IJPSR (2024), Volume 15, Issue 5 **(Review Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 30 September 2023; received in revised form, 02 April 2024; accepted, 12 April 2024; published 01 May 2024

OVERVIEW OF ORAL DISPERSIBLE TABLETS

Preeti Sharma

Ram Gopal College of Pharmacy, Sultanpur, Gurugram - 122506, Haryana, India.

Keywords:

Bioavailability, Mouth dissolving, Tablet, Oral route

Correspondence to Author:
Preeti Sharma

Assistant Professor,
Ram Gopal College of Pharmacy,
Sultanpur, Gurugram - 122506,
Haryana, India.

E-mail: Preetys244@gmail.com

ABSTRACT: The need to deliver pharmaceuticals to patients quickly and with minimal side effects has driven pharmaceutical companies to invest in the development of novel drug delivery systems. Solid dose forms, such as pills, are difficult for pediatric and geriatric patients to swallow. The best treatment for this issue is a mouth dissolving pill that dissolves or disintegrates quickly in the oral cavity. Additionally, they produce a pleasant tongue sensation. ODT has benefits like enhanced Bioavailability, rapid action, and patient compliance. As a result, mouth-dissolved tablets are a desirable substitute for liquid and traditional tablet dose forms. In recent past, several manufacturing technologies such as sublimation technique, spray drying technique etc. are employed to overcome the limitations of conventional tablet dosage forms. The mouth dissolving tablets must undergo a variety of evaluations after they are created in order to ensure their long-term stability and improved therapeutic effectiveness.

INTRODUCTION: Drug delivery through oral route is the most common and preferred route of drug administration both for solid and liquid dosage forms. However, solid dosage forms are popular because of the ease of administration, accurate dosage, self-medication, pain avoidance, and most importantly the patient compliance [1]. Tablets and capsules are the most popular solid dosage forms. However, many people face difficulty in swallowing tablets and hard gelatin capsules. This difficulty in swallowing is called dysphasia [2]. It has been found that this problem has been encountered in all groups of patients, but especially with paediatrics and geriatric populations.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.15(5).1340-45

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.15(5).1340-45

Thus, these conventional dosage forms result in high incidence of noncompliance and ineffective therapy with respect to swallowing specially in the case of paediatrics, geriatric, or any mentally retarded persons [3]. Tablets are solid preparations each containing a single dose of one or more active substances and usually obtained by compressing uniform volumes of particles. Tablets are intended for oral administration [4]. Some are swallowed whole, some after being chewed, some are dissolved or dispersed in water before being administered and some are retained in the mouth where the active substance is liberated [1].

Several categories of tablets for oral use may be distinguished [1]:

1. Uncoated tablets
2. Coated tablets
3. Effervescent tablets
4. Soluble tablets

5. Dispersible tablets
6. Orodispersible tablets
7. Gastro-resistant tablets
8. Modified release tablets

Orodispersible Tablets: Orodispersible tablets are solid unit dosage forms like conventional tablets, but are composed of superdisintegrants, which help them to dissolve the tablets within 3 minutes in the mouth in the presence of saliva without any difficulty of swallowing [5]. These are the best suit for the drugs that are to be given to unconscious, paediatric, geriatric and in the emergency conditions where the patient compliance and immediate release are required [6]. ODTs with good taste and increase the flavour acceptability of bitter drugs by various groups of population. Orally disintegrating tablets are also called as orodispersible tablets, quick disintegrating tablets, mouth dissolving tablets, fast disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, and rapimelts [7]. However, of all the above terms, United States Pharmacopoeia (USP) approved these dosage forms as ODTs. Recently, European Pharmacopoeia has used the term orodispersible tablet for tablets that disperses readily and within 3 minutes in mouth before swallowing [8].

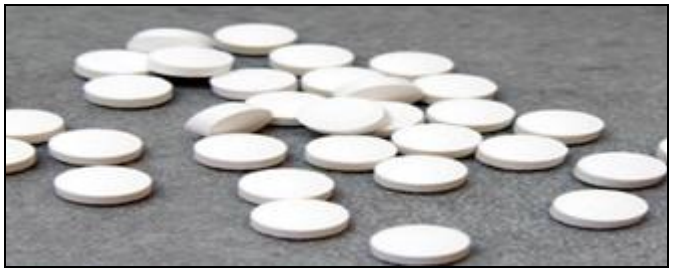

FIG. 1: ORODISPERSIBLE TABLETS

History: Cima Labs in the U.S. and Takeda Pharmaceutical Company in Japan led the development of orodispersible tablets. The first orodispersible tablet to get approval from the U.S. Food and Drug Administration (FDA) was Claritin (loratadine) in December 1996. It was followed by Klonopin (clonazepam) in December 1997 and Maxalt (rizatriptan) in June 1998.

Orodispersible Ttablets are also called as:

- Orally disintegrating tablets
- Mouth dissolving tablets
- Fast-dissolving tablets
- Rapid-melt tablets
- Porous tablets
- Quick-dissolving tablets
- Rapidly disintegrating tablets

Market Needs: The application of a drug delivery technology (DDT) to any molecule is based on market needs, product differentiation, and patient compliance. The goal is to get the product through the clinical studies with a stable formulation that can achieve the safety and efficacy required for Food and Drug Administration (FDA) approval. A detailed survey was conducted to determine the proportion of patients having difficulty in swallowing tablets and to identify the reasons for the difficulty.

More than 26 percent of patients mentioned problems in swallowing tablets. A prominent complaint was the size of the tablet, followed by the surface, form and taste of the tablets. Twice as many women as men experienced swallowing problems. Elderly patients (>70 years) had less difficulty than younger patients in swallowing tablets. Pediatric and geriatric patients in particular experienced the greatest difficulty in swallowing tablets as well as people who are ill and supine in bed and those patients who are busy traveling without having access to water.

To fulfill these medical needs, pharmaceutical technologists have developed a novel oral dosage form known as orodispersible tablets (ODTs) or fast disintegrating tablets (FDTs) or mouth melting tablets (MMTs) or mouth dissolving tablets (MDTs) which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to take water [9].

Advantage of Orodispersible Tablets [10]:

- Improved stability
- Suitable for controlled/sustained offers improved compliance and convenience to patients and prescribers.

- It improves patient adherence and reduces the development of resistance in the case of antimicrobials.
- For rapid drug delivery, ODTs are considered to be preferred dosage form.
- The drug is released quickly from this dosage form and gets dissolve in GIT tract without getting into the stomach, increased bioavailability can be achieved
- ODTs are very convenient for administering to various classes of patients from disabled, travellers and busy people, who do not always have access to water.
- Some drugs are absorbed from the pharynx and oesophagus as the saliva passes down into the stomach; in such cases, the bioavailability of drugs is increased.
- No water needed
- No chewing needs
- Better taste
- Release actives
- Allow high drug loading

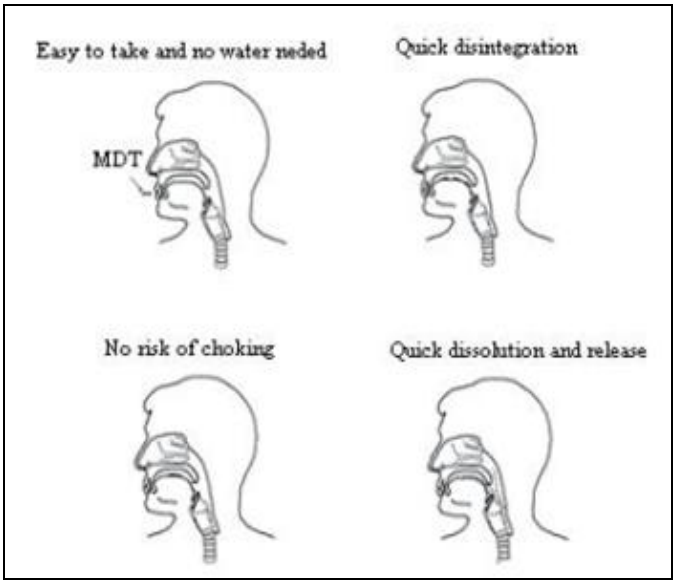

FIG. 2: DIAGRAM SHOWING ADVANTAGES OF ORODISPERSIBLE TABLETS

Challenges to Develop Orodispersible Tablets [11]:

- ✓ Rapid disintegration of tablet
- ✓ Avoid increase in tablet size
- ✓ Have sufficient mechanical strength
- ✓ Minimum or no residue in mouth
- ✓ Protection from moisture
- ✓ Good package design
- ✓ Compatible with taste masking technology
- ✓ Not affected by drug properties

Conventional Technologies used to Manufacture Orodispersible Tablets:

- Freeze drying
- Direct compression
- Spray drying
- Tablet molding
- Sublimation
- Effervescent method
- Phase transition process
- Melt granulation

Freeze-drying: Lyophilization is a process, which includes ejection of solvent from frozen suspension or solution of drug with structure forming additives. Freeze-drying of drug along with additives impart glossy amorphous structure ensuing highly porous and weightless product. The resulting tablet has rapid disintegration and dissolution when placed on the tongue and the freeze-dried unit dissolves immediately to release the drug [12].

Spray Drying: It involves spray drying of blend containing drug, effervescent agent, bulking agent and disintegrating agents which results in production of porous powder. Finaly this porous powder is compressed in to tablet [13].

Molding: The molding process comprises moistening, dissolving or dispersing the drug with a solvent, then molding the wet mixture into tablets, and finally drying up the solvent from drug solution or suspension at ambient pressure, respectively.

The molded tablets formed by compression molding are air-dried. As the compression force employed is lower than that of conventional tablets, the molded tablet results in highly permeable structure, which increases the disintegration and dissolution rate of the product. However, to improve the dissolution rate of the product, powder mixture should be sieved through a very fine screen. The molding process functions commonly with soluble ingredients (saccharides) which gives better mouth feel and disintegration of tablets. However, molded tablets have low mechanical strength, which leads to erosion and breakage during handling [12].

Sublimation Technique: Involves, the drug, volatilizing agent and other excipients that are compressed to form a tablet. The volatile material is then removed by sublimation, which, forms porous structure in tablet. The volatilizing agents are used such as ammonium bicarbonate, camphor, urea, ammonium carbonate [13].

Effervescent Method: Orodispersible tablets are also prepared by effervescent method by mixing sodium bicarbonate and tartaric contact angle. The lower the wetting time the quicker is the disintegration of the tablets. The wetting time can be measured by using five circular tissue papers of 10 cm in diameter, which are placed in a petri dish of 10 cm diameter. Ten millilitres of water-soluble dye like eosin solution is added to the petri dish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as the wetting time. For measuring water-absorption ratio, the weight of the tablet before keeping in the petri dish is noted (Wb). The wetted tablet from the petri dish is taken and reweighted (Wa) The water absorption ratio, R can be determined according to the following equation:

$$R = 100 (Wa–Wb) / Wb$$

Phase Transition Process: Another novel method to prepare ODTs with sufficient hardness by involving the phase transition of sugar alcohol. In this technique, ODT were produced by compressing powder containing erythritol (M.P. 122 °C) and xylitol (M.P. 93-95 °C) and then heating at about 93 °C for 15 minutes. After heating, the median pore size of the tablets was increased and tablet hardness was also increased. Heating process enhances the bonding among particles leading to sufficient hardness of tablets which was otherwise lacking owing to low compatibility [14].

Melt Granulation: It is a unique method for the preparation of orodispersible tablets by incorporating superpolystate. Superpolystates are hydrophilic waxy binders with a melting point 33-37°C and hydrophilic–lipophilic balance value is 9. They play a dual role as a binder that increases the physical resistance of the tablets and also as a disintegrants, which help the tablet to melt in the mouth and solubilize rapidly leaving no residue in the mouth. Superpolystates were introduced in the formulation of orodispersible tablets by melt granulation method. Here, granules are formed by the molten form of this material [14].

Compaction: By melt granulation, it is formulated by addition of hydrophilic waxy binder (superpolystate) PEG-6-stearate. This binder possesses dual action by increasing physical strength, it also increases disintegration. The characteristics of compaction method is that it rapidly melts in the mouth, thus, leaving no residue [15].

Tablet Disintegrants: Disintegrants are agents added to tablet and some encapsulated formulations to promote the breakup of the tablet and capsule slugs into smaller fragments in an aqueous environment there by increasing the available surface area and promoting a more rapid release of the drug substance. They promote moisture penetration and dispersion of the tablet matrix. Tablet disintegration has received considerable attention as an essential step in obtaining fast drug release.

The emphasis on the availability of drug highlights the importance of the relatively rapid disintegration of a tablet as a criterion for ensuring uninhibited drug dissolution behaviour disintegrants are an essential component to tablet formulations. The ability to interact strongly with water is essential to disintegrant function. Combinations of swelling and/or wicking and/or deformation are the mechanisms of disintegrant action. A disintegrant used in granulated formulation processes can be

more effective if used both "intra-granularly" and "extra-granularly" thereby acting to break the tablet up into granules and having the granules further disintegrate to release the drug substance into solution [10].

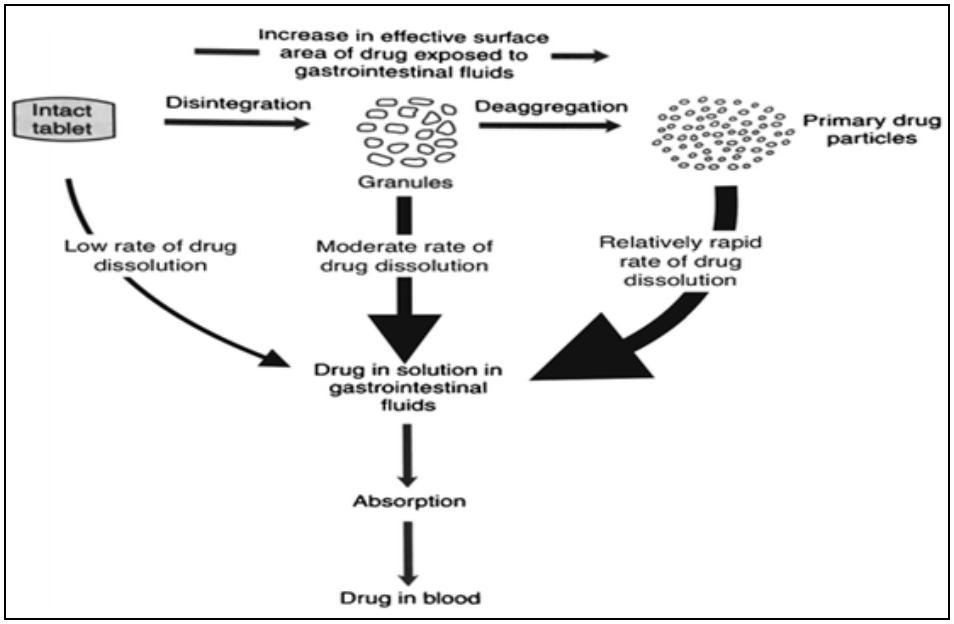

FIG. 3: SCHEMATIC OF THE DRUG RELEASE PROCESS FROM A TABLET

TABLE 1: DRUGS USED IN ORODISPERSIBLE TABLETS [16]

S. no.	Category	Examples
1	Antibacterial agents	Tetracycline, Erythromycin, Ciprofloxacin, Penicillin, Rifampicin, Doxycyclin, Nalidixic acid, Trimethoprim
2	Antidepressants	Trimipramine maleate, Nortriptyline HCl, Trazodone, HCl, Amoxapine, Mianserin HCl
3	Anthelmintics	Albendazole, Mebandazole, Thiabendazole, Ivermectin, Praziquantel, Pyrantel embonate, Dichlorophen
4	Antidiabetics	Glibenclamide, Glipizide, Tolbutamide, Tolazamide, Gliclazide, Chlorpropamide
5	Antihistamines	Acrivastine, Cetrizine, Cinnarizine, Loratadine, Fexofenadine, Triprolidine
6	Antiarrhythmics	Disopyramide, Quinidine sulphate, Amiodarone HCl
7	Antihypertensives	Amlodipine, Carvedilol, Diltiazem, Felodipine, Minoxidil, Nifedipine, Prazosin HCl, Nimodipine
8	Analgesics/Anti-inflammatory agents	Diclofenac sodium, Ibuprofen, ketoprofen, Mefenamic acid, Naproxen, Oxyphenbutazone, Indomethacin
9	Anti-convulsant/ Antiepileptic	Carbamazepine, Methsuximide, Phenytoin, Primidone, Phenobarbitone, Valproicacid, Phensuximide

TABLE 2: MARKETED ORODISPERSIBLE TABLETS IN INDIA

S. no.	Category	Examples
1	Calritin, Reditabs	Micronized loratadine
2	Mosid	Mouth melt tablet of mosapride citrate.
3	Imodium, Lingual	Imodium
4	Pepcidin, Rapitab	Quick releasing antiulcer, preparation of pepcid
5	Zyrof, Meltab	Rofecoxib
6	Nimulid	Nimesulide
7	Feldene	Piroxicam (10 or 20 mg),
8	Maxalt	Rizatriptan (5 or 10 mg), Peppermint flavor
9	Claritin, Reditab	Immediate Dissolving formulation of calritin
10	Pepcid RPD	Famotidine (20 or 40 mg),
11	Zyprexa Zydis	Olanzapine (5, 10, 15 or 20 mg),
12	Zofran ODT	Ondansetron (4 or 8 mg), strawberry flavor

RESULT AND DISCUSSION: The better patient compliance offered by ODTs over conventional dose forms, together with their convenience, bioavailability, and quick beginning of action, have

attracted the interest of numerous manufacturers for more than a decade. The introduction of quick dissolving dosage forms has alleviated some of the challenges associated with drug administration to pediatric and elderly patients, who account for a sizable proportion of the world's population. As a result, patient demand and the availability of diverse technologies have boosted the market share of Fast dissolving tablets, thereby extending a drug's patent life. Considering the benefits of the delivery mechanism, quickly dissolving dosage forms have been successfully commercialized, and these dosage forms are predicted to grow more popular due to increased patient demand. Thus, ODT for the majority of currently available medications may be created in the near future.

ACKNOWLEDGEMENT: Nil

CONFLICTS OF INTEREST: Nil

REFERENCES:

1. Sivadasan D, Sultan MH, Madkhali O, Javed S and Jabeen A: Formulation and in vitro evaluation of orodispersible tablets of fexofenadine hydrochloride. Trop J Pharm Res 2020; 19(5): 919-25.
2. Gandhi L and Akhtar S: Comparative study on effect of natural and synthetic superdisintegrants in the formulation of orodispersible tablets. J Drug Delivery Ther 2019; 9(2): 507-13
3. Panda S, Hemalatha N, Panchagnula US, Rao S and Baratam: Formulation and evaluation of orodispersible tablets of diclofenac sodium by using superdisintegrant from natural origin. International Journal of Applied Pharmaceutics 2019; 11: 190-7.
4. Ranganathan V and Yoong J: Development and evaluation of mouth dissolving tablets using natural superdisintegrants. J Young Pharm 2017; 9: 332-5.
5. Kumar V: Formulation and evaluation of meclizine HCl orally dispersible tablets by using natural super disintegrants. Int J Pharm Sci Res 2016; 2(1): 9-30.
6. Sresta N, Srinivasa Babu P and Pallavi K: Orodispersible tablets. The Indian Pharmacist 2017; 15(1): 30.
7. Dwivedi A and Darwhekar GN: Design, optimization and evaluation of empagliflozin orodispersible tablets using different superdisintegrants. Int J Pharm Pharm Sci 2019; 11(7): 32-41.
8. Reshma KJ and Senthila S: Superdisintegrants and their inevitable role in orodispersible tablet. Int J Res Rev 2020; 7(10): 462-71.
9. Gupta DK, Maurya A and Varshney MM: Orodispersible tablets of overview of formulation and technology. World Journal of Pharmacy and Pharmaceutical Pciences 2020; 9: 1406-18.
10. Tambe B: Mouth Dissolving Tablets. International Journal of Information Research and Review 2018; 5: 5451-59.
11. Roy A: Orodispersible tablets. a review. Asian J Pharm Clin Res 2016; 9: 19-26.
12. Mahal KR: Formulation and In-vitro Evaluation of Orodispersible Tablet. International Journal of Pharma Sciences and Research 2015; 6: 689-96.
13. Darade SC, Patil PB, Kalkotwar RS: Formulation and evaluation of orodispersible tablet containing piroxicam by sublimation method. Indian Journal of Pharmacy and Pharmacology 2017; 4: 77-82.
14. Gothainayaki C, Rajalakshmi AN: Fixed dose combination products as Oro-dispersible tablets. Journal of Drug Delivery and Therapeutics 2019; 9: 563-73.
15. Aggarwal P, Nautiyal U and Mali RR: A review on fast dissolving tablet. International Journal of Recent Advances in Science and Technology 2015; 2: 20-8.
16. Thapliyal S, Bhattb G and Kandpal G: Oro dispersible tablets. World J of Pharma Research 2018; 7: 146- 62.

How to cite this article:
Sharma P: Overview of oral dispersible tablets. Int J Pharm Sci & Res 2024; 15(5): 1340-45. doi: 10.13040/IJPSR.0975-8232.15(5).1340-45.