionally, maintaining uniform distribution of superdisintegrants and taste-masked particles is critical for batch-to-batch reproducibility. These challenges necessitate the application of Quality by Design (QbD) and Process Analytical Technology (PAT) approaches for robust manufacturing (Pabari & Ramtoola, 2012; Bandari et al., 2008).

8.4 Future scope in personalized medicine

The future of ODTs is strongly aligned with the concept of personalized and patient-centric drug delivery systems. Emerging technologies such as 3D printing, AI-assisted formulation design, and on-demand manufacturing are enabling the production of individualized ODT doses based on patient-specific requirements.

ODTs are particularly promising in pediatric and geriatric populations, where swallowing difficulties and dose adjustments are common. Integration of nanotechnology, mucoadhesive systems, and combination therapies is expected to further enhance therapeutic outcomes.

In addition, smart ODT systems capable of controlled release, targeted delivery, and real-time responsiveness are being explored. These innovations are expected to transform ODTs from conventional fast-dissolving systems into advanced precision oral drug delivery platforms (Trenfield et al., 2019; Alomari et al., 2015).

9. Conclusion

Orodispersible tablets (ODTs) have emerged as a highly promising oral drug delivery system designed to improve patient compliance, particularly among pediatric, geriatric, and dysphagic populations. Their ability to rapidly disintegrate in the oral cavity without the need for water offers significant advantages over conventional solid dosage forms, including improved convenience, faster onset of action, and enhanced therapeutic effectiveness.

Advancements in formulation strategies such as direct compression, freeze-drying, sublimation, and moulding techniques have enabled the development of ODTs with improved performance characteristics. In parallel, innovative technologies including Zydis, Orasolv, Wowtab, and FlashTab systems have further strengthened the clinical and commercial success of ODTs by addressing key challenges such as taste masking and disintegration efficiency.

Despite these advancements, challenges related to moisture sensitivity, mechanical strength, taste masking limitations, and large-scale manufacturing continue to restrict their broader application. However, ongoing research in nanotechnology, 3D printing, and co-processed excipients is steadily overcoming these limitations and paving the way for more robust and efficient formulations.

Overall, ODTs represent an evolving and patient-centric dosage form with strong future potential. With continued innovation and integration of advanced pharmaceutical technologies, ODTs are expected to play a central role in the development of next-generation oral drug delivery systems.

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11. Conflict of Interest

The authors declare that there are no conflicts of interest.

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