Orally Disintegrating Tablets (ODTs): An Overview

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Abstract:
There is a growing need for more patient-compliant dose forms in the current environment. The creation of mouth-dissolving tablets that quickly dissolve or disintegrate upon contact with the recipient's tongue or buccal mucosa is one significant advancement in this field. They have shown to be the best options for the elderly and paediatric populations, dysphagia patients, clinical circumstances when water intake is not possible, and medications with high first pass metabolism. The notion of higher patient compliance, quick absorption, rapid commencement of action, greater effectiveness, sufficient bioavailability to demonstrate needed pharmacological activity, and reduced toxicity are best suited by mouth-dispersing tablets (MDT). Brief information about ODTs, such as their definition, ideal and desired characteristics, advantages, limitations, and disadvantages is presented in this review. Other topics covered include drug candidates, formulation challenges, excipients with recent developments in super disintegrants, taste masking, manufacturing methods, evaluation criteria, and recent patents in ODTs.

Keywords: Mouth dissolving, Super disintegration, taste masking, Fast Disintegration

Introduction:
There are a number of ways to provide medicinal and other therapeutic substances that have a systemic impact, but the oral route is thought to be the most efficient and has the highest patient compliance. Orally disintegrating tablets (ODTs) are solid dose forms that dissolve in the mouth in less than a minute into a paste that is simple to swallow without the need for additional water. ODTs have advanced in recent years in an effort to create a secure and effective alternative to the traditional oral dose forms. Even better for paediatric and elderly individuals, there is no requirement for water during medicine administration. Orodispersible tablets are those without coatings that quickly scatter in the mouth before being swallowed. Orodispersible pills are often referred to as "melt in your mouth pills," "mouth dissolving pills," "Rapimelt pills," "porous pills," "quick dissolving pills," and "fast dissolving drug delivery." Due to their frequent need for tablets to maintain their healthy lifestyles, elderly patients find it difficult to administer conventional tablets. Children may also have difficulty swallowing pills due to their underdeveloped nervous and muscular systems, and patients who travel may also experience this issue. These issues can be resolved by using orodispersible tablets.[1,2,3]

Ideal property:[4]
- Be ionizable in the oral cavity.
- Be diffuse and dispersible in the mouth.
- Each tablet should contain no more than 50 mg of the active ingredient.
- The active ingredient's half-life should be brief and acceptable for frequent doses.
- It shouldn't taste or smell unpleasant.
- Should not require water to be dissolved in the oral cavity.
- Be resistant to environmental factors like humidity and temperature.
- Conventional packing techniques may be used.
being able to manufacture utilising inexpensive equipment
The medicine is stable for a long time since it is in solid form.
Due to the tablets' fast breakdown, solubility, and absorption, it delivers a rapid beginning of effect.

ADVANTAGES: [5,6,7]

- The main benefit for patients who have trouble swallowing medications, such as patients in a state of shock, stroke victims, bedridden patients, patients with renal failure, paediatric, and elderly patients, is its simpler method of administration.
- Creates a pleasant taste sensation that alters how the body perceives the medicine. When preparing a dosage for paediatric patients, this component is helpful.
- There is reduced danger of oxygen deprivation due to physical blockage when swallowed.
- Pregastric absorption of medications from the mouth, throat, and oesophagus as saliva goes down is done to produce rapid absorption or increase in bioavailability.
- Rapidly intervening pharmacological treatment.
- More precise dosage than liquids.
- It should not leave any smell in the mouth after administration.
- New commercial options such as patent life extension, life cycle management, and exclusive product promotion

DISADVANTAGES: [8,9]

- A little quantity of the medicine may be included in each dose.
- ODTs need to be handled with extreme caution since they aren't harsh enough.
- ODTs should not be used in fill coating processes.
- ODTs can occasionally be quite fragile.

CHALLENGES:

Hygroscopicity:
Under normal conditions of temperature and humidity physical integrity is not maintained by hygroscopic ODT so they are protected from humidity which is done by special product packaging.

Mouth Feel:
Disintegration of ODT should not have bigger particles instead the particles should be small with pleasant mouth feel.

Good Packaging Design:
At initial stage, packaging design should be improved for protecting ODTs from environment and moisture [10]

Mechanical Strength and Disintegration Time:
Because orodispersible tablets are highly breakable and have a high likelihood of breaking during packing and transportation, achieving reduced disintegration time for ODTs is difficult.

Taste Masking:
Drugs are flavour-masked to prevent the bitter taste from being detected in the mouth since the patient's compliance and acceptance of a medication are negatively impacted when a bitter tablet dissolves in the oral cavity.

Size of Tablet:
The size of the tablet, which is difficult to accomplish, is what determines how well it can be administered.

Amount of Drug:
The weight of the tablet should not exceed 500 mg, which is difficult to formulate when creating an ODT.
**Hygroscopicity:** Since hygroscopic ODT cannot retain their physical integrity in normal temperature and humidity settings, they must be protected from humidity using specific product packaging.

**Mouth Feel:** ODT should not disintegrate into larger particles; instead, the particles should be tiny and have a satisfying tongue feel.

**Good package:** Initial package design improvements are needed to protect ODTs from the environment and moisture [11].

**Desired characteristics of ODTs:**[12]

Because the way that ODTs are administered differs from the way that traditional tablets are administered, they must preserve a number of distinctive characteristics.

**Fast Disintegration** - ODTs should dissolve quickly in the mouth without the need for extra water. The disintegrating pill should turn into a smooth paste or liquid solution that is pleasant to the mouth and easy to swallow.

**Drug qualities** - The ideal ODT technology would not be affected considerably by the drug qualities.

**Taste of Active Ingredients** - In order for ODTs to be commercially successful, taste masking is a crucial prerequisite.

**Tablet Strength and Porosity** - Because ODTs are intended to dissolve quickly, excipients should have a high degree of wettability, and the tablet itself should be very porous. Sensitivity to Moisture: ODTs should be somewhat insensitive to dampness. This issue can be particularly difficult due to the use of several highly water-soluble excipients in formulation to improve quick dissolving capabilities. To safeguard ODTs, a suitable packaging design must be developed.

**INGREDIENTS USED FOR PREPARATION OF ODTs:** [13,14]

**Super disintegrants:**

The addition of super disintegrants accelerates the rate of disintegration and dissolution. They are more effective at dissolving and work even at low concentrations.

**Examples:** CMC, Microcrystalline Cellulose, Sodium Starch Glycolate, Crosspovidone, and others.

**Lubricants:**

Lubricants lessen the friction that occurs during tablet compaction and ejection.

**Example:** Talc and magnesium stearate.

**Binders:**

The chosen binders must create a rapid release of active substances and have the appropriate binding quality and correct melting properties. The right choice of binders helps to maintain the stability and integrity of tablets.

**Examples:** polyvinyl alcohol, PVP, and hydroxypropyl methyl cellulose.

**Emulsifying Agents:**

By adding emulsifying agents, it improves bioavailability and stabilises immiscible mixes. It enhances the solubility of ODTs by lowering the interfacial tension.

**Example:** sodium dodecyl sulphate.

**Colour:**

Adding colour will improve the dosage form's look.

**Examples:** Redironoxide, Sunset Yellow, and Amaranth 3.

**Flavours:**
Adding tastes helps to mask the bitterness and unpleasant taste, which increases acceptance and patient compliance.

**Example:** Citrus oil, vanilla, clove, and peppermint oil are a few examples.

**Bulking Agents:**
The use of bulking agents will enhance the drug's textural properties and speed its oral breakdown.

**Examples:** Hydrolysate starch and mannitol

**Conclusion:**
Orally dissolving medication carriers get around some of the problems with traditional. ODTs provide increased bioavailability, patient convenience, and quick commencement of action. Due to their quick effect, ODTs may become the most popular and prescribed dose form in the future. Due to several benefits including patient compliance, simpler administration for paediatric and geriatric patients, individuals with allergies, motion sickness, etc., orodispersible pills are frequently favoured over conventional dose forms. Cost-effective ODTs are created with the use of traditional and proprietary methods, and undesirable medications that treat a variety of diseases can be included in orodispersible tablets. The Orodispersible tablet technology is advancing daily, and ODTs are also accessible as over-the-counter drug.

**REFERENCE:**