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# A Review on Orodispersible Tablet

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**ABSTRACT:** Orally disintegrating tablets (ODTs) are solid dosage forms containing drugs that disintegrate in the oral cavity within less than 1 minute leaving an easy-to-swallow residue. The European Pharmacopeia adopted the term orodispersible tablet for a tablet that disperses or disintegrates within <3 minutes in the mouth before swallowing. ODT is a good choice of drug delivery for pediatric and geriatric patients because it troubleshoots the problem of dysphagia. The current article is focused on ideal characteristics, advantages and disadvantages, various technologies developed for ODT, evaluation methods along with recent research and future potential

**Keywords**: Orodispersible tablets, Mechanism of disintegration, fast dissolving films, recent research

**1. INTRODUCTION:** Oro-dispersible drug delivery system are novel drug delivery techniques that make the tablets disintegrate in the mouth without chewing and water, and immediate release and enhanced bioavailability, with better patient compliance. Recently, the European Pharmacopeia adopted the term Or dispersible tablet for a tablet that disperses or disintegrates within a minute or second in the mouth before swallowing. Undergo pregastric absorption when synthesised as ODTs may have enhanced oral bioavailability of drug. It offers superior stability, precise dosage, and simplicity in manufacture. Recent market surveys show that more patients prefer orodispersible tablets to other dosage forms, and the majority of customers would ask their doctors for them (70 percent), buy them (70 percent), or prefer them (more than 80 percent) over other types of tablets or liquids.[1]

 

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ODTs are also called as orodispersible tablets, quick disintegrating tablets, mouth dissolving tablets, fast disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, and rapidmelts. However, of all the above terms, United States pharmacopoeia (USP) approved these dosage forms as ODTs. The European Pharmacopoeia has used the term orodispersible tablet for tablets that disperses readily within 3 minutes in the mouth before swallowing United States Food and Drug Administration defined ODT as "A solid dosage form containing a medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue." The disintegration time for ODTs generally ranges from several seconds to about a minute [2]

**Ideal properties of Oro-dispersible tablet:[3]**

- It should be dissolve or disintegrate in the mouth or saliva within seconds.
- It should not require any liquid or water to show its action.
- It should have an acceptable taste masking property.
- It should leave no residue in mouth after the disintegration.
- It should exhibit low sensitivity to environmental conditions (temperature and humidity).
- More rapid drug absorption from the pre-gastric area i.e. mouth, pharynx and oesophagus
- It may produce rapid onset of action.
- It should be cost effective.

**Drug Selection Criteria of ODTs:[4]**

- Able to saturate the oral mucosa.
- Have the ability to diffuse and partition into the epithelium of upper GIT.
- BCS class-II class drug is good candidate for ODTs.
- At least moderately non-ionized at oral cavity PH.
- Molecular weight below 500 Dalton.
- Low dose drugs mostly less than 50 mg.
- Should have good stability in saliva and water.

 

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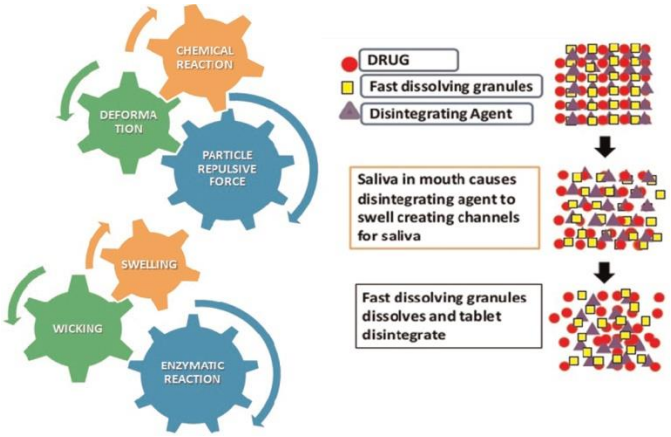
- Should have lower bio availability are good candidates for ODTs.
- Short half-life and frequent dosing drugs are unsuitable for ODTs.
- Very bitter taste and undesirable odor drugs are unsuitable for ODTs..

**Advantages of Oro-dispersible tablet:**[5]

- Ease of Administration to the patient who cannot swallow then consequently improved patient compliance
- No need of water.
- Rapid dissolution, absorption of the drug and increase bioavailability
- Pregastric absorption of drug be able to enhance oral bioavailability of drug, and as a result of reduces dose administration.
- Good chemical stability as conventional oral solid dosage form.
- Decreased first pass metabolism.

**Mechanism of action of Oro-dispersible Tablet:**[6]

The medicine is fast-dissolving granules and disintegrating agents are both present in the orodispersible tablet. When saliva from the mouth comes into touch with the oral dispersible tablets, the dissolving agents swell and produce channels for saliva.



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**Types of Superdisintegrants:**

a. Natural Superdisintegrants.
b. Synthetic Superdisintegrants.

**a. Natural Superdisintegrants:** These Super Disintegrate substances are naturally occurring because they are comparably less expensive, widely accessible, non-irritating, and non-toxic. Due to their wide availability, low cost, eco-friendliness, emollient and non-irritating character, and lack of toxicity, natural materials like gums and mucilages have been widely used in the field of medicine delivery. Several gums and mucilages are also available that have superdisintegranting action.[5]

**b. Synthetic Superdisintegrants: Examples:** Crosslinked Polyvinyl Pyrrolidone, Sodium Starch Glycolate, Croscarmellose Sodium, Chittin and Chitosan.

**Table 1.1. Natural Superdisintegrants**

| Name of Natural Superdisintegrants | Part Used | Application |
|---|---|---|
| Isapghula Husk | Seeds | Binding, super disintegrating and sustaining properties. |
| Lepidium sativum | Seeds | Binding, superdisintegrating, gelling |
| Fenugreek(Trigonella Foenum-graceum) | Seeds | Binding, disintegrating properties |
| Cassia tora | Seeds | Binder, superdisintegranting |
| Locust Bean | Seeds | Thickening and gelling agent |
| Hibiscus Rosa Sinesis | Seeds | Binder, superdisintegranting |

**Mechanism of Superdisintegrants:** [7]

Fast Dissolving Tablets need to dissolve more quickly, hence Super Disintegrate is required while creating ODT. The Super Disintegrate utilised has a higher disintegration efficiency, is more effective intra granularly, and is effective at low concentrations. This Super Disintegrate

 

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works by swelling, and as a result of swelling pressure applied in an outward or radial direction, it either causes tablets to burst or accelerates water absorption, which results in a huge increase in granule volume and facilitates disintegration.

1. By Swelling
2. Capillary action (wicking)
3. Deformation
4. Combination action
5. Repulsion.

**2.Future prospective for orodispersible tablets :**[8]

Future challenges for many ODT manufacturers include reducing costs by finding ways to manufacture with conventional equipment, using versatile packaging, improving mechanical strength and taste-masking capabilities. ODTs may be suitable for the oral delivery of drugs such as protein and peptide-based therapeutics that have limited bioavailability when administered by conventional tablets because these products usually degrade rapidly in the stomach. Furthermore, there is a scopeto develop controlled release ODTs prepared using different drug carriers

**3.Various methods of preparation of orodispersible tablets :** There are several methods for the preparation of orodispersible tablets but the prepared products vary in their properties depending on the method of preparation. The properties in which they vary are mechanical strength of the tablets, swallowability, bioavailability, drug dissolution in saliva, stability, and to some extent taste. Various process of manufacturing of orodispersible tablets are molding, compaction, spray-drying, freeze-drying, and some special methods are melt granulation, phase transition, and sublimation.[9]

**Molding methods :** Tablets formed by molding process are highly porous in structure, resulting in high rate of disintegration and dissolution. This process includes moistening, dissolving, or

 

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dispersing the drugs with a solvent then molding the moist mixture into tablets by applying lower pressure in compression molding, but always lower than the conventional tablet compression. The powder mixture may be sieved prior to the preparation in order to increase the dissolution. Molded tablets have low mechanical strength, which results in erosion and breakage during handling.[10]

**Compaction methods :** Conventional methods for the preparation of tablets such as dry granulation, wet granulation, and direct compression are also exist for the preparation of orodispersible tablets. Some important super disintegrants, which are used during preparation of orodispersible tablets, are crosspovidone, crosscarmellose sodium, sodium alginate, acrylic acid derivatives. Baclofen orodispersible tablets were prepared by direct compression method using crosspovidone and sodium starch glycolate as super disintegrants.Even orodispersible tablets of Carbamazepine were prepared by this method having microcrystalline cellulose and crosspovidone (2%-10%).In all the cases it has been found that preparation by compression method along with addition of super disintegrants in correct concentration obey all the properties of orodispersible tablets.[11]

**Spray-drying method** : Here, orodispersible tablets are made up of hydrolyzed or unhydrolyzed gelatin as supporting agent for matrix, mannitol as bulk agent, and sodium starch glycolate or croscarmellose sodium as disintegrating agent. Sometimes in order to improve the disintegration and dissolution, citric acid and sodium bicarbonate are used. Finally, the formulation is spray-dried in a spray drier. Orodispersible tablets prepared through this method are disintegrated in less than 20s.[12]

**Freeze-drying method** : This is a very popular process for the preparation of orodispersible tablets. Tablets prepared by this process have low mechanical strength, poor stability at higher temperature and humidity, but glossy amorphous structure resulting in highly porous, lightweight product. There are various patents on this particular technology.[13]

 

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## 4. SOME SPECIAL METHODS OF PREPARATION:

**Melt granulation :** It is a unique method for the preparation of orodispersible tablets by incorporating superpolystate.Superpolystates are hydrophilic waxy binders with a melting point 33-37°C and Hydrophilic –Lipophilic Balance value is 9. They play a dual role as a binder that increases the physical resistance of the tablets and also as a disintegrants, which help the tablet to melt in the mouth, and solubilize rapidly leaving no residue in the mouth. Superpolystates were introduced in the formulation of orodispersible tablets by melt-granulation method. Here, granules are formed by the molten form of this material. Crystallized paracetamol was used as a model drug along with mannitol and crosscarmellose sodium.[14]

**Phase transition process :** Kuno *et al*. investigated this process by compressing powder containing two sugars alcohols. One with high and another with low melting point, and they are heated at a temperature between their melting point and then compressed finally in order to get the tablets. Example of sugar alcohols are erythriol (m.p. 122°C), xylitol (m.p. 93-95°C), trehalose (97°C), and mannitol (166°C). After heating, tablet hardness was increased due to an increase in interparticle bonds or the bonding surface area in tablets induced by phase transition of lower melting point sugar alcohol.[15]

**Sublimation :** In this process, subliming material ‘camphor’ is used. It was sublimed in vacuum at 80°C for 30 min after preparation of tablets. Here, also tablets prepared are porous in nature. In conventional types, sometimes rapid disintegration does not occur. Therefore, in order to improve porosity, volatile substance camphor is added in the preparation, which gets sublimed from the formed tablet.[16]

 

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**Effervescent method :** Orodispersible tablets are also prepared by effervescent method by mixing sodium bicarbonate and tartaric acid of concentration 12% (w/w) along with super disintegrants like pregelatinized starch, sodium starch glycolate, crospovidone, and croscarmellose. First, sodium bicarbonate and tartaric acid were preheated at a temperature of 80°C to remove absorbed/residual moisture and thoroughly mixed in the motor. Finally, the blends are compressed in the punch.[17]

## 5. EVALUATION OF ORODISPERSIBLE TABLETS :

**Hardness/crushing strength :** The hardness of the tablet is measured by using conventional hardness testers like Monsanto hardness tester. The limit is toward the lower range in order to help early disintegration in mouth.[18]

**Friability :** It is a difficult job to maintain the percentage of friability within the limit, since all the methods of preparation of orodispersible tablets have a tendency to increase the percentage of friability. In all aspect, the range is within limit of 0.1%-0.9%. Roche friabilator is used in conventional form in order to measure friability of the tablets.[19]

**Wetting time :** Wetting time is the indication of the inner structure of the tablets and to the hydrophilicity of the excipients. Thus, wetting time of a dosage form is related with the contact angle. The lower the wetting time the quicker is the disintegration of the tablets. The wetting time can be measured by using five circular tissue papers of 10 cm in diameter, which are placed in a petridish of 10 cm diameter Ten millilitres of water-soluble dye like eosin solution is added to the petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as the wetting time. For measuring water-absorption ratio, the weight of the tablet before keeping in the petridish is noted ($W_b$).The wetted tablet from the petridish is taken and reweighted ($W_a$). The water-absorption ratio, R can be determined according to the following equation:[20]

$R = 100\ (W_a - W_b)/W_b$.

 

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**Moisture-uptake studies :** It is an important study in the case of orodispersible tablets. This study is carried out in order to assess the stability of the tablets. Ten tablets were kept in the desiccators over calcium chloride at 37°C for 24 h. The tablets were then weighted and exposed to 75% relative humidity, at room temperature for 2 weeks.Required humidity was achieved by keeping saturated sodium chloride solution at the bottom of the desiccators for 3 days. One tablet as control (without super disintegrant) was kept to assess the moisture uptake due to other excipients. Tablets are weighed and the percentage increase in weight is recorded.[21]

**Disintegration test :** The *in-vitro* disintegration time was determined by disintegration test apparatus. The time for disintegration of orodispersible tablets is generally <1 min and actual disintegration time that patient can experience ranges from 5 to 30 s. A tablet is placed in each of the six tubes of the apparatus, and one disc is added to each tube. The standard procedure of performing disintegration test for these dosage forms has several limitations. It is expected that disintegration test for orodispersible tablets should mimic disintegration in mouth within salivary contents. Sunada *et al*. performed disintegration test by using modified United States Pharmacopoeia Apparatus II by taking 900 ml of medium maintaining 37°C with r/min 100. It was carried out by taking a 1 l cylindrical vessel. Orodispersible tablets were placed in basket sinker in the middle of the vessel with a distance of 6-8.5 cm. Even Narazaki *et al*. carried out the disintegration test with rotary-shaft method. The apparatus consisted of stainless steel wire gauze on which orodispersible tablets were placed and slightly immersed in medium. Here, the rotary shaft is used to provide rotation and mechanical stress.[22]

Dissolution test : It is an important test as the drug-release profile can be obtained by performing this test. Both the USP dissolution test apparatus can be used. Dissolution of orodispersible tablets is very fast. Therefore, USP 2 Paddle-type apparatus at 50-100 r/min is used for dissolution testing. Swammy *et al*. carried out *in vitro* dissolution study of pheniramine maleate orodispersible tablets in type II apparatus with r/min 550 using 900 ml phosphate buffer of pH 6.8 at 37 ± 0.5°C as a dissolution medium.USP type I basket apparatus have certain application

 

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in the case of orodispersible tablets, but tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle. An erroneous-dissolution profile is obtained, where little or no effective stirring occurs. Thus, type II is more preferred due to reproducible-dissolution profile.[23]

**6. CONCLUSION**: The popularity of ODTs has increased tremendously over the last decade. Based on the literature surveyed, it may be concluded that Or dispersible tablets are particularly beneficial to the pediatric, geriatric, bedridden, and psychotic patients affected by dysphagia.These tablets get converted into a suspension with the salivary fluid n the oral cavity thereby showing rapid onset of action with improved bioavailability, better patient acceptance and offer better safety as compared to conventional oral dosage forms. Today, Orodispersible tablets are more widely available as over-the-counter products for the treatment of allergies, cold and flu symptoms. All the information's collected above about the ODT gives a better scientific based understanding. With continued research and development of new pharmaceutical excipients, one may expect some new technology for a more novel orodispersible tablets in the future.

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