INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

Review Article

Oro Dispersible Tablets: Recent Advancements, Challenges and Future Perspectives

Vikram Choudhary*, Deepak S, Gururaj Kulkarni

The Oxford College of Pharmacy, Bengaluru, Karnataka 560068

ARTICLE INFO

Published: 24 Oct 2025
Keywords:
ODTs, Drug release technology, Method of preparation, recent advancements, orally disintegrating tablets, wetting time, water absorption ratio
DOI:
10.5281/zenodo.17433338

ABSTRACT

Orally disintegrating tablets (ODTs) rapidly disintegrate or dissolve in the oral cavity without using water. ODTs are in greater demand, and the area has expanded in both academia and the pharmaceutical business. ODTs are said to offer a number of benefits over other traditional tablets. In these situations, the drug's bioavailability significantly increases since some of them are absorbed from the mouth, throat, and exophages as the saliva flows down into the stomach. Additionally, ODTs are3 a common oral dose form for youngsters, individuals with swallowing difficulties, and situations requiring a quick commencement of action due to their instant release feature. In addition to discussing various ODT formulation and their advantages and disadvantages, the current review paper provides various formulation technique, and resent advancements in ODT components and excipients used in ODT formulation. Additionally, necessary concerns and quality control procedures are provided.

INTRODUCTION

Oral administration is the mostly used and effective method with high stability & packaging size & better patient adherence. The Oro dispersible tablets are the delivery system which rapidly disintegrate in mouth when it comes into touch with saliva & they do not required water [1]. However, geriatric, paediatric & bed redden patients experience difficulty in swallowing tab and there may be less water availability while travelling and some people may throw up under these circumstances. To get beyond this weakness the conventional tablets is developed insnovative drug delivery system known as Oro dispersible tablet.[2]

This innovative method in which tablets get disintegrate faster compared to other conventional tablets & they enhance good oral bioavailability. Where most of the conventional drug undergo first pass metabolism problem & poor drug bio-availability.[3]

***Corresponding Author:** Vikram Choudhary
Address: *The Oxford College of Pharmacy, Bengaluru, Karnataka 560068*
Email : tvikramchoudhary5@gmail.com
Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

It is necessary to distinguish between two types of dispersible tablets: While one dose form dissolves instantly in the mouth and can be eaten without the need for water, the other tablet formulation dissolves easily in water and forms a dispersion that the patient can easily swallow.[4]

ODTs offer various advantages such as fast onset of action, no swallowing difficulty & better patient compliance, good stability, increased bio availability. The main principal ingredient involved in formulation of ODT is super disintegrant & their main function is to break down tablets when it comes into contact with saliva. The super disintegrants most frequently utilized in ODT formulation are poly vinal pyrrolidone (PVP), Sodium starch glycolate cross povidone, cross carmellose sodium. There are various methods for manufacturing ODT such as moulding, direct compression, mass extrusion, freeze dryer, sublimation, spray drying, extrusion.[5]

ANATOMICAL AND PHYSIOLOGICAL CHARACTERISTICS OF THE ORAL CAVITY

The buccal cavity has a complex anatomical physiological environment &is an essential entry point for medication administration made up of several areas such as lining, specialized mucosa, masticatory. The buccal cavity has a special property & is essential for drug absorption. This through investigation explores the complexities of salivary flow, oral mucosa vascularization & buccal epithelium, illuminating their application to fast dissolving tablets.[6]

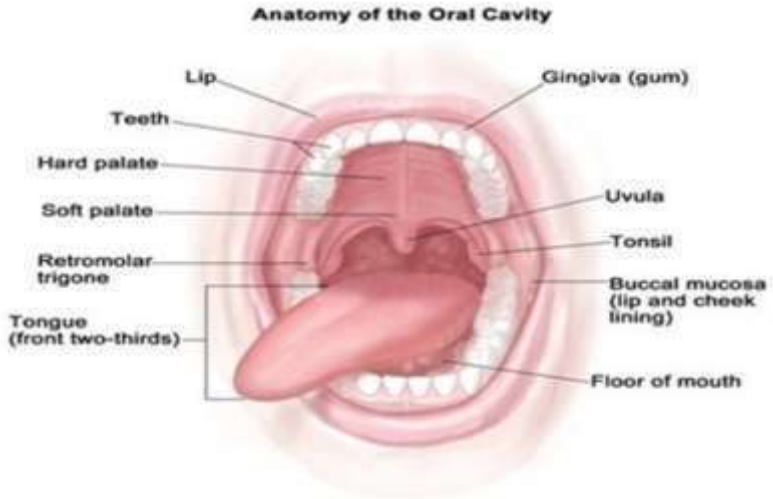

Figure 1: Anatomy of oral cavity

Masticatory mucosa

The gingiva and hard plate are protected by the masticatory mucosa, which has a thickness of 100-200µm. It makes almost 25% of oral mucosa and can tolerate abrasion &shear pressures during mastication, emphasizing its resilience and durability.[6]

Lining mucosa

The lining mucosa, which is 500-800µm thick and covers 60% of the oral mucosa is found on the surface of oral cavity, lips, cheeks, tongue its adaptability and coverage make it a crucial element of the overall mucosal structure. [6,7]

Specialized mucosa

The specialized mucosa which makes up to 15% of total mucosa which is located on the tongue's

dorsum & actively contributes to taste perception. Its specific functions highlight the diverse roles played by different regions within the buccal cavity

Buccal epithelium

The buccal epithelium, which is a non-keratinized stratified layer, exhibits several layers with different maturation patterns. The cells of basal layer are capable of dividing and maintaining epithelial population homeostasis. Homeostasis involved segregation, superficial cells proliferation and desquamation. Prickle cells that gather cytokeratin's and lipid of low molecular weight are found in the intermediate layer.

Oral mucosa vascularization

The vascular network of the oral mucosa comprises lymphatic, arterial and venous capillaries that pass through the multi layered epithelium and extend into the connective tissue. The buccal mucosa receives a highly vascularized supply, primarily originating from the externally carotid artery including mouth surface, tongue root, cheek mucosa.

Salivary flow

Saliva which plays a vital role in the breakdown or dissolution of drug formulation which is mainly delivered into the buccal cavity by the sublingual gland, parotid gland, submandibular gland and several small glands compressing about 99.5%water, saliva include electrolyte, gases, mucines, amino acid, proteins, digestive enzyme, proteolytic enzyme, immunoglobulin, serum albumin & phosphorous compounds. Saliva which has a weak buffer capacity & ph ranges of 6-7, varies in between 5.3 to 7.8 during stimulation Natural salivary flow is about 0.1 to o.2 ml/min, increasing to 6.5 ml/min during stimulation. The saliva serves to hydrate the oral cavity and its mucus layer underneath – ranging in thickness from 1-400µm act as a protective barrier to drug transport. [6,7]

SALIENT FEATURES OF ODTs

ODT Should depict some ideal features to distinguish them from traditional conventional. [8,9]

- Noo water is needed for swallowing, but it should dissolve or break down in the mouth within fraction of seconds.
- Provide pleasant felling in the mouth
- The capacity of loading drug is very high
- Exhibit low sensitivity to changes in environmental factors like humidity, temperature
- ODT can be transported easily without concerns about fragility, making them a convenient & use friendly dosage from
- ODT offers great stability
- Cost effective

ADVANTAGES OF ODTS [9]

- It is easy to administer to patients who are bedridden, elderly, young, and mentally challenged and who find it hard to swallow the tablet.
- The ODTs can be swallowed without water, unlike conventional dosage forms This is highly convenient for patients who are travelling or lack prompt access to water, and thereby offer enhanced patient compliance.
- Drugs' bioavailability is improved through absorption from the mouth, pharynx, and oesophagus. Improvement can result from pre-gastric absorption bioavailability and due to lower dosage, enhanced clinical performance by minimizing adverse effects.

- The tablet dissolves and absorbs in the oral cavity quickly, resulting in a rapid commencement of therapeutic activity.
- Excellent mouth feels, particularly for paediatric patients, as a taste-masking technique is employed to prevent the bitter taste of medications.
- Conventional processing and packaging equipment enable the low-cost production of tablets.
- The chances of dose dumping are less in case of dispersible tablets.

DISADVANTAGES OF ODTS [5]

- Due to their hygroscopic character, they must be stored in a dry place.
- Their mechanical integrity is quite low
- Special packaging is required owing to its unstable nature.
- Dose uniformity is very hard to maintain in these kinds of tablets.

FEATURES OF API & EXCIPIENTS

The majority of API used in ODT formulation produce systematic effect rather than local ones. The properties of the drug &excipients should not have an important impact on the tablet's properties, certain features such as solubility & particle size, crystal morphology hygroscopicity & A drug's compressibility can alter the final ODT properties. There are many requirements for a drug in ODT formulation can make ODT acceptable & ideal dosage form.

Table 1: Commercial ODT formulations on the market.

Active Ingredients	Product	Category	Manufacturing Technology
Paracetamol	Febrectal	analgesic	Zydis®
Risperidone	Risperdal	Anti-Psychotic	Zydis®
Ondansetron	Zofran	Anti emetic	Zydis®
Zolpidem	Ambien	sedative-hypnotics	FlashDose®
Tramadol	Ultram	analgesic	FlashDose®
Nimesulide	Nimulid-MD	anti-inflammatory	Zydis®
Montelukast	Romilast	Eukotriene receptor antagonists	Orasolv®
Zolmitriptan	Zomig	Anti migraine	Dura Solv
Loratadine	Clartin	Anti histamine	Zydis®
Rizatriptan	Maxalt	Anti migrain	Zydis®
Mirtazapine	Remeron	Anti dipresent	Orasolv®

For example, the medication must be ionized, distributed, and absorbed through the mucosa without leaving any behind in the oral cavity. Also, selection of the manufacturing method is equally as important as choosing the excipients. Due to the fact that different Technology has its own set of advantages disadvantages. Some of those are patented technology are WOWTAB, FLASHTAB, DURASOLV, EFVDAS, ZYDIS, QUICKSOLV, LYOC.[11]

The molecular weight of Api should not exceed 500 da for frequent use the active ingredients should be under 50 mg have a short life and possess a present taste and aroma moreover it is important to examine the compatibility of drug with excipients before choosing excipients. Interaction of physical, chemical & bio pharmaceutical nature & taken into account considering the possible interaction between excipients and API.[10]

ODT DRUG RELEASE TECHNOLOGY

The main action of ODT tablets depends on release pattern of super disintegrant used in it. The release of super disintegrant in following mechanism. [12-14]

1. **Deformation:** During the compression stage of tablet formulation, the disintegrant particles undergo deformation. However, upon administration, when they come into contact with water, the disintegrants return to their original precompression size through swelling, resulting in the tablet breaking apart.
2. **Swelling:** Certain disintegrants exhibit their effect through swelling, meaning that upon contact with water, they swell and lead to the tablet's fragmentation.
3. **Porosity and capillary action:** during administration the tablets are first dissolved in small amount of liquid, so that the water can easily penetrate inside the tablet and break it into minute partical

METHOD OF PREPARATION OF ODT

This review article summarizes the commonly used methods for preparing ODTs, including moulding, direct compression mass extrusion, spray-drying, sublimation, and lyophilization (freeze-drying).

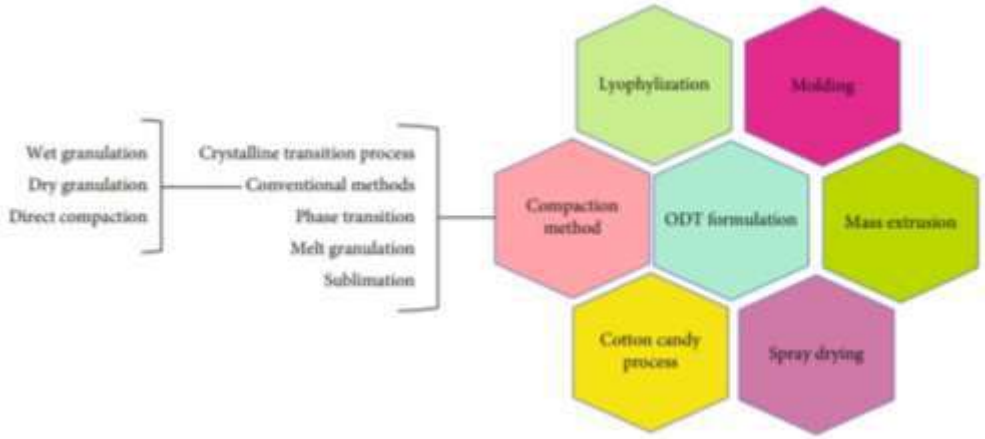

Figure 2: ODT formulation techniques

1. Moulding

ODTs made using the moulding technique break apart in 5 to 15 seconds. Moulding or solid dispersion can be divided into two categories: compression moulding and heat moulding. Moulded tablets are created from a molten substance that contains a drug in solution or dispersion.[15] First, a suspension of the drug is prepared using water-soluble sugars like mannitol, lactose, glucose, sucrose, sorbitol, or xylitol, along with agar. These sugars serve as a binding agent, and their presence contributes to a pleasant mouthfeel. After that the suspension is placed into moulds and blister packs. The solvent is then evaporated under vacuum at a temperature of 30°C. This process solidifies the agar solution and produces ODTs. In compression moulding, a powder blend is combined with a hydroalcoholic solvent and then compressed into Mold plates using a low force. The tablets are subsequently air-dried to remove the solvent, resulting in a porous structure with elevated disintegration and dissolution rates. This method is used to prepare valdecoxib and perphenazine ODTs. [16,17] The primary drawbacks of this technique are its high production cost and low mechanical strength, which results in the breakage of ODTs during handling or when blister packs are opened. To address this limitation, it may be beneficial to

incorporate binders such as acacia, polyvinylpyrrolidone, and PEG.[18]

2. Mass Extrusion

Water-soluble solvents like PEG, methanol or ethanol are employed in the mass extrusion process is to soften the powder mixture process. After that, it is either extruded through a sieve or syringed. Post-extrusion, alcohol was eliminated through evaporation. A gel in the shape of a solidified string was created, after which it was crushed into granules using a mortar. These granules could then be blended with other components and formed into ODTs through the compaction methods described in the subsequent sections.[19] In mass extrusion PEG stearate is utilized as a binder in mass extrusion to enhance physical strength and disintegration. This technique allows for masking the drug's bitter taste by coating granules with compounds such as Eudragit E 100, hydroxypropyl methylcellulose (HPMC), ethyl cellulose, hydroxypropyl cellulose (HPC), polyvinyl acetate, polyvinyl alcohol.[20]

3. Spray-Drying

Typically, solid dispersions and micronized drug/excipient particles are utilized in the spray-drying process. are ready to be administered orally or via inhalation.[21] To create a highly porous structure, a liquid mixture of materials is first sprayed into a heated chamber. These microparticles were then usually combined with mannitol, kneaded with distilled water, and dried for two hours at 60° C. The produced granules were then sieved, combined with additional excipients, and compacted into tablets using the compaction techniques covered in the sections that follow. made using this technique have a high porosity and break down quickly in the mouth. The product's fragility and high production costs, which render traditional packing techniques unsuitable for this dosage form, are the method's main drawbacks. This process produces tablets with high porosity that dissolve quickly in the mouth. This method's major drawbacks are the product's fragility and high production costs, which render traditional packing techniques unsuitable for this dosage form.

4. Cotton-Candy Process

This method produces crystalline flosses by using a unique spinning tool. When saccharides or polysaccharides, such as polymaltodextrin and polydextrose, are flash melted and spun simultaneously with the right flow at 180–266°C, a candy floss matrix is produced. The produced matrix is thereafter compressed into ODTs after being ground and combined with API and excipients. This practice is specifically used to mask the unpleasant taste of medications. Furthermore, the candy floss matrix's flow characteristics, compressibility, and mechanical strength may all be somewhat enhanced by recrystallization. Additionally, it leads to the accumulation of a lot of drugs, but it isn't suitable for medications that are heat-labile.[22]

5. Lyophilization

The process of lyophilization involves utilizing a vacuum to dry thermosensitive APIs at a low temperature. Lyophilizates are another name for freeze-dried ODTs. They typically disintegrate quickly, have highly porous structures, and are extremely light. Accurate dosage results from creating freeze-dried OTDs in a liquid form. Furthermore, handling powerful or dangerous APIs in the liquid condition is safer for operators than gritty powder. Nevertheless, the procedure is somewhat expensive and inappropriate for formulations that lose their stability at high temperatures and humidity levels. [23,24]

Two platforms for lyophilization are Zydis and Lyoc. The Zydis method begins with the formation of an aqueous bulk liquid made up of mannitol as a mechanical booster and gelatin as a polymeric binder. In the final ODT, gelatin serves as a glue to hold the filler and API particles together. Additionally, the addition of a hydrophilic filler—one that dissolves well in water—like mannitol may encourage disintegration.[25] The formulation can also include preservatives, colorants, pH adjusters, and taste-masking agents. The liquid composition is then quickly frozen using a tunnel freezer after being placed into blister pockets. Once Blisters are sent to sizable industrial batch freeze-dryers for vacuum-assisted primary and secondary drying after freezing. Blisters are packed and sealed after drying. The medicine in this platform is water-insoluble, low dosage, and has a small particle size to save processing time and provide a smooth mouthfeel.[26]

In Lyoc technology, water-soluble fillers like lactose or mannitol are used to create an oil-in-water emulsion. A paste-like shape is produced when a lot of fillers are used, which ultimately keeps the formulation from sedimentation. Then, in commercial freeze-dryers, freeze-drying phases occur, similar to the Zydis process. The Lyoc approach was less cost-effective due to low-porous particles and longer drying times.[27]

6. Compaction Methods

During this procedure, Crucial shapes like tablets or briquettes are prepared using a compression equipment.by exerting pressure to encourage particle agglomeration and bonding. The compression force that is applied is dependent on excipient characteristics, APIs, and tablet size. For instance, the study by Stoltenberg and Breitkreutz states that the compression force in the ODMT formulation should be between 3 and 8 kN.[28] Another important consideration is the excipient selection because compression reduces the product's porosity. This is necessary for a quick disintegration and requires the addition of super disintegrant and sugar-based fillers. Devices used in the compaction process include serial devices like extrusion and restricted devices like tabletting. The compaction methodology serves as the foundation for the following methods.[29]

7. Sublimation

Benzoic acid, ammonium bicarbonate, hexamethonium tetramine, urea, menthol, ammonium carbonate, camphor, naphthalene, phthalic anhydride, and urethane were among the excipients employed in the sublimation process. Sometimes, solvents like cyclohexane/benzene were employed to further increase porosity.[30] After compressing the produced blend into tablet form, the volatile substance is removed by temperature and pressure, leaving behind porous residual bulk. High The key component of tablets made using the sublimation approach is porosity. Furthermore, difficult processes like the sublimation of frozen water are eliminated by the volatilization of volatile material. The pharmacological impact of captopril, an angiotensin-converting enzyme inhibitor used to treat emergency hypertension, is expected to peak 1-2 hours after oral administration The necessity of giving patients captopril tablets Captopril is an excellent choice for ODT formulation because of its ability to help with swallowing issues.[31] Both in vitro and in vivo studies have been conducted on captopril ODTs made using this technique. A recent study found that captopril ODTs made with 10% camphor and 5% croscarmellose sodium (Ac-di-sol®) had the maximum in-vitro drug release (99:51 ± 0:24%) after 8 minutes, the shortest disintegration time (3:425 ± 0:12 kilopond, 17:48 ± 1:36 s), and the proper stiffness. Additionally,

the in vivo evaluation revealed that hypertensive rats' mean arterial pressure stabilized 15 minutes faster. The other OTD that Suresh and Joshi developed and assessed using the sublimation process is salbutamol sulphate ODTs. The ODT's physicochemical characteristics were enhanced by the addition of camphor/ammonium bicarbonate as a volatile material, which caused disintegration in 5–40 seconds.[32]

7. Phase Transition

Using this method, the powder is compressed with two sugar alcohols that have high and low melting points, and the compacted mass is then heated to a temperature in between their melting points. Employed this process to create ODTs because low compressibility and stronger interarticular connections reduce hardness, but heating causes the hardness to increase due to sugar alcohol solidification and diffusion.[33] A low compression force is followed by a humidity or heat treatment to boost mechanical strength in the phase transformation procedure to preserve porosity, while the use of heat or humidity may reduce the stability of medications that are water-sensitive or thermolabile.[34]

8. CONVENTIONAL METHODS

ODTs are produced via conventional methods like direct compression, dry granulation, and wet granulation. The most used method is wet granulation technique, according to Shanmugam's thorough assessment of granulation techniques.[35] While dry granulation involves no liquid, wet massing of the excipients and API using granulation liquid, with or without binder, produces granules.[36] The wet granulation technique is used to prepare the ODT of glibenclamide. The simplest method for producing tablets, especially for large-scale ODT production, is direct compression, which includes super disintegrants like Cross povidone, croscarmellose, alginic acid, and calcium silicate. Tramadol hydrochloride OTDs have been prepared using the direct compression method, which involves first creating taste-masked granules of the drug using the mass extrusion method with Eudragit E100, and then formulating OTDs using Cross povidone, Ac-Di-Sol®, and sodium starch glycolate as the super disintegrants. This allows for a quick onset of action, which reduces postoperative pain.[37]

CHALLENGES IN DEVELOPING ODT [38]

- Ensuring quick disintegration without sacrificing the tablet's mechanical strength is one of the main problems in ODT development.
- One of the biggest challenges in ODT formulation is striking a balance between the necessity to prevent excessive tablet size growth and the objective of quick disintegration.
- For ODTs to be successful, a compromise must be struck between attaining rapid disintegration and preserving sufficient tensile strength.
- Designing ODT that ensure a positive patient experience by leaving little to no residue in the mouth after administration is a challenge.
- Addressing the hygroscopic nature of some ODTS needs effective moisture protection techniques to ensure stability and prevent degradation
- One of the challenges in ODT formulation is creating packaging that is both protective and convenient to administer.
- Incorporating efficient taste masking characteristics into ODT formulations is crucial to ensuring patient acceptance, particularly for formulations that incorporate bitter medications.

EVALUATION OF ODTs

- Along with a few specialized tests, the evaluation parameters of the tablets listed in the Pharmacopoeias must be evaluated Once a tablet is formulated according to a regulation, its quality is often determined by the blends' physicochemical characteristics.[39] Mixing involves a number of formulation and process variables, all of which can have an impact on the properties of the blends that are created.[40]

- **Evaluation of blends before compression**: he various characteristics of blends to be tested before compression are [40,41]

- **Angle of repose**; The funnel method is used to determine the angle of repose. The precisely weighed mixture is transferred into a funnel. The funnel's height can be changed such that the tip of the funnel barely makes contact with the top of the pile of blend. The drug-excipient mixture (in the form of a solid dispersion) is permitted to freely flow to the surface of the funnel. The following formula is used to determine the powder cone's diameter and angle of repose.

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

where h and r stand for the cone's height and radius, respectively. An angle of repose of less than thirty degrees indicates that the material is flowing freely**.**

Table 2: Angle of repose as an indication of powder flow properties

Sr. No	Angle of Repose (°)	Type of Flow
1.	< 20	Excellent
2.	20 – 30	Good
3.	30 – 34	Passable
4.	> 34	Very Poor

- **Bulk density;** A weighed amount of blend is poured into a graduated cylinder, and the weight and volume are measured to calculate the apparent bulk density. The formula below can be used to determine bulk density:

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

- **Tapped density;** A graduated cylinder with a known mass of drug-excipient combination is placed to determine it. At 2-second intervals, the cylinder is permitted to drop 10 cm from a height onto a hard surface under its own weight. Until there is no more audible variation, the tapping is kept up. The following formula can be used to get the taped density:

$$\mathbf{Tapped\ Density = \frac{Weight\ of\ the\ powder}{Volume\ of\ the\ tapped\ packing}}$$

- **Compressibility index;** The blends' compressibility index is based on the compressibility index. The following formula can be used to compute the compressibility index:

$$\mathbf{Compressibility\ Index}(\%) = \frac{\mathbf{(TD - BD)}}{\mathbf{TD}} \times \mathbf{100}$$

Table 3: Relationship between % compressibility index and flow ability

Sr. No.	% compressibility index	Type of Flow
1.	5-12	Excellent
2.	12-16	Good
3.	18-21	Fair to Passable
4.	23-35	Poor
5.	33-38	Very Poor
6.	< 40	Very Very Poor

- **Hausner's ratio;** Hausner's ratio can be used to define a comparable index to show the flow characteristics. The following formula can be used to determine Hausner's ratio:

$$\textbf{Hausnes ratio}\frac{\textbf{Tapped density}}{\textbf{Poured density}} \times \textbf{100}$$

- **Void Volume**: The volume of the spaces is known as the void volume "V" and is given by the formula

$$\mathbf{V = Vb - Vp}$$

Were,
Vb = Bulk volume (volume before tapping)
Vp = True volume (volume after tapping)

- **Evaluation of Tablets:** All the formulated ODTs were subjected to the following quality control tests

- **Weight variation;** To make sure that the weight of the tablets in a batch is consistent, the weight variation test is conducted. Initially, the average can be calculated by calculating the total weight of 20 tablets from each formulation. To establish the weight variance, the specific weight of each tablet is also determined. [41,42,43]

- **Hardness;** A tablet's strength can be determined by its hardness. The force needed to break the tablet during evaluation is measured. For uncoated tablets, a hardness of roughly 3-5 kg/cm2 is deemed adequate, and the force is expressed in kilograms. Monsanto, Pfizer, and other hardness testers evaluate the hardness of ten tablets from each formulation.

- **Friability test;** Friability is the weight loss of the tablet in the container as a result of the surface being cleared of tiny particles. To determine the tablet's resistance to abrasion during handling, packing, and transportation, a friability test is conducted. The Roche friabilator is used to determine whether the tablets are friable. Each batch of 20 tablets should be weighed before being placed in a Roche friabilator that rotates for four minutes at 25 rpm. After dusting every tablet, reweigh it. The following formula can be used to determine the percentage of friability:

$$\textbf{\% Friability} = \frac{(W1-W2)}{W1} \times \textbf{100}$$

Where,
W1= Weight of tablet before test,
W2 = Weight of tablet after test

- **Disintegration test**; Six glass tubes that are "three long, open at the top, and held against ten" screen at the bottom end of the basket rack assembly make up the USP disintegration equipment. In a one-liter beaker of distilled water at 37± 2 °C, one tablet is put in each tube, and the basket rack is poisoned so that the tablets stay below the liquid's surface as they rise and fall no closer than 2.5 cm from the beaker's bottom.

- **Mechanical strength**: Tablets should have sufficient mechanical strength to withstand handling shocks during production, packing, and delivery. Two crucial factors in determining mechanical strength are crushing strength and friability. Crushing Tablet or Strength It is crucial to remember that high crushing strength drastically shortens the disintegration period. Tensile strength is the power needed to break a tablet by compression in the radial direction. Pfizer hardness testers are used to measure the tablet's crushing strength. The formula is used to determine the tensile strength for crushing (T).

$$\mathbf{T} = \frac{\mathbf{2F}}{\boldsymbol{\pi} * \mathbf{d} * \mathbf{t}}$$

Where
F is the crushing load, and

d and t denote the diameter and thickness of the tablet respectively.

- **Uniformity of dispersion**: For two minutes, carefully swirl the two tablets in 100 millilitres of water. 22 meshes are used to filter the dispersion. If there is no residue left on the screen, the tablets will be deemed to have passed the test.

- **Wetting time:** A simple technique is used to measure the tablets' wetting time. Five round tissue papers with a diameter of 10 cm should be placed in a Petri dish with 3 millilitres of a 0.2% w/v solution. The tissue paper's surface is gently covered with a tablet. The soaking time is the amount of time needed for the tablet's top surface to turn blue.

- **Water absorption ratio;** A small piece of tissue paper that has been folded twice is put in a tiny Petri dish with six millilitres of water. Measure the amount of time needed for the tablet to completely wet the paper after placing it on it. Next, the moist tablet is weighed again. The following formula is used to determine the water absorption ratio, or R.

$$\frac{\mathbf{Wa - Wb}}{\mathbf{Wb}} \times \mathbf{100}$$

Where,
Wb is the weight of tablet before water absorption
Wa is the weight of tablet after water absorption

- **In -Vitro disintegration test;** To determine the in-vitro disintegration time, a tablet is dropped into a beaker filled with 50 millilitres of Sorenson's buffer (pH 6.8). After choosing three tablets at random from each formulation, the in vitro dispersion time is measured.

- **In-Vivo disintegration test;** Two or three tablets are put in the mouth for the test, and the amount of time it takes for the tablets to completely dissolve is recorded in seconds.

- **In-Vitro dissolution test;** The USP Type II Apparatus (Paddle type) is used to conduct an in-vitro dissolution investigation at 50 rpm. 900 ml of phosphate buffer (pH 6.8) is used as a dissolving media, and it is kept at 37±0.5°C. At predetermined intervals of two minutes, remove an aliquot of the dissolving medium (10 ml) and filter. A suitable analytical procedure determines the amount of medication dissolved.

- **Stability Studies;** According to ICH recommendations, a stability study is conducted on the optimized formulation of ODTs to evaluate their stability in terms of their physical features and release characteristics.

ADVANCEMENTS IN ODT TECHNOLOGIES

Zydis technology

Zydis is a special kind of freeze-dried oral solid dose form that dissolves on the tongue in less than three seconds and can be taken without water. To make a product that dissolves quickly, the medicine is physically confined in a water-soluble matrix and then freeze-dried. Water-soluble saccharides and polymers (gelatin, dextran, and alginates) make up the matrix, which allows for quick dissolution and enough physical strength to resist handling. The method creates porous units for quick breakdown using water. Different gums are utilized to solve the drug's sedimentation issue. Glycine is utilized to stop the zydis unit from shrinking during processing and storage. Because the zydis dosage form has a low physical strength,

it comes in a peelable blister pack that makes it possible to remove the medicine without causing any damage. A medicine candidate for Zydis should have a tiny particle size (less than 50 microns), be water insoluble, and be chemically stable. The dosage of water-soluble medications is restricted to 60 mg since they may produce eutectic mixes and not freeze enough. During processing, bigger drug particles may cause sedimentation issues.[44]

Orasolv technology

It is the first fast-dissolving formulation developed by CIMA Lab. To reduce oral disintegration and dissolve time, tablets are made via direct compression with a low compression force. One type of mildly effervescent tablets that dissolves quickly in the mouth is Orasolv technology. The activity of effervescent agents disperses and masks the taste of the active medications in saliva. It gives the patient a pleasing feeling in their mouth. The limited mechanical strength of Orasolv technology is its main drawback. The generated tablets must be packed in a specifically made pack because they are soft and brittle.[45]

Durasolv technology

Additionally, CIMA Lab has a patent on the technique that creates second-generation ODTs. The medication, fillers, lubricant, and tablets made with traditional equipment are all included in the tablets made with this method. Because Durasolv formulations provide a stronger compaction pressure than their predecessors, they have a higher mechanical strength. Because Durasolv products are so long-lasting, they can be packaged in vials or conventional blister packs. It is among the best technologies for products that need little in the way of active chemicals.[46]

Wowtab technology

This invention was patented by Yamanouchi Pharmaceutical Company. "Wow" translates to "without water." Up to 50% of the tablet's weight may be made up of the active components. This method prepares the granules using saccharides with low and high moldability. The ability of a substance to be compressed is known as moldability. Because of its high compressibility, a highly mouldable substance dissolves slowly. To create tablets with the right amount of hardness, a mix of high and low moldability is utilized. After combining active components with low-moldability saccharides, high-moldability saccharides are granulated and crushed into tablets. It takes 15 seconds or less for the Wowtab substance to disintegrate. The Wowtab product is available in blister packs and regular bottles.[47]

Flash tab technology

The patent holder of this technology is Prographarm Labs. Microgranules of the taste-masked active medication are used in this method. Conventional methods such as Extrusion spherization, microencapsulation, and coacervation can all be utilized to create them. All of these procedures make use of standard tabletting technology. These taste-masked microcrystals of the active medication, dissolving agent, swelling agent, and additional excipients, such as soluble diluents, are compacted to create a multiarticulate tablet that breaks down quickly.[48]

AdvaTab technology

In order to disguise the taste and limit the drug's ability to dissolve in the mouth cavity, this method coats the drug particles with a gastrosoluble polymer using the microencapsulation process. In the mouth, AdvaTab tablets dissolve quickly—usually in less than 30 seconds. These pills are particularly well-suited for those who struggle with swallowing tablets and capsules. The ability

to combine AdvaTab with complementary particle technologies from Europe, such as its industry-leading Microcaps® (taste-masking technology) and Diffucaps® (controlled-release technology), sets it apart from other oral disintegrating tablet solutions.[46]

FUTURE OF ODTS;

ODT technology adds value by working with a variety of therapeutic agents, including generics, such as "super generics" for use in humans or animals.

To identify the technological features of oral disintegrating tablets and specify the features of ODTs, several new quality control techniques can be developed.

Therapeutics based on proteins and peptides that are consumed orally have a low bioavailability when taken as immediate-release tablets. These products often break down in the gastrointestinal tract right away. Improved oral protein delivery technology developed by ODTs that dissolve and/or disperse in saliva shows great promise for delivering high molecular weight proteins and peptides.

When ODTs with controlled release capabilities are developed to deliver medications with short half-lives, such as 12 to 24 hours, it would be a creative advancement in ODT technology. Such formulations' increased compliance and convenience will be greatly utilized.

Another significant technological advancement will also come from the ability to create medications in huge quantities. significant doses of medication will merely make the final formulation too bulky to manage, as ODT formulations typically call for significant volumes of excipients. It will be revolutionary to develop ODT formulations that use less excipients than the medication itself. Although ODT technologies are being developed, it is difficult to create ODT formulations with lipophilic active medicinal components. To solve this issue, new ODT technology ought to be created.

There aren't many delayed release ODTs available on the market, according to the literature. As the next generation of ODT technology, controlled release ODTs, purpose-based systems, and/or fixed dose combination ODTs can be created.[49]

CONCLUSION

In conclusion, the development and acceptance of Fast Dissolving Tablets (FDTs) mark a significant advancement in oral drug delivery systems. These tablets present a viable way to address the issues with conventional dosage forms, particularly for patients who have trouble swallowing, such as young children and elderly patients. FDTs' special qualities, such as their quick decomposition or disintegration They are a practical and patient-friendly substitute because they don't require water, have a large drug load capacity, and effectively mask flavour. The quick beginning of action linked to ODTs is facilitated by the architectural and physiological features of the buccal cavity, which are essential for drug absorption through the buccal mucosa. Optimizing medication formulations and improving therapeutic results requires an understanding of the intricacies of the salivary flow, oral mucosa vascularization, and buccal epithelium. The significance of novel formulations like ODTs is highlighted by the pharmaceutical industry's growing emphasis on non-invasive drug delivery methods as well as the need for improved bioavailability and patient acceptance.

REFERENCES

1. Basu B, Bagadiya A, Makwana S, Vipul V, Batt D, Dharamsi A. Formulation and evaluation of fast dissolving tablets of cinnarizine using superdisintegrant blends and subliming material. Journal of advanced pharmaceutical technology & research. 2011 Oct 1;2(4):266-73.
2. Siddiqui MN, Garg G, Sharma PK. Fast dissolving tablets: preparation, characterization and evaluation: an overview. International Journal of Pharmaceutical Sciences Review and Research. 2010 Sep;4(2):87-96.
3. Maheshwari S, Singh A, Varshney AP, Sharma A. Advancing oral drug delivery: The science of fast dissolving tablets (FDTs). Intelligent Pharmacy. 2024 Feb 8.
4. 4.Parkash V, Maan S, Yadav SK, Jogpal V. Fast disintegrating tablets: Opportunity in drug delivery system. Journal of advanced pharmaceutical technology & research. 2011 Oct 1;2(4):223-35.
5. Sharma MC, Leel M. A review: Oral dispersible tablets. Int J Drug Dev Res. 2022;14(1):171.
6. Maheshwari S, Singh A, Varshney AP, Sharma A. Advancing oral drug delivery: The science of fast dissolving tablets (FDTs). Intelligent Pharmacy. 2024 Feb 8.
7. Nagar P, Singh K, Chauhan I, Verma M, Yasir M, Khan A, Sharma R, Gupta N. Orally disintegrating tablets: formulation, preparation techniques and evaluation. Journal of Applied Pharmaceutical Science. 2011 Jun 30(Issue):35-45.
8. Shukla D, Chakraborty S, Singh S, Mishra B. Mouth dissolving tablets I: An overview of formulation technology. Scientia Pharmaceutica. 2009 Jun;77(2):309-26.
9. Nayak AK, Manna K. Current developments in orally disintegrating tablet technology. Journal of Pharmaceutical Education and Research. 2011 Jun 1;2(1):21.
10. Ghourichay MP, Kiaie SH, Nokhodchi A, Javadzadeh Y. Formulation and quality control of orally disintegrating tablets (ODTs): recent advances and perspectives. BioMed Research International. 2021;2021(1):6618934.
11. Abay FB, Ugurlu T. Orally disintegrating tablets: a short review. Journal of Pharmaceutics & Drug Development. 2015 Jun 25;3(3):303.
12. 12.Pandey P, Dahiya M. Oral disintegrating tablets: a review. International Journal of Pharma Research & Review. 2016 Jan;5(1):50-62.
13. Ramu S, Kumar YA, Rao DS, Ramakrishna G. Formulation and evaluation of Valsartan oral dispersible tablets by direct compression method. American Journal of Advanced Drug Delivery. 2014;2(6):719-33.
14. Khan T, Nazim S, Shaikh S, Shaikh A, Khairnar A, Ahmed A. An approach for rapid disintegrating tablet: a review. International Journal of Pharmaceutical Research & Development. 2011 May 21;3(3):170-83.
15. Kumar R, Patil MB, Patil SR, Paschapur MS. Development and characterization of melt-in-mouth tablets of haloperidol by sublimation technique. International journal of pharmacy and pharmaceutical sciences. 2009;1(1):65-73.
16. Modi A, Tayade P. Enhancement of dissolution profile by solid dispersion (kneading) technique. AAPS pharmscitech. 2006 Sep;7(3):68.
17. Wang L, Zeng F, Zong L. Development of orally disintegrating tablets of perphenazine/hydroxypropyl-β-cyclodextrin inclusion complex. Pharmaceutical development and technology. 2013 Oct 1;18(5):1101-10.

18. Debnath S, Yadav CN, Nowjiya N, Prabhavathi M, SaiKumar A, Krishna PS, Babu MN. A review on natural binders used in pharmacy. Asian Journal of Pharmaceutical Research. 2019;9(1):55-60.
19. Gryczke A, Schminke S, Maniruzzaman M, Beck J, Douroumis D. Development and evaluation of orally disintegrating tablets (ODTs) containing Ibuprofen granules prepared by hot melt extrusion. Colloids and surfaces B: biointerfaces. 2011 Sep 1;86(2):275-84.
20. M. G. Patil, S. M. Kakade, and S. G. Pathade, "Formulation and evaluation of orally disintegrating tablet containing tramadol hydrochloride by mass extrusion technique," Journal of Applied Pharmaceutical Science, vol. 1, no. 6, p. 178, 2011.
21. Vehring R. Pharmaceutical particle engineering via spray drying. Pharmaceutical research. 2008 May;25(5):999-1022.
22. Badgujar B, Mundada A. The technologies used for developing orally disintegrating tablets: A review. Acta pharmaceutica. 2011 Jun 1;61(2):117.
23. 23.Ghosh T, Ghosh A, Prasad D. A review on new generation orodispersible tablets and its future prospective. Int j pharm pharm sci. 2011 Jan;3(1):1-7.
24. Rameesa CK, Drisya MK. Orodispersible tablet: a patient friendly dosage form (a review). Bali medical journal. 2015;4(1):17-20.
25. Omar S, AbdAlla F, Abdelgawad N. Effect of mannitol on physical characters of lyophilized fast-disintegrating tablets. Journal of Advanced Pharmacy Research. 2017 Oct 1;1(4):228-33.
26. Kasper JC, Friess W. The freezing step in lyophilization: Physico-chemical fundamentals, freezing methods and consequences on process performance and quality attributes of biopharmaceuticals. European journal of pharmaceutics and biopharmaceutics. 2011 Jun 1;78(2):248-63.
27. Gulsun T, Cayli YA, Izat N, Cetin M, Oner L, Sahin S. Development and evaluation of terbutaline sulfate orally disintegrating tablets by direct compression and freeze-drying methods. Journal of Drug Delivery Science and Technology. 2018 Aug 1; 46:251-8.
28. I. Stoltenberg and J. Breitkreutz, "Orally disintegrating minitablets (ODMTs)–a novel solid oral dosage form for paediatric use," European Journal of Pharmaceutics and Biopharmaceutics, vol. 78, no. 3, pp. 462–469, 2011
29. Vanbillemont B, Everaert H, De Beer T. New advances in the characterization of lyophilised orally disintegrating tablets. International Journal of Pharmaceutics. 2020 Apr 15;579:119153.
30. Gosai AR, Patil SB, Sawant KK. Formulation and evaluation of orodispersible tablets of ondansetron hydrochloride by direct compression using superdisintegrants. Int J Pharm Sci Nanotechnol. 2008 Apr;26(1):106-1.
31. Hannan PA, Khan JA, Khan A, Safiullah S. Oral dispersible system: A new approach in drug delivery system. Indian journal of pharmaceutical sciences. 2016 Jan;78(1):2.
32. Suresh S, Pandit V, Joshi HP. Preparation and evaluation of mouth dissolving tablets of salbutamol sulphate. Indian journal of pharmaceutical sciences. 2007 May 1;69(3).
33. Kuno Y, Kojima M, Ando S, Nakagami H. Effect of preparation method on properties of orally disintegrating tablets made by phase transition. International journal of pharmaceutics. 2008 May 1;355(1-2):87-92.
34. Desai C, Prabhakar B. Development and evaluation of orally disintegrating tablets of cilostazol-β-cyclodextrin inclusion

complexes. Drug development and industrial pharmacy. 2015 Oct 3;41(10):1589-607.
35. Shanmugam S. Granulation techniques and technologies: recent progresses. BioImpacts: BI. 2015 Feb 18;5(1):55.
36. Jacob S, Shirwaikar A, Nair A. Preparation and evaluation of fast-disintegrating effervescent tablets of glibenclamide. Drug Development and Industrial Pharmacy. 2009 Mar 1;35(3):321-8.
37. Zhang Y, Li Z, Tang H, Ren W, Gao X, Sun Y, Zhao QX, Wang F, Liu J. Development and optimization of levodopa and benzylhydrazine orally disintegrating tablets by direct compression and response surface methodology. Drug Development and Industrial Pharmacy. 2020 Jan 2;46(1):42-9.
38. 38 Tranová T, Macho O, Loskot J, Mužíková J. Study of rheological and tableting properties of lubricated mixtures of co-processed dry binders for orally disintegrating tablets. European Journal of Pharmaceutical Sciences. 2022 Jan 1;168:106035.
39. Reddy LH, Ghosh B. Fast dissolving drug delivery systems: A review of the literature. Indian journal of pharmaceutical sciences. 2002;64(4):331-6.
40. Kuchekar BS, Badhan AC, Mahajan HS. Mouth dissolving tablets: A novel drug delivery system. Pharma times. 2003 Jun;35(1):7-9.
41. Shyamala B, Narmada GY. Rapid dissolving tablets: A novel dosage form. The Indian Pharmacist. 2002;13(8):09-12.
42. Bradoo R, Shahani S, Poojary S, Deewan B, Sudarshan S. Fast dissolving drug delivery systems. Jama India. 2001;4(10):27-31.
43. Makino T, Yamada M, Kikuta JI, inventors; Takeda Chemical Industries Ltd, assignee. Fast dissolving tablet and its production. United States patent US 5,720,974. 1998 Feb 24.
44. Manivannan R. Oral disintegrating tablets: A future compaction. Drug Invention Today. 2009 Nov 1;1(1):61-5.
45. Sharma I, Sharma V. A comprehensive review on fast dissolving tablet technology. Journal of applied pharmaceutical science. 2011 Jul 30(Issue):50-8.
46. Sreenivas SA, Dandagi PM, Gadad AP, Godbole AM, Hiremath SP, Mastiholimath VS, Bhagawati ST. Orodispersible tablets: New-fangled drug delivery system-A review. Indian Journal of Pharmaceutical Education. 2005 Oct;39(4):177.
47. Pawar PB, Mansuk AG, Ramteke KH, Sharma YP, Patil SN. Mouth dissolving tablet: A review. International Journal of Herbal Drug Research. 2011;1(2):22-9.
48. Pandey P, Dahiya M. Oral disintegrating tablets: a review. International Journal of Pharma Research & Review. 2016 Jan;5(1):50-62.
49. Abay FB, Ugurlu T. Orally disintegrating tablets: a short review. Journal of Pharmaceutics & Drug Development. 2015 Jun 25;3(3):

HOW TO CITE: Vikram Choudhary, Deepak S, Gururaj Kulkarni, Oro Dispersible Tablets: Recent Advancements, Challenges and Future Perspectives, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 10, 2471-2486. https://doi.org/10.5281/zenodo.17433338