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Review

Oral Disintegrating Tablet: A Review

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Abstract

Comfort of drug administration and patient compliance are important considerations in dosage form design. Strong, adaptable tablets with exceptional flavor masking and controlled release can be produced using new and emerging technology. Solid dose forms known as oral disintegrating tablets (ODTs) dissolve in the mouth in less than 60 seconds, allowing for waterless swallowing. Rapid pill disintegration results in rapid dissolving and, thus, a rapid start of action. Pediatrics, the elderly, psychotic, dysphagic, bedridden, comatose, young patients with underdeveloped neurological and muscular systems, patients with hand tremors, and patients who travel frequently are among the particular populations for which ODTs are an appropriate dosage form. It offers reduced packing size, precise dosing, superior stability, and convenience of manufacture. Since water is not needed during transportation, self-administration is feasible. ODTs are a cost-effective way to distribute medications. When a medicine is absorbed from the buccal cavity, ODTs are a crucial drug delivery method. For the creation of ODTs, a variety of scientific methods have been used, including as molding, direct compression, spray drying, sublimation, and freeze drying. ODTs are becoming more readily accessible as over-the-counter medications for the treatment of a wide range of illnesses. Reviewing ODTs' benefits, drawbacks, formulation difficulties, manufacturing processes, patented technologies, commercialformulations, and evaluation testing is the goal of this article.

Keywords: Oral Disintegration Tablet , Dysphagic condition, Precise dosing.

INRODUCTION

ODTs are likely the most popular way to administer therapeutic agents due to their low cost, self-medication, precise dosage, simplicity of use, and non-invasive approach, which results in a high degree of patient compliance. However, individuals who are traveling without access to water can benefit from taking traditional capsules or tablets orally. Some elderly patients may find traditional water-assisted capsules and tablets inconvenient or impracticable due to aging- related changes in neurological and physiological conditions, such as dysphagia or trouble swallowing. Solid dose forms pose serious administrative difficulties for several patient

populations, including toddlers, patients with mental disabilities, and patients who are uncooperative. Due to immature muscle systems and nervous control, pediatric patients may experience issues with ingesting.
The creation of viable dosage alternatives, or ODTs, has led to the development of a recent technology. Fast dispersing, rapid melt, rapid dissolve, fast melting, and/or quick disintegrating tablets are other names for ODTs. ODTs that dissolve in the mouth for less than three minutes before being swallowed were adopted by the European Pharmacoepia. It is readily absorbed in the bloodstream. The effectiveness of ODTs in promoting bioavailability has been assessed. Compared to medication solubility and absorption, clinical effect onset, and drug bioavailability, conventional dose forms may be noticeably less effective. [1-5]

Ideal properties of orodispersible tablets [6-7]

Should melt or disintegrate in the mouth in a matter of seconds and not require water toconsume.
Have a high drug loading capacity;
Work well with other excipients and flavor masking
Feel good in the mouth;
After oral delivery, leave little to no residue in the mouth;
Show little sensitivity to environmental factors such temperature and humidity.

Advantages of odts [8-13]

The tablet can be swallowed without water.
Have a pleasant mouthfeel and are compatible with flavor masking.
Easily provided to patients with mental disabilities, the elderly, and children.
Following administration, there is no residue in the oral cavity.
The tablets may be manufactured for the least amount of money utilizing standard processing and packaging equipment.
Permit a lot of drug loading.
Unlike liquids, an accurate dose may be administered.
The medicine dissolves and absorbs quickly, providing a quick start to action.
Better in terms of transportation and administration than liquid medication.
As saliva flows down into the stomach, some medications are absorbed from the mouth, pharynx, and esophagus. This lowers first pass metabolism, improving bioavailability andresulting in a lower dosage.

Disadvantage [14-15]

ODTs are rapid-melt tablets that must be kept in a cool, dry location due to their hygroscopicnature.
To preserve and stabilize the stable ODTs, ODTs must be put in specialized packaging.
Incorrect formulation may result in an unpleasant taste and a disconcerting sensation in themouth;
the pills' low mechanical strength necessitates careful handling.

ODTS formulation development/methods of preparation

One of the most important steps is the formulation of a medication. During bulk manufacture, the formulator must exercise extreme caution because a poorly designed product will undoubtedly fail to demonstrate its therapeutic efficacy as intended. There are various methods available for producing ODTs. Every methodology has advantages and disadvantages of its own; any of the following approaches may be used, depending on the kind of drug-excipient.

Freeze Drying: Lyophilization is primarily utilized for medications that are heat-labile. because it uses a low temperature to dry the medication. Sublimation allows the medications' moisture to escape. This method involves keeping the medication in a water-soluble matrix, which is subsequently dried by passing it through a freezing tunnel.The final product's bioavailability is increased because of its porous character, which causes it to dissolve in a matter of seconds [16-17]
Moulding: The molding process is among the best techniques for creating oral dispersible tablets. The product dissolves rapidly since only water-soluble components are used. Here, the dispersible tablets are compressed at a lower pressure after all of the solid constituents have been dissolved in hydroalcoholic liquids. The solvent is shelved using the air-drying process after compression. The end product has a high dissolving rate due to its high porosity [18].
Spray Drying: This technique is typically used when fine, highly porous powders are required. This approach uses mannitol as a bulk-forming agent and gelatin as a supporting ingredient. Effervescent compounds can also be used to improve dissolution and disintegration properties. Finally, a porous powder is created by spray drying the produced material [19].

Sublimation: Because compressed tablets have a low porosity, their rate of disintegration can occasionally be slowed. A tablet is created using the sublimation procedure by combining the volatilizing agent, the active medicinal ingredient, and an additional adjuvant. Sublimation is used to evaporate the volatile substance following compression. Typically, tablets made using this method dissolve rapidly [20].
Mass extrusion: This process softens the active mixture of solvents, which is a mixture of methanol and water-soluble polyethylene glycol. The softened mass is then put into a syringe or extruder to create a cylinder-shaped product, which is then further divided into tiny pieces to create tablets. The resulting substance can also be coated to disguise the taste of bitter medications. [21]

Direct compression

The simplest and most economical method of producing tablets is direct compression. By choosing the right excipient combinations that offer quick disintegration and the best possible physical resistance, this process can be used to create ODT. Because of its sweetness, aqueous solubility, pleasant mouthfeel, and effective flavor masking, sugar-based excipients are frequently utilized as bulking agents. Although they break down more slowly, tablets made using the traditional compression method are less friable. Tablets with enough structural integrity can be easily and affordably prepared using the compression method, either with or without wet granulation [21-22].

Challenges in formulating oral dispersible tablets: [23-24]

PALATABILITY: Drugs don't taste good. It dissolves or disintegrates in the patient's mouth after administration. Taste buds are used to release the active substances. Because medications can hide their flavor, patient compliance becomes crucial.
MECHANICAL STRENGTH: Oral dispersible tablets, which are composed of either soft- molded, highly porous material or compressed into tablets with minimal compression force, dissolve in the oral cavity. Low compression force results in tablets that are brittle, friable, and challenging to handle, as well as blister packaging that raises costs.
HYGROSCOPICITY: The hygroscopic nature of oral disintegrating dosage forms means they cannot maintain their physical integrity under typical humidity and temperature conditions. As a result, they require specific product packaging to keep out moisture.
AMOUNT OF DRUG: The quantity of drug that restricted ODTs can incorporate into each unit dose through the usage of technologies. For lyophilized dosage forms, the medicine must contain 60 mg of soluble drug and less than 400 mg of insoluble drug. When creating an ODT, this parameter is difficult to figure out.
AQUEOUS SOLUBILITY: Due to different formulation issues with water-soluble drugs, they create eutectic mixtures that have a lower freezing point and a glassy solid that may collapse when dried since the supporting structure was lost during the sublimation process. Such collapse can be avoided by utilizing matrix-forming excipients, like mannitol.
TABLET SIZE: The tablet's size is determined by how simple it is to administer. Tablets larger than 8 mm were the simplest to manage, and tablets between 7 and 8 mm were the easiest to swallow. As a result, it is challenging to find a tablet size that is convenient to carryand transport.

Patented technologies for orodispersible tablets

A variety of patented technologies were created to create orodispersible tablets, and they are detailed below.
ZYDIS TECHNOLOGIES
Scherer, a division of Cardinal Health, is the owner of the Zydis® technology [29]. In order to manufacture the tablets using this method, the active medication is mixed with a water-soluble matrix, which is then shaped into blister pockets and freeze-dried to eliminate water through sublimation. The matrix is composed of several components, such as alginates, gelatin, or dextran, which give it strength during handling and create a glossy, amorphous structure. Mannitol or sorbitol is added to give it hardness, elegance, and crystallinity, and different gums can be added to stop the dispersed drug particles from sedimenting. Glycine and other collapse protectants can be employed to stop dosage forms from shrinking during long-term storage and freeze drying. It takes two to three seconds for the Zydis product to dissolve on the tongue. The Zydis formulation is extremely light, brittle, and unstable at increasing humidity and temperature levels. It is highly susceptible to deterioration at humidity levels greater than 65% and easily absorbs water [30].

RAPID-DIS technology

This innovative intraoral medication delivery device, which is a thin, flexible, and rapidly dissolving film and is patented by Lavipharm, is known by the trademark Quick-DisTM. The film is held in place at the application location and quickly releases the active ingredient for either local or systemic absorption when it is placed on

the tongue's floor or top. The Quick- DisTM film, which has a thickness of 2 mm, usually disintegrates in 5–10 seconds. [30]

Oraquick technology

A proprietary flavor masking technology is used in the formulation of Oraquick rapid dissolving/disintegrating tablets. Since no solvents of any type are used in this flavor masking technique, production is accelerated and made more effective. Low heat is generated during processing, making this method appropriate for medications that are sensitive to heat. Additionally, according to KV Pharmaceuticals, the matrix that envelops and shields the medication powder in microencapsulated particles is more malleable. This method produces pillsthat dissolve quickly in a matter of seconds and have good taste concealing [31].

Technology from durasolv

The second-generation ODT tablet formulation developed by CIMA Lab, known as Durasolv®, is patented. It is made similarly to OraSolv and requires minimal amounts of active components. The tablets are made up of a medication, filler, and lubricant. Tablets with good stiffness (friability less than that 2%) are made with standard tableting equipment. These can be put into standard packaging systems like vials, blisters, or pouches. Because higher compaction pressures were used during tableting, it had a significantly higher mechanical strength than its predecessor [30]. In fact, stock bottles are used to distribute NuLev®, the most recent Durasolv® formulation [29].

Shearform technology

This method is based on the production of floss, commonly referred to as "Shearform Matrix," which is made by flash heating a feedstock that contains a sugar carrier. In this process, the sugar is simultaneously exposed to a temperature gradient and centrifugal force, which elevates the mass's temperature and produces an internal flow state that allows some of it to move in relation to the mass. Due of its amorphous nature, the resulting floss is further diced and recrystallized. After that, an active component and additional tablet excipients are combined with the recrystallized matrix. Tablets are formed by compressing the resultant mixture [9].

Technology for flash doses

Fuisz is the patent holder of flash dosage technology. Biovail Corporation's first commercial product is Nurofenmeltlet, a novel version of ibuprofen in the shape of melt-in-mouth tablets made with flash dosage technology [22]. Using a special spinning mechanism, the Flash Dose technology creates a crystalline structure that resembles floss, much like cotton candy. The medication can then be incorporated into this crystalline sugar and crushed into a tablet. The self- binding shear-form matrix known as "floss" makes up the Flash dosage tablets. Flash heat processing is used to create shear form matrices [33].

Technology using nanocrystals

Elan, King of Prussia, is the patent holder of this. Lyophilization of colloidal medicinal dispersions and water-soluble components packed into blister pockets is a component of nanocrystal technology. This approach is more beneficial for extremely powerful and dangerous medications because it skips manufacturing steps including granulation, blending, and tableting. This method works well for modest amounts of medication because the manufacturing losses are minimal [34].

Evaluation of odts

Precompression characterization of tablet

Prior to compression, the bulk and tapped densities of the powder blends should be measured. The compressibility index and Hausner's ratio should then be computed from these values, and the angle of repose should be used to evaluate the flow characteristics of the powder blends.

Angle of repose [35]

The angle of repose can be used to quantify the frictional forces in loose powder or grains. This is the angle formed by the horizontal plane and the surface of a pile of grains or powder. The funnel method determines it. Pour the mixture through a funnel that has a maximum cone height that can be raised vertically. It is necessary to measure the heap's radius (r). The followingformula is used to determine the angle of repose:

$$\tan \Theta = \frac{\text{height}}{\text{radius}}$$

BULK DENSITY [36]
Accurately weighed 5 gm of blend, previously passed through20# sieve is transferred into 100 ml graduated cylinder. The powder was carefully levelled without compacting and the unsettled apparent volume was noted.

$$\text{Bulk density} = \frac{\text{Weight of the powder}}{\text{Bulk density of the powder}}$$

Tapped density [36]

Accurately weighed 5 gm of the blend was transferred into100 ml graduated cylinder. Initial volume was observed. The cylinder was tapped initially 100 times from a distance of 14 + 2 mm and measured the tapped volume to the nearest graduated units. The tapped bulk density in gm/ml was calculated by using the following formula.

$$\text{Tapped density} = \frac{\text{Weight of the powder}}{\text{Tapped density of the powder}}$$

Hausner's ratio [37]
Hausner's ratio is an index of ease of powder flow. It is calculated by the following formula:

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Carr's index (compressibility)
Compressibility index of powder can be determined by following formula:

$$\text{Compressibility index} = \frac{(\text{Tapped density} - \text{Bulk density})}{\text{Bulk density}} \times 100$$

POSTCOMPRESSION CHARACTERIZATION OF TABLETS [38-40]

Weight variation test
Weigh each of the twenty randomly chosen tablets, then determine the average weight.

Tablet hardness
Monsanto hardness tester can be used to determine the crushing strength.

Tablet friability
Weigh twenty formulation tablets, then use a Roche friabilator set to 25 rpm for four minutes to abrasively grind them. To determine the percentage of friability, weigh the tablets and compare them to their initial weights.

$$\text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Thickness
The die and punches used to make the tablets determine their diameter and punch size. A screw gauge is used to measure the tablet's thickness. The thickness of tablets should be kept within a defined range of ±5%. Controlling the thickness is also necessary to make packaging easier. For density (BD), the thickness in millimeters (mm) should be determined separately, and the following formula should be used to determine the tapped density (TD):

In vitro disintegration time
Using a tablet disintegration tester, six tablets are used in water at 37 °C for this test. The amount of time needed for the pills to dissolve and fully flow through the sieve is noted.
IN VITRO DISSOLUTION STUDY

The USP dissolving testing device 2 (paddle method) is used to measure the drug release rate from ODTs. 900 ml of 0.1 N HCl is used for the dissolving test, which is run at 37±0.5 °C at 100rpm.

Wetting time
Take a 10.75 x 12 mm piece of tissue paper, fold it twice, and put it in a culture plate with 6 ml of water (d = 6.5 cm). Place a tablet on the paper, then note how long it takes for it to completelywet.

In vitro dispersion time
Place the tablets at 37±0.5 °C in 10 ml of phosphate buffer solution (pH 7.4). Calculate how long it takes for the tablets to completely dissolve.

Water absorption ratio (r)
Before placing the tablet in the petri dish (Wb), weigh it using a digital weighing balance. After the tablets have been moistened, note their weight (Wa). The following formula can be used to calculate the water absorption ratio, or R: where Wb and Wa are the tablet weights prior to and following water absorption, respectively.

$$R = \frac{Wa - Wb}{Wb} \times 100$$

CONCLUSION

The basic idea behind all known ODT technologies is to optimize the porosity structure of the tablet matrix in order to ensure rapid tablet disintegration in the buccal cavity, as well as acceptable taste-masking qualities and enough mechanical strength. Future difficulties for many ODT makers include improved mechanical strength, taste-masking potential, packaging variety, and cost reduction through the use of conventional machinery. Oral disintegrating pills are therefore more widely accepted due to patient demand and the availability of different technologies, which in turn extends a drug's patent life. The methods and tools discussed in this article illustrate how current advancements in formulation and processing technology contribute to the endeavor to create tablets that dissolve in the mouth. In the near future, further innovative technologies for ODTs may emerge. As a result, ODTs will soon have a great deal of potential asa drug delivery method for the majority of medication.

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