International Journal of Pharmacy and Analytical Research (IJPAR)

ISSN: 2320-2831

IJPAR |Vol.12 | Issue 3 | July - Sept -2023
www.ijpar.com

Review article *Pharmaceutics*

A Review on Orodispersible tablet

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Published on: 21.07.2023

ABSTARCT

The oral route is the most important and recommended route of drug administration. Oral route is the safest and convenient route of drug delivery because of wide range of drugs are administered through this route. Oro dispersible tablets are novel oral drug-delivery system as they have improved patient compliance and have some additional advantages compared to other oral formulation. Oral dispersible tablet are solid unit dosage forms, which disintegrate or dissolves quickly in the mouth within a minute in the presence of saliva without chewing or water. The dosage form containing super disintegrates which impart the quality of quick disintegration in the presence of saliva and also play an important role in the formulation of oral dispersible tablets. The present review is focused on ideal properties, objective, advantages and disadvantages and evaluation parameters.

Keywords: Oral dispersible tablets, hardness, friability, super disintegrants

INTRODUCTION

Oral route is the most preferred route of administration and tablet and capsules are the most preferred dosage forms. Orodispersible tablets have been placed in the mouth where they disperse fast before being swallowed and they are uncoated tablets. Orodispersible tablets disintegrate within 180 seconds when the disintegration tests have been conducted up to the test for disintegration of tablets.[1]

Additionally, it is desirable to synthesise medications with adequate oral mucosal absorption or those with immediate pharmacological effects in these dosage forms. Fast dissolving tablets are solid dose forms that contain medications and dissolve in the mouth in under a minute, leaving a simple-to-swallow residue. Placed in the mouth and allowed to spread or dissolve in the saliva, these dosage forms. The release the drug as soon as they come in contact with the saliva, making it unnecessary to use water during administration.[2]

The most common dose form is a tablet since it is easy to manufacture, compact, and self-administering convenient. The terms Oro dispersible tablets, quick-dissolving tablets, mouth-dissolving tablets, fast-dissolving tablets, rapid-dissolving tablets, porous tablets, and rapimelts are also used to describe oral disintegrating tablets.[3]

The quick dissolution of the dosage form into a solution or suspension in the mouth without the need of water is the process used in oral fast-disintegrating dosage forms (a tablet or a capsule.[4]

Oro dispersible tablets, as defined by the European Pharmacopoeia, are uncoated tablets that quickly dissolve in the mouth before being swallowed, transforming into a solution or suspension utilising the body's natural saliva and infrequently requiring the use of external liquids like water. ODTs are regarded as superior dose forms.[3]

Advantage of Oro dispersible Tablets

- Increased stability suitable for continuous, regulated, offers patients and prescribers increased compliance and convenience.
- ODTs are thought to be the ideal dose form for rapid medication delivery.[2]

- Improved quiet consistence.
- Rapid onsets of action should increase bioavailability.
- Comfort of taking and precise dosing when contrasted with fluid.[3,4]

Disadvantage of Orodispersible Tablets

- The tablets typically don't have enough mechanical strength. Therefore, careful handling is necessary.
- If the tablets are not made properly, they may leave a bad taste and/or grittiness in the mouth.[2,3]
- They need specific packaging because they cannot be packaged in regular strips or bottles.
- Bitter medications must be taste-masked using a variety of methods, which extends production time and costs.[3]

Ideal properties

- Not need water to swallow and may dissolve or disintegrate within the mouth inside many seconds.
- Permit high medication stacking.
- Have a delightful mouth feel.
- Show little sensitivity to temperature and stickiness in the environment.[5]
- Be flexible and compliant with established protocol
- Permit the fabricate of tablets utilizing standard process and equipment at low Cost.
- Permit the production of tablets using standard processing and packaging machinery.[6]
- Method of production should be cost effective.
- Time to get dissolve or disperse or disintegrate should be less than a minute.[4]

Objective

- To increase patient adherence
- In order to improve bioavailability
- To enhance stability
- To test masking
- To hormone adjusting blood glucose level [2]

Limitations of Oro dispersible Tablets

- When used for ODT formulation, soluble diluents frequently produce hygroscopic dose, which could cause stability problems.
- If the tablets are not made properly, they may leave a bad taste and/or grittiness in the mouth
- Some FDT are hygroscopic and cannot maintain their physical integrity when exposed to dampness, necessitating specialised packaging.
- The bioavailability overall and the rate of absorption from the saliva solution.
- Drug and dosage form stability.[7]

Need to formulate Oro dispersible tablets

- Paediatric patients who struggle to swallow because their internal muscles and central nervous system are still developing.
- Travelers who experience motion sickness and diarrhoea who do not have easy access to water, in particular those who experience chronic nausea for an extended period of time and are unable to swallow.[4,8]

Super disintegrants

Disintegrants are compounds that are added to tablet formulations (and some encapsulated ones) to encourage the tablet's (and the capsule's "slugs") breaking up into tiny fragments in an aqueous environment., increasing the surface area available and facilitating a more rapid release of the medicinal component. Using a disintegrant "intragranular" and "extra granularly" can increase the effectiveness of granulated formulation methods by breaking the tablet into granules and causing the granules to further disintegrate to release the medicinal component into solution. Most common tablets are those intended to be swallowed whole and to disintegrate and release their medicaments rapidly in the gastrointestinal tract.[9]

Disintegrating agents are compounds that are frequently added to tablet formulations to help break apart the compacted mass into the fundamental particles to make it easier for the active ingredients to dissolve or release when the tablet is placed in a fluid environment. Super disintegrants are new materials that have recently been developed to enhance disintegration processes.[9]

Croscarmellose sodium (Ac-Di-Sol), cross povidone (CP), sodium starch glycolate (SSG) and other super disintegrants are frequently used. Which represent example of crosslinked cellulose, crosslinked polymer and crosslinked starch respectively.[6]

Challenges to develop ODTs

- **Palatability** - FDTs typically contain the medication in a taste-masked form because most medications are unpleasant to consume. FDTs release their active chemicals into the patient's oral cavity after administration, coming into contact with their taste buds. Therefore, concealing the taste of the medications is essential to ensuring patient compliance.
- **Mechanical strength and disintegration time** - FDTs are either made of a very porous and softly molded matrix or are compressed into tablets with very little effort, which causes the tablets to be brittle, challenging to handle, and frequently break when handled. specialized peel-off blister packaging that could increase the cost. The only technologies that can create tablets that are tough and resilient enough to be put in multi-dose bottles are wow tab and durasolv.
- **Hygroscopicity** - At normal temperatures and humidity levels, several fast-dissolving dosage forms are hygroscopic and unable to maintain their physical integrity. As a result, they require humidity protection, which necessitates specialized product packaging.
- **Amount of drug** - The amount of medication that can be included in each unit dose restricts the applicability of technologies used for OFTs. For lyophilized dosage forms, the drug dose must be less than 400 mg for insoluble medicines and less than 60 mg for soluble pharmaceuticals. When creating fast-dissolving oral films or wafers, this parameter is very difficult to formulate.

- **Aqueous solubility** - Water-soluble medicines have a variety of formulation problems because the formation of eutectic mixtures lowers the freezing point and causes the formation of a glassy solid, which may collapse upon drying due to the loss of supporting structure during the sublimation process. It is occasionally possible to avoid such collapse by using a variety of matrix-forming excipients, such as mannitol, which induces crystallinity and gives the amorphous composite rigidity.
- **Size of tablet** - The size of a tablet affects how easily it may be administered. Tablets larger than 8 mm were said to be the easiest to manage, while tablets between 7-8 mm were said to be the easiest to swallow. Therefore, it is difficult to get the tablet size that is convenient for handling and taking.
- **Mouth feel** - FDTs shouldn't break down into bigger pieces inside the mouth. The particles that are produced after the FDTs disintegrate should be as tiny as feasible. Additionally, the oral feel is improved by the inclusion of tastes and cooling substances like menthol.
- **Sensitivity to environmental conditions** - Given that majority of the materials used in FDTs are designed to dissolve in small amounts of water, FDTs should have low sensitivity to environmental factors like humidity and temperature. [10]

Characterization of oral dispersible tablet

Weight variation test

The average was determined after twenty tablets were randomly chosen from the batch. Then individual tablets were weight and compare with average weight. None of tablets deviated from average weight by more than ± 5%.

%Weight variation= [(Average weight – Individual weight) / Average weight] *100

Tablet thickness

The thickness of a tablet is an important parameter of evaluation and also for uniformity of tablet size. Micrometre and vernier calliper are used for checking tablet thickness. Thickness is measured using venire callipers on three randomly selected samples. Five tablets are picked at random from the test batch, and each one is put into the testing apparatus one at a time before the findings are analyzed.[11,12]

Tablet hardness

Pharmaceutical companies utilize tablet hardness testing as a laboratory technique to examine how a tablet changes "under conditions of storage, transportation, packaging, and handling before usage" in order to establish its breaking point and structural integrity. A tablet's hardness is essential for safeguarding it from handling and transportation faults. Most probably Monsanto and Pfizer tester are used these days to find out the hardness of a tablet's form determines its breaking point.[13]

Tablet Friability test

Twenty tablets were weighed and put in the Roche friabilator, which was then rotated for four minutes at a speed of 25 rpm. The tablets were dusted and weighed after the revolution.[13] The following formula determines the friability:

% Friability = (Loss in weight /Initial weight) ×100

Wetting time

A straightforward approach was used to measure how long the tablets took to moisten. For this, a tablet is kept in a little Petri dish (ID=6.5 cm) with 6 ml of water on top of a piece of tissue paper that has been folded twice, and the duration of fully moistening is determined.

A piece of tissue paper (12 cm × 10.75 cm) folded twice was placed in a small Petri dish (ID = 9 cm) containing 6 ml pH 6.8 phosphate buffer. From each formulation, three tablets were randomly selected, and the average wetting time was noted.[14]

In vitro disintegration test

The disintegration test device is typically used to calculate the disintegration time of the tested tablets. Six pills are collected from the batch being evaluated and put into each of the apparatus's six tubes. These tubes contain an appropriate dissolving media that complies with pharmacopoeia specifications, and its temperature must remain constant at 37° 2°C. The equipment is turned on after all the conditions have been maintained. The exam is finished, and the outcome is declared.[15]

In vitro dissolution study

It is a crucial test since it can be used to determine the drug-release profile. You can utilize one of the USP dissolution test devices. USP type II paddle apparatus is most suitable and common choice for dissolution test of oral disintegrating tablets, where the paddle speed is 50 rpm is used, Phosphate buffer pH 6.8, 900 ml is used as dissolution medium which maintained at 37±0.5°C. At predetermined intervals (2 min), remove an aliquot of the dissolution medium (10 ml), filter it, and repeat. A suitable analytical technique is used to determine the amount of medication that has dissolved.[14]

CONCLUSION

As a conclusion orally disintegrating tablets have many such as better bioavailability, better patient compliance, stability and improved efficacy. The key feature of a ODTs formulation is rapid disintegration and dissolution in the mouth in presence of saliva. All of the new medicine delivery systems, this one is one of the best inventions.

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