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Orally Disintegrating Tablets: an Over Review

R.Priyadharshini[1], Dr.R.Murali[2]

Department of Pharmacy, Annamalai University, Chidambaram, Tamil Nadu, India.

Assistant Professor, Department of Pharmacy, Annamalai University, Chidambaram, Tamil Nadu, India.

Abstract: **Drug Delivery Systems (DDS) are getting more easier as the Pharmaceutical scientist are increasing their better perception towards the physicochemical and biochemical boundaries pertinent to their presentation. Recent improvements have introduced reasonable dose choices for patients who may experience issues in taking tablets or fluids. Mouth Dissolution Tablets (ODTs) have the interesting property of quickly dissolving and delivering the medication when they come into contact with salivation. ODTs are more significant for geriatric, paediatric, and confined to bed patients as they experience issues of swallowing and those with dysphasia. It is generally helpful for patients who are travelling and occupied patients who don't have simple admittance to water. Advances in this technology have empowered the improvement of an affordable and better technique for treating illness while keeping away from different issues related to other administration frameworks.**

Keywords: **Orally Disintegrating tablets, Direct compression, Taste masking, Mechanisms of Orally Disintegrating tablets.**

1. INTRODUCTION

The oral route of drugs administration is estimated as the most ordinary and easier route of administration for all types of patients. The tablet is a broadly recommended dosage system for its openness regarding its self-administration, and simplicity of improvement. Paediatric and geriatric patients specifically have issues in swallowing the tablets, and this issue can be more regrettable in conditions travelling because of the inaccessibility or restricted accessibility of water. These issues with ordinary dosage systems can emerge from the advancement of tablets that break up in the mouth. ODTs break down rapidly and disintegrate in salivation without the requirement for water. A few tablets may break up rapidly in a short span of time and quickly go into systemic absorption. Some other tablets contain disintegrating agents to improve the pace of crumbling of tablets in the oral pit since they can take some more time to break down. ODTs are expected to break up quickly in the mouth to give action before ingestion, the active pharmaceutical ingredient being planned for GI delivery or retention. The idea for the ODTs came from a desire to give patients a more traditional way of taking their drugs. To create an optimal fast delivery of dosage form to the patient, it is critical to mask the taste.

ADVANTAGES

The major benefits of the ODTs are that it joins with both fluid and traditional tablet dosage forms. Some other advantages of the ODTs are, It Does not need water or other fluid to swallow and easy disintegration or deterioration in spit shortly, it had a pleasant taste and compact and simple to convey, it is very helpful in cases, for example, movement affliction, chamois scenes of hypersensitive assault or hack, where an Ultra-quick onset of action required Precise dosing contrasted with fluids. The disintegration of the ODTs and its retention of the medication is quick, which offers a fast beginning of the activity. The bioavailability of the medication increments as certain medications are retained through the mouth, pharynx, and throat through the exchange of spit to the stomach. First-pass digestion is diminished, which improves bioavailability and subsequently lessens measurement and results. It is suitable for maintained/controlled delivery actives. The major advantage of ODTs is easy to manage without water, anyplace and whenever. It is suitable for geriatric and paediatric patients, which experiences issues swallowing and patients who may encounter issues utilizing the conventional dosage forms. It is more suitable for uncooperative patients. Due to its greater bioavailability, particularly in

instances of insoluble and hydrophobic medications, because of the quick deterioration and disintegration of these tablets. The Stability for this dosage form has a more extended time since the medication has increased bioavailability.

Ideal Properties

The medications should be suitable for the ODTs if they possess the following properties

- Those medications can diffuse into the epithelium of the upper gastrointestinal parcel (log P> 2).
- Short half-life drugs with frequent dosages.
- Drugs that produce harmful metabolites by first-pass metabolism.
- Controlled and sustained delivery drugs are not reasonable for multidrug-safe medications.
- Very unpleasant prescriptions with an unsatisfactory taste are not appropriate for multi-drug safe medications
- It doesn't need water for oral administration however it deteriorates and breaks down in the oral depression shortly.
- Is adequately intense to withstand the afflictions of the assembling cycle and post-assembling taking care of.
- It permits a high medication load and has a pleasant mouthfeel and is harsh toward ecological conditions like moistness and temperature.
- It is versatile and vulnerable to existing bundling and handling apparatus.
- It is productive.

Limitations:

When the ODTs had a lot of benefits, they too had a certain limitation. They are as follows Some of the ODTs Dosage forms had a lack of mechanical strength of the finished product. It had sensation in the mouth after taking in a prolonged period, and some ODTs tablets had left the terrible taste or coarseness in the mouth if not defined fitting. It can also have the following limitations too, they are

1. Ingestion pace of salivation arrangement and
2. Worldwide bioavailability.
3. Dry mouth because of less secretion of saliva.
4. Tablet plans.

Mechanisms of Orally disintegrating tablets:

Swelling*:* By this technique, certain disintegrating agents (like starch) will deteriorating impact upon contact with water, which causes the tablet breakdown. for example, Sodium starch glycolate, Plantago Ovata.

Porosity and Capillary Action*:* The disintegrating activity of some ODTs are by the capillary activity and porosity. The disintegrating particles act to improve porosity which passes on ways for the saturation of liquid into tablets. After that through capillary activity or wicking activity, the fluid is drained up, this outcome in inter particulate bonds breakdown and at last tablet deterioration. Example: Crospovidone, Croscarmellose Sodium.

Deformation: At the point when the pressure applied to the starch grains they disintegrate and when pressure is eliminated, they will come into a unique shape. But when they compacted into tablets they deformed forever which release their energy when interacting with water.

Particle Repulsive Forces: These are the mechanisms related to non-swell capable of disintegrants. For that Guyot-Hermann has given particle repulsion theory. As per that-deterioration of electric repulsive forces between particles are liable for the water. It is accepted that no single mechanism is liable for the activity of most disintegrants. In any case, it is the consequence of between connections between these significant systems

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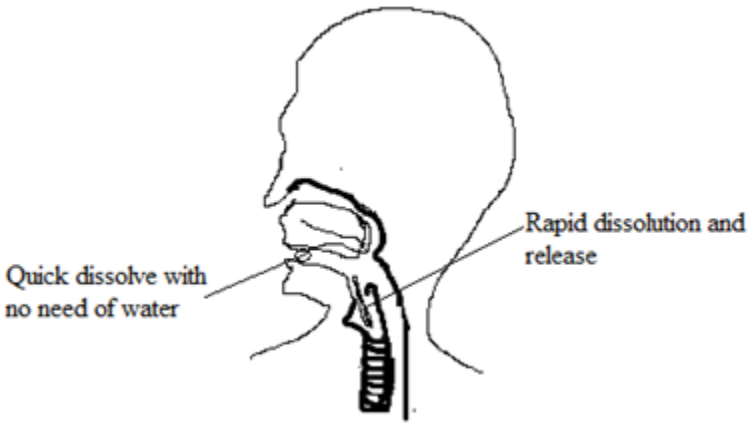

Figure 1: Mechanism of Tablet disintegration

Manufacturing of ODTs

- Freeze-drying or Lyophilization
- Spray drying
- Moulding
- Cotton candy process
- Mass extrusion
- Sublimation

Freeze Drying or Lyophilization:

Lyophilization is a process, which incorporates the removal of solvent from a frozen suspension or solution of medication with structure-framing added substances the material is frozen to bring it underneath its eutectic point. At that point, essential drying is completed to decrease the dampness to around 4% w/w of dry substances. Then, the secondary drying is done to reduce the bound moisture to the necessary volume. Lyophilization brings about arrangements, which are highly permeable, with a very high specific surface region, which break down quickly and show improved ingestion and bioavailability.

Spray drying:

A high permeable and fine powder is prepared by spray-drying a fluid composition containing a support lattice and different segments. By utilizing this procedure to plan and prepare the ODTs, which deteriorates within 20 seconds inside the mouth.

Moulding: Mouth dissolving tablets that are prepared by this technique are solid dispersion. The physical type of medication in the tablets relies upon whether and how much it breaks up in the wetted mass. The medication can exist as discrete particles or miniature particles in the grid.

Cotton candy process:

The cotton candy process includes the development of a matrix of polysaccharides or saccharides by the concurrent activity of flash melting and spinning. The matrix framed is partially re-solidified to have improved stream properties and compressibility. This candy floss lattice is processed and mixed with active ingredients and excipients and then compressed to an ODTs.

Mass extrusion:

In this method, mix the API and excipients and it is softened by using a solvent combination of water solvent polyethene glycol and methanol. Afterwards, the softened mass is extruded through the extruder or needle to get a round shaped of

tablets which is then cut into even fragments with the assistance of warmed sharp-edged blades to get tablets. The drying chamber can be utilized to coat the granules of unpleasant tasting drugs and thereby masking the unpleasant taste.

Sublimation:

This is a process that includes the mixing of some inert volatile substances like urea, urethane, naphthalene, camphor, and other excipients, By applying the pressure over the mixture, it can form the tablet. Evacuation of volatile material by sublimation creates pores in tablet structure, from which tablet breaks up when comes in contact with saliva.

EVALUATION:

Tablets that break down in the mouth are assessed dependent on different boundaries like hardness, friability, weight variety, drug content, and so on. But these ordinary endpoints, some particular boundaries are significant in setting up the effectiveness of ODTs for drug delivery purposes. These boundaries are wetting time, disintegration time, dissolution study, and moisture retention study.

Weight variation test:

The quantity of powder fill in the die of the tablet press determines the tablet weight and if any improper flow of powder to the die, it forms the uneven tablets which contain the low dose or high dose of the drug. So the weight variation test for ODTs was estimated by individually weighing 20 tablets, by electronic balance and comparing the weight of individual tablet to the average weight of the tablets.

Tablet thickness

The Tablet thickness for ODTs was measured by placing a tablet in between two arms of the Vernier caliper. Take the five tablets randomly from the batch and their thickness was measured.

Tablet hardness

The tablet hardness is the force required to break an ODT tablet in a diametric compression force. The hardness analyser used in the test was Monsanto hardness tester. It applies an external force to the ODT tablet diametrically with the help of an inbuilt spring.

Friability

Friability is a tablet's durability or the tablets ability to withstand the mechanical shocks during manufacturing, handling, packing, shipping and it is intended to determine the physical strength of the tablet. For ODTs the tablets of an average weight of 0.65g or equivalent weight to be taken and rotate the tablets 100 times at 25 rpm in the drum using the Roche Friabilator and then the final weight of the tablets should be measured.

Wetting time

The wetting time of ODTs is identified with the contact point. It should be surveyed to give the breaking down properties of the tablets; a lower wetting time implies a faster deterioration of the tablet. For this reason, a tablet is placed on a piece of tissue paper folded twice and kept in a little Petri dish (ID = 6.5 cm) which contains 6 ml of water, and then wetting time is estimated.

Dissolution Test

A dissolution study is vital for mouth dissolving tablets. In-vitro dissolution investigation of mouth dissolving tablets is done by utilizing the tablet dissolution test apparatus (USP XXII sort) at 50 pm. Phosphate buffer pH 6.8 is utilized as the dissolution media and the temperature should be at 37 ± 0.5 °C. Test samples are withdrawn at various time stretches and investigated by a suitable method.

Disintegration test

The ideal opportunity for breaking down of ODTs is generally less than one minute and the actual disintegration time that patient can feel is from 5-30 seconds. The standard methods for performing disintegration test for these ODTs has few limitations and they are not fit for the estimation for short disintegration times. The disintegration test is performed in 900 ml salivation liquid pH 6.8 at 37 ± 0.5 °C temperature and the rate of 30 ± 2 cycles/min.

Moisture uptake studies

When ODTs are taken for moisture uptake examinations, it should be noted that various excipients which are used are hygroscopic in nature. In the desiccator with calcium chloride arbitrarily ten tablets are taken up and saved at 37 °C for 24 h. For about fourteen days the tablets are then weighed and open to 75% relative humidity at room temperature.

Patented Technologies for Mouth Dissolving Tablets:

Zydis Technology: The tablet breaks up in the mouth within the seconds after placing it on the tongue. A Zydis tablet is produced by lyophilizing or freeze-drying the medication in a framework as a rule comprising of gelatin. The item is extremely lightweight and delicate and should be given in a special blister pack. Patients to be encouraged not to push the tablets through the foil film, yet they are advised to peel the film back to deliver the tablet. The Zydis product is made to break down on the tongue in 2 to 3 seconds. The Zydis products are self-protecting since the last water focus in the freeze-dried product is too low to allow taking into consideration for microbial development. If essential, suspending agents and pH changing agents might be utilized.

Durasolv Technology: Durasolv is the licensed innovation of CIMA labs. The tablets made by this innovation comprise medication, fillers and oil. Tablets are set up by utilizing regular tabletting machines and have good rigidity. These can be packed into ordinary packaging like blisters. Durasolv is a fitting innovation for items requiring low measures of APIs.

Orasolv Technology: Orasolv Technology has been created by CIMA labs. In this system active medicament taste is masked. It contains effervescent disintegrating agent and tablets which are made by direct compression method at low-pressure force to limit oral dissolution.

Flash Dose Technology: This technology has been protected by Fuisz. Nurofen meltlet, another type of Ibuprofen as soften in-mouth tablets, arranged by utilizing Flash Dose Technology and it is the first business item dispatched by Biovail Corporation. Flash Dose Technology comprise a self-restricting shear form matrix named floss. Shearform matrix is arranged by flash heat processing.

Flash tab Technology: Prographarm research centres, a french based company, have protected the Flash tab innovation. Tablets prepared by this system comprise APIs as microcrystals. Drug micro granules might be prepared by utilizing regular techniques like Coacervation, microencapsulation, and extrusion spheronisation. All the processing aids used the conventional tabletting process. These taste-masked microcrystals of active medication, disintegrating agent, swelling agent and other excipients are compressed multi particulate tablet that disintegrates quickly.

2. CONCLUSION

As an end orally disintegrating tablets have numerous benefits when compared with other oral dosage forms, like better bioavailability, improved patient compliance, and efficacy. By considering tablet weight, friability, manufacturing technology, disintegration time and packaging should be considered. Prescription ODT items at first were created to defeat the trouble in swallowing the regular tablets among the paediatric, geriatric, and psychiatric patients with dysphagia. Later patterns of patient-oriented dosage forms to accomplish patient compliance. The new advancements of manufacturing give the tablets quick onset of action, and improved bioavailability, lower the side effects and better security. With the continued improvement of new drug excipients, one can anticipate the rise of more novel innovations for ODTs in the days to come.

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