Indian J. Applied & Pure Bio. Vol. 40(3), 1811-1819 (2025). **ISSN: 0970-2091**
A web of Science Journal

Orally disintegrating Tablet: Advancement and Therapeutic Application

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Abstract

Orally disintegrating tablets (ODTs) are tablets that carry medicinal substances which can very quickly disintegrate or dissolve within the oral cavity without requiring water for dissolution. Their prominent immediate release characteristic in many respects make the ODT a popular oral dosage form in special circumstances and situations such as institutionalized patients, travelling patients and patients with swallowing challenges. In this review we will discuss on the latest development in formulation, preparation techniques including their suitability and selection, as well as evaluation of parameters of orally disintegrating tablets. Recent advances in the orally disintegrating tablet dosage form will also be discussed.

Key words : Orally Disintegrating tablet, Therapeutic, Sublingual tablet, Taste masking.

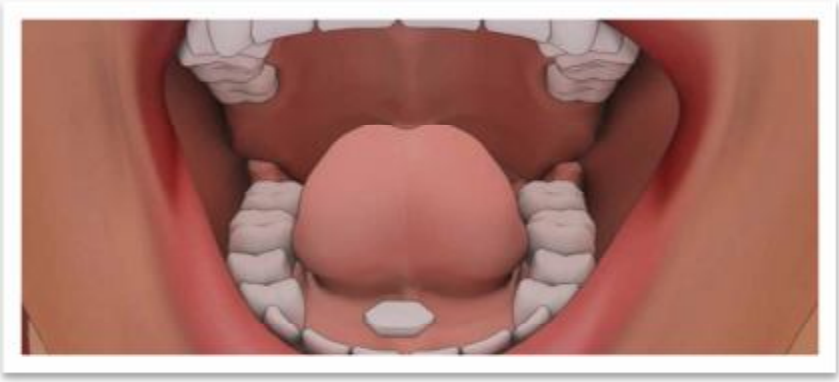
The best way to provide drugs is still orally, but tablets and capsules present problems, such as difficulty swallowing, which can result in non-compliance. Many individuals benefit from Orally Disintegrating Tablets (ODTs), which dissolve rapidly in saliva without the need for water. ODTs, also known as fast-disintegrating or rapid-melt tablets, are defined by the FDA and the European Pharmacopoeia.

Many patients benefit from Orally Disintegrating Tablets (ODTs) because they are easy to take, require no water, are stable, and provide precise dosage. Pre-gastric absorption improves efficacy by avoiding first-pass metabolism and increasing bioavailability. Superdisintegrants for quick disintegration and taste-masking to improve patient compliance—particularly for bitter-tasting medications—are important formulation features.[1]

Sublingual Tablet

Formulation approaches of orally disintegrating Tablets :

The selection of excipients to be used in the formulation comes first in formulation procedures, followed by reformulations



investigations.

Selection of excipients :

Orally Disintegrating Tablets (ODTs) contain excipients that meet pharmacopoeial requirements while ensuring a shorter disintegration time and patient adherence. New developments in excipient selection place an emphasis on quality by design. Some are process-specific, such as acesulfame for flavor masking. Under formulation and taste masking, important excipients used in ODT formulation will be covered.

Superdisintegrants :

When the oral disintegrating pill is placed on the tongue, superdisintegrants help it break. These ingredients should be added to the formulation at the ideal concentration because their presence affects the disintegration time. Superdisintegrants have concentration ranges within which they function well and can be employed either alone or in combination in the formulation.[8,9]

When choosing the superdisintegrant or disintegrants, the following characteristics should be taken into account

- The capacity to compress and flow,
- Poor water solubility and poor gel formation
- Maintaining adequate hydration and not being able to create complexes with medications

Lepidium sativum, fenugreek, and *isapghula* husk mucilage are examples of natural superdisintegrants, whereas sodium starch glycolate, croscarmellose sodium, and crospovidone are common synthetic ones. Disintegration time is improved by modified polysaccharides. For the best tablet performance, selection takes into account variables such concentration, drug characteristics, mixing technique, hardness, friability, surfactants, and mouthfeel.[2]

Binders :

Tablet particles are held together by binder, which promotes formulation stability. Sugar alcohols, gelatin, hydroxypropyl cellulose (HPC), hydroxypropyl methylcellulose (HPMC), lactose, starches, microcrystalline cellulose, sucrose, and synthetic polymers like PVP,

PEG, and PVA are examples of common binders. Binders fall into one of two categories: dry binders (for direct compression) or solution binders (used in wet granulation). Tablet friability decreases with increasing binder content, yet disintegration may be delayed due to increased hardness. Starch and other enzyme-labile binders promote ODT breakdown. For tablets to continue dispersing quickly, the right proportion is essential.[3]

Taste Masking :

Exposure to taste buds during the disintegration of Orally Disintegrating Tablets (ODTs) may result in an unpleasant flavor, which lowers patient compliance. Polymeric coating, cyclodextrin complexation, ion exchange resins, salt forms, liposomes, microencapsulation, and sugar-based excipients such as mannitol, maltose, and sorbitol are some of the different taste-masking methods. Taste is improved by sweeteners like aspartame, which is 200 x sweeter than sucrose, and saccharin, which is 450 × sweeter. However, mixing artificial sweeteners with cutting-edge masking techniques guarantees higher palatability and increased patient acceptance of ODT formulations for medications that are exceedingly bitter.

Flavouring agents for taste masking

Salt	Apple, apricot, peach, anilla, winter green mint
Basic Taste	Masking (flavoring) agent
Bitter	Wild cherry, walnut, chocolate, mint, anise
Sweet	Vanilla, fruit and berry
Sour	Citrus flavor, licorice, root beer, raspberry

It's also advisable to employ intermediary methods like matrix entrapment or coating For instance, encasing a lipophilic medication in a lipoidal matrix can hide its taste Ion exchange resins can be used to disguise the taste of an ionic medication. Orally disintegrating tablets containing mosapride citrate-resin complex were effectively manufactured by Tong Wu *et al*. (2018) and disintegrated in 18 seconds. Table-2 lists the flavor masking methods as well as the medication characteristics that need to be taken into account. Simple methods include complexation as well as the addition of flavoring agent, sweetener, and other excipients. While sophisticated approaches require the synthesis of prodrugs and salts, intermediate techniques involve coating and matrix entrapment.[4]

Summary of drug properties and the taste masking techniques

Properties of drugs	Characteristic of drug	Method of taste masking
Dose	Low	Simple technique
	High	Intermediary techniques
Particle size	Fine	
Ionic characteristic	Ionic	Intermediary techniques
	Non- ionic	Simple technique
Solubility	Hydrophilic	Intermediary techniques
	Lipophilic	Simple technique
Particle shape	Spherical	Simple technique

Coatings or matrix trapping that release the medication after it leaves the mouth are necessary for taste-masking in oral disintegrating tablets (ODTs). Granulation is an easy and efficient way to cover up bitterness. Research indicates that adding sweeteners to medications both before and after granulation improves taste-masking, which in turn increases patient compliance and palatability.

By mixing a medication with an artificial sweetener, a new taste-masking method is created: a sweet salt. By doing this, the medication and sweetener are released into the saliva simultaneously, avoiding early bitterness exposure. Compared to merely adding sweets during formulation, this technique improves taste-masking and increases patient compliance.

The flavor of ODT has been improved by the effective use of acesulfame to create sweet salts with bitter medications. Chenguang Wang *et al*. (2017) used this technique to enhance the flavor of metformin and diphenhydramine ODTs. Furthermore, ODT formulation difficulties for high-dose medications were addressed by the introduction of greater Metformin doses made possible by sweet salt synthesis.[5]

Diluents :

In ODTs, diluents serve as bulking agents, guaranteeing accurate compression and formulation. They ought to be pleasant, non-hygroscopic, and inert. Sorbitol, sucrose, lactose, starch, mannitol, and microcrystalline cellulose are examples of common diluents. Lactose and mannitol improve compressibility, while microcrystalline cellulose's swelling characteristics facilitate disintegration as well.

Lubricants :

Lubricants in ODTs reduce friction, prevent sticking, and enhance granule flow. Proper concentration and mixing time (2–5 minutes) are crucial. Excess lubricant weakens tablets and prolongs disintegration. A study by Kanugo *et al*. (2013) showed increasing lubricant concentrations raised disintegration time while reducing tablet hardness, affecting formulation quality.[6]

Formulation development :

In ODT formulation, quality by design reduces mistakes and material waste while improving product quality. Powders are evaluated for direct compression utilizing twelve characteristics, such as density, compressibility, flowability, and stability, by the SeDeM expert system, which was created in 2005. Optimized powder qualities for better ODT formulation and compression are guaranteed by advanced excipient engineering.

A list of some of the available functional excipients and their composition is provided in given Table

Functional excipients and their composition

Functional Excipients	Composition
F-MELT	Mannitol, Xylitol, Calcium Sulphate, Crosspovidone, and Mangesium Alumino metasillicate
Ludipress	Lactose, Kollidon 30 and Kollidon CL
Ludiflash	D-mannitol, crospovidone, polyvinyl acetate and small amounts ofpovidone
Pharmburst	Consisting of Mannitol, Starch, Crosspovidone, Colloidal Silica and Silica

Parteck, the functional excipient, was used in the final formulation along with other ingredients (Avicel PH-102, magnesium stearate, and Aerosil) because it demonstrated the highest compressibility value when compared to Ludiflash and Ludipress. S1la Gülba *et al*. (2017) prepared memantine ODT formulation using the SeDeM expert system during excipient selection.[7]

Preformulation studies in orally disintegrating tablets :

Examining drug-excipient compatibility is the initial stage in developing a dosage form in order to avoid unfavorable interactions that could compromise stability. These interactions are analyzed using methods such as DSC, FTIR, SEM, and HPLC. Differential scanning calorimetry (DSC) compares individual and combined thermograms to evaluate thermal characteristics. Peak decrease, removal, or the development of new peaks are signs of interaction. Minor peak differences, however, might not matter. By choosing excipients that preserve the medicine's stability and efficacy, compatibility helps optimize the formulation for efficient drug distribution.

Evaluation of powder properties before compression[8]

Both the amount and quality of the tablets produced are impacted by powder flow. Good powder flow properties are one of the elements that contribute to tablets' consistency in weight, hardness, and content. The following are the primary parameters that should be assessed in order to characterize the flowability and compressibility of powder, despite the fact that several parameters have been presented for evaluation by various systems.

Bulky density :

The weight of an undisturbed powder sample divided by its volume, including void spaces, is known as the bulk density. Weighing the powder and recording its untapped volume in a measuring cylinder yields the measurement, which is expressed as g/mL or g/cm³. When developing a formulation, this parameter is crucial for powder characterization.

$$\text{Bulk density} = \frac{\text{Weight of powder}}{\text{Volume of powder packing}}$$

Tapped density :

It is calculated by dividing the powder sample's weight by its tapped volume. The graduated cylinder containing the medicine excipient blend of known weight is mechanically tapped, and the new volume known as the tapped volume—is then measured. Following the determination of the tapped volume, the following formula is used to obtain the tapped density of the powder/drug-excipient blend;

$$\text{Tapped density} = \frac{\text{Weight of powder}}{\text{Tapped volume of powder}}$$

Carr index :

This value, which is calculated using the following formula, indicates how compressible the powder mixture is.

$$\text{Compressibility Index} = \frac{\text{Tapped density–Bulk density}}{\text{Tapped density}} \times 100$$

Hausner's *ratio :*

The flowability of the powder or granules is measured by this additional powder characterization metric.

$$\text{Hausner Ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Angle of Repose :

By letting powder flow through a fixed funnel onto a surface in the shape of a cone, the height and base diameter of the cone are measured, and the angle is computed using the formula to measure powder flow and friction.

$$\text{Tan } \theta = \frac{h}{r}$$

where r is the cone's base radius and h is the cone's height.

Orally disintegrating tablets preparation techniques :

Compression, melting, and freeze-drying methods are used to create mouth-dissolving tablets. The porous pills produced by freeze-drying dissolve quickly but have little strength. Compression is frequent, and spray drying is frequently used to increase porosity and speed of disintegration. For efficient tablet manufacturing, granulation techniques including melt and wet granulation improve powder flow and compressibility.

The easiest technique for creating oral disintegrating tablets is direct compression, which requires little processing and standard equipment. It needs excipients like mannitol and microcrystalline cellulose that have good flow and compressibility. Porosity produced by sublimating agents like camphor and ammonium bicarbonate improves disintegration following sublimation in a hot air oven.

In order to improve the flavor and palatability of orally disintegrating tablets for better patient compliance, mass extrusion and the cotton candy process are used to mask the taste of the drug prior to compression. Mass extrusion produces microspheres, while the cotton candy method uses saccharides or disaccharides to create a floss-like crystalline structure that is generated by a spinning motor.

Patent techniques for preparing ODTs.[9]

To make sure that differences within tablets fall within permissible bounds (specifications), oral disintegrating tablets should be assessed. The following tests are listed in the US Pharmacopoeia as required to be performed:

- Tablet's thickness
- Tests for in vitro dissolution
- Tablet hardness
- Tablet friability
- Weight fluctuations
- Content homogeneity
- Tablet disintegration time

Various parameters must be assessed based on ODT characteristics, such as adhesive properties for muco-adhesive ODTs and dissolution/permeability tests for fixed-dose

combinations. Stability studies evaluate tablet properties like hardness, friability, disintegration, and dissolution after storage under accelerated conditions (40°C, 75% humidity) for one to three months.

Recent advances and development in orally disintegrating tablets :

Advancements in ODT formulation include novel taste-masking techniques, quality by design approaches, and improved drug delivery strategies. Key developments include fixed-dose combinations, modified-release formulations, and innovative disintegration testers. These improvements enhance patient compliance, drug efficacy, and overall product quality, making ODTs more effective and widely applicable in therapy.

Fixed Dose combination (FDC) :

Compared to conventional fixed-dose combination (FDC) pills, which are frequently big and challenging to swallow, oral disintegrating tablets (ODTs) provide an improvement. ODTs increase patient compliance by dissolving in the mouth. Direct compression methods are used in their formation, as demonstrated by studies such as those conducted by Dennison *et al*. (2017) and Sharma *et al*. (2018).

Orally disintegrating tablets modified release formulations[10]

The creation of ODTs with modified release formulations is yet another advancement in this dosage form.

Extended release formulations :

By combining immediate and sustained release, extended-release (ER) oral disintegrating tablets (ODTs) improve medication delivery. This strategy is demonstrated by Neos Therapeutics' Cotempla XR-ODT and Adzenys XR-ODT. Using microsphere technology, Patil *et al*. (2016) created domperidone ODTs that had a 23% initial release in an hour and a continuous release over nine hours.

Enteric coated orally disintegrating tablets:

ODT formulations shield medications against inactivation or gastrointestinal discomfort. Eudragit coatings were used by Alotaibi *et al*. (2019) to create enteric orodispersible diclofenac sodium tablets. The pills completely dissolved in intestinal fluid but released very little medication (less than 10%) in gastric fluid. The breakdown time in simulated saliva varied between 20 and 46 seconds.

Muco-adhesive orally disintegrating tablets:

Muco-adhesive ODTs prolong drug retention at the location, which improves local activity. For oral hygiene, Kiniwa *et al*. (2019) created tea powder ODTs covered with tamarind gum. Compared to other polysaccharides, these tablets showed better adherence and retention; they disintegrated in 30 seconds while maintaining a steady effect at the intended location.

Novel disintegration tester for orally disintegrating tablets :

It's possible that conventional disintegration tests don't faithfully replicate

ODT activity in the mouth. Other techniques have been developed, such as specialized testers and texture analyzers. While Kiniwa *et al*. (2019) employed ODmate to measure disintegration in simulated saliva with controlled agitation, Koner *et al*. (2019) introduced the Aston tester, which replicates oral circumstances.

Limitations of orally disintegrating tablets:

Orally disintegrating tablets have certain drawbacks despite the fact that they have a number of benefits over traditional oral dosing forms. Among these restrictions are

- low mechanical strength, which could make handling difficult. Fragile tablets may need special packaging to prevent breakage during storage, handling by patients, and transit.
- Bitterness may linger in the mouth even after swallowing the saliva if flavor masking is not done well. The patient's cooperation may be impacted by this.
- It might be challenging to synthesize medications with high dosages into pills that dissolve in the mouth.
- ODTs should be stored in a dry location since they may draw water from the environment because the excipients used in the formulation of this dosage form are designed to dissolve or disintegrate in the least amount of water.
- Special Population: People using anticholinergic medications or suffering from Sjogren's syndrome, a disorder that causes dry mouth from reduced saliva production, might not be the ideal candidates for these tablets.

Tablets that dissolve in the mouth offer a lot of potential to improve drug therapy. Since giving patients their medications orally is still the most popular method, it is necessary to provide an oral dose form that is simple and convenient for patients.incredibly pleasant and easy to absorb. The majority of these desired properties are present in oral disintegrating tablets, and it is hoped that with the advancements in pharmaceutical sciences and recent advancements in this dosage form, oral disintegrating tablets that will get past the present obstacles will be developed.

The authors are thankful to Management and Director of Acropolis Institute of Pharmaceutical Education and Research, Indore MP for their continuous support and motivation throughout the study.

References :

1. Ahamad Dabeer. Ayaj Ahmad, Chandan Sharma, Varun Dangi, and Ashish Gupta., (2010). *International Journal of Pharmacy and Life Sciences, 1*(5): 250-256.
2. Bharkatiya, M., S. Kitawat, and K. Gaur, (2018). *American Journal of Pharmacological Sciences, 6:* 1-6.
3. G.V., P. C., J., P. A., P., K., S.M., H. R., (2012). *Journal of Pharmacy Research, 5:* 2117-2121.
4. Jain, N., S. Mandal, J. Banweer, and S. Jain, (2012). *International Current Pharmaceutical Journal, 1:* 62-67.
5. Janardhan, D., J. Sreekanth, P. T. P.

Kumar, and M.V. Krishna, Research Paper Formulation and Evaluation of Baclofen Orally Disintegrating Tablets.

6. Kumavat Sonali, Pravin Kumar, Sharma, Ravi Sharma, Ashish Gupta, and G N. Darwhekar, (2021). *Journal of Drug Delivery & Therapeutics,* 5: 208-212.
7. Mahaveer, P., M. Gupta, B. Anil, S. Natasha, and A. Dilip, (2011). *Der pharmacialettre, 3:* 108-118.
8. Pokhariya, P., G. Ganarajan, and P. Kothiyal (2016). *Indo American Journal of Pharmaceutical Sciences, 3:* 713-727.
9. Priyanka, S. and S. Vandana, (2017). *International Journal of Drug Research and Technology, 3:* 11.
10. Shahtalebi, M. A., M. Tabbakhian, and S. Koosha, (2015). *Journal of HerbMed Pharmacology,* 4.