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ORODISPERSIBLE TABLETS: A REVOLUTIONARY APPROACH TO ORAL DRUG DELIVERY– A REVIEW

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ABSTRACT

The oral route remains the most widely used and convenient method for drug administration, offering various dosage forms such as tablets, capsules, syrups, suspensions, and elixirs. However, certain patient populations—including children, the elderly, and bedridden individuals—often face challenges in swallowing conventional solid dosage forms. To overcome these limitations, researchers have developed orodispersible tablets (ODTs), an innovative drug delivery system designed to dissolve quickly in the mouth without the need for water. Orodispersible tablets enhance patient compliance, particularly in populations with swallowing difficulties, while also improving drug bioavailability and ensuring faster onset of action. Their convenience allows administration anytime and anywhere, making them an ideal alternative to traditional formulations. The production of ODTs involves various advanced techniques, including tablet molding, spray drying, freeze drying, sublimation, and mass extrusion, alongside newly developed patented technologies. These methods ensure the rapid disintegration and effective drug release of ODTs, making them a preferred choice in modern pharmaceutical formulations

KEYWORDS: Orodispersible tablets, Rapid disintegration, Drug bioavailability, Patient-friendly dosage forms, Advanced formulation techniques.

INTRODUCTION

Across the years, the demand for the development of orally disintegrating tablets (ODTs) has significantly increased due to their positive impact on patient compliance. ODTs provide a crucial advantage for individuals who experience difficulty swallowing, such as pediatric, geriatric, and bedridden patients. Dysphagia, a condition characterized by difficulty in

swallowing, affects a large portion of the population, including elderly individuals and patients with neurological disorders. Conventional solid dosage forms can pose challenges for these individuals, leading to poor adherence to prescribed medications. ODTs effectively address this issue by disintegrating rapidly in the mouth without the need for water, ensuring ease of administration and improving overall treatment outcomes.

The rising preference for ODTs in the pharmaceutical industry has driven advancements in formulation technologies, including direct compression, freeze drying (Lyophilization), spray drying, and sublimation techniques. These methods enhance the disintegration and dissolution properties of the tablets, ensuring rapid drug release and improved bioavailability.

With their ability to enhance medication adherence and provide a convenient alternative to traditional tablets and capsules, ODTs continue to gain widespread acceptance in modern drug delivery systems.[1] One of the key factors influencing the success of orally disintegrating tablets (ODTs) is their taste and flavor. By effectively masking bitterness, ODTs improve palatability, making them more acceptable across different patient populations, particularly children and elderly individuals who may struggle with conventional tablets. A pleasant taste enhances compliance, ensuring patients adhere to their prescribed treatments without hesitation. ODTs are known by various names, including quick-disintegrating tablets, mouth-dissolving tablets, fast-dissolving tablets, rapid-dissolving tablets, porous tablets, and rapimelts. However, the United States Pharmacopoeia (USP) officially classifies these formulations as orally disintegrating tablets (ODTs).

In addition, the European Pharmacopoeia defines orodispersible tablets as those that disperse in the mouth within three minutes before swallowing. This rapid disintegration makes ODTs an ideal choice for patients who experience difficulty swallowing or require medication without water, offering a convenient and effective alternative to traditional dosage forms. With advancements in pharmaceutical technology, ODTs continue to gain popularity, providing faster drug absorption, improved patient compliance, and enhanced therapeutic outcomes.

As research and innovation progress, ODTs are expected to become a standard in modern drug delivery.[2,3]

Ideal properties of ODTs[4]

1. No requirement of water when taking by oral route.
2. ODTs are easily disperse or breakdown in saliva within few seconds, which placed on tongue.
3. Pleasant taste and smell.
4. No residue is present on the mouth when administered.
5. Transportation is easy.
6. Easily handled.
7. Environmental conditions like temperature, humidity etc. is less susceptible.
8. Low cost.
9. Compatible with taste masking.

Advantages of ODTs[5,6,7]

1. No need for water – ODTs can be taken without water, making them convenient for patients in any situation.
2. Easy administration – Suitable for all patient groups, including pediatrics, geriatrics, and bedridden individuals.
3. Improved patient compliance – More acceptable than conventional tablets, especially for those with swallowing difficulties (dysphagia)
4. Accurate dosage – Ensures precise dosing compared to liquid formulations, reducing the risk of under- or overdosing.
5. Rapid drug dissolution – The drug dissolves quickly in the mouth, allowing for faster absorption and effectiveness.
6. Fast onset of action – ODTs work faster than conventional tablets as they begin dissolving immediately upon contact with saliva.
7. No need for chewing – Unlike chewable tablets, ODTs disintegrate effortlessly in the mouth.
8. Ideal for travel – Convenient to carry and use in situations where water is unavailable, such as during travel.
9. High chemical stability – More stable than liquid dosage forms, reducing the risk of degradation.
10. Protection from degradation – The drug is shielded from pH variations and gastrointestinal (GIT) enzymes, ensuring stability.

11. Enhanced bioavailability – Faster absorption through the oral mucosa improves drug effectiveness and therapeutic outcomes.

Disadvantage of ODTs[8,9]

1. Risk of dose dumping – Uncontrolled or rapid drug release may occur, potentially affecting safety and efficacy.
2. Specialized packaging required – Due to their moisture sensitivity, ODTs require protective packaging, increasing production costs.
3. Lower mechanical strength – ODTs are more fragile than conventional tablets and must be handled with care to prevent breakage.
4. Moisture sensitivity – Since ODTs absorb moisture easily, they must be stored in a controlled environment with low humidity and stable temperature.
5. Fragility issues – Some ODT formulations are highly fragile, making transportation and handling more challenging.

Challenges in formulated of ODTs[10]

1. Mechanical strength and disintegration
2. Tastes masking
3. Aqueous solubility
4. Size of tablets
5. Amount of drug
6. Hygroscopicity
7. Mouth feel
8. Sensitivity to environmental conditions

Methods for formulation of ODTs

Various methods used in the formulate of mouth dissolving tablets / orodispersible tablets include:

1. Freeze-drying or lyophilization
2. Sublimation
3. Spray drying
4. Tablet moulding
5. Mass extrusion
6. Direct compression

Freeze drying or lyophilization: Freeze-drying, or lyophilization, is a highly effective method for formulating orodispersible tablets (ODTs). It results in tablets with high porosity and quick disintegration properties, making them ideal for rapid dissolution in the mouth. Here's a detailed explanation of the process: In this method, the product undergoes freezing followed by sublimation, which removes the water content. The process begins by freezing the drug formulation, which forms ice crystals. At this stage, the eutectic point (the temperature and pressure at which the freezing point of a substance is lowered) is crucial, as it determines the point at which sublimation occurs.[5]

Sublimation: The sublimation technique is an effective method used to create orodispersible tablets (ODTs) with a highly porous structure, enabling rapid dissolution. This method involves integrating volatile substances with the other tablet ingredients to generate a porous matrix that dissolves quickly when placed on the tongue.[11]

Spray drying: This system is generally used when need of fine powder and porous materials. In this method the mannitol is use as a bulk forming agent and gelatin is use as a supporting agent. For better dissolution and disintegration characteristics effervescent agents can also be employed. At last the prepared mass is spray dried to form a porous powder.

Tablet molding: Tablet molding is an effective method for preparing orodispersible tablets (ODTs), particularly when a rapid dissolution rate is desired. This technique is suitable for formulating tablets that dissolve quickly in the mouth without requiring water. Here all the solid ingredients are dissolved in hydroalcoholic solvents, after that at a lower pressure the dispersible tablets are compressed. After compression the solvent is shelved by airdrying method. The resultant material is very permeable in nature which offers great dissolution.[12]

Mass extrusion: This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol and methanol and subsequent expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablets.[13]

Direct compression: Direct compression is one of the most commonly used and simplest methods for preparing orodispersible tablets (ODTs). This technique involves compressing a blend of the active pharmaceutical ingredient (API) and excipients directly into a tablet form without the need for any solvent or liquid processing.

Advantages of direct compression for ODTs

1. Less time and low energy required.
2. It is cost effective.
3. Hard tablets are formed so not fragile.
4. Easy to handle.
5. No requirement of granulator and dryer.
6. No specific packaging is required.

Excipients used in the formulation of odt tablets

Excipients play a major role to formulate the ODT tablet so some excipients are –

1. Disintegrants

These excipients are crucial in enhancing the rapid disintegration of ODTs. They help the tablet break down quickly when it comes into contact with saliva, ensuring a fast onset of action.

a. Sodium starch glycolate
b. Croscarmellose sodium
c. Crosslinked polyvinylpyrrolidone (PVP)
d. Crospovidone
e. Sodium carboxymethylcellulose

2. Emulsifying agents

These agents are used to rapidly dissolve and liberate the drug without required drinking water or swallowing and no need for chewing the tablet. These can be added of about 0.05% to 15% by the weight of the final formulation is prepared. Some emulsifying agents are used like Sucrose esters, propylene glycol esters, lecithin etc.

3. Flavoring & Sweetening agents

These agents are use to make the orodispersible tablets more palatable and pleasing for patients and sweeteners to improve the pleasant taste in formulation and some sweeteners are dextrose, sugar, fructose & sodium saccharine etc.[14]

4. Bulking substances

These agents are play a major role to enhance the bulkiness property of formulation and to get the texture and to increase the dissolution time in mouth. Some agents included mannitol, lactose derivatives, sorbitol, fructose etc.[15]

Evaluation parameters

Precompression parameters

1. Angle of repose
2. Bulk Density
3. Tapped Density
4. Carr's index

1. **Angle of repose:** The angle of repose of powder was carried out using the fixed funnel method. The accurately weighed quantity of powder mix was taken in a funnel. The height of the funnel was maintained in such a way that the tip of the funnel just touched the apex of the heap of the powder. The powder was allowed to flow through the funnel without any resistance on to the surface. The diameter and height of the powder cone was measured.[16]

The angle of repose was determined using the following equation:

Tan θ= h/r,

where h and r are the height and radius of the powder cone, respectively.

2. **Bulk density:** It was measured with the help of measuring cylinder. Firstly weigh required volume of the powder and transfer into a measuring cylinder and initial weight is noted. So the initial volume is known as the bulk volume.[17,18]

It is expressed in g / ml and the formula is given below:

Bulk Density = Weight of Powder / Volume of Powder

3. **Tapped density:** It is the ratio of total mass of the powder to the tapped volume of the powder. Volume was measured by tapping the powder for 750 times and the tapped volume was noted if the difference between these two volumes is less than 2%. If it is more than 2%, tapping is continued for 1250 times and tapped volume was noted. Tapping was continued until the difference between successive volumes is less than 2 % (in a bulk density apparatus). [17,18]

The formula is given by Tapped Density = Weight of Powder / Volume of Powder

4. **Carr's index:** Carr's Index is an important parameter used to assess the flow properties of powders, particularly in the pharmaceutical industry. It gives an indication of how well a powder will compress and flow, which is essential for processes like tablet formulation.

A high or low Carr's Index can suggest how easily powders can be processed into tablets or capsules.

Formula for Carr's Index:

Carr's Index (CI)=Tapped Density−Bulk Density /Tapped Density×100

Where:

Tapped density: The density of the powder after it has been subjected to tapping, which compacts the powder and reduces the air spaces between particles.

Bulk density: The density of the powder in its loose state, with air spaces between the particles. [17,18]

Postcompression parameters

1. Weight variation test
2. Thickness
3. Hardness
4. Friability
5. In vitro disintegration test
6. Wetting time
7. In vitro dissolution study

1. **Weight variation test:** Each film was subjected for weight variation study by individually weighing the film. The average weight of each formulation is calculated.[19]

2. **Thickness:** The thickness of ODTs which can be determined using Varnier calipers. The test is done on an average of five tablets.[20]

3. **Hardness:** Hardness is a vital parameter that prevents breakage of tablets during transportation, handling, and storage. The hardness of tablet was measured with the Monsanto hardness tester.

4. **Friability:** Friablity means measure the mechanical strength of the tablet during the transportation. These testing are tested by using the friabilty tester or friabilator. In this testing, the ten tablets are weighted and placed in a transparent chamber of the friabilator and the chamber rotating at 25rpm for 4 minutes, where height of 6 inches. During this process, the loss of tablet weight due to abrasion effects and complete the process then reweighted the tablets and calculate the % friability by this formula.[21]

F = (1- Wi / Wf) x 100

Where,

Wi = Initial weight of the tablets

Wf = Final weight of the tablets

5. **In vitro disintegration test:** The tablet disintegration test apparatus was used to determine the disintegration time for all formulations. Six tablets were placed individually in each tube of disintegration test apparatus. The medium was maintained at a temperature of 37 ± 2 ◦C, and the time was noted for the entire tablet to disintegrate completely.[22]

6. **Wetting time:** A tissue paper was taken and folded twice and placed in a Petri dish (with an internal diameter of 5 cm) containing 6mL of water. A tablet was cautiously placed on the top of the tissue paper in the Petri dish. Wetting time was noted as the time required for water to reach the upper surface of the tablet and to completely wet it.[23]

7. **In-vitro dissolution studies:** The USP dissolution test apparatus (Electrolab TDT - 08 L Dissolution testers USP) type 2 (paddle) was used. The medium was maintained at a temperature of 37 ± 2 ◦C, and the time was noted for the entire tablet to disintegrate completely. 900ml of buffer medium was used as the dissolution medium which was maintained at 37±0.5degree centigrade. Aliquots of dissolution medium (5ml) were withdrawn at specific time intervals and were filtered. The amount of drug dissolved was determined by UV spectrophotometer by measuring the absorbance of sample.[15]

CONCLUSION

Orally disintegrating tablets (ODTs) offer significant advantages over traditional dosage forms, making them an increasingly popular choice for both manufacturers and patients. The benefits of ODTs, including improved patient compliance, enhanced convenience, increased bioavailability, and rapid onset of action, have captured the attention of the pharmaceutical industry over the past decade. These tablets, formulated using various advanced technologies, possess sufficient mechanical strength and disintegrate quickly in the mouth without the need for water.

ODTs are especially beneficial for children who have lost their primary teeth and for geriatric patients who may struggle with swallowing conventional tablets due to the loss of teeth. This

makes ODTs a more accessible option for these populations. Additionally, ODTs combine the advantages of both solid and liquid dosage forms, as they remain stable in their solid state during storage and transform into a liquid form almost immediately after administration.

Looking ahead, ODTs have the potential to be developed for a wider range of drugs, offering a more patient-friendly and effective means of drug delivery. The continuous advancement of formulation techniques by researchers is helping meet the increasing demand from patients who seek more convenient and efficient ways to take their medications. As these innovations progress, ODTs are likely to become a widely used and versatile dosage form in the near future.

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