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Review Article

Review of Orodispersible Tablet: The Current Trends

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Abstract



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Orodispersible tablets (ODTs) are an advanced dosage form that disintegrate rapidly in the oral cavity upon contact with saliva, without the need for water or chewing. This unique property makes them particularly advantageous for pediatric and geriatric populations, as well as for patients experiencing dysphagia or poor compliance with conventional solid dosage forms. Beyond improving ease of administration, ODTs can enhance drug absorption, patient adherence and therapeutic effectiveness. The development of ODTs involves the incorporation of specialized excipients such as superdisintegrants, diluents and taste masking agents that promote rapid disintegration and improve palatability. Various manufacturing approaches have been employed, including conventional techniques like tablet moulding, freeze drying as well as advanced methods such as spray drying, sublimation and the application of nanotechnology. More recently, three-dimensional (3D) printing has emerged as a promising tool, enabling personalised dosage forms with improved functionality. Quality evaluation of ODTs encompasses parameters such as hardness, friability, weight variation, disintegration time and drug content uniformity while packaging plays a vital role in ensuring stability and protection against environmental factors. With several marketed formulations already available, ODTs continue to gain importance as a patient-friendly and effective drug delivery system, offering significant potential for future pharmaceutical innovations.

Keywords: Orodispersible, Superdisintegrants, Formulations, Lyophilization, Microencapsulation, Nanotechnology.

1. INTRODUCTION 1:

Among all routes of administration, oral drug delivery is considered the most convenient and commonly preferred method. Conventional tablets are often hard to swallow, particularly for pediatric and elderly patients. Oro-dispersible tablets (ODTs) were formulated to overcome this issue, as they dissolve quickly in saliva within seconds without water, offering easier administration and improved patient compliance

2. ORODISPERSIBLE TABLET 2:

According to the USFDA, Oro-dispersible tablets (ODTs) are solid dosage forms that break down within seconds once placed on the tongue. Likewise, the European Pharmacopoeia describes them as tablets that quickly disperse in the mouth before being swallowed. Unlike traditional tablets, ODTs often exhibit better bioavailability because they contain superdisintegrants, which enable them to dissolve in under a minute with just saliva. After dispersal, the drug is absorbed either

through the oral cavity or the digestive tract, ensuring quicker and more effective action.

2.1 Objectives of orodispersible tablet 3:

1. To improve patient compliance.
2. To enhance the drug's bioavailability.
3. To enhance the stability.

2.2 Ideal properties 4:

1. It should dissolve and disintegrate in saliva within a minute.
2. It should withstand environmental conditions like humidity, temperature, etc.
3. Easy for administration.
4. It should have greater stability.

2.3 Advantages⁴:

1. Easy administration of drugs, particularly for the elderly, children, and patients with swallowing difficulties.
2. Provides rapid therapeutic action due to rapid dissolution and absorption.
3. Improved patient compliance.
4. Enhanced bioavailability results in reduced dosage.
5. Offers the efficacy of a liquid dosage form but in a solid preparation.

2.4 Disadvantages⁴:

1. When a drug needs a large dose, it becomes tough to make it into an Orodispersible tablet (ODT).

2. Anticholinergic tablets cannot be formulated easily into an orodispersible tablet.
3. It may have low mechanical strength. So, careful handling is required.
4. Orodispersible tablet requires special packing.

3. MECHANISM OF ACTION⁵:

The disintegrating agent in the tablet swells in the oral cavity in the presence of saliva



The tablet rapidly disintegrates in the oral cavity



The desired action is produced

4. EXCIPIENTS USED IN ORODISPERSIBLE TABLETS⁵:

Different types of excipients are employed in the formulation of orodispersible tablets.

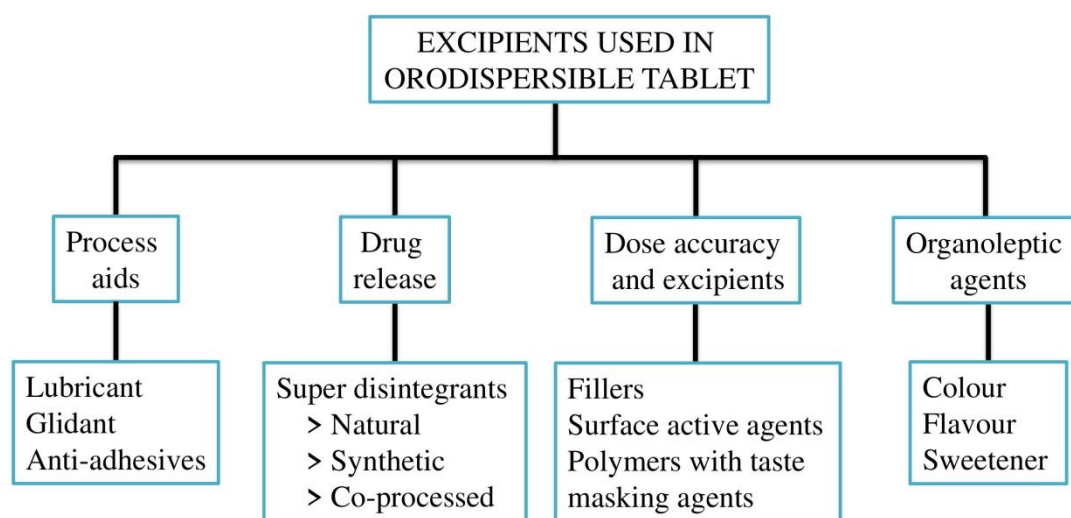


Figure 1: Excipients used in an orodispersible tablet⁵

4.1 Super disintegrants⁸:

A superdisintegrant, also known as a disintegrating agent, is added to tablets to help them break apart quickly after swallowing. Its main aim is to break the compact tablet into smaller particles, which makes it easier for the active ingredient to be released and absorbed in the body.

Superdisintegrant provides an inherent weakener for a solid dosage form.

It provides effective compatibility and compressibility.

4.2 Requirements for a superdisintegrant⁹:

1. It should have a pleasing texture when in the mouth.
2. It must not interact with other excipients.
3. It should exhibit excellent flow characteristics.
4. It should possess limited solubility and gel formation.

5. Increased capacity for hydration is essential.

4.3 Mechanism of superdisintegrants⁷:

1. Porosity and capillary action
2. Swelling
3. Chemical reaction
4. Heat and wetting
5. Deformation recovery
6. Enzymatic reaction
7. Repulsive force of particles

1. Porosity and capillary action [wicking]:

When the tablet is exposed to a liquid environment, liquid can penetrate the tablet, pushing out the trapped air within the particles, thereby reducing the strength of bound (intermolecular) forces in the tablet.

2. Swelling:

Disintegrants induce swelling when they interact with an appropriate medium, generating swelling forces that break down the matrix. Tablets with lower porosity exhibit greater swelling force than those with higher porosity.

3. Chemical reaction:

Occasionally, the tablet breaks down due to the release of carbon dioxide gas. This reaction occurs when citric acid & tartaric acid interact with bicarbonates in the presence of H₂O. The interaction generates pressure inside the tablet, leading to the tablet's disintegration.

4. Heating & wetting:

Disintegrants that exhibit exothermic properties become moist, resulting in localized pressure from the expansion of confined air due to capillary action, which causes the tablet to break apart; this effect is restricted to a limited number of disintegrants

5. Deformation recovery:

When compression occurs, the shape of the disintegrant particle is altered, increasing the deformed particle size and ultimately leading to tablet failure.

6. Enzymatic reaction:

The enzymes weaken the binders' binding action in the tablet, leading to disintegration.

7. Repulsive force of particle:

On contact with the medium, it passes through hydrophilic pores and forms a starch network.

Hydrogen bonds will break during this process.

Repulsive electric forces between particles promote disintegration.

Category of superdisintegrants:

- a. Natural disintegrating agents,
- b. Synthetic disintegrating agents.

a. Natural disintegrating agents:

These are derived from natural sources. They are considered safe, non-irritating, and nontoxic. Examples include Agar, pectin from mango peel, chitin and chitosan, Guar gum, mucilage from fenugreek seeds, among others.

b. Synthetic disintegrating agents:

These enhance the rate at which drugs dissolve and their solubility. They are increasingly utilized in modern formulations. Examples include Croscopovidone, croscarmellose sodium.

5. NOVEL FORMULATION METHODS OF ORODISPERSIBLE TABLET^{6,10,11,12,13,14,16:}

1. Lyophilization
2. Tablet molding
3. Spray drying
4. Mass extrusion
5. Microencapsulation
6. 3D(Three Dimensional) printing
7. Nanotechnology

5.1 Freeze drying/ lyophilization ^{6:}

1. Lyophilization refers to the process of drying substances at a lower temperature while removing water through sublimation.
2. Tablets produced via lyophilization dissolve quickly, taking less than 5 seconds.
3. This method is advantageous for heat-sensitive substances.

5.2 Tablet moulding ^{6:}

1. Tablets produced by this technique fall under the category of solid dispersion.
2. The inclusion of water-soluble sugars within the dispersion matrix improves palatability.
3. It is carried out by,
 1. Heat method
 2. Solvent method

5.3 Spray drying ^{6:}

1. A liquid is first prepared with the support matrix and other ingredients.
2. This liquid is then spray-dried to form a fine, porous powder.
3. Its lightweight and porous nature allows the powder to disintegrate the tablets within
4. 20 seconds upon contact with saliva or water.

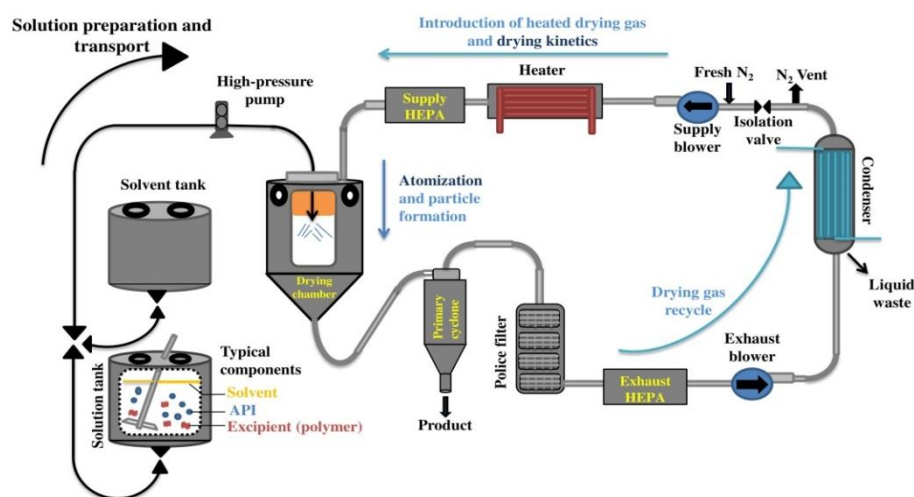


Figure 2: Spray dryer ¹⁷

5.4 Mass extrusion⁶:

1. The material is shaped into a cylinder using an extruder or syringe and then cut into uniform pieces.
2. The segments apply as a coating over bitter granules, aiding in the taste profile of an oral dispersible tablet.

5.5 Microencapsulation ¹⁰:

1. Microencapsulation utilizing ODT technology effectively masks the bitterness of active pharmaceutical ingredients.
2. This technique is suitable for both soluble and poorly soluble substances, and it can also be applied to formulations that require high doses.
3. In microencapsulation, the coacervation method is used. It is a coating method that fully encloses individual drug particles, providing excellent palatability.
4. A significant challenge for an orally disintegrating tablet (ODT) employing taste-masking polymers lies in the difficulty of achieving bioequivalence with the reference product in its conventional form.

5.6 Microspheres in orodispersible tablets ¹⁰:

1. A microsphere is defined as a tiny sphere with a uniform coating surrounding it, which imparts several beneficial characteristics such as taste masking and controlled release.
2. Their diameters typically range from 1 μm to 1000 μm.
3. Various methods can be utilized to prepare microspheres, including air suspension, congealing, solvent evaporation, etc.
4. Among these, the solvent evaporation method is convenient for producing microspheres.

Preparation of microsphere:

1. Method: solvent evaporation technique

2. Ingredient: Eudragit E100, ethanol, dichloromethane, magnesium stearate, light liquid paraffin, N-hexane, and N-hexamine
3. Temperature: 40°C
4. Filtration: Whatman filter paper
5. Storage: drying chamber

Evaluation of microspheres:

Percentage yield determination:

$$\% \text{ yield} = \frac{\text{weight of microspheres}}{\text{Total weight of solid material}} \times 100$$

Entrapment efficiency:

$$\text{Entrapment efficiency} = \frac{\text{Practical drug content}}{\text{Theoretical drug}} \times 100$$

5.7 Three-dimensional (3D) printing ^[11]:

Three-dimensional printing (3DP) has been utilized in creating innovative pharmaceutical dosage forms.

This technique enhances patient health management and supports optimal therapeutic results.

3DP enables the combination of different active pharmaceutical ingredients into tablets, leading to polypills and reducing the number of tablets a patient needs to take, thereby improving adherence to medication regimens.

Digital process in three-dimensional (3D) printing:

1. A Computer-Aided Design (CAD) model is created using software,
2. The software slices the CAD model into a thin layer,
3. Modifying the type and color of filament in FDM 3D printing,
4. Changing the infill percentage and layer height,
5. Setting the extruder temperature and the build plate temperature in FDM printing,
6. Adjusting the printing speed.

Types of Three-Dimensional (3D) printing:

1. Fused deposition modelling,
2. Inkjet 3DP,
3. 3D-based extrusion printing.

1. Fused deposition modelling¹²:

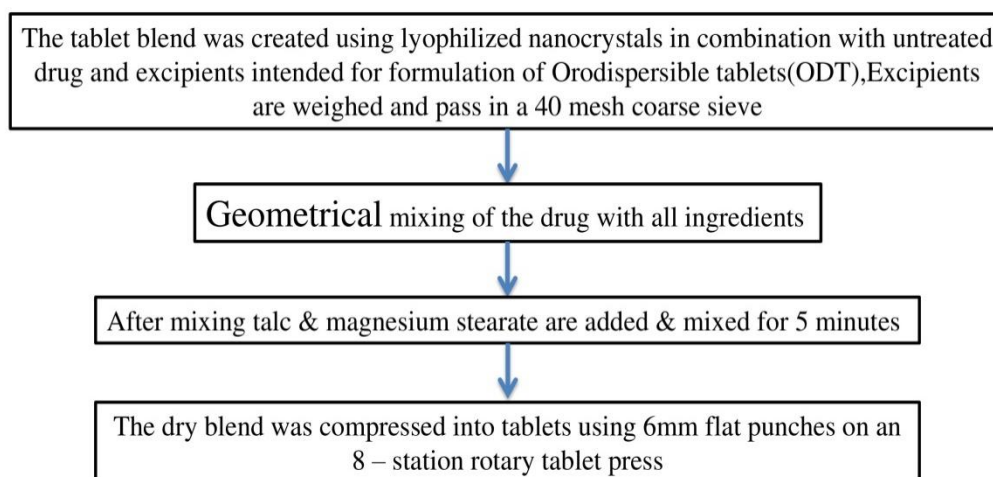
1. Fused deposition modelling is a well-known and economical technique for quickly manufacturing 3 Dimensional Printing (3DP) tablets.
2. This method facilitates rapid and easy adjustments to printing parameters while creating products with robust mechanical properties.
3. This method improves the dissolution rate.
4. For FDM-printed immediate-release tablets, including those that dissolve rapidly, the disintegration time is under 3 minutes.
5. These immediate-release tablets produced by FDM utilize
 1. Polyvinyl alcohol PEG-PVA
 2. Hydroxypropyl cellulose
 3. Copovidone
 4. Povidone
6. The above ingredients are used to increase the disintegration and dissolution of the drug.

5.8 Nanotechnology¹⁵:

1. Nanotechnology is used in the creation of Orodispersible tablet (ODT), especially for children.
2. The main concerns arise from the permeability and solubility of API, which limit the drug's absorption, distribution, or overall effectiveness.
3. These issues can be mitigated by leveraging nanostructures, which can be achieved by either reducing the API to a nanoscale dimension.
4. The first approach involves generating nanocrystals, while the second often makes use of polymeric and lipid-based nano-carriers.

5.9 Nanocrystals¹³:

1. The nanocrystals are designed to be incorporated in the Orodispersible tablet (ODT) to increase the dissolution and solubility of drugs.
2. Initially, nanosuspension was created by using the nano precipitation method.
3. From the solidification of nanosuspension, nanocrystals were produced, which increases the dissolution rate.
4. Solidification method- spray drying, hydrogen formation, pelletization, and freeze drying.

**Figure 3:** Preparation of Orodispersible tablet containing nanocrystals¹³**5.10 Nanoparticles¹⁴:**

Nanoparticles have been created and documented for use in pharmaceuticals to ↑se the poorly soluble drug's dissolution rate, which can significantly boost their bioavailability

1. Reducing the particle size from microns to nanometers results in a notable enhancement in both surface area and dissolution rates.

2. Oral fast-disintegrating tablets that incorporate nanoparticles represent a new approach to drug delivery.
3. It serves as a replacement for traditional dosage forms.

Preparation of an orodispersible tablet containing nanoparticles:

METHOD – DIRECT COMPRESSION

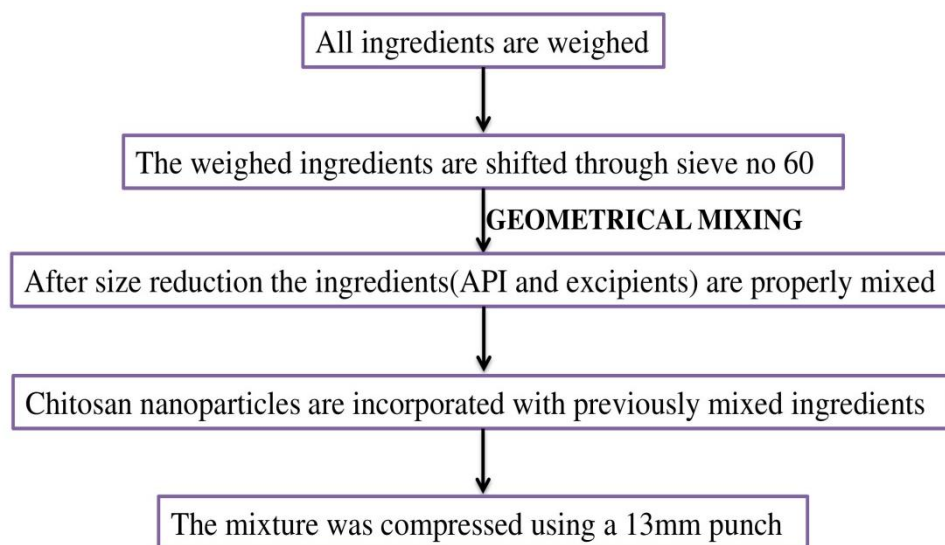


Figure 4: Preparation of orodispersible tablet containing nanoparticles¹⁴

6. EVALUATION OF ORODISPERSIBLE TABLET

2,5 :

1. Weight variation test²:

This test assesses the consistency of tablet weight in a batch by randomly selecting 20 tablets, weighing them together, and calculating the average weight of one tablet.

According to the United States Pharmacopoeia (U.S.P):

Table 1: Weight variation test ²

Average weight of tablets	Percentage deviation
80mg or < 80mg	±10
>80mg but <250mg	±7.5
250 mg or > 250mg	±5

2. Friability test ⁵:

Twenty tablets were randomly selected, weighed, and placed in a United States Pharmacopoeia (USP) type Roche friabilator, operated at 25 rpm for 4 minutes. Afterwards, the tablets were reweighed, and the percentage weight loss was calculated using,

$$\% \text{ Friability} = 1 - (\text{loss of weight} / \text{initial weight}) \times 100$$

Limitation = <1

3. Water absorption ratio ⁵:

A petri dish containing 6 ml of water was set up, and a double-folded tissue paper was placed in it. The tablet was gently placed on top, and the water absorption ratio was determined using the formula.

$$\text{Water absorption ratio: } R = 100 \times (W_a - W_b) / W_b$$

Where, w_a – weight of the tablet before water absorption,

w_b – weight of the tablet after water absorption

4. Wetting time ⁵:

A Petri dish with 6 ml of water was prepared, and a tissue paper, folded twice, was placed inside. The tablet was carefully positioned on top, and the time for water to reach the tablet's surface and fully wet it was recorded as the wetting time.

5. Content uniformity test ⁵:

A UV spectrophotometer was employed to assess the uniformity of drug content. The calibration curve technique was used.

Average content: 85 to 115% as per Indian Pharmacopoeia (I.P).

6. Dissolution test ⁵:

The (United States Pharmacopoeia) USP, 2 apparatus is used for dissolution studies of an Orodispersible tablet at a speed of 50rpm. Orodispersible tablets generally dissolve rapidly under the conditions specified in the United States Pharmacopoeia (USP) monograph.

PH = 4.5

Temperature = 37±0.5°C

Limit = >80% Drug release

7. Disintegration test ⁵:

The disintegration test measures how long a tablet takes to break down. Six tablets were each placed separately into the tubes of the disintegration apparatus. The medium was maintained at 37 ± 2 °C, and the time required for complete disintegration of the tablet was recorded.

Limit = 30 seconds as per United States Pharmacopoeia (USP).

8. Hardness test ²:Limit: 2 to 4 kg /cm² as per Indian Pharmacopoeia (I.P).

Tablets were randomly selected from the batch and their hardness was measured using a Monsanto hardness tester. The hardness values were recorded in kg/cm²

7. MARKETED FORMULATION:**Table 2:** Marketed formulation ¹⁸

DRUG NAME	BRAND NAME	INDICATION
Clozapine	Fazaclo(USP)	Schizophrenia
Domperidone	Domstal(USP)	Chemotherapy-induced vomiting and nausea
Famotidine	Pepcid RPD(USP)	Peptic ulcer
Ondansetron	Zofran (USP)	Antiemetic

Note: United States Pharmacopoeia**8. CONCLUSION:**

The present review focuses on Orodispersible tablets, highlighting their formulation, development and evaluation. Various formulation techniques are discussed in detail, with the role of superdisintegrants and other essential excipients in achieving rapid disintegration. It is developed to make medication intake easier, especially for children, older adults and patients who struggle with swallowing. The novel approach has further enhanced their effectiveness and acceptability. Overall, orodispersible tablets offer a promising and patient-friendly approach to drug delivery with significant potential for future advancement.

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