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Review Article

Orodispersible Tablets Advances and Formulation Strategies: A Review

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ABSTRACT

Orally disintegrating tablets (ODTs) have emerged as a patient-centric oral dosage form designed to disintegrate rapidly in the oral cavity without the need for water, offering enhanced patient compliance and rapid onset of action. These tablets are particularly beneficial for pediatric, geriatric, and psychiatric patients, as well as for situations where water is unavailable, while also providing improved bioavailability for drugs susceptible to first-pass metabolism. A major challenge in ODT development is the poor aqueous solubility of many active pharmaceutical ingredients (APIs), especially BCS Class II and IV drugs, which limits dissolution and therapeutic efficacy. Spray drying has proven to be an effective and scalable technique for solubility enhancement, producing amorphous solid dispersions with improved dissolution profiles and stability. This review provides a comprehensive overview of ODTs, discussing their significance, formulation strategies, and the role of spray drying in enhancing the solubility and bioavailability of poorly soluble drugs. It also addresses challenges in taste masking, mechanical fragility, hygroscopicity, and drug-excipient compatibility. Future directions emphasize the development of robust, cost- effective, and patient-friendly ODTs with high drug loading, rapid disintegration, and improved therapeutic outcomes. By integrating advanced formulation strategies with scalable solubility enhancement techniques, ODTs are poised to play a prominent role in modern oral drug delivery, offering a convenient and effective alternative to conventional solid dosage forms.

INTRODUCTION

Orally disintegrating tablets are that which dissolves or disintegrates in the oral cavity without the need of water or chewing. The novel technology of oral disintegrating dosage forms is known as fast dissolve, rapid dissolve, rapid melt and quick dispersible tablets. An orally disintegrating tablet has been defined by the United States Food and Drug Administration

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(FDA), Center for Drug Evaluation and Research (CDER) as "A solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue." Also been described by European Pharmacopoeia as "uncoated tablets intended to be placed in the mouth where they disperse rapidly before being swallowed and as tablets which should disintegrate within 3 minutes". Other names that have been given to ODTs have included Fast disintegrating tablets (FDTs), oral dispersible, fast dispersing, fast dissolving, quick disintegrating, fast melt, effervescent drug absorption system. [1]

Significance of orally disintegrating drug delivery system: [2]

- Improved patient compliance.
- Rapid onset of action
- Improved bioavailability.
- Useful for geriatric and psychiatric patients.
- Suitable during traveling where water is may not be available.
- No specific packaging required, can be packaged in push through blisters.
- Smooth mouth feels and pleasant taste.
- Conventional manufacturing equipment.
- Cost effective.
- Good chemical stability as conventional oral solid dosage form.

The Biopharmaceutics Classification System (BCS) is a cornerstone in pharmaceutical sciences, providing a systematic approach to evaluate a drug's solubility and permeability. Drugs are divided into four categories under the BCS, based on their solubility in water and ability to permeate the intestinal lining.[3] Based on the above criteria, drugs are assigned to one of the following BCS classes.

Table 01. BCS classification of Drugs

BCS class	Solubility and permeability of Drug	Example
BCS class I:	High solubility, high permeability	Metformin
BCS class II	Low solubility, high permeability	Carbamazepine
BCS class III	High solubility, low permeability	Cimetidine
BCS class IV	Low solubility, low permeability	Griseofulvin

Drugs categorized as BCS Class II exhibit poor solubility but high permeability, making their absorption primarily limited by the rate of dissolution. In contrast, BCS Class IV drugs suffer from both low solubility and low permeability, creating significant obstacles for attaining sufficient bioavailability.4,5 BCS class II drugs:(Low solubility and high permeability) Are ideal candidates for modified release formulations. By controlling the release rate, these formulations can enhance drug dissolution and increase bioavailability. Common strategies include the use of amorphous solid dispersions, nanoparticles, and micro particles. BCS class IV drugs: (Low solubility and low permeability) can benefit from modified release formulations to enhance solubility, dissolution, and ultimately, bioavailability. Techniques like solid dispersion, lipid-based formulations, and cyclodextrin complexation can be employed. Solubility is the phenomenon of dissolution of solid in liquid phase to give a homogenous system and is one of the important parameters to achieve desired concentration of the drug in systemic circulation for pharmacological response. BCS class II drugs pose challenging problems in their pharmaceutical product development process because of their low solubility and dissolution rates. They require enhancement in solubility and dissolution rate in

their formulation development especially solid dosage forms such as tablets and capsules. Several conventional methods and new emerging technologies have been developed for formulation development of poorly soluble drugs.6,7

Spray drying is a process where a liquid (solution, suspension, or emulsion) is turned into tiny droplets using a method called atomization. These droplets are then dried quickly in a chamber with hot gas, forming fine particles. The particles are later separated from the gas using a cyclone or a filter. Spray dryers can work in an open cycle for water-based liquids or a closed loop for organic-based liquids. This method uses moderate heat for a short time, making it gentler than other techniques like melt extrusion. The rapid drying in seconds or milliseconds also helps prevent the drug and polymer from separating.7,8

Orally disintegrating tablets:

ODTs are uncoated tablets designed to be placed in the mouth, where they disperse rapidly prior to swallowing, with a disintegration time not exceeding three minutes. These tablets are also referred to by various names, including oro-dispersible, mouth-dissolving, rapidly disintegrating, fast-melt, and quick-dissolve systems.[8,] ODTs improve drug dissolution as well as onset of clinical effect and the pre- gastric absorption of drugs, which avoids first pass hepatic metabolism to reduce the dose than those observed from conventional dosage forms and finally, increase the bioavailability of drugs. ODTs release drugs in the mouth for absorption through local oro-mucosal tissues and through pre-gastric (e.g., oral cavity, pharynx, and oesophagus), gastric and post-gastric segments of the gastrointestinal tract (GIT). ODTs allow the luxury of much more accurate dosing the primary alternate, oral liquids. ODTs with good taste and flavor increase the acceptability of bitter drugs by various groups of population. From the perspective of the pharmaceutical industry, ODTs may provide new business opportunities in the form of product differentiation, line extension and life cycle management, exclusivity, uniqueness, and patent life extension. The performance of ODTs largely depends on the manufacturing method. Their key feature is the ability to rapidly disintegrate or dissolve in the mouth without needing water.[9]

Ideal ODTs should have the following properties:[10-12]

- Easy to administer without water, disintegrating within seconds in the mouth.
- Allow high drug loading.
- Provide a pleasant mouthfeel.
- Be compatible with taste-masking and excipients.
- Leave little to no residue after administration.
- Be strong enough to withstand manufacturing and handling.
- Be stable under different environmental conditions.
- Be compatible with standard processing and packaging equipment at low cost.

Advantages of ODTs:[10-12]

- Easy to take for children, elderly, bedridden, or mentally challenged patients.
- No water is needed, making them convenient during travel.
- Provide accurate dosing, portability, and good stability.
- May improve drug bioavailability through absorption in the mouth and oesophagus.
- Rapid onset of action due to quick disintegration and absorption.
- Pleasant taste, especially for pediatric patients, with taste-masking.

- Reduced risk of choking compared to conventional tablets.
- Allow faster drug therapy intervention.
- Can be manufactured at low cost using conventional equipment.
- Simple packaging, often in push-through blisters.
- Offer commercial benefits like product differentiation, patent extension, and life-cycle management.

Fig. No 1: Advantages of ODTs

Challenges in Formulating ODTs:[12]

- Most drugs have an unpleasant taste, so ODTs require effective taste masking to ensure patient compliance, as they dissolve directly in the oral cavity.
- To disintegrate quickly, ODTs are made from soft, porous matrices or lightly compressed tablets. This often makes them fragile, hard to handle, and may require specialized blister packaging, increasing costs. Only a few technologies achieve sufficient mechanical strength for multidose bottles.
- Tablet size affects both swallowability and handling. ODTs around 7–8 mm are easiest to swallow, while slightly larger tablets are easier to handle, making an ideal compromise difficult.
- Water-soluble drugs can form eutectic mixtures, leading to glassy solids that may collapse during drying. Using excipients like mannitol can induce crystallinity and provide structural rigidity.

Many ODTs are hygroscopic and sensitive to humidity, requiring protective packaging to maintain stability.

Excipients and method of preparation of ODTs:[13-15]

Table No 2 Approved excipients used in ODT formulation:

Ingredient type	Example	Role
Super-disintegrant	• Crospovidone • Croscarmellose sodium • Sodium starch glycolate • Sodium carboxymethyl cellulose • Microcrystalline cellulose • Spray-dried lactose, acrylic acid • Sodium alginate • Soy polysaccharides, • Pregelatinized starch modified corn starch • Ion exchange resins • Gas evolving disintegrants	Disintegration facilitators.
Diluents	• Sugar and sugar-based derivatives: Dextrose, Fructose, Isomalt, Lactitol, Maltitol, Maltose, Mannitol, Sorbitol, Starch, Hydrolysate, Polydextrose, and Xylitol	Textural properties.
Emulsifier	• Alkyl sulphates • Propylene glycol • Lecithin • Sucrose esters • Sodium dodecyl sulphate • Sodium lauryl sulphate • Poly oxyethylene sorbitan • fatty acid esters (Tweens)	Disintegration accelerator.
Sweetener	• Sodium saccharin sugar alcohols • Natural sugars (sugar, dextrose, fructose) • Sugars derivatives • Aspartame • Vanilla • Bubble gum • Grapefruit	Masks the bitter taste And enhances the acceptability.
Flavour	• Peppermint flavour • Clove oil • Bay oil • Anise oil • Eucalyptus oil • Thyme oil • Citrus oils • Fruit essences	Patient compliance and improves acceptability.

Method of preparation of ODTs:[16,17]

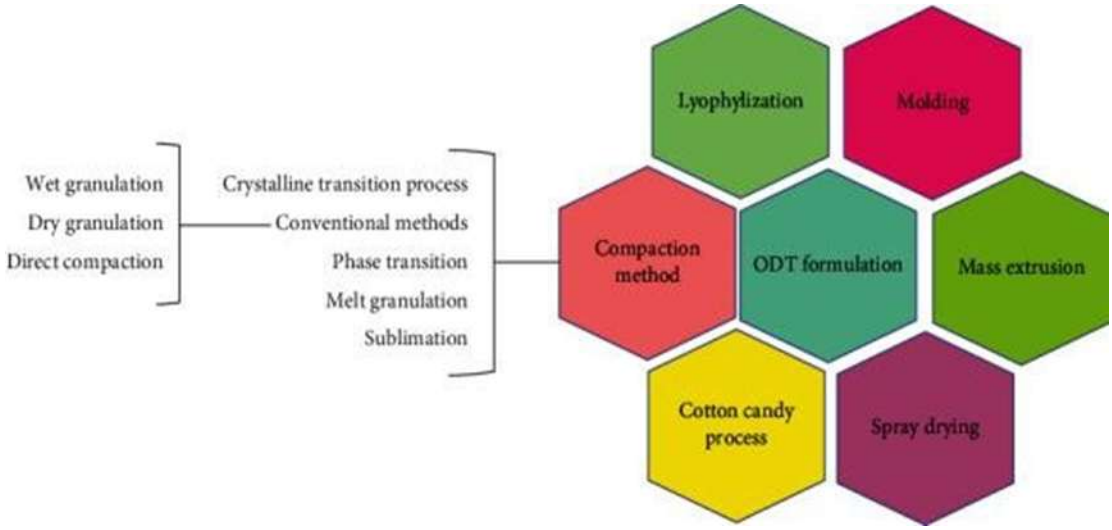

Fig No 02: Method of preparation of ODTs

Moulding:

- Moulding is a technique where a drug-excipient mixture is shaped into tablets using moulds.

Mass Extrusion:

- Mass extrusion softens the powder mixture with solvents to form a paste that is extruded into granules.

Spray Drying:

- Spray drying converts liquid drug-excipient mixtures into dry, porous particles by spraying into hot air.

Lyophilization (Freeze-Drying):

- Lyophilization is a freeze-drying process used to make highly porous ODTs from liquid formulations.

Cotton-Candy Process:

- The cotton-candy process forms ODTs using flash-melted saccharides spun into crystalline floss.

Compaction Methods:

- Compaction forms ODTs by applying pressure to powders or granules to create tablets.
- **Sublimation:** Volatile substances like camphor or ammonium bicarbonate are included in the blend, compressed, and removed by heat or vacuum to create porosity.
- **Melt Granulation:** Waxy binders with low melting points form granules that harden at room temperature, enhancing tablet ability and controlling release.
- **Crystalline Transition:** Mixing high- and low-compressibility sugars creates ODTs with adequate hardness through crystallization.
- **Phase Transition:** Compressed sugar alcohols are heated between melting points to strengthen tablets while maintaining porosity.
- **Conventional Methods:** Wet granulation, dry granulation, and direct compression are standard approaches; direct compression often uses super- disintegrants and taste-masked granules for rapid onset

Future perspectives of ODTs:[18-23]

- **Enhanced Formulations**: Innovative excipients, advanced taste-masking approaches, and optimized disintegration technologies are being explored to achieve rapid dissolution and consistent bioavailability, even for drugs with poor solubility. Additionally, the development of moisture-resistant and robust formulations aims to enhance shelf-life and patient acceptability.

- **Expanded Therapeutic Applications:** ODTs are gradually being considered for a wider spectrum of therapeutics, including not only conventional small-molecule drugs but also biologics, vaccines, and paediatric or geriatric medications. This expansion could significantly enhance patient adherence by offering convenient, non-invasive, and easy-to-administer dosage forms, particularly for populations with swallowing difficulties or limited mobility.[11]

- **Personalized Medicine:** The customization of ODTs to suit individual patient needs is an emerging trend. Formulations may be tailored based on age, gender, genetic factors, comorbidities, and personal preferences. Personalized ODTs could allow precise dosing, improve therapeutic outcomes, and minimize adverse effects, thereby aligning with the growing paradigm of precision medicine.

- **Technological Integration:** The integration of ODTs with digital health platforms, such as smart packaging, adherence-tracking devices, and patient education apps, has the potential to further optimize therapy. These technologies could provide real-time feedback on medication use, improve compliance, and facilitate remote monitoring, particularly in chronic disease management.[11]

CONCLUSION:

Orally disintegrating tablets (ODTs) represent a notable advancement in oral drug delivery, offering rapid disintegration, enhanced patient compliance, and improved bioavailability, particularly for drugs susceptible to first-pass metabolism. The adoption of modern formulation strategies, notably spray drying, has enabled the production of amorphous solid dispersions, improving solubility, dissolution, and stability of poorly water-soluble drugs, making them well-suited for ODT incorporation. Despite these advantages, ODT formulation presents challenges such as taste masking, mechanical fragility, hygroscopicity, and stability issues. Careful excipient selection, process optimization, and consideration of Biopharmaceutics Classification System (BCS) properties are essential to address these limitations. Complementary techniques, including lyophilization, melt granulation, and phase transition methods, provide formulation flexibility to meet both therapeutic and patient-centered requirements.

Future developments in ODTs are focused on cost-effective, robust, and patient- friendly formulations with high drug loading, rapid disintegration, and enhanced bioavailability. Innovations such as one-step tableting and super generic strategies are expected to broaden the accessibility and commercial potential of ODTs, positioning them as an effective, convenient, and patient-preferred alternative to conventional oral dosage forms.

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