

ORAL DISPERSIBLE TABLETS: A PHARMACEUTICAL AND ECONOMICAL INSIGHT

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ABSTRACT

An orally disintegrating tablet (ODT) is a type of medication that quickly dissolves or disintegrates in the mouth without the need for water. It is designed to dissolve on the tongue within seconds, making it easier for individuals who may have difficulty swallowing pills, such as children or elderly patients. ODTs are commonly used for medications that treat conditions like nausea, pain, or allergies. The unique formulation of ODTs helps ensure that the active ingredient is rapidly absorbed into the bloodstream, providing quicker relief. The present review work will focus on the formulation and commercial aspects of ODTs.

INTRODUCTION

The medicines are the base of treatment in any type of ailment. But the best and most suitable route of drug administration is very much important in the treatment.^[1-5] The mode of treatment is influenced by the route selected to administer the drug. All the route of drug administration has got its own merits and demerits. This will have direct role in the selection of the drug delivery system. The most common and preferred route of drug administration is through the oral route. Oro-dispersible tablets are gaining importance among novel oral drug-

delivery system as they have improved patient compliance and have some additional advantages compared to other oral formulation. They are also solid unit dosage forms, which disintegrate in the mouth within a minute in the presence of saliva due to super disintegrants in the formulation. Thus this type of drug delivery helps a proper per-oral administration in pediatric and geriatric population where swallowing is a matter of trouble.^[6-7] The basic advantages and disadvantages of oral dispersible tablets are specified in the table 1.

Table 1: Advantages and Disadvantages of oral dispersible tablets.^[8-12]

| S. No. | Advantages | Disadvantages |
|--------|---|---|
| 1 | Allow high drug loading | Dose dumping may occur |
| 2 | Better taste and Active Release | Sometimes may require more frequency of administration |
| 3 | No water and chewing needed | Rapid drug therapy intervention is not possible |
| 4 | Suitable for controlled/sustained Offers improved compliance and convenience to patients and prescribers | Reduced potential for accurate dose adjustment |
| 5 | It improves patient adherence and reduces the development of resistance in case of antimicrobials | Usually have insufficient mechanical strength |
| 6 | Simplifies the logistics of procurement and distribution | For properly stabilization and safety of the stable product, ODT requires special packaging |
| 7 | For Rapid drug delivery, ODTs are considered to be preferred dosage form | Sometime unpleasant taste and/or grittiness in mouth |
| 8 | Some drugs are absorbed from the pharynx and esophagus as the saliva passes down into the stomach; in such cases, the bioavailability of drugs is increased | ---- |
| 9 | ODTs are very convenient for administering to various classes of patients from disabled, travelers and busy people, who do not always have access to | ---- |

| | | |
|----|---|------|
| | water | |
| 10 | The drug is released quickly from this dosage form and gets dissolve in GIT without getting into the stomach, increased bioavailability can be achieved | ---- |

Methods of preparation

In the pharmaceutical world, the medicines having the numerous methods of preparations are considered to be suitable candidate for maximum sustainability. The ODT can be prepared by the different methods and are considered to be the best candidate among the different oral dosages form. There are several methods for the

preparation of orodispersible tablets but the prepared products vary in their properties depending on the method of preparation. The properties in which they vary are mechanical strength of the tablets, swallowability, bioavailability, drug dissolution in saliva, stability, and to some extent taste.^[13-18]

Table 2: Specifies the Different Methods of ODTs Formulations.

| S. No. | Preparation Method | Details |
|--------|---------------------------------|---|
| 1 | Spray drying | Spray drying is one of the oldest forms of drying and one of the few technologies available for the conversion of a liquid, slurry, or low – viscosity paste to a dry solid (free – flowing powder). The spray – drying process is carried out in three fundamental stages. The first stage is: atomization of a liquid feed into fine droplets. In the second stage, spray droplets mix with a heated gas stream and the dried particles are produced by the evaporation of the liquid from the droplets. The final stage involves the separation of the dried powder from the gas stream and collection of these powders in a chamber. The components included supporting agents like non hydrolyzed and hydrolyzed gelatin, a bulking agent like mannitol and a volatilizing agent |
| 2 | Sublimation | In this technique, highly volatile substances like camphor, urea and urethane are added to the blend before compression. When highly volatile substances are compressed, they can be easily removed by sublimation. This improves the dissolution rate as the end product is a porous structure due to the evaporation of the volatile substances |
| 3 | Lyophilization or freeze drying | It is a process in which solvent is removed from a frozen drug solution or a suspension containing structure forming excipients Freeze drying process normally consists of three steps: A) Material is frozen to bring it below the eutectic point B) Primary drying to reduce the moisture around 4 % w / w of dry product and C) Secondary drying to reduce the bound moisture up to required final volume The resulting tablets are usually very light and have highly porous structures that allow rapid dissolution or disintegration. This process may result in a glassy amorphous structure of excipients as well as the drug substance leading to the enhanced dissolution rate |
| 4 | Molding | The powder blend is moistened with the solvent and the tablet is molded. This process is called solvent molding. The low compression pressure used results in a porous structure which leads to enhanced dissolution rate; the powder blend is generally passed through a very fine screen. The major drawback of the molded tablets is that they lack the mechanical strength. The molded forms have also been prepared directly from a molten matrix in which the drug is dissolved or dispersed (known as heat molding) or by evaporating the solvent from a drug solution or suspension at ambient pressure (no – vacuum lyophilization) |
| 5 | Wet granulation method | The wet granulation method was carried out using two binding agents viz. PVP K – 30 and starch. PVP K – 30 in isopropyl alcohol in different concentrations such as 1 %, 2 %, 3 % and 4 %. The other binding agent starch was used in different concentrations |
| 6 | Cotton candy process | Cotton candy process involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed partially recrystallized to have improved flow properties and compressibility. This candy floss matrix is then milled and blended with active ingredients and excipients and subsequently compressed to dispersible tablets. This process can accommodate high dose of drug and high process temperature limits the use of this process |

| | | |
|---|--------------------|---|
| 7 | Granulation method | In dry granulation method all the ingredients were passed through # 60 mesh separately. The drug and the diluents were mixed in small portion of both each time and blending it to get a uniform mixture and kept aside. The other ingredients were weighed and mixed in geometrical order. |
|---|--------------------|---|

Economical and Commercial Aspects of ODTs

There are lots of options in the pharmaceutical world to explore. The tablets in many forms with alterations are available in the market. The ODTs too have the wider

scope with different marketing options. The commercialized products of ODTs which are available in market are gaining more popularity with the merits of treating the wider number of diseases.^[19-20]

Table 3: Marketed Formulations of ODTs.

| S. No. | Active pharmaceutical ingredients | Brand name | Manufacturer |
|--------|-----------------------------------|-------------------|--------------------------|
| 1 | Diphenhydramine | Benadryl Fastmelt | Pfizer |
| 2 | Montelukast | Romilast | Ranbaxy lab |
| 3 | Zolmitriptan | Zomig ZMT | Astra Zeneca |
| 4 | Valdecocixib | Valus | Glenmark |
| 5 | Olanzapine | Zyprexa | Eli lilly |
| 6 | Rofecoxib | Rofaday MT | Lupin |
| 7 | Olanzapine | OlanexInstab | Ranbaxy |
| 8 | Mosapride | Mosid MT | Torrent |
| 9 | Rofecoxib | Orthoref MD | Biochem |
| 10 | Ibuprofen | Cibalginadue FAST | Novartis Consumer Health |

There are the several key factors are driving the growth of the ODT market. The increasing prevalence of chronic diseases, including mental health disorders, gastrointestinal issues, hypertension, and others, is creating a demand for more accessible drug delivery

options. Moreover, advancements in research and development of novel drug delivery systems are boosting innovation within the market. Rising healthcare investments, coupled with growing patient awareness and compliance, further contribute to this expansion.



Figure 1: Market Growth Scenario of ODTs.

The global orally disintegrating tablet market size was valued at USD 14.76 billion in 2024 and is projected to grow from USD 16.33 billion in 2025 to USD 28.88 billion by 2033, exhibiting a CAGR of 7.38% during the forecast period (2025-2033). According to a research report published by Spherical Insights & Consulting, the Global Orally Disintegrating Tablet Market Size is expected to grow from USD 13.05 billion in 2023 to USD 28.45 billion by 2033, at a CAGR of 8.11% during the forecast period 2023-2033.

CONCLUSION

Orally disintegrating tablets are gaining popularity in the generic drug market due to their numerous benefits, such as rapid disintegration and the ability to be taken without water. These advantages are particularly attractive for patients who require easier medication options. The growing use of ODTs in generics is helping to make medications more accessible and convenient for a larger population. The economical intensification rates of ODTs are focusing on the futuristic values which are the clear indication of growth. The growth in the ODTs

market will be key factor in the sustainability of ODTs in the near future.

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