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Current scenario of orally disintegrating tablets

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Abstract
In current scientific environment, drug distribution system has become tremendously competitive and is fast improving in response to growing demand. Orally disintegrating tablet (ODT) is one form of new and exclusive medication delivery system that is rapidly gaining traction in the quick dissolving technology research area. Because a large range of medications can be taken via the oral route, it is the most convenient and safest method of drug delivery. Researchers recently produced a fast dissolving tablet (FDT) that dissolves or disintegrates quickly in oral saliva without the need for water. Many problems, such as dysphagia or lack of access to water while travelling, have been overcome by this innovative medication delivery, such as FDT or MDT (mouth dissolving tablet). This review article contains different techniques used for preparing FDT, silent features, various patented technologies and mechanism of super disintegration, challenges faced and the limitations.

Keywords: oral route, mouth dissolving tablet, super disintegrates, dysphagia, fast dissolving tablet

Introduction

There is increase in demand for more patient-friendly & compliant dose forms during the last decade. As a result, the demand for new technology development has been expanding year after year [1]. Because the cost of developing a new drug molecule is so high, pharmaceutical companies are now concentrating their efforts on the development of new drug dosage forms for current API that have better-quality care and effectiveness while requiring less frequent dosing, as well as the production of more cost-effective dosage forms. Because of its simplicity of delivery, the oral cavity is a popular location for drug administration. Oral administration is used for a variety of dose forms, including tablets, capsules, and liquid preparations [2]. Orally disintegrating tablet, which allows tablets to dissolve in the mouth without chewing or additional water intake, have gotten a lot of press in the previous decade.

Fast melting, fast dispersing, rapid dissolve, rapid melt, and or quick disintegrating tablet are all terms used to describe the MDT. FDA classifies all MDTs as orally disintegrating tablets. The word orodispersible tablet was recently coined by the European Pharmacopeia to describe a tablet that disperses or dissolves in the mouth in less than 3 minutes before being swallowed. Patients can easily swallow such a tablet since it fragments into smaller grains or melts in their mouth from a hard solid to a gel-like structure. The time it takes for excellent MDTs to disintegrate varies from a few seconds to nearly a minute [3-5]. The benefits of both dry and liquid formulations are combined in this dose form. Some modern ODT technologies provide high drug loading, have a pleasant mouth feel, and leave minimum residue in the mouth following oral administration. Mouth Dissolving Tablet have been studied for their potential to improve bioavailability of unwell soluble medications by changing the drug's solubility profile & hepatic metabolism pharmaceuticals [6].

Ideal Properties of Orally Disintegrating Tablets [7-8]

- Within a few seconds, easily dissolve or disintegrate in salivary fluid.
- Have a delectable taste.
- When taken, it leaves little to no trace in the mouth.
- Be lightweight and easy to travel.
- The manufacturing process is straightforward and inexpensive.
- Low sensitivity to external factors such as temperature and humidity.

Advantages of Orally Disintegrating Tablets [9-10]

- Do not require water to swallow the tablet.
- Due to physical obstruction, the risk of choking or suffocation during oral administration of conventional formulation is eliminated, resulting in greater safety.
- When compared to liquids, precise dosing is possible.
- Rapid drug therapy intervention.
- The bioavailability of drugs taken through pregastric absorption from the mouth, pharynx, and oesophagus is greater.

Techniques for Orally Disintegrating Tablets

- **Freeze Drying/Lyophilization:** It is one of the main generation procedures for making MDT, in which water is sublimated from the product after it has been frozen. Due to the presence of a glossy amorphous structure to bulking agents and occasionally to medication, the formulations have improved dissolving characteristics. Relative water insolubility with tiny particle size and strong aqueous stability in suspensions are ideal pharmacological features for this method [11]. The production of a eutectic mixture due to freezing point depression and the formation of a glassy solid on freezing, which may collapse on sublimation, are the main issues with water-soluble medications. The inclusion of mannitol or crystal forming materials causes amorphous material to crystallise and become stiff. The benefit of adopting the freeze-drying procedure is that medicinal ingredients can be treated at room temperature, avoiding heat impacts. The high cost of equipment and processing prevents this approach from being widely used. Lack of resistance required for conventional blister packs of final dose forms is another issue [12].

- **Molding [12-15]:** The two types of moulding techniques are the solvent method and the heat method. The solvent method comprises moistening the powder mixture with a hydro-alcoholic solvent before compressing it in moulded plates at low pressures to produce a wetted mass (compression molding). Air drying is used to remove the solvent. The tablets have a porous structure that helps them dissolve faster and are less compact than compacted tablets. During the heat moulding procedure, a suspension containing a medicine, agar, and sugar is formed (e.g. mannitol or lactose). This suspension is poured into the blister packaging wells, and then the agar is solidified at room temperature to form a jelly, which is then vacuum dried at 30°C. The mechanical strength of these moulded tablets is a major concern, which can be improved by adding binding agents. The flavour masked medication particles were made by spray congealing a molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol, and an active component into a lactose based tablet triturate form. The moulding approach produces tablets that are easier to scale up for industrial scale manufacturing than the lyophillization technique.

- **Sublimation [16]:** This procedure entails combining inert volatile chemicals such as urea, urethane, naphthalene, camphor, and other excipients with other excipients and compressing the blend into a tablet. Sublimation of volatile materials causes pores in the tablet structure, causing the tablet to dissolve when it comes into contact with saliva. Several solvents, including as cyclohexane, benzene, and others, can also be utilised as pore generating agents. This approach was used to create mouth-dissolving tablets with a porous structure and excellent mechanical strength.

- **Sprays-Drying [17]:** As a matrix support, the formulations included hydrolyzed and non-hydrolyzed gelatin, mannitol as a bulking agent, and sodium starch glycolate or croscarmellose as a disintegrant. Disintegration and dissolution were improved by adding an acid (e.g., citric acid) or an alkali (e.g., sodium bicarbonate). Spray drying the aforementioned suspension, which had been compacted into tablets, yielded the porous powder. In an aqueous media, this approach produces tablets with a disintegration time of less than 20 seconds.

- **Direct Compression [18-19]:** Direct compression is the simplest and most cost-effective method of tablet production. Because of the availability of better excipients, such as super-disintegrants and sugar-based excipients, MDT can be manufactured using this technique.

a. Super-disintegrants: - The rate of disintegration gets affected by the addition of superdisintegrants and hence the dissolution. Other ingredients like water-soluble excipients and effervescent agents also increase the disintegration.
b. Sugar based excipients: - The sugar based excipients which are commonly used are especially bulking agents (like dextrose, fructose, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol) which display high aqueous solubility and sweetness, and hence impart taste masking property and provide pleasing mouth feel. On the basis of moulding and dissolution rate, Mizumito *et al* divided sugar-based excipients into two types: Lactose and mannitol (type 1) have a low mouldability but a high dissolving rate. Type 2 saccharides (maltose and maltilol) are highly moldable but have a slow dissolving rate.

- **Mass Extrusion [20]:** This approach softens the active blend by utilising a solvent mixture of water soluble polyethylene glycol and methanol. This softened mixture is extruded with a syringe or extruder, resulting in a cylindrical extrusion that is then cut into even segments with a hot blade to form tablets. This method can be used to coat bitter pharmaceutical granules and mask their flavour.

- **Nanonization [21]:** Nanomelt technique employs a wet-milling process to reduce drug particle size to nanoscale. Adsorption of the drug's nano crystals on selected stabilisers inhibits agglomeration, and the stabilisers are then incorporated into MDTs. This approach is particularly useful for water-insoluble drugs as well as a wide range of dosages (up to 200 mg of drug per unit).

- **Cotton Candy Process [21]:** -MDDDS is produced utilising Shearform TM and Ceform TITM technologies to eliminate the medication's bitter taste. Shear form technology is used to make a 'floss' matrix that comprises a mixture of excipients, either alone or in conjunction with medications. Cotton-candy fibres resemble cotton-candy fibres. Floss is a fibrous fibre made up of saccharides including sucrose, dextrose, lactose, and fructose that can withstand temperatures ranging from 180 to 266 degrees Fahrenheit. Polysaccharides such polymaltodextrins and poly-dextrose, on the other hand, can be turned into fibres at temperatures 30–40% lower than sucrose. Because of this change, thermo labile drugs can now be safely incorporated into formulations.Due to the rapid solubilization of sugars in the presence of saliva, this procedure produces a very porous product with a very pleasant mouth feel.

Challenges to Develop Orally Disintegrating Tablets [22-24]:

- **Palatability:** Because most drugs are unpleasant, FDTs usually contain the medication in a taste-masked form. After delivery, FDTs crumble or dissolve in the patient's mouth, releasing the active ingredients that come into touch with the taste buds. As a result, concealing the taste of the medications is crucial for patient compliance.

- **Mechanical Strength and Disintegration Time:** In order to permit FDTs to fragment in the oral cavity, they are made of either very porous and soft-molded matrix or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and often requiring specialized peel-off blister packing that may add to the cost. Only wow tab and durasolv technologies can produce tablets that are sufficiently hard and durable to allow them to be packaged in multi-dose bottles.

- **Hygroscopicity:** Because several orally disintegrating dosage forms are hygroscopic and cannot maintain physical integrity under normal temperature and humidity conditions, humidity protection is required, which needs particular product packaging.

- **Quantity of Drug:** The amount of medicine that can be included into each unit dose limits the application of FDT technologies. The medication dose must be less than 400 mg for insoluble pharmaceuticals and 60 mg for soluble drugs in lyophilized dosage forms. This characteristic is especially difficult to work with when creating fast-dissolving oral films or wafers.

- **Water Solubility:** Water-soluble pharmaceuticals provide a number of formulation issues due to the development of eutectic mixtures, which induce freezing-point depression and the formation of a glassy solid that may collapse upon drying due to the loss of supporting structure during the sublimation process. The use of matrix-forming excipients like mannitol, which can induce crystallinity and hence contribute rigidity to the amorphous composite, might occasionally prevent such collapse.

- **Tablet Size:** The size of a tablet determines how easy it is to administer. The easiest size of pill to swallow is 7-8 mm, whereas the easiest size to handle is one larger than 8 mm, according to research. As a result, finding a tablet size that is both easy to take and easy to hold is tough.

- **Mouth Feel:** FDTs should not break down into bigger particles in the mouth. After the FDTs disintegrate, the particles created should be as little as possible. Flavorings and cooling substances like menthol also make the tongue feel better.

- **Sensitivity to environmental conditions:** Because most of the materials used in FDTs are designed to dissolve in a small amount of water, they should be somewhat insensitive to environmental variables such as humidity and temperature.

Future Prospects

Even though the FDT sector is no longer in its infancy, as evidenced by the large number of commercial products on the market, there are still many aspects of FDT formulations that can be improved. Despite advances in FDT technology, hydrophobic drug formulation remains a challenge, especially when large amounts of medication are involved. Low-dose drugs like Loratadine (10 mg) do not cause difficulties, but as the amount increases, the formulation loses its ability to dissolve quickly. A new approach is being developed that will allow larger quantities of hydrophobic medications to be added without sacrificing their fast dissolving properties. Although the majority of FDTs on the market have acceptable disintegration times (within 60 seconds), there is always room for improvement. Because disintegration time is linked to other formulation parameters, a balance must be achieved between minimising disintegration time and preserving other tablet characteristics. Tablet hardness, friability, and stability can all be improved to the point that multi-tablet packaging in ordinary bottles is no longer uncommon. The development of FDTs with controlled release properties is crucial for the future of FDTs. If one FDT could deliver drugs with short half-lives for 12–24 hours, it would be a huge step forward in FDT technology. The convenience and compliance benefits of such formulations would be enormous. FDTs' future depends on the development of effective taste-masking properties. Although it increases the total volume

of the final formulation, coating bad-tasting drugs is a common practise. There may not be a cure in the works, but better utilisation of existing taste masking technologies is expected to relieve taste masking difficulties. Another significant technological improvement will be the ability to synthesise medications in big quantities. Huge volumes of excipients are required in most FDT formulations, and bulky doses of medication will just make the final formulation too large to handle. A breakthrough would be an MDT preparation that uses rarer excipients than the medicine itself. While the challenges to be solved are not simple, history implies that they will be solved sooner or later. A lot of companies have their own fast-dissolving tablet brands. The availability of diverse technologies, as well as the numerous benefits of quick dissolving tablets, will almost certainly enhance their appeal in the near future.

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