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Original Article

A Comprehensive Review on Oral Disintegrating Tablets

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ABSTRACT

Over the past three decades, orally disintegrating tablets (ODTs) have garnered significant attention as a preferred alternative to conventional tablets and capsules due to better patient compliance. ODTs are solid dosage forms containing medicinal substances that disintegrate rapidly, typically within seconds, when placed on the tongue. Products of ODT technologies entered the market in the 1980s and have steadily grown in demand, with their product pipelines expanding at a rapid pace. Pharmaceutical scientists are working to better understand the physicochemical and biochemical parameters relevant to drug delivery systems that dissolve quickly and start to work quickly as well. ODTs are an appropriate dose form for specific populations, such as young patients with underdeveloped muscles and neurological systems, patients with hand tremor issues, elderly patients, dysphagic patients, psychotic patients, immobile patients, comatose patients, and pediatric patients.

Keywords: Tablet, ODT, system, disintegration

INTRODUCTION

The demand for more patient-friendly and compliant dosage forms has increased over the past ten years, which has led to an annual increase in the need for developing new technologies1. Because it is very expensive to develop a new drug molecule, pharmaceutical companies are now concentrating their efforts on developing new drug dosage forms for existing drugs that have improved safety and efficacy along with reduced dosing frequency, as well as the production of more cost-effective dosage forms. For the majority of therapeutic agents used to produce systemic effects, the oral route still represents the preferred means of administration due to its many benefits and high patient compliance when compared to many other routes. The population is impacted by this issue, which ultimately raises the risk of therapy noncompliance and inefficiency. These factors have led to a great deal of interest in tablets that break down in the mouth [3]. Among all pharmaceutical formulations. NS, oral tablets with solid dosage have the most prominence [4] The ODT formulation is described as "a solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds when placed upon the tongue" by the Food and Drug Administration (FDA). The Zydis ODT formulation of Claritin (loratadine) was authorized by the US Food and Drug Administration in December 1996. The Zydis ODT formulation of Klonopin (clonazepam) and the Zydis ODT formulation of Maxalt (rizatriptan) came after it in December 1997 and June 1998, respectively. Moreover, a handful of medications have received regulatory authority approval for ODT formulations [5]

Mechanisms of Disintegration:

Unless the tablet is made for rapid surface erosion, it must first disintegrate before dissolving. Starches, agar, amylose, cellulose and its derivatives, gum and its derivatives, gelatin, resins, and silicone compounds are among the substances used as dissolves. Several mechanisms of action have been proposed for disintegration. The first mechanism involves the development of gas from an effervescent pair, such as citric acid and sodium bicarbonate, when water is absorbed. The disintegration of the pill may occur due to the expansion of gas. Another mechanism involves the disintegration of the tablet structure by swelling caused by the absorption of water [6].

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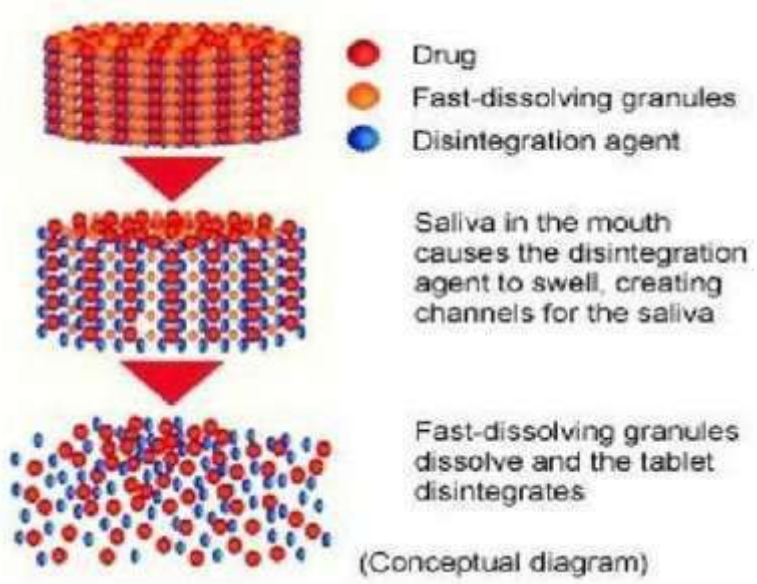

- **Ideal properties of ODTs:**

For many medication classes, ODTs are preferred over typical rapid launch dosage bureaucracy due to their superior dosage administration. It is expected to go through a few top. Notch functions that create the ordeal. ODTs dissolve or break up in the mouth in an extremely short amount of time. They are solid under environmental conditions, give a good flavor masking home, don't require water for administration, and don't leave any residue in the mouth after oral administration. ODTs no longer need water when administered, have flavor- covering appropriate qualities, can load a lot of pills, have a pleasing mouthfeel, and are robust in the environment. Circumstances and must now cease leaving any trace in the mouth following oral ingestion [7]. The advantages of utilizing ODTs over rapid launch formulas may also include the convenience of method design and production, unit packing, and patient handling [8,9,10]. Fast pill Disintegration leads to quick dissolution and quick absorption, which can improve healing effectiveness due to prolonged bioavailability. There is also less need for water after administration. [11]

Limitations of ODTs:

It includes [12-14]:

- The tablets commonly have insufficient mechanical strength. Hence, conscientious handling is necessary.
- The tablets may leave an unpalatable taste and grittiness in the oral cavity if not formulated properly.
- Drugs that have large doses, can cause problems in formulating them into ODTs.
- Patients who simultaneously take anticholinergic drugs are not suitable candidates for ODTs.

- **Advantages of OTD's:** [15-20]

- The tablet can be swallowed without water. They are pleasant to the mouth a nd work well at disguising tastes.
- Easily provided to individuals who are intellectually impaired, elderly, or pediatric. There isn't any leftover in the oral cavity following ingestion.
- It is possible to manufacture the tablets at a minimal cost by using standard processing and packaging equipment. Permit heavy drug loading.
- Correct dosage can be administered in contrast to liquids
- The medication has a swift onset of effect due to its rapid dissolution and absorption.
- Advantageous in terms of administration and transportation compared to liquid medication.
- There is no chance of asphyxia from physical blockage when ingested, providing increased safety.
- ODTs work well with controlled and sustained release actives. Packages in units.

The Need for Development of ODTS: [21-24]

Because of patients' low acceptance of and adherence to current delivery regimens, the small market for pharmaceutical companies and medication users, and the high expense of illness management. There is a continuing need for non-invasive delivery systems. Patient-related variables. For individuals who find it difficult to swallow conventional tablets and capsules with a b ounce glass of water, oral disintegrating dose forms are very helpful. Among these are the subsequent items: Patients in their pediatric and geriatric years who experience difficulties chewing or swallowing solid dose forms

- Patients who are unwilling to take solid food due to the fear of choking
- Very elderly patients who may not be able to swallow a daily dose of an antidepressant.
- A child with allergies who is eight years old and would prefer a more convenient dosing form than antihistamine syrup
- An H2-blocker may be too nauseating for a middle-

An aged lady receiving radiation therapy for breast cancer needs to swallow. A patient experiencing continuous nausea who may be on the go or have limited access to water; a schizophrenic patient in an institutional environment who would attempt to smuggle a traditional pill under his or her tongue to avoid taking their daily dose of a typical antipsychotic.

Factors related to manufacturing and marketing

Regardless of size, the pharmaceutical industry's ability to exist depends on its ability to discover innovative drug delivery technologies and apply them to product development. When a medication's patent expires, pharmaceutical companies frequently create a new, improved dosage form for that particular drug. A new dosage form allows a producer to provide a more convenient dosage form to its patient population while also extending market exclusivity, distinctive product differentiation, value- added product line expansion, and patent protection. Targeting underserved and undertreated patient populations concurrently increases revenue 25.

Example- in response to a generic challenge brought up by Ranbaxy in the United States, Eisai Inc. introduced Aricept ODT, a line extension of donepezil for the treatment of Alzheimer's disease, in Japan in 2004 and in the United States in 2005. Lipola M (simvastatin ODT), a line extension of Merck's popular cholesterol- lowering medication Zocor®, was introduced by its Japanese affiliate in response to seventeen generic registrations of the drug filed for in Japan in 200424. When marketers provide a distinctive, simple-to-- Taking the form that meets the needs of a patient demographic that is underserved, they enhance their company's image and brand.

- **Tablet size: [27]**

The size of a tablet affects how easy it is to take. It has been noted that tablets with a size of 7- 8 mm tablets are the simplest to swallow, while tablets larger than 8 mm are the easiest to manage

. It is so challenging to create a tablet size that is both convenient to carry and manage.

ODT Evaluation of Special Concern:

Pharmacopoeias can be consulted for guidance in assessing crushing strength and friability. However, a few tests warrant particular attention. These include the following: During the wet period the contact angle and the dosage form's wetting time are connected. It must be evaluated in order to provide insight into the tablets' disintegration characteristics; a shorter wetting time indicates a faster tablet disintegration. To determine the time required for complete wetting, a tablet is placed on a piece of tissue paper that has been folded twice and stored in a tiny Petri dish (ID = 6.5 cm) with 6 ml of water [28].

Test of disintegration ODTs

Typically dissolve in less than a minute, and patients may experience disintegration times of anything between five and thirty seconds. These dosage forms have multiple restrictions with the usual disintegration test approach, making it unsuitable for measuring extremely short disintegration periods. For ODTs, the procedure must be changed since the test must replicate breakdown in salivary contents because disintegration without water is necessary. When the compendial approach is employed, an ODT with a disintegration time that is too quick to discern variations between tablets is given modified

dissolution equipment. In a container holding 900 mL of water, a basket sinker holding the tablets is positioned slightly below the water's surface. [29]. Several scientists have created novel in vitro techniques that enable precise disintegration test determination. The texture analyzer tool is used to conduct the disintegration test. A cylindrical probe with a flat end is inserted into the disintegrating tablet while it is submerged in water for this test. The gadget is programmed to sustain a tiny force for a predetermined amount of time while the tablet dissolves. The tablet disintegration profile as a function of time is provided by the plots of the probe's travel distance that are produced by the instrument's software. [30]

Industrial Applications:

- Creating an oral disintegrating dosage form and utilizing currently available disintegrants
- Improving the technology of ODTs further
- Optimizing the mixture of disintegrants or excipients to produce ODTs
- Choosing and creating appropriate packaging materials and systems for improved

Both the product's stability and the creation of an affordable product Developing disintegrants from diverse polymers that are employed as coating materials by particular modifications and using them to manufacture oral drug formulations (ODTs) is one goal. Another is arriving at an alternative taste masking agents and creating pleasant dose forms to increase patient compliance.

Prospects:

These dosage forms could work well for the oral administration of medications like protein- and peptide-based- Based therapies, which have a low bioavailability when taken as regular tablets. These goods often break down quickly in the stomach. If the majority of next- Generation medications contain protein or peptides, tablets could not be the most common form for administering these components. Patients typically prefer not to utilize injections unless they are made easier by advanced auto-injectors. Although inhalation is a viable approach for administering these medications, the majority of biopharmaceuticals produced thus far have been low molecular weight chemicals due to increased research into the field. It looks highly promising for the delivery of these medications as ODTs have developed improved oral protein delivery technology that may release these pharmaceuticals in the oral cavity.

CONCLUSION:

When compared to traditional oral dose forms, oral disintegrating tablets have higher patient acceptance and compliance and may have better biopharmaceutical qualities, increased efficacy, and improved safety. Script ODT solutions were first created to help pediatric, elderly, and mentally disabled patients with dysphagia who had trouble swallowing traditional pills. ODTs are now more extensively accessible as over-the-- Over-the-counter (OTC) medications are used to treat allergies and symptoms of the flu and colds. The intended audience now includes people who wish to easy dosage without water, at any time, or place. Because of the availability of new technology, along with significant market acceptability and patient demand, the future for such digital forms appears positive. Pharmaceutical businesses can leverage ODTs for first-to-- market goods or product line extensions by keeping a close eye on technological advancements. Future developments of ODTs should see the introduction of more cutting-edge- edge technology due to the ongoing research and development of new pharmaceutical excipients

REFERENCE

1. Shyamalan B, Narada GY. Rapid dissolving tablets: A Novel dosage form. The Indianpharmacist,2002;13(8):09-12.
2. Valbri, Mura P, Maestrelli F, Cirri M, Ballerina R, Development and evaluation of glyburide fast-dissolving tablets using solid dispersion technique. Drug Dev Ind Pharma,2004,30(5):525-34.
3. Hirani J, Rathdrum D, Vadalia K. Orally disintegrating tablets. Tropical Journal of Pharmaceutical Research 2009;8(2):161-172.
4. Olmez SS, Vural I. Advantages and quality control of disintegrating tablets. FABAD Journal of Pharmaceutical Science 2009;34(1):167-172.

5. Fuy, Yanks, Jeong SH, Kimura S, Parker K. Orally fast disintegrating tablets: development, technologies, taste masking, and clinical studies. Critical Reviews in Therapeutic Drug Carriers Systems 2004;21(6):433-475.
6. Vaibhav S, Mahaveer PK, Gupta MK, Agarwal D, and Sharma N: Orally disintegrating tablet: friendly dosage form. International Journal of Research in Ayurveda and Pharmacy 2010;2(1):81-88.
7. Abdelbary G, Prinder P Eouanic, Joachim J, Raynier JP, Piccerelle P. The preparation of orally disintegrating tablets using a hydrophilic waxy binder. Int J Pharm.2004; 278:423-33.
8. Kuno Y, Kojima M, Andos, Nakagami H evaluation of rapidly disintegrating tablets manufactured by phase transition of sugar alcohols. J Control Release 2095; 105:16-22.
9. Koizumi K, Watanabe Y, Morita K, Utoguchi N, Matsumoto M, New method of preparing high porosity rapidly saliva soluble compressed tablet using mannitol with camphor. A sublime material. Int J Pharm 1997;152:127-31.
10. Swamy PV, Divate SP, Shrisand SB, Rajendra P. Preparation and evaluation of Orodispersible tablets of pheniramine maleate by effervescent method. Indian J Pharm Sci 2009; 71:151-4.
11. Kaushik D, Dureja H, Saini TR. Formulation and evaluation of Olanzapine mouth dissolving tablets by effervescent. Indian Drugs 2004;41(7):410-12.
12. Habib W, Khankari R, Hontz J.fast dissolving drug delivery system, Critical Reviews in Therapeutic Drug Carrier Systems 2000;17(1):61-72.
13. Behnke K, Sogaard J, Martin S, Baume J, Ravindran AV, Agren H, et al. Mirtazapin orally disintegrating tablet versus sertraline: a prospective onset of action shidy. Journal of clinical Psychopharmacology 2003;23(4):358-364.
14. Gafitanu E Dumistracel I, Antochis S. formulation and bioavailability of propyphenazone in lyophilized tablets. Revista Medico-Chirurgicala a societatti De Medici Si Naturalisti Din Lasi_1991;95(1_2):127-128.
15. Brown D. Orally disintegrating _Taste over speed. Drug delivery Technology 2093,3(6):58-61.

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