International Journal of Advanced Multidisciplinary Research
ISSN: 2393-8870
www.ijarm.com
(A Peer Reviewed, Referred, Indexed and Open Access Journal)
DOI: 10.22192/ijamr Volume 8, Issue 7 -2021

Review Article

DOI: http://dx.doi.org/10.22192/ijamr.2021.08.07.004

A Review: A new trend in drug delivery Oro-dispersible tablets

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Abstract

As most of drugs are unpalatable, Oro-dispersible drug delivery system usually contain the medicament in a taste masked form. Delivery systems dissolve or disintegrate in the patient's mouth, thus releasing the active ingredients which come in contact with the taste buds and hence, taste masking of drug becomes critical for patient compliance. Oro-dispersible tablets are gaining importance among novel oral drug-delivery system as they have improved patient compliance and have some additional advantages compared to other oral formulation. ODTs are the very good choice for the paediatric and geriatric patients. To improve the bioavailability of many drugs, oro-dispersible drug delivery systems are used extensively. Advanced technologies used for manufacturing oro-dispersible tablets are by direct compression method, freeze drying method, sublimation method, mass extrusion and cotton candy process. Taste is the important factor because these tablets disintegrate directly in the mouth. ODTs are evaluated by following parameters like hardness test, friability test, disintegration test and dissolution test. Many technologies are introduced for producing controlled release Oro-dispersible tablets which broadens the applications of this dosage form. These tablets are also known as mouth dissolving tablets and fast dissolving tablets. In this review article we can focus on ideal properties, challenges, advantages, disadvantages, conventional techniques, patented technologies and evaluation of Oro-dispersible tablets.

Keywords

Oro-dispersible;
Saliva;
Novel;
Bioavailability;
Disintegrates.

Introduction

The oral course of medication organization is most favoured and generally acknowledged course of organization for assortment of medications and nutraceuticals [1]. It offers various preferences, for example, simplicity of organization, more prominent adaptability in measurement frame and configuration space alongside quick large scale manufacturing with high level of computerization and low assembling expense. Oro-dispersible tablets are also called as orally disintegrating tablets, mouth-dissolving tablets, rapid dissolving tablets, fast-disintegrating

tablets, fast-dissolving tablets. Recently, European Pharmacopoeia has used the term Oro-dispersible tablets. This may be defined as uncoated tablets intended to be placed in the mouth where they disperse readily within 3 min before swallowing[2]. The United States Pharmacopoeia has also approved these dosage forms as oro-dispersible tablets. Thus, oro-dispersible tablets are solid unit dosage forms like conventional tablets, but are composed of super disintegrants, which help them to dissolve the tablets within a minute in the mouth in the presence of saliva without any difficulty of swallowing[3].Its ease of administration in the population especially for paediatric, geriatric, or any mentally retarded persons makes it a very popular dosage form. Due to the presence of super disintegrants, it gets dissolved quickly, resulting in rapid absorption of drug which in turn provides rapid onset of action.[4] Since the absorption is taking place directly from the mouth, so, bioavailability of the drug increases.[5] Drugs present in oro-dispersible tablets are also not suffering from first pass metabolism. This type of drug delivery is becoming popular day by day due to its numerous advantages.

Various methods of preparation of oro dispersible tablets:

Molding methods

Tablets formed by molding process are highly porous in structure, resulting in high rate of disintegration and dissolution. This process includes moistening, dissolving, or dispersing the drugs with a solvent then molding the moist mixture into tablets by applying lower pressure in compression molding, but always lower than the conventional tablet compression. The powder mixture may be sieved prior to the preparation in order to increase the dissolution.[6]

Compaction methods

Conventional methods for the preparation of tablets such as dry granulation, wet granulation, and direct compression are also exist for the preparation of oro-dispersible tablets. In all the cases it has been found that preparation by compression method along with addition of super disintegrants in correct concentration obey all the properties of oro-dispersible tablets.[7,8]

Spray-drying method

Here, oro-dispersible tablets are made up of hydrolyzed or unhydrolyzedgelatin as supporting agent for matrix, mannitol as bulk agent, and sodium starch glycolate or croscarmellose sodium as disintegrating agent. Oro-dispersible tablets prepared through this method are disintegrated in less than 20s.[9,10]

Freeze-drying method

Tablets prepared by this process have low mechanical strength, poor stability at higher temperature and humidity, but glossy amorphous structure resulting in highly porous, lightweight product. There are various patents on this particular technology.[11]

Evaluation of oro dispersible tablets:

Hardness/crushing strength

The hardness of the tablet is measured by using conventional hardness testers like Monsanto hardness tester.[12] The limit is toward the lower range in order to help early disintegration in mouth.

Friability

It is a difficult job to maintain the percentage of friability within the limit, since all the methods of preparation of oro-dispersible tablets have a tendency to increase the percentage of friability. Wetting time

Wetting time is the indication of the inner structure of the tablets and to the hydrophilicity of the excipients. The wetting time can be measured by using five circular tissue papers of 10 cm in diameter, which are placed in a petridish of 10 cm diameter.[13] Ten millilitres of water-soluble dye like eosin solution is added to the petridish. For measuring water-absorption ratio, the weight of

the tablet before keeping in the petridish is noted (Wb).The wetted tablet from the petridish is taken and reweighted (Wa). The water-absorption ratio, R can be determined according to the following equation:

$$R = 100 (Wa – Wb)/Wb.$$

Moisture-uptake studies

It is an important study in the case of oro-dispersible tablets. This study is carried out in order to assess the stability of the tablets. Ten tablets were kept in the desiccators over calcium chloride at 37°C for 24 h.

Disintegration test

The in-vitro disintegration time was determined by disintegration test apparatus. The time for disintegration of oro-dispersible tablets is generally <1 min and actual disintegration time that patient can experience ranges from 5 to 30 s.[4] A tablet is placed in each of the six tubes of the apparatus, and one disc is added to each tube.[13] The standard procedure of performing disintegration test for these dosage forms has several limitations. [14]

Dissolution test

It is an important test as the drug-release profile can be obtained by performing this test. Both the USP dissolution test apparatus can be used.

Dissolution of oro-dispersible tablets is very fast. Therefore, USP 2 Paddle-type apparatus at 50-100 r/min is used for dissolution testing. carried out in vitro dissolution study of pheniramine maleate oro-dispersible tablets in type II apparatus with r/min 550 using 900 ml phosphate buffer of pH 6.8 at 37 ± 0.5°C as a dissolution medium.[15,16] USP type I basket apparatus have certain application in the case of oro-dispersible tablets, but tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle.

Industrial applications [17]

Industrial Applications Include The Following

- To develop an orally disintegrating dosage forms and to work with existing disintegrants
- To further improve upon the existing technology of ODTs
- To optimize the blend of disintegrants or excipients to achieve ODTs
- To select and develop proper packaging material and system for enhanced stability of theproduct and also develop a costeffective product
- To arrive at different taste-masking agents and prepare palatable route of administration thereby increasing patient compliance
- To develop disintegrants from different polymers which are used as coating materials by certain modifications and use them for formulating ODTs.

Limitations of Oro-dispersible Tablets [18,19]

- Many times the soluble diluents used for formulating the ODTs might give hygroscopic dosage which may lead to stability issues
- The tablets are unpleasant to taste and/or roughness in the mouth if not formulated properly specialized packing might be required for hygroscopic and light-sensitive drugs.
- Precautions to be taken while administering immediately after removing from the pack.
- Light sensitive drugs, ODTs may not be suitable as no option for film coating.

Future prospective for oro dispersible tablets [20,21]

Future challenges for many ODT manufacturers include reducing costs by finding ways to manufacture with conventional equipment, using versatile packaging, improving mechanical

strength and taste-masking capabilities. ODTs may be suitable for the oral delivery of drugs such as protein and peptide-based therapeutics that have limited bioavailability when administered by conventional tablets because these products usually degrade rapidly in the stomach. Furthermore, there is a scope to develop controlled release ODTs prepared using different drug carriers.

Patented technologies for oro dispersible tablets [22]

There are number of patented technologies which were developed forthe formation of oro-dispersible tablets and are described as under:

Zydis technology, Quick-dis technology, Oraquick technology, Durasolv technology, Shearform technology, Ziplet technology, Nanocrystal technology, Wowtab technology, Flashtab technology.

Some examples of recently prepared oro-dispersible tablets.[23,24]

Drug and Method:

Ofloxacin- Taste masked microspheres of the ofloxacin were prepared as a using Eudragit and oro dispersible tablets of the formulated microspheres were using the nature of the super disintegrant.

Nimesulide- Oro dispersible tablets were then completed using locust bean gum as a natural of the super disintegrant.

Cetirizine- dihydrochloride Tablets were organized using cetirizine along with camphor and mannitol in different quantity

Pheniramine- maleate Effervescent method

Diazepam- ODTs were organized using different types of super disintegrants at changed concentration using wet granulation and direct compression methods.

Valsartan- Tablets were arranged by freeze-drying method

Ondansetron- HCl Direct compression technique.

Roxithromycin- ODTs were arranged using modified polysaccharides as fast disintegrating excipients.

Indomethacin- The tablets were complete by the non-aqueous wet granulation method with super disintegrant included both of the intragranularly and extra granularly.

Conclusion

Oro- dispersible tablets are widely preferred over conventional dosage form due to many advantages like patient compliance, easier administration for paediatric and geriatrics patients, patients with allergies, motion sickness etc. They have improved patient compliance, convenience, bioavailability, and rapid onset of action. However, common people are not much aware of this delivery system. Therefore, pharmacists are responsible to spread the knowledge regarding this system. It is the duty of the pharmacist to counsel the patients regarding its use, advantages, storage and maintenance. This dosage form should be handled carefully since they do not have sufficient mechanical strength.

Patients who suffer from dryness of mouth should not be prescribed oro dispersible tablets, since minimum volume of saliva is necessary for it to disintegrate/dissolution. This dosage form is very much suitable for children having no primary teeth and for geriatric patients who have lost their teeth permanently. Thus, in near future, it is expected that this delivery system will get much importance as that of conventional delivery. The consideration takes place in technologies, pharmaceutical companies cantake advantage of ODTs for product line extensions or for first-to-market products. With continued development of new pharmaceutical excipients, one can expect the appearance of more novel technologies for ODTs in the days to come.

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Quick Response Code	Website: www.ijarm.com Subject: Pharmaceutical Sciences
DOI:10.22192/ijamr.2021.08.07.004	

How to cite this article:
Indas Pawara, Anup Akarte, Pankaj Chaudhari, Rupali Shimpi, Prakash Patil. (2021). A Review: A new trend in drug delivery Oro-dispersible tablets. Int. J. Adv. Multidiscip. Res. 8(7): 26-30.
DOI: http://dx.doi.org/10.22192/ijamr.2021.08.07.004