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Fast Dissolving Tablet Review of Formulation & Evaluation.

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ABSTRACT

The idea behind the Mouth Dissolving Drug Delivery System was to give patients a traditional way to take their medications.

Among these, mouth-dispensing drug delivery systems (MDDDS) have gained a significant foothold in the market by resolving issues with administration that had previously arisen and helping to prolong the patent life.

The following are some of the desired qualities and difficulties for creating fast-disintegrating drug delivery systems: quality control tests; mass extrusion technologies; tablet molding methods; sublimation techniques; spray drying techniques; lyophilization technologies; direct compression methods; and applications of super-disintegrates.

Keywords: Medication administration, tablet dissolving by mouth, Taste maskin, superdisintegrant, and mucosal membrain.

Introduction

For conventional use, many pharmaceutical dosage forms are given as pills, granules, powder, or liquid. Nonetheless, some patients have trouble chewing or swallowing solid dosage forms, especially those who are younger or older. The fear of a bitter taste prevents many elderly and pediatric patients from taking these solid preparations. Several mouth-dispersing drug delivery systems have been developed to help these patients.(1)

The Idea of mouth dissolving tablets, or MDTs, came about with the intention of increasing patient compliance. Creating sophisticated oral drug delivery systems has always drawn scientists looking for ways to increase patient compliance. Among these, mouth-dispensing drug delivery systems (MDDDS) have gained a significant foothold in the market by resolving issues with administration that had previously arisen and helping to prolong the patent life.(1, 2)

These techniques are based on the principles of increasing porosity and/or addition of superdisintegrants and water soluble excipients in the tablets. The formulations prepared from these techniques differ from each other on the basis of the factors like mechanical strength of final product, drug and dosage form stability, mouth feel, taste, rate of dissolution of the formulation in saliva, rate of absorption from saliva and overall drug bioavailability . (3)

Children's immature neurological and muscular systems may also make it difficult for them to swallow Traveling patients who might not have easy access to water also clearly struggle with swallowing . (4)

Advantages of mouth dissloving tablet

Patients' compliance in the case of incapacitated patients in beds, as well as travelers and busy individuals without easy access to water.

Pregastric absorption can lead to decreased dosage, increased bioavailability, and better clinical outcomes by minimizing adverse effects. (5, 6)

Increased bioavailability and quick absorption can be attained by pre-gastric absorption of medications from the mouth, throat, and esophagus as saliva travels down.

Quick intervention with medication therapy. (7)

Product differentiation, line extension, life-cycle management, exclusive product promotion, and patent life extension are examples of new business opportunities. (8)

Ideal properties of MDT

i. Possess a pleasing oral feel

ii. Work well with other excipients and taste masking.

iii. Permit heavy drug loading. (8)

iv. Feel good in the mouth

v. Be less pliable and more robust.

vi. After administration, leave little to no residue in the mouth

vii. Possessed a passable ability to disguise taste. (9)

Silent features (10)

1)As saliva travels down into the stomach, some medications are absorbed from the pharynx and oesophagus; in these situations, the medication's bioavailability is enhanced.

2)The drug's quick dissolution and absorption, which could result in a quick start of action.

3)Compared to liquids, ease of administration and precise dosage.

4) Simplicity of administration for patients—such as young children, elderly adults, and mental health patients—who refuse to swallow a tablet.

Limitations

-Usually, the tablets' mechanical strength is inadequate.

-Therefore, handling must be done carefully.

- If the tablets are not made correctly, they may leave an unpleasant taste and/or grittiness in the mouth.

- It is challenging to formulate drugs with comparatively higher doses into MDT; an example of this is the antibiotic ciprofloxacin, which comes in adult dose tablets containing 500 mg of the medication.

-Patients may not be the best candidates for MDT if they also take anticholinergic medications. Likewise, individuals experiencing dry mouth as a result of reduced salivary flow might not be suitable candidates for these tablet formulations

Evaluation parameters of mouth dissloving tablet(11)

1.Tablet weight variations

Twenty tablets were chosen at random and weighed precisely. Mean values ± SD are used to express the results.

2.Tablet thickness

Ten randomly chosen tablets were measured for thickness using a vernier caliper. The findings are presented as mean values.

3.friability test

The percentage Friability is equal to W-W0 × 100 / W.

Where W0 is the starting weight W is the weight following friability.

Percentages Tablets with less than 1% friability are regarded as acceptable.was run for four minutes at 25 rpm or up to 100 revolutions. Once more, the tablets were weighed. The following formula was then used to determine the percentage friability.(12)

4.wetting time

Five circular tissue papers, each measuring 10 cm in diameter, were placed in a petridish that also had a 10 cm diameter. To add petridish, ten millimeters of water containing the water-soluble dye Eosin are needed. Next, gently place a tablet on the tissue paper's surface.

Wetting time is defined as the amount of time it takes for water to reach the tablet's upper surface.(13)

5.Disintegration time

The literature has provided an explanation of the techniques for evaluating in-vivo disintegration time .

Although the disintegration time difference is usually only a few seconds, the results of this kind of test usually show inadequate reproducibility and are unreliable. Furthermore, there are ethical and volunteer safety limitations associated with the in-vivo disintegration test.

Currently, the Pharmacopoeias' disintegration test for conventional tablets is used to measure the disintegration time of MDTs. With traditional disintegration equipment, EP has set a maximum disintegration time of three minutes for MDTs. However, the pharmacopoeias do not specify any specific equipment for the disintegration test of MDTs, and the currently used conventional method appears to be unsuitable for drug.(14)

6.Dissolution time

The in-vitro assessment of MDT could be done using the standard dissolution method [30]. For early in-vitro studies, the dissolution conditions for the reference listed drugs that are available in USP can be used to simulate better in-vivo conditions. In addition to the aforementioned, multimedia dissolution studies in different buffer solutions with varying pH values, such as pH 4.5, 6.8, and 0.1 N HCl buffers, should be conducted in order to interpret their in-vivo performance and pharmaceutical equivalency.

Since MDT typically dissolves in less than thirty seconds in a dissolution vessel, its disintegration time has little bearing on the discriminating characteristics of the resulting dissolution profile. Therefore, the purpose of the in-vitro dissolution study is to ensure that the medication is completely released into the media within the allotted time frame. A multipoint dissolution profile is necessary for the assessment of a controlled release system, whereas single point dissolution is adequate for an immediate release dosage form based on the functionality of the dosage form (15 , 16)

7.water adsorption ratio

Six milliliters of water are contained in a tiny Petri dish with a piece of tissue paper folded twice inside. On the tissue paper, a tablet is placed and given time to get completely wet. After that, the wet tablet is weighed. The following formula is used to calculate the water absorption ratio, or R.

R is equal to 100 × Wa–Wb/Wa.

Where Wa is the tablet's weight following absorption of water.

Wb = Tablet weight prior to water absorption

8.In-vitro disintegration time

Disintegration Time in voThe USP tablet disintegration apparatus is used to measure the disintegration times of sublingual tablets. The medium used is either 0.1 n HCl or phosphate buffer with a pH of 6.8. The medium has a volume of 900 ml and a temperature of 37 ± 2 °C. The amount of time, measured in seconds, that the tablets take to completely dissolve and leave behind no palatable mass inside the device is recorded

Drug taste masking becomes essential to patient compliance when delivery systems dissolve or disintegrate in the patient's mouth, releasing the active ingredients that come into contact with the taste buds.

Porosity, friability, and strength of tablets: Fast disintegrating tablets are composed of either very porous or soft-molded matrices or compressed into tablets with very low compression force, which makes it possible for the tablets to dissolve in the mouth.9.In-vivo disintegration time

Using the paddle method and the busket method of the United States Pharmacopoeia (USP) XXIV dissolving testing apparatus, the in-vitro release rate of sublingual tablets is measured. The dissolution test is run at 37± 20C and 50 rpm with 900 ml of 6.8 pH phosphate buffer or 0.1 N HCl. At various intervals of time (min), a sample (5 ml) of the solution is removed from the dissolving apparatus. Fresh, identical-quantity dissolution medium is used to replace the samples(17, 18)

Desired characteristics and challenges for developing fast Disintegrating drug delivery system

1)The amount of time needed for disintegration .

2) MDTs should dissolve, dissolve, disperse, or melt in the mouth in an extremely brief amount of time—possibly 60 seconds—without the need for water.

3) The active ingredient's flavor .

4) Since most medications have an unpleasant taste, fast-dissolving drug delivery systems typically include the medication in a form that masks its tasteDrug taste masking becomes essential to patient compliance when delivery systems dissolve or disintegrate in the patient's mouth, releasing the active ingredients that come into contact with the taste buds.

5) Porosity, friability, and strength of tablets: Fast disintegrating tablets are composed of either very porous or soft-molded matrices or compressed into tablets with very low compression force, which makes it possible for the tablets to dissolve in the mouth.(19)

Future prospective

Future developments in pharmaceutical excipients should lead to the appearance of more cutting-edge MDT technologies. These innovations could entail tweaking the composition and processing of the formulation to reach new performance endpoints, or they could entail fusing new technological developments with conventional pharmaceutical processing methods to create novel dosage forms that dissolve in the mouth. It is reasonable to anticipate that novel technologies will continue to be created by combining various technological disciplines in future drug delivery system innovations.(20, 21)

Conclusion

Superdisintegrants that could dissolve in less than 30 minutes, such as sodium starch glycolate, croscarmellose sodium, and crospovidone, were used to create a mouth-dissolving tablet.

All formulations' post-compression parameters were calculated, and the results were shown to be acceptable. The formulation F3, which contains 30 mg of crospovidone, was found to be the best formulation based on the drug content and in-vitro dissolution studies of the formulations.(22)

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Reference

1)Metkar P. S., Gayke A. U., Aglawe S. B.1, Sancheti V. P.1, and Gayke A. U.

2) J.J. Hirani, D.A. Rathod, and K.R. Vadalia (2009). Review of tablets that dissolve in the mouth. 2009; Trop J Pharm Res., 8: 161-72

3) Habib W., Khankari R., and Hontz J. Rapid dissolving drug delivery system: an essential therapeutics review. Drug Carr Sys., 17(61–72) years.

4) Shah D, Patel V, Prajapati B, Lala I, and Modasiya M. Piroxicam Fast Disintegrating Tablets: Design and Characterization. Journal of PharmaTech Research International, 2(1), 353-357 (2009).

5) Lindgren S, Janzon L. Clinical findings and the prevalence of swallowing complaints in a population of men and women aged 50-79 years living in an urban area. (1991) Dysphagia 6: 187

6) A Synopsis of Formulation Technology for Mouth Dissolving Tablets I, S Dali, C Subhashis, S Sanjay, M Brahmeshwar. Sci Pharm.

7) Dellarosa DM, and Avery SW. Methods for treating patients who have brain injury

8) Jana G, Panda O, Mahapatra S, Biswal P, Mishra B, Sahoo S, and Biswal O. Rapid Dissolving Tablets: A Possible Method for Delivering Drugs? Drug Invention, 2010; 2(2): 130–135.

9)Hanawa T. Silk fibroin gel preparation and characterization: a novel oral dosage form for elderly patients. 1995; 43: 284–288; Chem Pharm Bull. PMid: 7728934

9) Gisel EG. Oral motor skills after sensorimotor intervention in a child with cerebral palsy who has moderate eating impairment.

1994; 9: 180–192. Doi:10.1007/BBF00341263

10) The development and optimization of prometazine theoclate mouth dissolving tablets was carried out by Nayak U, Patra S, Rout P, Patro B, and Nayak B. Indian Pharmacist, 4 (2008), 65-68

11)Gupta G, Kumar S, Gill B, and Kaur T. Mouth Dissolving Tablets: A Novel Approach to Drug Delivery.

Journal of Current Pharmaceutical Research International, 3(1), 1–7 (2011)

12)Fast Dissolving Drug Delivery System: A Literature Review by Reddy L, Ghosh B, and Rajneesh R. 64(4), 1-3, Indian Journal of Pharmaceutical Sciences, 2002.

13) H. K. Patil*, G. M. Patil, V. H. Jain, S. A. Tadvi, S. P. Pawar

14) Fast Dissolving Drug Delivery Systems, R. Bradoo, JAMA India, 4 (10), 27–31, 2001. 17. SR Parakh, AV Gothoskar. A summary of tablet technologies that dissolve in the mouth. 2003; Pharm Technol. 27: 92–100

15) Bi Y., Otsuka A., Dayo K., Sunada H., Yonezawa Y., and Iida K. (1996). Preparing and assessing a tablet that has been compressed and is quickly disintegrating in the mouth. Tokyo Chem. Pharm Bull. 44: 2121-2127.

16) Sandip S. Kshirsagar2, Rajesh J. Oswal2, Sagar A. Konapure1 *, Prafulla S. Chaudhari1, Rishikesh V. Antre2, and Trushal V. Chorage3

17)Sagar N. Pati, Y P Sharma, Kuldip H. Ramteke, Avinash G. Mansuk, and Prashant B. Pawar .

18) J. Klancke. "Orally disintegrating tablet dissolution testing." Dissolution Technol. 2003; 10(2): 6–8.

19) Fix JA, Johnson MI, Dor JM. A novel in vitro technique for calculating a fast disintegration tablet's disintegration time. 1999; 26: 939–940. Proc Int Symp Control Rel Bioact Mater.

20) A new method for producing high porosity quickly saliva soluble compressed tablets using mannitol and camphor as a subliming material was developed by Koizumi K.I., Watanabe Y., Morita K., Utoguchi N., and Matsumoto M. 1997; Int J Pharm. 152: 127–131

21) Fast Dissolving Drug Delivery Systems: A Brief Overview, Internet J. Pharmacology, 2006, 4(2), Biradar, S. S., Bhagavati, S. T., Kuppasad, I. J.

22) Formulation of zolmitriptan sublingual tablets prepared by direct compression with different polymers: In vitro and in vivo evaluation, B Ziya, T Cetin, T Umut, E Halil, KO Cansel, SYAyhan. 2011; 78: 499–505 in European Journal of Pharmaceutics and Biopharmaceutics.