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Review Article

Oral Dispersible Tablet: Technologies, Challenges and Future Perspectives

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ABSTRACT

Oral route of drug administration is the most common route of drug administration. Oral dispersible tablet producing beneficial effects among Novel oral drug delivery system because they improved patient compliance and have more beneficial advantages from other oral dosage formulations. They are also solid dosage forms that break down in the mouth, when saliva is present because of super disintegrates in the formulation. Consequently, this method of drug delivery facilitates effective oral administration for both paediatric and geriatric populations where swallowing can be challenging. Numerous researchers have developed orodispersible tablets using various techniques. The compression method is the most widely used preparation technique. Other specialized methods include molding, melt granulation, phase-transition processes, sublimation, freeze-drying, spray-drying, and the effervescent method. Since these tablets dissolve immediately in the mouth, their taste plays a crucial role. Several strategies have been implemented to mask the unpleasant taste of the drug. From all other dosage for they are also evaluated as hardness, friability, wetting time, moisture content, disintegration test and dissolution test.

INTRODUCTION

The most widely used solid dose forms are tablets. In Different Dosage form, for both liquid and solid dose forms, oral administration is the most popular and recommended method of drug administration. Nonetheless, the convenience of administration, precise dosage, self-medication, pain avoidance, and above all patient compliance makes solid dosage forms appealing. [1] However, a lot of

people have trouble swallowing firm gelatine capsules and tablets. Dysphasia is the term for this swallowing issue. All patient groups have been shown to experience this issue, however paediatric and geriatric populations have been particularly affected. Therefore, these traditional dosage forms lead to a high rate of noncompliance and insufficient swallowing therapy, particularly for children, the elderly, and those with mental

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retardation. [2] Orodispersible tablets are also called as orally disintegrating tablets, mouth-dissolving tablets, rapid-dissolving tablets, fast-disintegrating tablets, fast-dissolving tablets. Recently, European Pharmacopoeia has used the term orodispersible tablets. This may be defined as uncoated tablets intended to be placed in the mouth where they disperse readily within 3 min before swallowing. [3]

United States Pharmacopoeia has also approved these dosage forms as orodispersible tablets. Thus, orodispersible tablets are solid unit dosage forms like conventional tablets, but are composed of super disintegrates, which help them to dissolve the tablets within a minute in the mouth in the presence of saliva without any difficulty of swallowing. It offers several advantages with respect to its stability, administration without water, accurate dosing, easy manufacturing, small packaging size, and handling. [4] Its ease of administration in the population especially for paediatric, geriatric makes it a very popular dosage form. Due to the presence of super disintegrates, it gets dissolved quickly, resulting in rapid absorption of drug which in turn provides rapid onset of action. Since the absorption is taking place directly from the mouth, so, bioavailability of the drug increases. Drugs present in orodispersible tablets are also not suffering from first pass metabolism. This type of drug delivery is becoming popular day by day due to its numerous advantages. [5]

Merits of Orodispersible tablets [6]: -

1. It's improve compliance and convenience to patient and prescribers.
2. It's improve stability of drug.
3. Orodispersible tablets provide fast drug delivery.

4. This dosage form has improved bioavailability.
5. No Water needs
6. No chewing needs
7. Allow high drug Loading.

Demerits of Orodispersible tablets [7]: -

1. Orodispersible is hygroscopic in nature so must be keep in dry place
2. ODT requires special packaging for properly stabilization and safety of stable product
3. Dose uniformity is a technical challenge.
4. Not Provide to Unconscious Patients

Methods of Preparation of Orodispersible Tablets

There are so many methods used for preparation of these type of tablets. Various process of manufacturing of orodispersible tablets are molding, compaction, spray-drying, freeze-drying, and some special methods are melt granulation, phase transition. [8]

1. Molding Method: -

This method is mostly used for preparation of orodispersible tablets because it creates highly porous in structure, this increase the rate of disintegration and dissolution profile. In this process, drug is dissolved in suitable solvent and then the moist mixture mould into the tablets by applying lower pressure in compress moulding. Molded tablets have low mechanical strength, which results in erosion and breakage during handling. [9]

2. Conventional/ Compaction Method: -



Direct compression is also used for the preparation of orodispersible tablets. Some important super disintegrates, which are used during preparation of orodispersible tablets, are croscarmellose sodium, sodium alginate, acrylic acid derivatives. In this method, it has been found that preparation by compression method along with addition of super disintegrants in optimum concentration follow all the properties of orodispersible tablets. [10]

3. Spray-drying method: -

Spray drying method is a continuous, one-step process that atomizes a liquid solution of API and excipients into a hot gas stream, rapidly transforming them into spherical, free-flowing, and uniformly sized particles suitable for direct compression, the formulation is spray-dried in a spray drier. Orodispersible tablets prepared through this method are disintegrated in less than 20s. orodispersible tablets are made up of gelatine (hydrolyzed or unhydrolyzed) as supporting agent for matrix, mannitol (bulk agent), and disintegrating agent (sodium starch glycolate or croscarmellose sodium). Sometimes in order to improve the disintegration and dissolution, citric acid and sodium bicarbonate are used. [11]

4. Freeze Drying Method: -

Freeze-drying in tablets is a manufacturing method that produces highly porous, fast-disintegrating tablets by freezing an aqueous drug solution and removing water via sublimation under vacuum. This is a very popular process for the preparation of orodispersible tablets. Tablets prepared by this process have low mechanical strength, poor stability at higher temperature and humidity, but glossy amorphous structure resulting in highly porous, lightweight product. This low-temperature process preserves heat-sensitive compounds and

creates tablets that dissolve rapidly in the mouth, often within seconds. [4]

5. Melt Granulation Method:

It is a unique method for the preparation of orodispersible tablets. It is a specialized process that use low melting binder to agglomerate powder by eliminating solvents and water. In Superpolystates are hydrophilic waxy binders with a melting point 33-37°C and Hydrophilic – Lipophilic Balance value is 9. They play a dual role as a binder that increases the physical resistance of the tablets and also as a disintegrates, which help the tablet to melt in the mouth, and solubilize rapidly leaving no residue in the mouth. Superpolystates were introduced in the formulation of orodispersible tablets by melt-granulation method. [12]

6. Phase transition process

Mouth dissolving (MD) tablets manufactured by the phase transition method. MD tablets were produced by compressing powder containing LMP-SA (Low melting point sugar) and HMP-SA (High melting point sugar), and then heating at about 93°C for 15 min. The hardness and oral disintegration time of the heated tablets increased with an increase of the LMP-SA content. The median pore size of the tablets was increased and tablet hardness was also increased. [13]

7. Sublimation:

This process is also used to prepare Oral dispersion tablets. In this process drug, Volatilizing agent and other excipients are mixed together to form compressed tablets after that process the sublimation process done to remove the volatile compound and form porous structure in tablets the volatilizing agents are used such as ammonium

bicarbonate, camphor, urea, ammonium carbonate. [14]

Evaluation of Orodispersible Tablets [15]

1. Hardness Strength: -

Conventional hardness testers, such as the Monsanto hardness tester, are used to measure the tablet's hardness. To promote early breakdown in the mouth, the limit is in the lower range [16].

2. Wetting agent: -

Wetting time indicates the stability condition of tablets. It indicates the inner surface of the tablets and the hydrophilicity of the excipients. It is correlated to the contact angle. The lower the wetting time the quicker is the disintegration of the tablets.

3. Friability: -

Maintaining the friability percentage within acceptable limits is challenging, as all preparation methods for orodispersible tablets tend to elevate the friability percentage. Typically, this range should be maintained between 0.1% and 0.9%. The Roche friabilator is commonly employed to assess the friability of the tablets. [17]

4. Moisture-uptake Studies: -

In the case of orodispersible pills, this investigation is significant. The purpose of this study is to evaluate the tablets' stability. For 24 hours, ten pills were stored at 37°C in desiccators over calcium chloride. After that, the tablets were weighed and left at room temperature for two weeks with a 75% relative humidity.

5. Thickness

The thickness and diameter of the tablets was determined using a Micrometer screw gauge. Five tablets from each type of formulation were used

and average values were calculated. It is expressed in mm.

6. Disintegration Time: -

Disintegration time is an important parameter for evaluating the bioavailability. The time used for disintegration of the tablets is less than 1 minute and the actual time for disintegration of the orodispersible tablets in the mouth is between 5-30 seconds.

7. Dissolution Time: -

This test is crucial because it can be used to determine the drug-release profile that alternates the bioavailability of orodispersible tablets. You can use the USP dissolution test devices. Orodispersible pills dissolve relatively quickly.

Recent advancement technologies in ODT: -

1. 3D printing of ODT

Powder-based 3D printing, an advanced additive manufacturing technique, can produce oral disintegrating tablets (ODTs) without disintegrating, creating larger-pored tablets via layer-by-layer powder stacking for better water absorption. This technology precisely offers related to tablet geometry, porosity, dose distribution and distribution behaviour. [18]

2. Nanotechnology based ODT

Nanotechnology is used in the development of oral dispersible tablets. In this technique, the particle size is reduced from 10nm to 1000nm to increase the dissolution property of the tablets that also increase the bioavailability, improved stability and improved patient compliance. [19]

3. Fast dissolving films comparison

Fast dissolving films are fast-acting oral drug delivery systems designed to dissolve speedily,



when compared to traditional pills, fast-acting oral drug delivery systems are made to dissolve quickly in the mouth without need of water and increasing patient compliance. It creates flexible and less brittle in structure. Their form physical characteristics, dosage capacity, disintegration behaviour and patient experience. [20]

4. Artificial Intelligence in ODT formulation

AI provides a data-driven substitute that can stimulate intricate connections between formulation elements and performance attributes including dissolving profile, hardness test and disintegration time. It helps to avoid time consuming and initiate resource-intensive. This technique also provides Predictive Modelling for ODT Characteristics [21]

Challenges in the preparation of Oral dispersible tablets [22,23]: -

- Mechanical Strength and Disintegration time
- Tastes masking
- Aqueous solubility
- Size of Tablets
- Amount of Medicament
- Hygroscopic nature of Medicament
- Good packaging design

DRUGS USED IN ORODISPERSIBLE TABLETS [23]

Table No: -01 DRUGS USED IN ORODISPERSIBLE TABLETS

Sr. no.	Category	Examples
1	Antibacterial agents	Tetracycline, Erythromycin, Ciprofloxacin, Penicillin, Rifampicin, Doxycyclin, Nalidixic acid, Trimethoprim
2	Antidepressants	Trimipramine maleate, Nortriptyline HCl, Trazodone, HCl, Amoxapine, Mianserin HCl
3	Anthelmintics	Albendazole, Mebandazole, Thiabendazole, Ivermectin, Praziquantel, Pyrantel embonate, Dichlorophen
4	Antidiabetics	Glibenclamide, Glipizide, Tolbutamide, Tolazamide, Gliclazide, Chlorpropamide
5	Antihistamines	Acrivastine, Cetirizine, Cinnarizine, Loratadine, Fexofenadine, Triprolidine
6	Antiarrhythmics	Disopyramide, Quinidine sulphate, Amiodarone HCl
7	Antihypertensives	Amlodipine, Carvedilol, Diltiazem, Felodipine, Minoxidil, Nifedipine, Prazosin HCl, Nimodipine
8	Analgesics/ Anti-inflammatory agents	Diclofenac sodium, Ibuprofen, ketoprofen, Mefenamic acid, Naproxen, Oxyphenbutazone, Indomethacin
9	Anti-convulsant/ Antiepileptic	Carbamazepine, Methsuximide, Phenytoin, Primidone, Phenobarbitone, Valproicacid, Phensuximide

CONCLUSION

Over the last Decade, ODT has become much more popular for patients. It can be concluded that patients with dysphagia who are young, elderly, bedridden and psychotic patients benefit most from ODT. These tablets convert into a suspension

with the help of salivary fluid and increase the therapeutic index by increasing the bioavailability. This type of formulation increases demand day by day for fast dissolving compare to other tablet dosage form. There are various technologies used for preparation and maintain stability of the oral dispersible tablet that resist the future challenges



of ODT. Today, Orodispersible tablets are more widely available as over-the-counter products for the treatment of allergies, cold and flu symptoms. All the information's collected above about the ODT gives a better scientific based understanding. With continued research and development of new pharmaceutical formulation, one may expect some new technology for a more novel orodispersible tablets in the future.

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