WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.453
Volume 14, Issue 21, 43-62. Review Article ISSN 2277–7105

"ORODISPERSIBLE TABLETS: A REVOLUTION IN ORAL MEDICINE"

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Article Received on 28 Sept. 2025,
Article Revised on 18 October 2025,
Article Published on 01 Nov. 2025,

https://www.doi.org/10.5281/zenodo.17471533

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How to cite this Article: *Sujay Yadav D. K., Dr. R. Yogananada, Chethan Patel DN, Varun Shankar, Pramod Sangam P. (2025). "Orodispersible Tablets: A Revolution In Oral Medicine". World Journal of Pharmaceutical Research, 14(21), 43–62.

ABSTRACT

Orodispersible tablets (ODTs) represent a pivotal advancement in oral drug delivery, engineered to disintegrate within seconds in the buccal cavity and thereby enhance therapeutic efficacy and patient compliance. They provide distinct advantages for geriatric, pediatric, and dysphagic populations by bypassing swallowing difficulties and improving dosing accuracy. Sophisticated formulation strategies, including lyophilization, sublimation, spray drying, and effervescent systems, have been integrated with novel excipient technologies to optimize disintegration, palatability and bioavailability. Recent progress in nanocrystals, microencapsulation, and co-processed excipients further extends their potential in taste masking and drug stability. Nonetheless, critical challenges remain in balancing rapid disintegration with mechanical integrity, cost-effectiveness and packaging robustness. This review encapsulates contemporary innovations, persisting limitations and the prospective evolution of ODTs as a transformative dosage form in modern pharmaceutics.

1. INTRODUCTION

Solid oral dosage forms remain the backbone of modern therapeutics, largely owing to their cost-effectiveness, stability, accurate dosing, and suitability for self-administration. Among them, tablets and capsules are the most extensively utilized; however, the clinical utility of these forms is often compromised by swallowing difficulties, a condition commonly referred to as dysphagia. This challenge affects not only geriatric and pediatric populations but also

individuals under conditions where water may not be readily available, such as during travel. Factors including tablet size, shape, surface texture, and palatability contribute to this limitation and have driven the pharmaceutical industry toward more patient-friendly alternatives.

In response to these challenges, researchers and technologists have introduced Orodispersible Tablets (ODTs), a novel oral dosage system designed to disperse or disintegrate rapidly in the oral cavity without the need for additional liquid. Typically disintegrating within seconds, ODTs are capable of releasing the active ingredient for absorption either through the oromucosal lining or further along the gastrointestinal tract. This dual pathway of absorption has expanded their relevance in various therapeutic areas and contributed to the growing recognition of ODTs as an important advancement in drug delivery science.[1]

ODTs are often referred to by various terminologies such as fast-dissolving tablets, mouth-dissolving tablets, rapid melts, porous tablets, and fast-disintegrating tablets. Despite the nomenclature differences, the central concept remains consistent: a formulation engineered to achieve rapid disintegration and drug release in the oral cavity. To standardize this definition, pharmacopoeias and regulatory agencies have established specific criteria. The European Pharmacopoeia describes ODTs as solid dosage forms that disperse within three minutes, while the United States Food and Drug Administration (FDA) defines them as formulations that disintegrate in seconds when placed upon the tongue. Similarly, the United States Pharmacopoeia (USP), the British Pharmacopoeia (BP), and the Center for Drug Evaluation and Research (CDER) have acknowledged ODTs as a distinct and recognized dosage form.[2]

The establishment of regulatory definitions and Pharmacopeia standards underscores the growing global acceptance of ODTs as a specialized formulation. Their evolution reflects a paradigm shift in oral drug delivery, moving beyond conventional tablets and capsules toward systems that integrate convenience, precision, and advanced formulation technologies. This review aims to explore the scientific foundation, formulation methodologies, technological innovations, evaluation parameters, and future directions of ODTs within the broader context of pharmaceutical research and development.[3]

1.1 Ideal Properties of Orodispersible Tablets (ODTs)[4, 5]

- Disintegrate rapidly in the mouth without water.
- Provide pleasant mouthfeel with no residue.
- Have adequate drug loading and dose uniformity.

- Exhibit sufficient mechanical strength and stability.
- Be compatible with taste-masking agents and excipients.
- Allow cost-effective and scalable manufacturing.
- Remain stable under normal storage conditions.

1.2 Advantages of Orodispersible Tablets (ODTs)[6,7]

- Suitable for patients with swallowing difficulties such as geriatrics, pediatrics, stroke victims, psychiatric patients, and bedridden individuals.
- Allow administration in situations where water is not readily available (e.g., during travel, outdoor settings, or emergency care).
- Enhanced palatability through taste-masking strategies and improved mouthfeel, particularly beneficial for pediatric and sensitive patient groups.
- Provide more accurate dosing compared to syrups or suspensions, eliminating issues of dosing variability.
- Combine the ease of liquid formulations with the stability and portability of solid dosage forms.
- Enable rapid drug absorption through the oral mucosa and upper gastrointestinal tract, resulting in faster onset of therapeutic action.
- Facilitate pre-gastric absorption, which helps bypass first-pass metabolism, improves systemic bioavailability, and can reduce required dose levels.
- Improve clinical outcomes by lowering side effects associated with fluctuating drug plasma levels.
- Enhance patient adherence by transforming the perception of tablets into a user-friendly format, often described as “melt-in-mouth” medication.
- Offer greater flexibility in drug design, making them suitable for a wide range of therapeutic agents, including poorly soluble drugs.
- Provide opportunities for product line extension, brand differentiation, and patent protection strategies for pharmaceutical companies.
- Useful in emergency conditions (e.g., migraines, allergic reactions, motion sickness, or pain management) where quick drug action is desired.
- Enable administration without risk of choking or aspiration, particularly important in pediatric and geriatric care.
- Can be developed with improved stability compared to liquid dosage forms, reducing the

need for preservatives.

- Support universal acceptance across patient demographics, making them a versatile dosage form in both developed and developing healthcare settings.

1.3 Disadvantages of Orodispersible Tablets (ODTs)[8]

- Hygroscopic nature requires moisture-protective storage.
- May cause unpleasant mouthfeel.
- Need special packaging for stability and safety.
- Dose uniformity and drug loading can be challenging.
- Often have higher production costs and lower mechanical strength.

Table 1: List of Marketed Orodispersible Tablets (ODTs).[9, 10]

Name of Drug	Brand Name	Manufacturer	Therapeutic Use
Acyclovir	Acivir DJ	Cipla	Anti-viral agent
Cefixime	Cefinar DJ	Zydus Alidac	Anti-bacterial agent
Mirtazapine	Remeron Soltab	Organon	Antidepressant
Piroxicam	Feldene Fast Melt	Pfizer, NY, USA	NSAID
Ondansetron	Zofran ODT	Glaxo Wellcome	Anti-emetic
Nimesulide	Esulide MD	Doff Biotech	NSAID
Mosapride	Mosid MD	Torrent Pharma	Migraine treatment
Valdecoxib	Valus	Glenmark	NSAID
Loratadine	Alavert	Wyeth	Anti-allergic
Olanzapine	Zyprexa	Eli Lilly, Indianapolis	Anti-psychotic
Famotidine	Pepcid RPD	Merck & Co., NJ	Anti-ulcer
Selegiline	Zelpar TM	Amarin Corp., London	Anti-parkinsonism

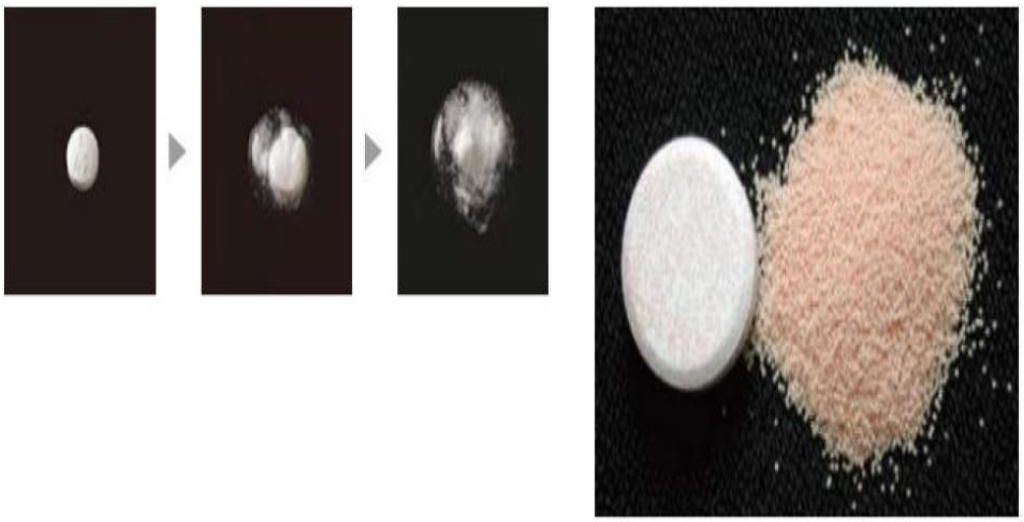

Figure 1: Orodispersible tablets.

2. Preparation of Orodispersible Tablet

2.1 Method of Preparation

2.1.1 Direct compression

It is a highly favored method in pharmaceutical tablet manufacturing due to its simplicity, efficiency, and cost-effectiveness. Unlike wet or dry granulation, direct compression allows the formulation of tablets by compressing powders directly, eliminating the need for heat or moisture, which makes it especially suitable for thermolabile and moisture- sensitive drugs. The success of this method depends on the use of powders with excellent flow properties and compressibility, along with the careful selection of excipients such as diluents (microcrystalline cellulose, lactose, dibasic calcium phosphate), binders, disintegrants (crospovidone, sodium starch glycolate), and lubricants. Direct compression provides advantages such as uniform drug distribution, reduced processing time, and scalability for large-scale production. However, it has limitations, including poor compressibility of certain active pharmaceutical ingredients and potential variability in tablet hardness and friability. Despite these challenges, direct compression continues to be a preferred method for formulating conventional tablets, orodispersible tablets, chewable tablets, and other solid dosage forms, owing to its ability to maintain drug stability, enhance patient compliance, and simplify manufacturing processes.[11]

2.1.2 Nanonization

Nanonization is the process of reducing drug particles to the nanometer scale, typically less than 1,000 nm, to enhance their physicochemical and biopharmaceutical properties. This technique primarily aims to improve the solubility, dissolution rate, and oral bioavailability of poorly water-soluble drugs. By decreasing particle size, the surface area increases significantly, resulting in faster dissolution according to the Noyes-Whitney principle and improved gastrointestinal absorption. Nanonization can be achieved through top-down approaches such as high-pressure homogenization and wet milling, which break down larger particles, or bottom-up approaches like precipitation, where drug molecules self-assemble into nanoparticles. The resulting nanosuspensions are typically stabilized with surfactants or polymers to prevent aggregation and ensure physical stability. Nanonized formulations have demonstrated enhanced pharmacokinetic profiles, reduced dose requirements, and improved therapeutic efficacy. Despite these advantages, challenges such as particle aggregation, long-term stability, and scalable production need to be carefully addressed during formulation development.

Melt Granulation

Melt granulation is a solvent-free technique in which pharmaceutical powders are agglomerated using a meltable binder, making it an environmentally friendly and efficient alternative to conventional wet or dry granulation. High-shear mixers, equipped with a heating jacket or relying on frictional heat from impeller blades, raise the product temperature to the melting point of the binder, enabling uniform granule formation. Waxy hydrophilic binders such as Superpolystate© (PEG-6-stearate), with an HLB value of 9 and a melting range of 33–37°C, are widely employed. These binders provide excellent mechanical integrity to fast-dissolving tablets (FDTs) while promoting rapid disintegration and dissolution in the oral cavity without leaving any residue. The method also offers better control over granule size, density, and compressibility, which translates to improved tablet uniformity and reproducibility.[12]

Cotton Candy Process

The cotton candy process is named after the floss-like crystalline structures it produces, which resemble spun sugar, and is sometimes referred to as the candy floss technique. In this process, polysaccharides or saccharides are flash-melted and spun simultaneously to form a light, porous matrix, which is then partially recrystallized to enhance flowability and compressibility. The resulting material is ground, mixed with active ingredients and excipients, and compressed into ODTs with enhanced mechanical strength. This technique allows high drug loading and produces tablets with rapid disintegration and improved mouthfeel. However, its application is limited by the high temperatures required, which may affect thermolabile drugs, necessitating careful optimization of process parameters.

Mass Extrusion

Mass extrusion involves softening the drug-excipient blend using a solvent system, commonly a mixture of water-soluble polyethylene glycol and methanol. The softened mass is then extruded through a syringe or extruder to form uniform cylindrical shapes, which are segmented into tablets using a heated blade. This approach allows precise control over tablet size, shape, and weight, making it suitable for personalized dosing or multiparticulate systems. Additionally, the process can be combined with flavoring or colorants to enhance patient acceptability, particularly in pediatric formulations.[13]

Phase Transition

The phase transition technique leverages the differential melting properties of sugar alcohols

to produce ODTs with optimal hardness and rapid disintegration. Tablets are formulated with two sugar alcohols—one with a high melting point and the other with a low melting point—and then heated to induce particle bonding. This selective fusion creates a robust tablet matrix that maintains mechanical strength while allowing rapid oral dissolution. The method is versatile, capable of accommodating various excipients and active drugs, and provides an efficient, solvent-free approach to producing ODTs with consistent quality attributes.

Freeze Drying or Lyophilization

Freeze drying, also known as lyophilization, is a technique in which a frozen drug solution or suspension containing excipients is subjected to solvent removal under low- temperature conditions. This process produces extremely light and porous tablets that dissolve rapidly in the oral cavity. The combination of the amorphous, glassy structure of excipients and the finely dispersed drug enhances solubility and bioavailability. The lyophilization process typically involves three stages: (1) freezing the material below its eutectic point, (2) primary drying to remove about 4% of residual moisture, and (3) secondary drying to achieve the desired low moisture content. Conducting the entire procedure at low temperatures minimizes thermal degradation, preserving the stability of heat-sensitive drugs.[14]

Tablet Molding

Molded tablets are generally composed of water-soluble excipients and are produced by moistening the powder blend with a solvent, such as ethanol or water, and shaping it into tablets under low pressure. The solvent is subsequently removed by air drying, resulting in tablets with a highly porous structure that facilitates rapid dissolution. To enhance dissolution further, the powder blend is often passed through a fine mesh before molding. Recent advancements include vacuum lyophilization for molded forms and the preparation of tablets directly from molten matrices, enabling uniform distribution of the active ingredient and rapid disintegration.

Spray Drying

Spray drying is a widely used technique for producing highly porous, fine powders suitable for orally disintegrating tablets (ODTs). In this method, the liquid drug-excipient blend is atomized into a hot drying chamber, forming rapidly dried particles with a highly porous structure. Typical excipients include mannitol as a bulk agent, hydrolyzed or unhydrolyzed gelatin, and disintegrants such as sodium starch glycolate and croscarmellose sodium, while citric acid and sodium bicarbonate can further enhance dissolution. ODTs prepared using spray

drying often disintegrate in less than 20 seconds, demonstrating superior performance compared to direct compression, particularly when using excipient bases like Kollidon CL.

Sublimation

Sublimation is employed to create highly porous tablets by incorporating volatile substances such as camphor, urea, ammonium bicarbonate, or hexamethylenetetramine into the formulation. The mixture is compacted into tablets, and the volatile components are removed through sublimation, leaving behind a porous structure that facilitates rapid disintegration. For instance, camphor can be sublimated under vacuum at 80°C for 30 minutes to create pores, resulting in tablets that disintegrate within 10–20 seconds. Additionally, various solvents, including benzene and cyclohexane, can be used as pore-forming agents to further enhance porosity and dissolution rates.[15]

2.2 Latest Patented Technologies[16]

Table represents the patented technologies and the technique used in the preparation of Orodispersible tablets.

S.No	Technology Name	Technique / Key Feature
1	Zydis	Freeze drying process
2	Lyoc	Freeze-dried emulsion
3	Shearform	Heat flash process
4	Flashdose	Self-binding shear form matrix
5	Flashtab	Microgranulation of microcrystals
6	Quick-dis	Thin, flexible & quick film
7	Durasolv	High compaction pressure
8	OT	Low compression force
9	Wowtab	Two different types of saccharides
10	Oraquick	Microencapsulation
11	Nanocrystal	Nanocrystal technique
12	Ziplet	Water-soluble inorganic excipients
13	Pharma burst	Co-processed excipients

3. Excipients used in Formulation of Orodispersible Tablets[17,18,19]

Excipients used in the formulation of fast-dissolving tablets (FDTs) typically include superdisintegrants, diluents or bulking agents, and lubricants, along with optional components such as swelling agents, permeabilizing agents (depending on the nature of the drug), sweeteners, and flavoring agents. In addition, binders, glidants, and saliva-stimulating agents may also be incorporated to improve tablet integrity, enhance flow properties, and facilitate rapid disintegration. Collectively, these excipients play a crucial role in ensuring the

mechanical strength, palatability, stability, and overall performance of FDTs, thereby contributing significantly to patient compliance and therapeutic effectiveness.

3.1 Super Disintegrants

In direct compression-based ODT technologies, the incorporation of superdisintegrants plays a vital role in enhancing the rate of disintegration and thereby improving drug dissolution. The use of additional excipients such as water-soluble agents and effervescent substances can further accelerate this process. Superdisintegrants are blended into the formulation to improve compatibility, enhance compressibility, and minimize any reduction in mechanical strength, thus supporting the development of various dosage forms including fast-dissolving tablets, mouth-dissolving tablets, capsules, and orodispersible tablets. These agents are generally classified into two types: natural and synthetic. Natural superdisintegrants, which are derived from plant or natural sources, are non-toxic and non-irritating, with common examples including soy polysaccharide, isapghula husk mucilage (Plantago ovata), chitosan, guar gum, and agar. Synthetic superdisintegrants, on the other hand, are chemically derived and widely used due to their high efficiency and reproducibility; typical examples include croscarmellose sodium, sodium starch glycolate, and crospovidone.

3.2 Emulsifying agents

These compounds are used to quickly dissolve and release the medication without requiring the user to swallow, drink water, or chew the tablet. When the final formulation is developed, they can be added in amounts ranging from 0.05% to 15% by weight. A variety of emulsifying agents are employed including lecithin, propylene glycol esters, and sucrose esters.

3.3 Bulking substances

Bulking substances play a crucial role in the formulation of orally disintegrating tablets (ODTs) by enhancing bulkiness, improving texture, and optimizing oral dissolving time. These excipients not only provide the required mass for tablet compression but also contribute to mouthfeel and patient acceptability. Commonly used bulking agents include mannitol, fructose, sorbitol, and lactose derivatives, which impart a smooth texture, pleasant taste, and cooling effect in the oral cavity. In addition to improving palatability, bulking substances also aid in the stability of the formulation and ensure uniform distribution of the active pharmaceutical ingredient, thereby contributing to both functionality and patient compliance.

3.4 Effervescent agents

The patented Orasolv technology (OT), which is widely utilized to create over-the- counter medications, is based on the evolution of CO2 as a disintegrating mechanism. The product contains microparticles and is slightly effervescent in nature. The tablet dissolves when the effervescent agent is activated by saliva.

3.5 Sugar based excipients

This is another direct compression approach for creating ODT. Sugar-based excipients include bulking agents like dextrose, fructose, lactitol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose, and xylitol, especially those with high water solubility and sweetness. These substances also offer a pleasant mouthfeel and taste-masking abilities. Based on the dissolution rate and molding, Mizumito et al. classified sugar-based excipients into two groups.

3.6 Diluents

Diluents are essential excipients in ODT formulations, primarily used to increase tablet bulk, improve compressibility, and enhance mouthfeel. Commonly used diluents include magnesium trisilicate, mannitol, magnesium carbonate, sorbitol, calcium carbonate, and xylitol. Depending on the formulation requirements, their concentration may range from 0–85%.

3.7 Binders

Binders are incorporated to impart cohesion to the powder blend, ensuring adequate tablet strength and integrity during handling and storage. Frequently used binders in ODTs include polyvinylpyrrolidone (PVP), polyvinyl alcohol, and hydroxypropyl methylcellulose (HPMC), generally employed in concentrations of 5–10%.

3.8 Antistatic agents

Antistatic agents are added to prevent electrostatic charges during processing, which can otherwise cause handling difficulties and poor powder flow. Examples include sodium lauryl sulfate, sodium dodecyl sulfate, polyoxyethylene sorbitan fatty acid esters, and polyoxyethylene stearates, typically used in concentrations ranging from 0–10%.

4. Evaluation of Orodispersible Tablet[20,21]

4.1 Pre-compression parameters

4.1.1 Angle of repose

Using a fixed funnel approach, the angle of repose of powder was measured. A funnel was used to hold the precisely weighed amount of powder mixture. The funnel was kept at a height where the tip of the funnel just touched the top of the powder pile. The powder was allowed to flow through the funnel without any resistance on to the surface. Measurements were taken for the powder cone's height and diameter.

The following formula was used to find the angle of repose:

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

Where,

h is the powder cone's height and r is its radius.

Following is the table of flow properties based on the Angle of Repose:

Sl. No.	Angle of° Repose ()	Type of Flow
I.	25 to 30	Excellent
II.	31 to 35	Good
III.	36 to 40	Fair
IV.	41 to 45	Passable
V.	46 to 55	Poor
VI.	56 to 65	Very Poor
VII.	> 66	Very Very Poor

4.1.2 Bulk density and tapped density

A 25-mL measuring cylinder was filled with 5 g of powder. To break up any agglomerates that might have developed, it was first given a gentle shake. After recording the initial volume, the cylinder was let to tall on a hard surface by itself at intervals of two seconds, at a height of 2.5 cm. Until a constant volume was noticed, tapping was continued. Using the following formulas, the loose bulk density (LBD) and the taped bulk density (TBD) were determined:

LBD = Weight of the powder / volume of the packing TBD =Weight of the powder / tapped volume of packing

4.1.3 Compressibility Index

The compressibility index of granules was determined using Carr's Compressibility Index, which provides an indication of the flowability of powders. It was calculated using the following formula:

Carr's Compressibility Index (%) = (TBD−LBD) TBD×100

Following is the table of relation between %Compressibility and flowability:

Sl. No.	%Compressibility	Flowability
I.	<10	Excellent
II.	11 to 15	Good
III.	16 to 20	Fair
IV.	21 to 25	Passable
V.	26 to 31	Poor
VI.	32 to 37	Very Poor
VII.	> 38	Very Very Poor

4.1.4 Hausner Ratio

Measurement of the flow property of the drug-excipients mixed powder. The formula for calculating Hausner Ratio is:

Hausner Ratio = Tapped Density / Bulk Density.

Following is the table of relation between Hausner Ratio and Flowability:

Sl. No.	Hausner Ratio	Flowability
I.	1.00 to 1.11	Excellent
II.	1.12 to 1.18	Good
III.	1.19 to 1.25	Fair
IV.	1.26 to 1.34	Passable
V.	1.35 to 1.45	Poor
VI.	1.46 to 1.59	Very Poor
VII.	> 1.60	Very Very Poor

4.1.5. Porosity

Experimentation can confirm the expectations that porosity is an excellent indicator of how liquids will penetrate the tablet matrix. In a study on the development of tablet formulations, tablet volume and total weight were used to calculate the porosity values. The equation helps to calculate the porosity is:

% (€) = [(1 - (W/Vρ)) x 100]

Where,

W = Tablet weight, V = Tablet volume,

ρ = Powder True density

4.2 Post-compression parameters

4.2.1 Content uniformity

To ascertain if the individual content is within the limit, the assay of the drug substance(s) in several individual dosage units serves as the basis for the uniformity of content test. Tablets containing less than 25 mg or less than 25 percent of a single tablet must undergo the content uniformity test. Using the assay-described procedure, the active component content is ascertained in each of the ten dosage units that are consumed at random. If every component contains 85–115% of the average content, the preparation passes the test.

4.2.2 Hardness (crushing strength)

Tablet hardness is measured with hardness testers like Monsanto. A tablet is placed in the hardness tester and load required to crush the tablet is measured. The hardness of ODTs is generally kept lower than conventional tablets as increased hardness delays the disintegration of the tablet. The force is measured in kg and the hardness of about 3-5 kg/cm2 is considered to be satisfactory for uncoated tablets.[22]

4.2.3 Tablet Thickness

Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets were taken and their thickness was recorded using micrometer.

4.2.4 Friability

According to Pharmacopoeia a friability test should be done for 4 minutes at 25 rpm (100 rotations). The maximum acceptance limit for weight loss is 1% of its original weight. After tumbling, if any tablet gets cracked, chipped or broken, the whole sample gets disqualified from the test41. The test is not performed for tablets made with the Lyophilization technique or Flash dose Technique. But for tablets made with the direct compression method and moulding method, this test is most recommended. The purpose of this test is to make sure the tablet has sufficient mechanical strength to endure shipping related abrasion.[23]

The percentage of Friability can be determined by this equation:

$$\% \text{ Friability} = \{(W1 - W2) / W1\} \times 100$$

Where,

W1 = Initial weight, W2 = Final weight.

4.2.5 Moisture Uptake Study

A lot of hydrophilic additives with least amount of hardness is contained in ODTs, which collectively increases their sensitivity to moisture absorption. Special care must be taken when storing and packaging these forms of dosage to safeguard their structural integrity and surface texture. Therefore, it is strongly recommended to perform moisture uptake study for ODTs. Ten tablets can be used for the test, along with calcium chloride, and they can be kept in a desiccator for a day at room temperature. After weighing keep it in room temperature for two weeks at 75% relative humidity.

The weight gain percentage is calculated after reweighing the tablets. A product needs a dedicated dehumidified room for manufacture and packaging if its tendency to absorb moisture is high. For packaging, it is best to utilize materials with a high degree of moisture resistance. It is strongly advised to use an appropriate amount of adsorbent in HDPE bottle pack with the least amount of head space possible to ensure the longevity of the product throughout its shelf life.

4.2.6 Weight variation test

A digital balance was used to weigh each of the twenty tablets that were randomly selected. To calculate weight variation, the average weight and each individual weight were recorded and compared.[24]

4.2.7 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 waterabsorption ratio, the weight of the tablet before keeping in the petridish is noted

(Wb).The wetted tablet from the petridish is taken and reweighted (Wa).

The water absorption ratio, R can be determined according to the following equation:

R = 100 (Wa – Wb)/Wb.

4.2.8 Disintegration time

According to the European pharmacopoeia the fast disintegrating or Orodispersible tablets should disintegrate within 3 minutes without leaving any residue on the screen. However it is difficult to assess the disintegration rate even in small amounts of water. Further the conventional test employs a volume of 900 ml of distilled water compared to the volume of saliva in humans, which is limited to a few ml. Thus the disintegration rate obtained from conventional test does not appear to reflect the actual disintegration rate in human mouth. To overcome these problems, several new methods have been proposed. One of these methods uses a Charge Couple Device (CCD) camera or texture analyser to evaluate the disintegration time of tablets. In another method, a modified DT apparatus is used. Here a wire basket of 3cm height and 2 cm diameter and mesh size of #10 is placed above a beaker containing 900 ml of simulated saliva. The basket is so positioned in the liquid that it contains only 6 ml of the liquid. The assembly is supported with a heater to maintain temperature at 37°C and a magnetic stirrer. DT is noted at 25 rpm. One of the simplest methods is to take 6ml of simulated saliva in a measuring cylinder and place the tablet in it. The liquid is neither shaken nor stirred and DT is noted.[25]

4.2.9 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 rotations/min is used for dissolution testing. Swammy et al. carried out in vitro dissolution study of orodispersible tablets in type II apparatus with 550 r/min using 900 ml phosphate buffers at 37±0.5°C as a dissolution medium. USP type I basket apparatus have certain application 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.

4.2.10. Stability Study

The ICH recommendations for accelerated studies specify that the tablets which fast dissolves

is kept in specific conditions for a certain duration of time after being packaged, i.e. at 37±1°C, 40±1° and 50±1°C, with a RH of 75%±5%. Then the removal of tablets and their physicochemical properties (like hardness, friability, visual flaws disintegration, and so on) and content of drug were examined after 15 days. First order equation is employed to determine the degradation kinetics. The shelf life at 25°C is calculated using accelerated stability data displayed with the Arrhenius equation.[26]

5. Challenges in Formulation of ODT[27, 28]

5.1 Mouth feel

ODTs should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the ODTs should be as small as possible. ODTs should leave minimal or no residue in mouth after oral administration. Moreover addition of flavours and cooling agents like menthol improve the mouth feel.

5.2 Disintegration Time and Mechanical Strength

ODTs are designed to achieve disintegration times that are typically less than sixty seconds. A major issue when doing this is maintaining strong mechanical strength. Most oDTs are fragile, so there is a good probability that a few of these fragile tablets will shatter while being packed, transported, or handled by patients. Special packaging is required for tablets built with some patented technology like Zydis. It makes perfect sense that improving mechanical strength will decrease the disintegration process. So, it's always important to find a decent balance between both of these variables.

5.3 Tastes masking

Many drugs are bitter in taste. A tablet of bitter drug dissolving/ disintegration in the mouth will seriously affect patient compliance and acceptance for the dosage form. In order to prevent the bitter medication from being detected in the mouth, it is necessary to effectively mask its bitter taste.

5.4 Hygroscopicity

Under normal storage conditions of temperature and humidity, most of the orally disintegrating dosage forms cannot maintain their physical integrity due to their hygroscopic nature. As a result, they require humidity protection, necessitating the use of specific product packaging.

5.5 Size of tablet

The degree of ease when taking a tablet depends on its size. It has been reported that the easiest size of tablet to swallow is 7-8 mm. While the easiest size to handle was one larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve.

5.6 Amount of Drug

The maximum amount of drugs which can be included in a single dose restricts the applicability of MDT technology for MDTs. The amount of drug used during lyophilized formulations must be below 400 mg in insoluble drugs as well as below 60 mg in soluble drugs. This characteristic presents a challenge when creating oral film and wafer that dissolve quickly.

5.7 Cost

When it comes to the price of the finished product, the methods employed for MDT preparation need to be affordable. The cost is significantly increased by techniques including Orasolv and Zydis which require special equipment and unique packaging.

6. CONCLUSION

Oally Disintegrating Tablets (ODTs) represent a significant advancement in modern drug delivery, offering a convenient, effective, and patient-friendly alternative to conventional dosage forms, particularly for populations with swallowing difficulties such as pediatric, geriatric, and dysphagic patients. By eliminating the need for water, ODTs enhance medication adherence and provide faster onset of action, thereby improving therapeutic outcomes. However, their formulation presents multiple challenges, including balancing mechanical strength with rapid disintegration, achieving effective taste masking, addressing poor aqueous solubility, managing drug load limitations, and controlling tablet size. Additional concerns such as hygroscopicity, friability, stability, mouthfeel, and the need for robust packaging further complicate development. With continuous advancements in excipient design, manufacturing technologies, and novel drug delivery approaches, many of these hurdles are being effectively overcome, paving the way for more stable, scalable, and patient-compliant ODT formulations. Overall, ODTs hold immense potential to improve patient compliance, expand therapeutic applications, and contribute significantly to the evolution of pharmaceutical care.

7. Future Prospective

The future of Orally Disintegrating Tablets (ODTs) lies in the integration of advanced formulation strategies and innovative technologies aimed at overcoming current limitations. The use of novel excipients with multifunctional properties, nanotechnology-based drug delivery systems, and particle engineering approaches can significantly enhance solubility, stability, and bioavailability of poorly water-soluble drugs. Furthermore, emerging techniques such as 3D printing and hot-melt extrusion offer great potential for designing personalized ODTs with precise drug dosing and improved patient acceptability. Research into taste-masking agents, saliva-stimulating excipients, and novel packaging systems will also play a key role in enhancing the overall patient experience. With continued advancements in material science and manufacturing technologies, ODTs are expected to evolve into more robust, versatile, and patient-centric dosage forms, contributing to improved therapeutic outcomes and broader clinical applications in the future.

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