International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 284-287 www.ijprajournal.com ISSN: 2456-4494

Evaluation of Mouth Dissolving Tablets of Melatonin

[1]Dyaneshawar Gite
1Students, 1 guide prof. Latif Bagwan
1 m.pharm

Date of Submission: 04-07-2023 Date of Acceptance: 16-07-2023

Abstract
Melatonin is a drug that is used as a dietary supplement and medication in the treatment of sleep disorders such as insomnia and circadian rhythm sleep disorders like delayed sleep phase disorder, jet lag disorder, and shift work disorder. It is a naturally produced hormone. It can also be used as a mouth dissolving tablet. As, mouth dissolving tablet dissolve automatically in the mouth without any need of water.Generally, two types of techniques are used in the formulation of Mouth dissolving tablet. a.Conventional and b.Patented.
Precompression study involves Bulk density, Tap density, Compressibility index, Hausner's ratio,Angle of repose. Post compression study involves Hardness, Thickness, Percent friability, Disintegration time, Wetting time, Water absorption time, Weight variation, Dissolution study for % drug release. Various parameters have been come to know like it's appearance as White to off white crystalline powder, colour, melting point, solubility, assay.Various excipients have been used such as Sodium starch glycolate, Crospovidone, Dextrose monohydrate, Sucralose, Vanilla flavour, Magnesium stearate.Disintegration time study showed that a 6mg (4%) concentration of Crospovidone showed less disintegration time and the highest drug release because of their good wetting and swelling properties. A synthetic superdisintegrant (Crospovidone) was selected for further study.In this study it was concluded that process parameter like disintegration time, and dissolution rate has significantly effect on performance of the mouth dissolving tablet (MDT).

I. Introduction

An ideal dosage regimen in the drug therapy of any disease is the one, which immediately attains the desire therapeutics concentration of drug in plasma and maintains it constant for the entire duration of treatment. This is possible through administration of conventional dosage form in a particular dose and at a particular frequency. Thus drug may be administered by variety of routes in a variety of dosage forms.

In fact, the development of pharmaceutical products for oral delivery, irrespective of physical form involves varying extents of optimization of dosage form within the inherent constraints of GI physiology. Therefore, a fundamental understanding of various disciplines, including GI physiology, pharmacokinetics, pharmacodynamics and formulation design are essential to achieve a systemic approach to the successful development of an oral dosage form.

Melatonin is a naturally produced hormone by the pineal gland that helps regulate in response to the body's sleep/wake cycles. It has been used to treat sleep problems such as insomnia, jet lag, shift-work and circadian rhythm disorders. It has also been used to help patients re-program their circadian clocks to account for changes in light/dark cycles due to time changes.

Now a day mouth dissolving tablets are gaining more importance in the market. Conventional oral melatonin treatments present several problems. It well absorbed in from GI tract, its variable oral bioavailability when it given in orally administered dose.

Different dosage form of melatonin have manufactured to specific target population, pediatric patients, having potential difficulty taking other dosage form, Mouth dissolving tablet of Melatonin is design is design in order to improve the disintegration time, ease of administration, avoid swallowing problem and hence, improve the patient compliance.

Hence it was thought to formulate novel and convenient solid dosage form i.e. Mouth dissolving tablet.

Melatonin is an ideal drug candidate for mouth dissolving tablets.

The conventional tablets also show poor patient compliance particularly by the geriatric and pediatric patients who have difficulty in swallowing other oral forms, and by those who are bed ridden or

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 284-287 www.ijprajournal.com ISSN: 2456-4494

who are traveling and do not have an easy access of water. The risk of chocking or suffocation during oral administration of conventional formulations due to physical obstruction avoided, thus providing improved safety. Sometime, it may be difficult to swallow conventional product due to non-availability of water.

These conditions are those which require drug to be formulated mouth dissolving tablet. Some patient prefers mouth dissolving tablet to conventional tablet due to best of easy administration, swallowing, rapid disintegration and absorption of drug, pleasant taste and availability in several flavors.

These problems lead to the development of novel type of solid oral dosage form called as mouth dissolving tablets which disintegrate/dissolved rapidly to release the drug as soon as they come in contact with saliva even within few seconds.

Mouth dissolving tablets are increased bioavailability and faster/quick onset of action is a major maintain of these formulations. Because the tablets disintegrate inside the mouth, drugs may be fast absorbed in the buccal, pharyngeal, and gastric regions.

II. Materials and Methods

PREFORMULATION STUDIES

Drug Authentication:

1) Organoleptic properties:

The received sample of Melatonin was examined for its appearance and color.

2) Melting point:

The melting point was determined by the melting point apparatus. The melting point of Melatonin was determined by Thiele's tube method i.e. by taking a small amount of drug in one end closed capillary tube placed in the melting point apparatus and the temperature at which the drug melts was noted.

3) Solubility:

The solubility of API was determined by dissolving compound in various solvents.

- ★ Water: slightly soluble
- ★ Methanol: soluble
- ★ 0.1N Hydrochloric acid: sparingly soluble
- ★ Acetone: soluble

4) Assay:.

Preparation of sample:

Weighed 20 tablets and powdered. Weighed a quantity of powdered tablet containing 20mg of a drug is taken, dispersed in 20 ml methanol and mix with then allow to 10min sonication and then shake for 60 min. Dilute1volume of the resulting solution to 10 volume with methanol. Dilutions prepared and then take absorbance on UV visible spectrophotometer.

5) UV Spectroscopy:

Therefore in the present work, UV Spectrophotometric method was used for analysis of Melatonin. **A.**

Determination of λmax:

A stock solution of 100 µg/ml of Melatonin was accurately weighed and prepared by dissolving 10 mg melatonin in 100 ml methanol. Then these solutions are allowed to stand for 10 min for sanitations and then filtered. Finally, the sample was scanned in the range 200-400nm. The wavelength of the maximum absorption was noted and the UV spectrum was recorded. **B. Preparation of standard stock solution:**

A stock solution of melatonin drug concentration 100µg/ml was prepared in methanol. The UV spectrophotometer and maximum absorption at 278 nm was noted down. The calibration curve was constructed using the standard solution in the range of 10 to 50µg/ml diluting with methanol.

C. Preparation of calibration curve:

A stock solution of 100 µg/ml of Melatonin was accurately weighed and prepared by dissolving 10 mg melatonin in 100 ml methanol. Then this solution was allowed to stand for 10min for sonication and then filtered. Then 1ml solution was withdrawn and transferred to the 10ml volumetric flask. The volume was made up of 10ml with methanol, so as to gives 10µg/ml solution of the concentration of standard solution of 100µg/ml. These solutions were considered at seven different levels which were 2µg/ml, 4µg/ml, 6µg/ml, 8µg/ml, 10µg/ml, and 12µg/ml were prepared in the calibration curves for melatonin was constructed by plotting the peak area against the drug concentration. The dilution was scanned in the range of 200-400nm.

6) FTIR spectroscopy of pure drug:

FTIR spectra for pure Melatonin were determined to check the purity of drug. FTIR spectrum of Melatonin drug was recorded by using KBr technique at solution of 4cm1. Over the region of 4000 to 400 cm-1 for its, authentication and to study the principle peak using (FTIR 8400 S, Shimadzu).

7) Drug Excipients Compatibility Study:

The Drug-Excipients compatibility of drug and the excipients was studied using their physical mixture in ratio 1:1. Accurately weighed quantities of

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 284-287 www.ijprajournal.com ISSN: 2456-4494

Melatonin and individual excipients were mixed as per ratio. Individual blend was then sifted through 30# sieve. This mixed blend was filled in amber colored glass vials, closed with punctured polypropylene caps. These samples were subjected to temperature and humidity condition i.e. 40±2°C/ 75±5%RH (Open exposure condition) for 30 days.

Reference :

[1]. Brahmankar DM, Jaiswal SB. Biopharmaceutics & Pharmaceutics. First Edition. 1995; 335.
[2]. Chain YW. Novel drug delivery systems. New York Marcel Dekker Inc. 1992;139-140.
[3]. Howard C. Ansel, Nicholas G. Popvich, Loyd V. Allen, Pharmaceutical Dosage Forms and Drug Delivery System. First Edition. 1995; 78.
[4]. Arijit Gandhi. Mouth Dissolving Tablets: A New Venture in Modern Formulation Technology. The Pharma Innovation. 2012;1(8):14-31.
[5]. Tejvir Kaur, Bhawandeep Gill, Sandeep Kumar, GD. Gupta. Mouth dissolving tablet: A Novel Approach To Drug Delivery. International Journal of Current Pharmaceutical Research. 2011;3(1):1-7.
[6]. Erande Kumar, Joshi Bhagyashre. Mouth Dissolving Tablets – A Comprehensive Review. International Journal of Pharma Research & Review. 2013; 2(7):25-41.
[7]. Alok Kumar Gupta, Anuj Mittal, Prof. KK. Jha. Fast Dissolving Tablet- A Review. The Pharma Innovation. 2012;1(1):1-8.
[8]. Kumar Pankaj, Kaur Parminder, Kaur Poonamjeet, Piplani Mona. In-vitro and in-vivo characterization of mouth dissolving tablet: An updated review. Journal of Drug Delivery & Therapeutics. 2013; 3(3):153157.
[9]. Vemuri Pavan Kumar N. Vishal Gupta. A Review on quality by design approach (QBD) for Pharmaceuticals. Int. J. Drug Dev. & Res. 2015;7(1): 52-60.
[10]. Geetika Sharma, Rupinder Kaur, Sukhdev Singh. Mouth dissolving tablets: A current review of scientific literature. International Journal of Pharmaceutical and Medical Research. 2013;1(2): 73-84.
[11]. Nagar PK, P Nayyar, Sharma PK. Superdisintegrants- current approach. Journal of Drug Delivery & Therapeutics. 2014;4(3):37-44.
[12]. Puttalingaiah L, Kavitha K, Mani TT. Fast disintegrating tablets: An Overview of Formulation, Technology and Evaluation. Res J Pharmaceutical Biological Chem. Sci. 2011;2(2): 589-601.
[13]. Turkoglu, MA. Sakr. Tablet Dosage Forms. In Modern Pharmaceutics. 481-498.
[14]. S. Madhavi, GNV Rama Raju, B. John Kalyan, G. Kamesh. Formulation and evaluation of metformin orodispersible tablets. Indo American Journal Pharmaceutical Science. 2015; 2(1):567-572.
[15]. Dhiraj A. Khairnar, SP. Anantwar, Chetan S. Chaudhari, PA. Shelke. Superdisintegrants: An Emerging Paradigm In Orodispersible Tablets. International Journal of Biopharmaceutics. 2014; 5(2): 119-128.
[16]. R Santosh Kumar, Kumari Annu. Superdisintegrant: crucial elements for mouth dissolving tablets. Journal of Drug Delivery & Therapeutics. 2019; 9(2):461-468.
[17]. R. Pahwa, N. Gupta. Superdisintegrants In The Development of Orally Disintegrating Tablets: A Review International Journal of Pharmaceutical Sciences Research, 2011; 2(11): 2767-2780.
[18]. Ashish Garg, M.M. Gupta. Mouth Dissolving Tablets: A Review. Journal of Drug Delivery & Therapeutics; 2013; 3(2):207-214.
[19]. 19.Bagul U, Bagul N, Kulkarni M, Sawant S, Gujar K, Bidkar A. Current status of tablet disintegrants: a review. Pharmainfonet.html. 2006; 4(4).
[20]. Mohanachandran PS, Sindhumol PG, Kiran TS. Super disintegrants: An Overview. International Journal of Pharmaceutical Sciences Review and Research. 2011; 6(1):105- 109.
[21]. Roberta M. Leu. Sleep in Children with Neurodevelopmental Disabilities Melatonin. Springer. 2018;339-350.
[22]. Sylvie Tordjman, Sylvie Chokron, Richard Delorme, Annaëlle Charrier, Eric Bellissant.Melatonin: Pharmacology, Functions and Therapeutic Benefits. Current Neuropharmacology. 2017; 15:434-443.
[23]. "Melatonin: Uses, Side Effects, Dosage (Kids/Adults)." Drugs.com, www.drugs.com/melatonin.html.
[24]. Zizhen Xie, Fei Chen, William A. Li, Xiaokun Geng, Changhong Li, Xiaomei

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 284-287 www.ijprajournal.com ISSN: 2456-4494

Meng, Yan Feng, Wei Liu. A review of sleep disorders and melatonin. A Journal of Progress in Neurosurgery, Neurology and Neurosciences.2017; 1-7.

[25]. Herxheimer A, Petrie KJ. Melatonin for the prevention and treatment of jet lag (Review). 2009;3: 1-23.

[26]. Swati C. Jagdale, N. Fernandes, BS. Kuchekar. Selection of superdisintegrant for Famotidine rapidly disintegrating tablets. Journal of Chemical and Pharmaceutical Research. 2010, 2(2): 65-72.

[27]. PR. Kumar, R. Bhargavi, Shaik S. Formulation and evaluation of oral Disintegrating tablets of Zingiber officinale. The Pharma Innovation Journal. 2019; 8(3): 150-155.

[28]. Mahajan Yogesh, Tekade Bharat W. Formulation & Evaluation of Orally Disintegrating Tablet of Ondansetron Hydrochloride. International Journal of Drug Delivery.2012; 4: 09-19.

[29]. Setty CM, Prasad DVK, Gupta VRM. Development of fast dispersible aceclofenac tablets: Effect of functionality of superdisintegrants. Indian J Pharm Sc. 2008; 70(2):180- 185.

[30]. O. N. C. Umeh, J. C. Azegba. Effect of Hydrophilic Diluents on the Release Profile of Griseofulvin from Tablet Formulations. Indian Journal of Pharmaceutical Sciences, 2013; 75(6):726-729.

[31]. Deepak Sharma, Rajindra Singh. Design Development and In Vitro Evaluation of Novel Orally Disintegrating Tablets in Fixed-dose Combination Containing Ambroxol Hydrochloride and Cetirizine Hydrochloride Prepared by Direct Compression Technique. Asian Journal of Pharmaceutics. 2018; 12(1): 1-10.

[32]. Jain CP, Naruka PS. Formulation and evaluation of fast dissolving tablets of Valsartan. Int J Pharmacyand Pharm Sci. 2009;1(1):219-227.

[33]. K. P. R. Chowdary, KR. Aishwarya. Preparation And Evaluation of Fast Dissolving Tablets of Paracetamol Employing Superdisintegrants. Journal of Global Trends in Pharmaceutical Sciences .2013; 4(4):1329-1334.

[34]. Md.N Siddiqui, G Garg, P Kumar Sharma. Fast Dissolving Tablets: Preparation, Characterization and Evaluation: An Overview, International Journal of Pharmaceutical Sciences Review and Research. 2010; 4(2):87-96.

[35]. Shirsand SB, Sarsija S, Swamy PV, Nagendra kumar D, Rampure MV. Design and evaluation of fast dissolving tablets of Clonazepam. Indian J Pharm sci. 2008; 70(6):791- 795.

[36]. Santosh B. Jadhav, AD Mali. Formulation and evaluation of immediate release tablets of Imipramine hydrochloride.International Journal of Biomedical And Advance Research. 2014; 05(11):560-565.

[37]. Chaturvedi H, Garg A, Rathore U. Post-compression evalution parameters for tablets-An overview. European journal of pharmaceutical and medical research. 2017;4(11): 526-530.

[38]. http://www.drugbank.ca.