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An Oro-Dispersible Tablet: A Brief Review

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ABSTRACT
Due to increased patient compliance, improved solubility, and stability, orodispersible tablets (ODTs) have attracted substantial attention as a preferable alternative to conventional tablets and capsules over the last three decades. When placed on the tongue, ODTs are solid dosage forms containing medical chemicals that breakdown quickly, usually in a matter of seconds. When a medicine is absorbed through the buccal cavity, ODTs constitute a critical drug delivery method. ODTs have been developed using a variety of scientific approaches including as spray drying, sublimation, freeze drying, moulding, direct compression, and so on. ODTs are becoming more commonly available as over-the-counter medications for the treatment of a variety of disorders. The purpose of this article is to go over the benefits, drawbacks, formulation issues, production procedures, patented technologies, commercial formulations, and so on. evaluation tests of ODTs.
Keywords: *orodispersible tablets, Historical development, Conventional Technology, Evaluation parameter.*

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INTRODUCTION

Medicinal and other therapeutic substances that have a systemic effect can be administered by a variety of methods, but the oral route is believed to be the most successful and has a high level of patient compliance. [1] The oral route of administration is still the preferred method of administration for most therapeutic drugs used to elicit systemic effects, owing to its numerous advantages and high patient compliance when compared to other routes. [2] Orally disintegrating tablets, mouth-dissolving tablets, quick dissolving tablets, fast-disintegrating tablets, and fast-dissolving tablets are all terms for orodispersible tablets. The word orodispersible tablets was recently coined by the European Pharmacopoeia. The United States Food and Drug Administration defined ODT as "a solid dosage form containing a medicinal substance or active ingredient that disintegrates rapidly, usually within a matter of seconds when placed upon the tongue." The disintegration time for ODTs generally ranges from several seconds to about a minute. [4,5]

DESIRED CRITERIA FOR ORODISPERSABLE DRUG DELIVERY SYSTEM:

- Have a pleasant mouth feel and are compatible with flavour masking.
- After oral administration, there should be little or no residual in the mouth.
- As a result, it doesn't need to be swallowed with water, but it should dissolve or disintegrate in the mouth in a matter of seconds. [6]

SALIENT FEATURES OF ORO DISPERSABLE TABLETS:

- Patients who refuse to swallow pills or capsules, such as juvenile, geriatric, and mental patients, will find it easier to administer.
- Rapid dissolving and absorption of the drug, resulting in a rapid commencement of action.
- Patient compliance and convenience for disabled, bed-ridden patients, as well as those who are travelling and do not have rapid access to water.
- As saliva flows down into the stomach, some medications are absorbed from the mouth, pharynx, and oesophagus, increasing drug bioavailability.
- Pregastric absorption can boost bioavailability and reduce dosage while also improving clinical outcomes by eliminating unwanted side effects.
- Does not need to be swallowed with water and should dissolve or disintegrate in the mouth in a matter of seconds. After oral administration, there should be little or no residue in the mouth.
- Have enough strength to survive the rigours of the manufacturing process and post-production handling; and

- show little sensitivity to external factors like humidity and temperature. [7,8]

IDEAL PROPERTIES OF ORODISPERSIBLE TABLETS

- Does not necessitate the use of water when taken orally.
- ODT is less sensitive to temperature and environmental conditions.
- Excessive drug loading is permitted.
- Have sufficient hardness and are less friable
- It should leave no or very little residue in the mouth after administration.
- ODTs should have a pleasant tongue feel and hide the taste of the drug they contain;
- production methods should be cost effective; and preparation and packaging must be done using traditional procedures. [9-11]

HISTORICAL DEVELOPMENT OF ORODISPERSIBLE TABLETS:

Many have similar absorption and bioavailability to typical oral dose formulations, with GI absorption remaining the predominant route. A fast disintegration time and a small tablet weight, on the other hand, can help with buccal absorption. ODTs were developed by Catalent Pharma Solutions (previously Scherer DDS) in the United Kingdom, Cima Labs in the United States, and Takeda Pharmaceutical Company in Japan. The first ODT version of a medicine to receive FDA approval in the United States. In December 1996, the Food and Drug Administration (FDA) approved the Zydis ODT formulation of Claritin (loratadine). In December 1997, a Zydis ODT formulation of Klonopin (clonazepam) was released, and in June 1998, a Zydis ODT formulation of Maxalt (rizatriptan) was released. Many have similar absorption and bioavailability to typical oral dose formulations, with GI absorption remaining the predominant route. A fast disintegration time and a small tablet weight, on the other hand, can help with buccal absorption. ODTs were developed by Catalent Pharma Solutions (previously Scherer DDS) in the United Kingdom, Cima Labs in the United States, and Takeda Pharmaceutical Company in Japan. The first ODT version of a medicine to receive FDA approval in the United States. In December 1996, the Food and Drug Administration (FDA) approved the Zydis ODT formulation of Claritin (loratadine). In December 1997, a Zydis ODT formulation of Klonopin (clonazepam) was released, and in June 1998, a Zydis ODT formulation of Maxalt (rizatriptan) was released.

CHALLENGES TO DEVELOP ODT:

Rapid disintegration of tablet
ii. Avoid increase in tablet size
iii. Have sufficient mechanical strength
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iii. Have sufficient mechanical strength
Rapid disintegration of tablet
ii. Avoid increase in tablet size
iii. Have sufficient mechanical strength

i. Mechanical Strength and Disintegration Time: ODTs should have a shorter disintegration time, which is achieved by maintaining a high hardness, which is a significant problem because orodispersible tablets are readily broken and have a high risk of breaking during packaging and transportation.

ii. Taste Masking: When a bitter medication tablet dissolves in the oral cavity, the bitter taste is hidden, and the patient's compliance and acceptance of the drug is altered.

iii. Tablet Size: The ease with which tablets can be administered is dependent on their size, which is difficult to establish.

iv. Amount of Drug: The weight of the pill should not exceed 500mg, which is difficult to do when creating an ODT.

v. Hygroscopicity: Physical integrity is not maintained by hygroscopic ODT under normal temperature and humidity levels, hence they are protected from humidity by specific product packaging.

vi. Mouth Feel: ODT disintegration should not have large particles, but rather fine particles with a pleasant mouth feel.

vii. Good Packaging Design: Packaging design should be enhanced at the earliest stage to protect ODTs from the environment and moisture. [12-14]

METHODS FOR THE PREPARATION OF ORODISPERSIBLE TABLETS:

Orodispersible tablets can be made in a variety of ways, but the qualities of the finished product differ depending on which method was used. Mechanical strength of the tablets, swallowability, bioavailability, drug dissolution in saliva, stability, and to some extent taste are the features that differ.

Conventional Technology:

Freeze Drying:

Freeze-drying or lyophilization are common procedures for preparing ODTs. These methods provide an extremely porous structure in the dosage form, which causes it to breakdown or dissolve quickly when it comes into contact with saliva in the oral cavity. This method of preparation necessitates freezing the substance below its eutectic point. The amount of bound moisture is then reduced to the desired volume by drying. The bulking agent and even the medicine are given a glossy amorphous structure by lyophilization, which increases the extent of disintegration. However, freeze-drying is an expensive procedure that necessitates expensive equipment and processing. However, without freeze drying, the resulting tablets have limited mechanical strength and are unstable at higher temperatures and humidity.

- **Advantages:** More rapid dissolution than other available solid products.
- **Disadvantages:** High cost of the equipment's & lack of physical resistance in blister packs. [16,17]

Sublimation:

Excipients such urea, urethane, naphthalene, camphor, menthol, and ammonium bicarbonate are employed in this method because they have a high volatility and are chemically inert. These are added after the blend has been compressed into a tablet. The sublimation process leaves pores in the tablet structure once these volatile elements are eliminated. When the tablet comes into touch with saliva, this helps to impart a high dissolving property. This approach can be used to create mouth-dissolving tablets with a porous structure and high mechanical strength.

Advantage: Tablets dissolve in 10-20 sec. and exhibit sufficient mechanical strength.[18]

Molding: This process is used to make quick disintegrating tablets. The matrix is present in the tablets created using this procedure. In the matrix, the drug can exist as discrete particles or tiny particles. Compressed tablets are more compact than moulded tablets. The porous structure of these moulded tablets allows for quick breakdown and dissolution. The water-soluble carbohydrates in the dispersion matrix of moulded tablets improve the taste of the tablets. Molded tablets, on the other hand, lack mechanical strength and are susceptible to fracture or erosion during handling and blister pack opening. Sucrose, acacia, or polyvinyl pyrrolidone can be used to improve the mechanical strength of these moulded tablets.

- **Advantage:** Because the dispersion matrix is generally formed of water-soluble carbohydrates, moulded tablets disintegrate more quickly and have a better taste.
- **Disadvantages:** Moulded tablets are not very strong mechanically. When handling and opening blister packets, erosion and breaking occur. [19,20]

Spray Drying:

This method uses a particulate support matrix, which is made by spray drying an aqueous composition comprising the support matrix and other ingredients into a highly porous and fine powder. The active components are then added, and the mixture is crushed into tablets. For the purpose of obtaining rapid dissolution.

Mass Extrusion:

In this method, a mixture of active drug and other ingredients is softened with a solvent mixture of water-soluble polyethylene glycol and methanol, and the softened mass is then extruded through an extruder or syringe to produce a cylindrical structured product, which is then cut into even segments with heated blades to produce tablets. The dried cylinder can be used to coat the granules of bitter-tasting medications, concealing their flavour. [21]

PATENTED TECHNOLOGIES:

Zydis Technology: Zydis formulation is a one-of-a-kind freeze-drying technology that results in a tablet with the medicine physically entrapped or dissolved within the matrix. The matrix is made up of a quick-dissolving carrier substance. When Zydis OTDs are swallowed, the freeze-dried structure rapidly disintegrates and does not require water to facilitate ingestion. Zydis matrix is made up of unique materials to achieve a variety of goals, such as giving strength and resilience during handling by employing polymers like gelatin, dextran, or alginates. The usage of these polymers gives the tablet a glossy amorphous structure that adds strength. [22]

Flashtab Technology: Prographarm laboratory uses Flashtab technology, which they have patented. Rapidly disintegrating tablets in the form of microcrystals with active ingredient are created utilising a variety of traditional procedures such as coacervation, extrusion spheronization, simple pan coating methods, and microencapsulation to create drug microgranules. These microcrystals of active component microgranules are then mixed to a granulated mixture of excipients (made by wet or dry granulation) and crushed into tablets. The entire process is carried out using traditional tableting technology. Experts discovered that prepared tablets have good mechanical strength and a disintegration time of less than one minute. [23]

Orodis Technology:
Compressed technology is Orodis®. It creates pills that disintegrate quickly in the mouth (15 to 30 seconds). It has a number of advantages over other technologies.
i. It generates firm, non-fragile tablets, making compositions simple to handle.
ii. The production of tablets does not necessitate special packaging. Push-through blisters can be used to package them.
iii. Tablets have a pleasant taste in the mouth.
iv. Tablets have a pleasing taste due to the use of taste masking agents and flavours.
v. This method's materials all meet USP and EP requirements.
vi. Conventional manufacturing equipment - easy to relocate to the final manufacturing location.
vii. It is cost-effective. [24]

Durasolve Technology:
DuraSolv is Cima's second-generation fast-dissolving/disintegrating tablet composition. Durasolv Technology uses a higher compaction pressure during tableting, resulting in higher mechanical strength formulations than Orasolv. These tablets are manufactured with standard tableting equipment and have a high degree of stiffness (friability less than 2 percent). As a result, products are produced at a faster rate and at a lower cost. DuraSolv tablets are packaged in traditional blister packaging, pouches, or vials. [25]

Oraquick Technology:
Oraquick technology uses patented flavour masking technology that does not need any solvents for taste masking, resulting in more efficient production. Because this method is treated with low heat, it is suited for heat sensitive drugs. KV Pharmaceuticals says that their "MicromaskTechnology" is better to other tastemasking technologies in terms of tongue feel. [26]

Pharmaburst Technology:
It is a quick dissolving system that uses coprocessed excipients to combine the medicine, lubricant, and flavour into tablets that dissolve in 30-40 seconds. The tablets are delivered in blister packets because they have sufficient mechanical strength. [27]

Melt Ease Technology:
Melt Ease Technology, created by nutrition formulators and allowing pill disintegration in 5 seconds, plays a critical role in nutritional supplement formulations for children and the elderly. [28]

Lyoc Technology:
The first lyophization-based approach for ODTs is Lyoc technology. Fillers, thickening agents, surfactants, nonvolatile flavouring agents, and sweeteners are used in the production of drug suspensions, which is then put into blister cavities and lyophilized. [29,30]

Table.No.01. Examples of some patented orodispersible tablets available in the market

Patented Technology	Technology	Based on Technology developed by Company	Example (Brand name)
Zydis	Lyophilization	R.P.Scherer, Inc	Olanzapine (Zyprexa Zydis)
Lyoc	Lyophilization	USA Farmalyoc France	Phloroglucinol Hydrate (Spasfon Lyoc)
Flashtab	Direct compression	Ethypharm France	Ibuprofen (Nurofen FlashTab)
Orasolv	Direct compression	Cima Labs, Inc. USA	Paracetamol (Tempra Quicklets)
Advatab	Microcaps and diffuscap CR Technology	Eurand International Italy	Cetrizine hydrochloride AdvaTab cetrizine
Flashdose	Cotton Candy Process	Fuisz Technology, Ltd. USA	Tramadol HCl (Relivia Flash dose)

INGREDIENTS USED FOR ORODISPERSIBLE TABLETS:
Orally disintegrating tablets need the use of substances that aid in the disintegration of the dosage form and result in rapid medication release. Both active and inactive ingredients are included. Binders Lubricants Bulking agent Agents that emulsify Sweeteners and flavours Superdisintegrants [31,32] are a type of Superdisintegrants.

MECHANISM OF ACTION OF SUPERDISINTEGRANTS:
Following are the primary mechanism by which a tablet can disintegrate into its primary particles:

1. Swelling:
Due to a lack of sufficient swelling force, tablets with a high porosity disintegrate poorly. The tablet with poor porosity, on the other hand, receives significant swelling force. It's worth noting that if the packing percentage is really high, fluid cannot penetrate the tablet and disintegration is halted once more.

2. Capillary Action:

The initial phase is always disintegration via capillary action. When we immerse the tablet in an appropriate aqueous medium, the medium enters the tablet and replaces the air adsorbed on the particles, weakening the intermolecular link and causing the tablet to disintegrate into fine particles. The hydrophilicity of the medication and excipient, as well as tablet production circumstances, influence water uptake. The maintenance of a porous structure and low interfacial tension towards aqueous fluid is required for these types of disintegrants, which aids in disintegration by forming a hydrophilic network around the drug particles.

3. Repulsive Force between Particles:

Another disintegration process tries to explain why tablets constructed with 'nonswellable' disintegrants swell. Guyot-Hermann presented a particle repulsion theory based on the discovery that non-swelling particles are also responsible for tablet disintegration. The mechanism of disintegration is electric repelling interactions between particles, and water is necessary. Researchers discovered that wicking comes second to repulsion.

4. Release of Gases:

Carbon dioxide is released into the tablet as it wets due to the interaction of carbonates and bicarbonates with tartaric or citric acid. Due to this gas, a pressure is created between the tablets. This combination of carbonates and citric acid is also used to make effervescent tablets that dissolve quickly.

5. Enzymatic Reaction:

Body enzymes act as a dissolving agent for tablets. They work as a disintegrating agent by diminishing the binding effect of the binder and so disintegrate the tablet.

6. Deformation:

Hess demonstrated that fragmented particles get deformed during tablet compression, and that these deformed particles revert to their original structure when they come into touch with watery medium like water. When starch granules were extensively distorted during compression, the swelling capacity of the starch was occasionally improved. The tablet breaks up due to the increased size of the distorted particles. This could be a starch mechanism that has only lately been investigated. [33-35]

EVALUATION OF ORODISPERSIBLE TABLETS:

1. Tablet thickness:
2. Weight variation
3. Friability
4. Hardness (Crushing strength)
5. Water absorption ratio
6. Uniformity of dispersion
7. Wetting time
8. Disintegration time
9. In vivo disintegration time
10. Taste/ Mouth sensation
11. Dissolution test [36-38]

ADVANTAGES: [31, 33, 39-41]

- The tablet can be swallowed without the use of water.
- Have a pleasant mouth feel and are compatible with flavour masking.
- It's simple to give to children, the elderly, and mentally ill individuals.
- After administration, there is no residual in the oral cavity. At a low cost, the tablets can be manufactured using standard processing and packaging equipment.
- Allow for a lot of medication loading.
- Accurate dose can be given as compared to liquids.
- The tablet can be swallowed without the use of water.
- Have a pleasant mouth feel and are compatible with flavour masking.
- It's simple to give to children, the elderly, and mentally ill individuals.
- After administration, there is no residual in the oral cavity. At a low cost, the tablets can be manufactured using standard processing and packaging equipment.
- Allow for a lot of medication loading.

DISADVANAGES:

- Because these are exceedingly hygroscopic, care must be given when storing them. Drugs with relatively greater doses, such as antibiotics like ciprofloxacin, are difficult to synthesise into ODTs, with an adult dose tablet having roughly 500 mg of the medication.

- ODTs can be extremely brittle due to their porous structure. ODTs necessitate particular packaging for optimum stabilisation and product safety. Special care must be taken after using ODTs, such as the restriction of eating and drinking for a period of time. [42]

LIST OF ABBREVIATIONS

ODTs: Orodispersible tablets
FDA: Food and Drug Administration

CONCLUSION

ODTs are solid unit dosage forms containing super disintegrants, which allow for rapid disintegration in the presence of saliva while avoiding swallowing difficulties. The drug is released as soon as the tablet is fragmented in the mouth; it is then dissolved or disseminated in saliva and absorbed sublingually. As a result, bioavailability improves. Self-administration, quick or immediate beginning of action, no water required for swallowing, reduced ulceration risk, avoiding first pass metabolism of the drug, and enhanced bioavailability are all advantages of ODTs. Orodispersible tablets (ODTs) are cutting-edge medication delivery technologies with potential benefits over traditional dose forms. Though much study has been done in the development of ODT formulations and technologies, more intensive research is needed in this promising area to provide newer, more cost-effective technologies and better products.

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