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Review Article

Review On Orodispersible Tablets: Opportunity & Challenges

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ABSTRACT

Orodispersible tablets (ODTs) represent a significant advancement in drug delivery systems, offering rapid disintegration in the oral cavity without the need for water. This formulation is particularly beneficial for pediatric, geriatric, and dysphagic patients, ensuring improved compliance and ease of administration. The opportunities associated with ODTs include enhanced bioavailability, market expansion, and their applicability across various therapeutic areas. However, challenges such as taste masking, mechanical strength, moisture sensitivity, limited drug load capacity, and regulatory compliance must be addressed to optimize their development. Continued innovation in formulation technologies and quality control measures is essential for the successful commercialization of ODTs.

INTRODUCTION

The pharmaceutical industry has witnessed remarkable advancements in drug delivery systems aimed at improving patient compliance and therapeutic efficacy. Among these innovations, orodispersible tablets (ODTs) have emerged as a novel and promising solid dosage form that offers numerous benefits over conventional tablets and capsules. ODTs are designed to rapidly disintegrate in the oral cavity without the need for water, making them particularly advantageous for pediatric, geriatric, and dysphagic patients who often struggle with swallowing conventional dosage forms. ODTs provide an enhanced user experience by facilitating ease of administration, thereby ensuring better adherence to prescribed medication regimens. The formulation of these tablets is based on advanced techniques such as direct compression, lyophilization, and spray drying, which contribute to their rapid disintegration and bioavailability enhancement. These attributes make ODTs an attractive alternative for a wide range of therapeutic applications, including pain management, central nervous system (CNS) disorders, and gastrointestinal diseases. The rising global demand for patient-centric formulations has spurred

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significant research and development efforts in the field of ODTs. Pharmaceutical companies are increasingly investing in ODT technology to expand their product portfolios and improve medication accessibility. Despite these advantages, several challenges persist in the formulation, manufacturing, and regulatory approval of ODTs. Issues such as taste masking, mechanical strength, moisture sensitivity, and drug load limitations require innovative solutions to optimize product performance and market acceptance. The regulatory landscape for ODTs is also evolving, with stringent quality control measures necessitating rigorous testing of disintegration time, dissolution, stability, and taste-masking efficacy. Addressing these challenges requires a multidisciplinary approach involving pharmaceutical scientists, formulation experts, and regulatory authorities to ensure the successful development and commercialization of ODTs.

Oral Drug Delivery System

Over the past decade, the need of advancement in the current conventional dosage form has increased because development of new chemical entity requires large amount of investment in research and development and also time to develop new chemical entity is quite long and thus nowadays formulation scientists are continuously focusing on developing new and improved dosage forms for delivering same drug in an efficacious way. This help to increase the patient compliance and to overcome the commonly encountered problems with conventional dosage forms. Oral route is the oldest and most convenient route of administration of drugs and has been used since forever. Oral drug delivery system includes various dosage forms such as tablets, capsules, liquids and many more. Tablet is one of the most preferred oral dosage forms because of ease of manufacturing, stability and accurate dosing. Though tablet is the most commonly used dosage form for oral delivery, it has encountered several problems over years such as difficulty in swallowing by pediatric and geriatric patients and also mentally ill patients and persons with motion sickness experience difficulty in administering conventional tablets because they require immediate action. Also, in case of motion sickness and altitude sickness, availability of water is a major issue and thus lead to the development of orodispersible tablets.

Orodispersible Tablets For Paediatric

Pediatrics and geriatrics encompass diverse patient populations, necessitating tailored approaches for creating suitable dosage forms. Advances in pharmaceutical technology, such as Fixed-Dose Combinations (FDCs), multi-particulates, and orodispersible dosage forms, offer unique avenues for innovating and developing appropriate formulations for both established and emerging drugs. Despite the implementation of the European Union's regulation on medicinal products for pediatric use in 2007, which aimed to enhance rational, evidence-based prescribing and age-appropriate formulations for children, many products still lack essential pediatric data. In contemporary medicine, the availability of dosage forms suitable for children is essential and constitutes a fundamental requirement for effective pediatric drug treatment. Experts have long advocated for a fundamental change, moving away from traditional liquid forms towards innovative oral solid dosage forms. A novel formulation approach has emerged, introducing the latest advancements in drug delivery systems in the form of orally disintegrating mini tablets (ODMTs). These ODMTs leverage the beneficial characteristics of both orally disintegrating tablets (ODTs) and mini tablets, with a specific focus on pediatric therapy. Consequently, ODMTs can be regarded as advanced, compact versions of ODTs tailored for use in pediatric patients. Mini ODTs typically range from 2 to 4 mm in diameter,

accommodating different age groups and the specific active substances they contain. Experimental research has demonstrated that 2 mm tablet formulations are suitable for children aged 0.5 to 6 years, while 3 mm tablets can also be utilized for children between 2 and 8 years of age. Furthermore, these studies have highlighted that ODMTs containing dietary supplements may have a diameter of up to 4 mm. Another crucial consideration is that when formulating oral tablets intended for pediatric use, it's imperative to ensure that the excipients incorporated into these formulations adhere to the regulations set forth by the International Harmonization Conference (ICH), the European Medicines Agency (EMA), and the European Food Safety Authority (EFSA). Furthermore, the processes for preparing and the quality controls, both before and after compression, of orally disintegrating mini tablets (ODMTs) closely resemble those employed in the production of orally disintegrating tablets (ODTs).

Advantageous and Disadvantageous of ODT

Advantageous	Disadvantages
• Best for patient with oesophageal problems and have difficulties of deglutition tablets • High drug loading is possible. • Have acceptable taste and pleasant mouth feeling. • Leave minimum residue in the mouth after oral administration. • Guarantee a rapid onset of action when required. • Pleasant mouth-feel. • Cost effective	• Hygroscopic in nature. • Low amount of drug can be incorporated in each dose. • Some time it possesses mouth feeling • Highly fragile sometimes. • ODT requires special packaging for properly stabilization & safety of stable product. • Eating and drinking may become restricted

Ideal Properties Of Orodispersible Tablets

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.

Techniques for preparing ODTs.

Many techniques have been reported for the formulation of Orodispersible tablets.

- Freeze drying/lyophilization
- Tablet Moulding
- Spray drying
- Sublimation
- Direct compression
- Mass extrusion
- Wet Granulation
- Dry Granulation
- Melt Granulation
- Phase transition process
- Three-dimensional Printing (3DP)
- Cotton Candy Process
- Nanonization
- Effervescent Method
- Hot melt extrusion
- Solid dispersion extrusion
- Rolling method

1. Freeze Drying/Lyophilization

A drying process where water is removed under vacuum at low temperatures, resulting in highly porous tablets with rapid disintegration.

The tablets manufactured by freeze drying are very permeable and rapidly dissolve when placed on tongue in mouth saliva. In this method, after the freezing water is sublimate from the substances. Firstly, the product is frozen to bright when eutectic point is below.

Lyophilization- is a technology of pharmaceutical which allows drying of heat sensitive substances and bilogically at low temperature so that conditions water is removed by the sublimation process.

2. Tablet Moulding

Uses a solvent or heat process to create highly porous tablets with enhanced solubility.

3. Spray Drying

Utilizes a drying chamber with hot air to rapidly remove solvent, producing highly porous and fast-dispersing tablets.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.

4. Sublimation

Volatile substances are integrated and generate porous mixture, which method of sublimation. High volatile substances like ammonium bicarbonate, camphor, benzoic acid, urea, ammonium carbonate, phthalic anhydride, urethane and nephthalene etc. are mixed with other inactive ingredients and dense into a tablet form. The volatile substances are then removed, leaving a extremely absorbent matrix by the help of sublimation process. Tablets are formulated by this technique, the dissolution time is usually 10 20 seconds.

Volatile substances (e.g., camphor, ammonium bicarbonate) are used to create pores upon sublimation, enhancing disintegration.

5. Direct Compression

Involves blending excipients with superdisintegrants and compressing into tablets using conventional equipment. Orodispersible tablets were prepared by direct compression technique using three different approaches namely; super disintegrant addition, effervescence and sublimation. In addition combination between different approaches was proposed and evaluated to optimize tablet characteristics.

Advantages of direct compression

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.

6. Mass Extrusion

A solvent-based process where a mixture is extruded through a syringe or die to form porous matrices. 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.

7. Wet Granulation

Uses a liquid binder to agglomerate powder particles before compression into tablets.

8. Dry Granulation

Compresses powder mixtures into granules without using a liquid binder, suitable for moisture-sensitive drugs.

9. Melt Granulation

A binder is melted and mixed with powders to form granules that solidify upon cooling.

10. Phase Transition Process

Involves processing excipients with different melting points to induce disintegration upon phase transition.

11. Three-Dimensional Printing (3DP)

Uses additive manufacturing techniques to fabricate ODTs layer by layer.

12. Cotton Candy Process

Involves spinning sugar-based carriers to create a highly porous matrix that dissolves quickly. Candy floss is obtained from polysaccharide matrix is recrystallized and then API and excipients are mixed and compressed to produce tablets. These are also able to maintain the strength of tablets

13. Nanonization

Reduces drug particle size to nanoscale, enhancing solubility and bioavailability in ODTs.

14. Effervescent Method

Incorporates an effervescent system (citric acid and sodium bicarbonate) to enhance tablet disintegration.

15. Hot Melt Extrusion

Uses heat and pressure to mix drug and polymer, forming a matrix that dissolves quickly.

16. Solid Dispersion Extrusion

Enhances drug solubility by dispersing it in a polymeric carrier using extrusion techniques.

17. Rolling Method

Involves rolling wet mass into thin sheets and cutting them into tablets, used for rapid-dissolving ODTs.

Factors influencing drug release from ODTs

Table 1: Various factors influencing release of drugs from ODTs

Category of factor	Factors influencing drug release	Influence on drug release
Physiological factors	Volume and composition of saliva	Variation in the composition and volume of saliva impacts consistency of drug release.
	pH of oral cavity	Variation in pH of oral cavity influences ionization and solubility of APIs.
	Temperature of oral cavity	Higher temperature enhances drug dissolution and release.
Physical properties of drug	Particle size of API	Smaller the particle size, greater the surfaced area, faster the dissolution.
	Hydrophilicity vs Hydrophobicity of API	Hydrophilic APIs dissolve faster while hydrophobic API need solubilizers to solubilize.
Formulation related factors	Type and concentration of binders	High concentration of binders slows down the process of disintegration and dissolution.
	Superdisintegrants	Mainly increase the disintegration.
	Diluents	Soluble diluents fasten dissolution while insoluble fillers delays dissolution.
Technological factors	Manufacturing process	Direct compression relies on excipients for drug release while freeze-drying method helps in achieving fats disintegration.
	Use of combination of superdisintegrants	Use of two or more different kind of superdisintegrants

		which works by different mechanism helps to achieve faster disintegration.
Property of tablet	Porosity and hardness of tablet	Higher porosity allows for rapid penetration of saliva while hardness is opposite to porosity.

Excipients Used In The Formulation Of Orodispersible Tablets

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

1. Super disintegrants: These agents are mixed to prepare the formulation then increase the compatibility, compresibility and fewer chances to affect the mechanical strength so these super disintegrants are enhance the applications of fast dissolving tablets, capsules, mouth dissolving tablets, orodispersible tablets etc. These are two types super disintegrants are used such as –

a) Natural Super disintegrants: These super disintegrants are obtained by natural origin and they are non- irritating and non-toxic in nature.

The natural substances are used as super disintegrants such as Soy polysaccharide, Isapghula Husk Mucilage (Plantago ovata), Chitosan, Guar Gums, and Agar.

b) Synthetic Super disintegrants: These super disintegrants including Croscarmellose sodium, sodium starch glycolate and crospovidone.

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.

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.

Evaluations Of ODTs

Like any other dosage forms, oro-dispersible tablets too are evaluated for cetain parameters for formulation of stable and optimized product. These parameters (pre and post compression parameters) are discussed below:

- **Precompression parameters:** These includes tapped density, bulk density, carr's index, hausner's ratio for powder blend of ODT formulations which are ready to compress into tablets.
- **Tapped density:** It is denoted by the ratio of total weight of the powder to the tapped volume of the powder. Powder is tapped 750 times and if the difference between the two volumes is less than 2% then volume difference is noted. Tapping is continued for 1250 times if it is more than 2% then tapped volume is noted
- **Bulk density:** It is the ratio of total weight of powder (M) to the bulk volume (Vb) of powder. It is measured by pouring the weight powder (passed through standard sieve # 20) into a measuring cylinder and initial weight was noted. This initial volume is called the bulk volume. It is given by Db = M/ Vb Where, M is the weight of powder Vb is the bulk volume
- **Carr's index:** It indicates powder flow properties. It is expressed in percentage and is given as

$I = Dt– Db/Dt * 100$

Where, Dt is the tapped density of the powder, Db is the bulk density of the powder.

- **Hausner's ratio:** It denotes easiness of powder flow, it is related to inter particulate friction as such, could be used to predict powder flow properties. It is calculated by following formula.

Hausner's ratio =Tapped density/Bulk density

Post compression parameters:

- **Weight variation test**: In this test, tablets are randomly selected and individual weight is taken.

Then weight variation is checked as per specifications

- **Thickness test**: Vernier callipers is used to measure the thickness of the tablets and provides knowledge of thickness variation. The tablet thickness may also be measured by screw gauge
- **Hardness:** It is an important parameter which shows resistance of the tablet to chipping, breakage and abrasion under the conditions of handling, transportation and storage. Monsanto hardness tester is used for determining hardness and expressed in Kg/cm2
- **Friability test:** Mechanical strength of tablets is measured by Roche fribilator. In this test, pre weighed tablets are placed in the plastic chamber of fribilator which revolves at 25rpm for 4 minutes, and then the tablets are dropped from 6 inches distance.
- **Disintegration test:** Disintegration test apparatus is used for determination of disintegration time of prepared tablets. As specified in I. P.-1996, the test is carried out on 6 tablets using the apparatus at 37 ^{o}C ± 2^{o}C, then time is recorded for complete disintegration of tablets.
- **Dissolution test:** USP paddle apparatus is used for in vitro dissolution studies. It is carried out at 50 rpm in 900 ml of phosphate buffer (pH 6.8), maintained at 37°C ± 5°C. At regular intervals, 5 ml of sample is withdrawn and assayed spectrophotometrically
- **Wetting time:** It represents the time taken for the tablet to disintegrate when kept motionless on the tongue. In this test, the tablet is placed on a piece of tissue paper folded double in a petri plate (internal diameter is 6.5 cm) containing 6 ml of water. Then the tablet's complete wetting time is notted. The test is carried out at 37^{o}C
- **Stability study:** It may be defined as the capacity of a drug substance or product to remain within the specifications provided to maintain its identity, strength, quality and purity throughout the expiration dating period.

Conditions for accelerated studies as prescribed by ICH guidelines are:

(i) 40 ± 1°C

(ii) 50 ± 1°C

(iii) 37 ±1°C and RH 75% ± 5%

After a period of 15 days, the tablets are withdrawn and analyzed for physical characterization

Marketed ODTs

Various drug manufactured as orodispersible tablets are given in Table 2

Table 2: Marketed orodispersible tablets

S. No	Brand name	Drug	Manufacturing company
1	Fazalco	Clozapine	Alamo
2	Solupred	Prednisolone	Sanofi-Aventis
3	Niravam	Alprazolam	Schwarz Pharma
4	Parcopa	Levodopa	Schwarz Pharma
5	Proxalyoc	Piroxicam	Cephalon
6	Spasfon-Lyoc	Phloroglucinol	Cephalon
7	Romilast	Montelukast	Ranbaxy
8	Olanex INSTAB	Olanzapine	Ranbaxy
9	Feldene melt	Piroxicam	Pfizer
10	Benadryl Fast melt	Diphenhydramine	Pfizer
11	Torrox MT	Rofecoxib	Torrent Pharma
12	Pepsid RPD	Famotidine	Merck and Co.
13	Mossid-MT	Mosapride citrate	Torrent Pharma

Opportunities in ODT Development

1. Improved Patient Compliance

ODTs are particularly beneficial for patients who have difficulty swallowing conventional tablets

and capsules, such as children, elderly individuals, and psychiatric patients.

2. Rapid Onset of Action

ODTs enhance drug absorption in the oral cavity and gastrointestinal tract, leading to a faster onset of therapeutic effects.

3. Increased Bioavailability

For drugs that undergo extensive first-pass metabolism, ODTs improve bioavailability by enabling absorption through the oral mucosa.

4. Suitability for Special Populations

ODTs provide an alternative for individuals with dysphagia, motion sickness, and mental health conditions where conventional formulations are inconvenient.

5. Potential for Market Growth

The global ODT market has expanded due to advancements in formulation technologies and increasing demand for user-friendly dosage forms.

Challenges in formulation of orodispersible tablets

Following are some of the challenges involved in formulation of orodispersible tablets:

1 Mechanical strength and disintegration time: Mechanical strength of the tablets should be maintained, as it is accepted that on increasing the mechanical strength, disintegration time is delayed. To allow good disintegration in oral cavity, ODTs should be made with very low compression force

2 Taste masking: In case of unpalatable drugs, taste masked form of medicament for rapid drug delivery is preferred. Drug delivery system releases active ingredients by disintegrating or dissolving in the oral cavity. Hence, taste masking is very critical step to provide patient compliance.

3 Aqueous solubility: Water soluble drugs forms eutectic mixtures, so they form glassy solid which may break on drying due to lack of supporting structure during sublimation method, so this presents various formulation challenges for manufacturers

4 Mouth feel: ODTs should be disintegrated into smaller fragments in the patient's oral cavity. For patient's palatability, generated fragments should not be large as well as the taste of drug should not be too bitter

5 Hygroscopicity: Orodispersible tablets should have less sensitivity to humidity. This might be challenging task for manufacturer as various hydrophilic excipients are added in the formulation in order to get faster dissolution. Hence, ODTs usually need higher protection from humidity

6 Amount of drug: Amount of drug that has to be incorporated in each unit dose can be a limitation factor for development of ODTs. Quantity of drug in lyophilization technology should be less than 400mg and 60mg for insoluble drugs and soluble drugs respectively.

7 Size of tablet: Tablet size should be selected by considering its ingestion as well as handling. Reported size of tablet to swallow is 7-8 mm, but for handling purpose it should be larger than 8 mm. So, the tablet size which is easy to take and handle is difficult to achieve.

8 Environmental conditions: ODTs are meant to dissolve in minimum quantity of water, so many excipients are added which may be sensitive to environmental condition such as temperature and humidity

Future Prospects of ODTs:

Conventional tablets are inadequate for delivering drugs like protein and peptide-based therapeutics due to their limited bioavailability and rapid degradation in the stomach. Injections, while effective, may not always be the preferred method for administering these substances. [40] Inhalation is a viable approach for drug delivery, but most research in the biopharmaceutical field has focused on low molecular weight compounds. However, there is growing interest in exploring oral delivery options for high molecular weight proteins and peptides, and Orodispersible Tablets

(ODTs) offer a promising solution. ODTs can release these drugs in the oral cavity, providing a compelling alternative for delivering these complex and valuable biopharmaceuticals.

CONCLUSION

Orodispersible tablets present a promising platform for enhancing patient compliance and expanding pharmaceutical markets. However, overcoming challenges related to formulation, stability, and regulatory compliance is crucial for successful commercialization. Continuous innovation in formulation technologies and regulatory strategies will drive the future growth of ODTs in the pharmaceutical industry.

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