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A Brief Introduction on Oro Dispersible Tablets

Yogaraj R[1]*, Surinder Kaur[2], Padmaa M Paarakh[3]

[1,2]Department of Pharmaceutics, The Oxford College of Pharmacy, Bengaluru, India.*
[3]Department of Pharmacognosy, The Oxford College of Pharmacy, Bengaluru, India.

Corresponding Email: [1]yogarajr1999@gmail.com*

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Abstract: ***Oro dispersible tablets (ODTs), which have improved solubility and stability over the past three decades, have drawn a lot of interest as a superior alternative to traditional tablets and capsules. ODTs—solid dosage forms with medications that dissolve on the tongue fast, usually in a few seconds. New ODT technologies answer a wide range of pharmaceutical preparations and patient needs, to enhance the lifecycle management to straightforward dosage regimen for dysphagic, children, old, and mentally imbalanced patients. Methods for administering orally dispersible drugs are frequently used to improve patient compliance and bioavailability. Researchers in academia and business have been motivated by this to create novel technologies and orally disintegrating formulations in this field. This article's main objective was to cover the development of ODTs, formulation concerns, novel oral dispersible technology, different types of methodology to evaluate, the selection of drug candidates, and novel possibilities in future.***

Keywords: ***Super Disintegrants, Oro Dispersible Technology, Bioavailability, Oro Dispersible Tablets, Oro Dispersible Technologies.***

1. INTRODUCTION

The tablets are the most popular solid dosage form, which is ideal for taking medicine without any trained person or self. compact, accurate in dosage, and simple to produce. As a result, several efforts have been undertaken to create chemicals that are most effective in solid dosage forms and deliver reliable and effective plasma concentrations following delivery. The biggest issue with oral dosage forms is swallowing problems, particularly for young patients and older patients who are bedridden and experiencing nausea or mental illnesses. A solid dose form that may swiftly dissolve even when taken orally without water has been created in order to address this issue and enhance the patient's intake and compliance.

A relatively new dosage form technology is the rapidly disintegrating oral dosage form (tablet or film), which swiftly disperses in the oral cavity in absence of water. The dosage form starts to break down as soon as it comes into contact with saliva, and full breakdown

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normally happens 30 to 50 seconds after administration. The active ingredient is absorbed by the gastrointestinal tract's epithelium after the solution containing it enters the body, serving the intended function and having the desired effect. The clinical effect is more pronounced the faster the medicine dissolves and is absorbed.

Oro dispersible tablets are "unit solid dosage form containing a therapeutic agent, which typically disintegrates immediately and with in less than few seconds on contact with the tongue," according to the U.S. FDA. ODT typically disintegrates within a few seconds or a minute. The medication is absorbed through the mouth, pharynx, and oesophagus when saliva enters the stomach. A portion of the drug's pre gastric absorption may stop the metabolism of gastric acid. When compared to conventional tablet dose forms, the drug's bioavailability in this instance is noticeably higher. The term "Oro dispersible tablet" was recently coined by the European Pharmacopoeia to describe pills that dissolve easily in the mouth before being swallowed.

The terms mouth-dissolving tablets, rapid disintegrating tablets, and quick dissolving tablets are all used to describe oral disintegrating tablets. These dosage forms have been assigned an ODT by the United States Pharmacopeia (USP) for each of the aforementioned conditions.

Advantages of ODTs

ODT are ideal for patients who cannot swallow tablets or capsules, such as the old patients and also people who have had strokes, people who are bedridden, geriatric patients, and patients who are in psychiatric facilities, enhancing patient compliance.

1. Cost effective.
2. Rapid drug therapy intervention.
3. It includes research that showed enhanced bioavailability and shown quick drug absorption through stomach absorption of drugs from the mouth, throat, and oesophagus as saliva starts flow down.
4. Therefore, ODT is more ideal for passengers and people who sometimes do not have easy access to water.
5. No need to chew.
6. ODT has a pleasant mouthfeel, which alters how people view medications.
7. Allows rapid administration.
8. The risk of suffocation caused by the oral conventional preparations due to disability in the movement is avoided, thereby improving patient compliance.
9. Quick onset of action.
10. Suitable for motion sickness (motion sickness), sudden allergic attacks or coughs that require quick onset.

Disadvantages

1.ODTs requires proper packaging for safety and stabilization of drugs.
2.ODTs are hygroscopic in nature, so must kept in dry place.
3.ODTs shows the fragile, effervescence granules property.
4.ODTs if not formulated properly, it will leave unpleasant taste in mouth.

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Ideal characteristics of ODTs

1. Water is not needed for oral administration.
2. It dissolves quickly in saliva or is easily dissolved.
3. Pleasant flavour.
4. It leaves nearly no aftertaste in the mouth after oral use.
5. Easily Transportable and portable.
6. The ability to manufacture at a minimal cost using standard, easy methods.
7. Not very sensitive to external factors like humidity and temperature.
8. It must be compatible with taste masking substances.

Problems in development of ODTs

Mechanical strength and disintegrating time

ODT formulations may lead to disintegration times that are typically under a minute. It can be difficult to keep up good mechanical strength, though. Many ODTs are delicate, and such delicate tablets are liable to break during packaging, shipping, or patient handling. Finding a good compromise between these two factors is always required because increasing mechanical strength would inevitably lengthen the period before disintegration.

Taste masking

The taste of many medications is bitter. Patient compliance and dose acceptance are significantly impacted by the bitter taste of the pill that dissolves/disintegrates in the mouth. Consequently, it is important to adequately disguise the bitter medicine taste to prevent tongue perception of the drug.

Water solubility

Due to the eutectic mixture that they produce, which lowers the freezing point and creates a glassy solid that loses support during sublimation and subsequently decomposes during drying, water-soluble pharmaceuticals face a number of formulation issues. Typically, different matrices are not required to create fillers like mannitol, which cause crystallisation and subsequently harden the amorphous composite material.

Tablet size

How much of a tablet is taken depends on its size. The best tablet size for swallowing is between 7-8 mm, whereas larger than 8 mm tablets are the easiest to manage. As a result, making pills that are simple to hold and swallow is difficult.

Drug amount

The use of ODT technology is constrained by the amount of medication that may be included in each unit dose. ODT tablets should normally weigh no more than 500 mg, according to the USP. The recommended daily dosage for soluble drugs is 60 mg, and for insoluble pharmaceuticals, no more than 400 mg.

Hygroscopicity

All oral dosage forms are hygroscopic and unable to retain their physical integrity in settings of normal temperature and humidity. As a result, they need to be protected against moisture, which necessitates particular product packaging.

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Mouth feel
ODTs shouldn't break down into bigger pieces inside the mouth. The ODTs should disintegrate into the smallest feasible number of particles. The taste can also be enhanced by adding menthol and other flavouring and cooling substances.

Good packaging design
Early on in the development process, the package design should be taken into account to protect ODTs from moisture and other environmental hazards.

Formulation consideration for Oro dispersible tablets
Drug Properties: The medicine should be able to be produced into a tiny tablet and should have good oral solubility and stability. The texture and taste of the medication might also be crucial considerations because they have an impact on how well the patient takes their prescription.

Excipients: The excipients utilised in the creation of ODTs should be suitable for oral administration. They ought to be able to offer the desired dissolving or disintegration properties as well. Disintegrants, sweeteners, and flavouring compounds are examples of common excipients. Examples include mannitol, sorbitol, and sodium starch glycolate.

Compression Technology: Compression technology is commonly used in the production of ODTs. The tablets ought to be made with a porous structure that enables for quick dissolving and disintegration. To guarantee that the tablets are stable during handling and transit, the hardness and friability of the tablets should also be carefully managed.

Packaging: ODTs should be shielded from exposure to humid environments because they are typically moisture sensitive. The stability and shelf life of the tablets should be guaranteed by using suitable packaging, such as blister packs or sachets.

Regulatory Requirements: ODTs may be subject to different regulations than other oral dose forms, such as immediate-release pills. It is crucial to confirm that the manufacturing and formulation processes adhere to all applicable regulatory requirements.

Evaluation Parameters of ODTs
Disintegration time: ODTs should dissolve quickly in the mouth, often between 30 seconds and 3 minutes, depending on the particular substance. The disintegration test outlined in pharmacopoeias can be used to calculate disintegration time.

Drug Content: Each tablet should have an equal amount of active pharmaceutical ingredient (API) to fulfil the promise made on the label. Validated analytical techniques can be used to determine the presence of drugs.

Weight Uniformity: To achieve precise dosing, each pill should weigh the same amount. To evaluate the homogeneity of weight, one might utilise a weight variation test from the US Pharmacopeia (USP).

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Friability: ODTs must be capable of handling and transportation without cracking or disintegrating. The capacity of the tablets to break or crumble is measured by their friability, which can be determined using the USP friability test.

Hardness: ODTs should be tough enough to endure handling and transit, but not so tough that they take a long time to break down in the mouth. A tablet hardness tester can be used to gauge hardness.

Dissolution Rate: The medication's duration and start of effect may be impacted by how quickly the API dissolves in the mouth. Validated dissolution methods can be used to calculate the dissolving rate.

Taste and mouthfeel: Patients' compliance and acceptance of ODTs may be impacted by their flavour and texture. To evaluate the tablets' acceptability and palatability, sensory evaluation tests can be carried out.

Stability: ODTs should continue to be stable over time and in various storage environments. To assess the tablets' shelf life and storage circumstances, stability studies can be performed.

Excipients used in Oro dispersible tablets [15-17]

The ingredients employed in ODT must be able to release the medicine quickly, hence speeding up dissolution. Adjuvants and active substances are included in this. The adjuvants maintain the qualities of the ODT active components in balance. To prevent interactions with active compounds, this calls for a thorough undertaking of the chemistry of these auxiliary substances. For formulators, figuring out the price of these substances is another difficulty.
Excipients play a crucial role in the creation of Oro dispersible tablets. When used together, these inert, food-grade components offer the finished product the appropriate organoleptic qualities and efficacy. Excipients are common and can be used with a wide variety of active substances, except for a few active compounds that require masking agents.

a. Bulking agents: Bulking agents enhance the textural qualities, which enhance the disintegration in the mouth. Adding bulk also lowers the concentration of the active ingredient in the composition.
E.g., Mannitol, polydextrose, lactitol, DCL, Microcrystalline cellulose, etc. Bulking agents are incorporated into the final composition in amounts ranging from 10% to 90% by weight.

b. Super disintegrates:

Super disintegrates have a higher mechanical strength and disintegration efficiency, making them more effective at lower concentrations. The super disintegrant will swell, hydrate, alter volume or form when it comes into touch with water, which will cause a disruptive change in the tablet.
E.g., Crospovidone, Microcrystalline Cellulose, Sodium Starch Glycol, Dehydrated Banana Powder, Calcium Carboxymethylcellulose, modified corn starch. Banana powder that has been dehydrated naturally disintegrates well and is similar to Crospovidone in this regard.

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c. Lubricants
Lubricants are chemicals that remove grit from food and facilitate the passage of medications from the mouth to the stomach.
E.g., Talc, polyethylene glycol, liquid paraffin, colloidal silicon dioxide, magnesium stearate, magnesium stearic acid, zinc oxide, calcium oxide, and other materials.

d. Flavours and Sweeteners: Patients will find the items to be more pleasant and pleasing when flavours and taste-masking substances are included. These substances help to mask the bitterness and unpleasant tastes of some active compounds.
E.g., Flavours- oil of bitter almonds, eucalyptus, bay, anise, peppermint, clove, and so on.
Sweeteners- derivatives of sugar, aspartame.

Selection of Super disintegrates
The super disintegrant must fulfil specific requirements in addition to having swelling qualities because it is employed as a filler for tablets. Disintegrants must meet specific requirements, which must be specified. The perfect disintegrant ought to have-
1. Lack of solubility
2. Ineffective gel formation.
3. Strong capacity for hydration.
4. Effective flow and deformation behaviour.
5. Does not create drug-drug complexes.
6. Pleasant mouthfeel.
7. It must also possess the necessary tablet characteristics and be compatible with other excipients.
8. It must also have the desired tablet characteristics and be compatible with other excipients.

Mechanism of super disintegrates
1. Swelling
The most frequent cause of pill disintegration is probably swelling. High-porosity tablets can't dissolve well since there isn't enough expansion force. On the other hand, each pill has enough swelling force if the porosity is modest. It should be noted that the disintegration slows down again if the container is overfilled with material since the tablet cannot absorb any liquid.

2. Porosity and Capillary action
Whenever decomposition occurs, capillary action occurs first. When a tablet is immersed in a suitable aqueous media, which permeates the tablet and replaces the air adsorbed on the particles, the intermolecular bonds of the tablet are weakened, and the tablet is broken up into little particles. The hydrophilicity of the medicine or excipient, as well as the circumstances surrounding tablet manufacture, affect the tablet's water absorption. These forms of disintegrants must maintain a porous structure and low interfacial tension in compared to an aqueous liquid to facilitate disintegration by forming a hydrophilic network around the drug particles.

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3. Due to particle disintegration

The tablet swells from the "non swelling" disintegrant, according to another disintegration mechanism. Based on the discovery that even unexpanded particles had the ability to shatter tablets, Guyot Hermann created the particle repulsion theory. The mechanism of decomposition, which necessitates water, is the electrostatic attraction between particles. The researchers discovered that the wick is what is causing this rejection.

4. Due to deformation

When compressed, the broken pill pieces take on a new shape. These warped particles restore their normal structure when they come into contact with water or an aqueous solution. In the event that you need to change your mind about the purchase, it is a good idea to have a backup strategy. As the size of the deformed particles grows, the tablet breaks.

2. CONCLUSION

In comparison to traditional oral dose forms, orally disintegrating tablets have higher patient acceptance and compliance as well as the potential to offer superior biopharmaceutical characteristics, increased efficacy, and improved safety. Prescription ODT medications were initially created to help paediatric, geriatric, and psychiatric patients with dysphagia who had trouble swallowing regular tablets. ODTs are now more readily accessible as over-the-counter medications for the relief of allergy, cold, and flu symptoms. Due to the availability of new technologies, along with their great market acceptance and patient demand, these dosage forms have a promising future. Pharmaceutical businesses can benefit from ODTs for product range extensions or for first-to-market goods by closely monitoring technological advancements.

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