OPEN ACCESS

Saudi Journal of Medical and Pharmaceutical Sciences

Abbreviated Key Title: Saudi J Med Pharm Sci
ISSN 2413-4929 (Print) |ISSN 2413-4910 (Online)
Scholars Middle East Publishers, Dubai, United Arab Emirates
Journal homepage: http://scholarsmepub.com/sjmps/

Original Research Article

Formulation and *In-vitro* Evaluation of Mouth Dissolving Tablets of Aceclofenac

Soumi Pramanik, Sudipta Das*, Debjani Das

Department of Pharmaceutics, Netaji Subhas Chandra Bose Institute of Pharmacy, Chakdaha, Nadia, West Bengal, India

DOI: 10.36348/sjmps.2020.v06i01.008 | **Received:** 08.01.2020 | **Accepted:** 15.01.2020 | **Published:** 17.01.2020

***Corresponding author:** Sudipta Das

Abstract

Objective: The objective of the study was to formulate a mouth fast dissolving tablets of Aceclofenac and its *invitro* evaluation. ***Materials and methods*:** Aceclofenac mouth dissolving tablets were prepared by direct compression method. Three batches were prepared. The tablets were evaluated by hardness, friability, disintegration test, wetting test and *in-vitro* dissolution method. ***Results*:** The granules were evaluated by determining the angle of repose (24.58±0.602° to 30.29±0.327), bulk density, tapped density, Hausner ratio, and Carr's index. The prepared Aceclofenac tablets were subjected to measurement of hardness (4.2 ±0.08, 4.5 ±0.06 and 5.5 ±0.05 kg/cm^2 respectively), friability (0.88±0.02, 0.67±0.08, and 0.55±0.07 % respectively), disintegration, wetting and *invitro* release study. All parameters were satisfactory within limit. ***Conclusion:*** So, it is concluded that the F3 batch is better than another batch. The release pattern is depending upon the amount of Sodium starch glycolate added. Though long-term stability study is required for future development of these formulations.

Keywords: Mouth dissolving tablets, Aceclofenac, Sodium starch glycolate.

INTRODUCTION

Aceclofenac has outstanding anti-inflammatory and analgesic properties. Difficulty in swallowing is the major problems for conventional tablets and capsules especially in elderly and children. In order to solve this problem, this project is conducted so that the patients compliance can be improved, a new dosage form convenient for use by geriatric and pediatric dysphasic patients, reduce the cost of medication for those patients who cannot afford, and additionally to produce improved products which are available in the market [1].These type of tablets are mostly used because of self-administration. Oral fast-dissolving dosage forms (tablets) also known as 'mouth-dissolving'dosage forms [2]. For administration of drugs, oral route is the most widely used route. When tablet or capsule is placed in the oral cavity, which deteriorates quickly and release the medication that disintegrates in the saliva. Tablets available in the market which are not suitable for acute pain, analgesic and inflammatory conditions where quick onset of action of drug is required. Poorly soluble orally administered drugs have the rate of absorption which often controlled by the rate of dissolution.

MATERIALS AND METHODS

Materials: Aceclofenac, talc, magnesium stearate, sodium lauryl sulfate, sodium starch glycolate, and micro crystalline cellulose are purchased from Yarrow chem. Pvt. Ltd.

Methods

Preparation of Aceclofenac mouth dissolving tablets [3]

Aceclofenac, the fast mouth dissolving tablets are prepared by direct compression method. In the method Aceclofenac and excipients were passed through 40 number mesh Then required quantity of super disintegrate like sodium starch glycolate in various quantities (0.4, 0.6 and 0.8 gm) added and finally magnesium stearate and talc were added. Then the materials were subjected to compression utilizing single punch tablet machine. Batch F1, F2 & F3 were prepared to check the consistency of the formulations.

Characterization of granules and tablets

Preformulation Studies: Preformulation studies were done by determining angle of repose, bulk density, tapped density, Hausner ratio, Carr's index.

Hardness: Hardness of the tablets was measured by Monsanto hardness tester [4].

Friability: Friability of the tablets was measured by Roche friabilator [5].

Disintegration Test: Disintegration test that was resolute by Disintegration Test Apparatus [6].

Wetting test: The wetting time of the tablets can be measured by using the simple procedure. A piece of tissue paper folded double was placed in a Petri dish (internal diameter is 6.5 cm) containing 6 ml of water. The tablet was placed on the paper, and the time for complete wetting of the tablet was measured in seconds. The method was slightly modified by maintaining water at 37°C [6].

In vitro dissolution study of tablets: The dissolution test was performed by USP dissolution test apparatus Type II containing 900 ml of 7.4 phosphate buffer for 90 minutes at 50 rpm [7, 8].

RESULTS AND DISCUSSION

The results of precompression characterization of granules were shown in table 1. All the parameters like bulk density, tapped density, angle of repose etc. were found satisfactory. The hardness, wetting time, friability and wetting time of prepared tablets were found good and shown in the table 2. The in-vitro release study of all three batches was shown in figure 1. The F3 batch shows 90.02 % release in 10 minutes which is better than other batch.

Table-1: Pre compression characterization

Formulation code	Bulk Density (Kg/ cm^3)	Tapped Density (Kg/cm^3)	Carr's index	Hauser's ratio	Angle of Repose(°)
F1	0.30±0.007	0.42±0.005	26.72	1.34	24.62±0.235
F2	0.38±0.011	0.55±0.003	27.25	1.38	30.29±0.327
F3	0.28±0.008	0.40±0.008	22.80	1.29	24.58±0.602

All values are expressed as Mean±(t x SEM), n=3

Table-2: Post compression evaluation of Aceclofenac Mouth dissolving Tablets

Evaluation Parameters	F1	F2	F3
Hardness (kg/cm^2)	4.2 ±0.08	4.5 ±0.06	5.5 ±0.05
Wetting time (minutes)	1.82 ±0.007	1.36 ±0.005	0.65 ±0.008
Disintegration time (minutes)	3.09 ±0.002	2.47 ±0.001	2.31 ±0.003
Friability (%)	0.88±0.02	0.67±0.08	0.55±0.07

[* All value are express as Mean± (t X SEM), n =6]

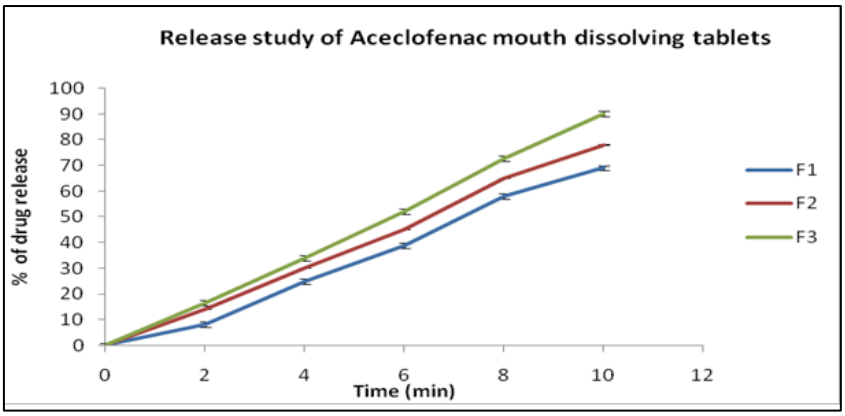

Fig-1: *In-vitro* release study of different batches (F1, F2 and F3) of Aceclofenac Mouth dissolving tablets

CONCLUSION

From the experiment it was shown that the release study of F3 batch is better than other batches. The release pattern is depending upon the amount of sodium starch glycolate added. Though, long-term stability study is required for future development of this formulation.

ACKNOWLEDGMENT

The authors would like to thank principal and authority of Netaji Subhas Chandra Bose Institute of Pharmacy, Chakdaha, Nadia – 741 222, West Bengal, India, for providing the necessary facilities to perform the present study.

REFERENCES

1. Ranganathan, V., Yoong, J. (2017). Development and Evaluation of Mouth Dissolving Tablets using Natural Super Disintegrants. *J Young Pharm*, *9*(3), 332–335.
2. Chandrasekhar, R., Hassan, Z., Alhusban, F., Smith, A.M., Mohammed, A.R. (2009). The role of formulation excipients in the development of lyophilised fast-disintegrating tablets. *Eur J Pharm Biopharm*, *72*(1), 119–29.
3. Sharma, V., Chopra, H. (2012). Formulation and evaluation of taste masked mouth dissolving tablets of levocetirizine hydrochloride, *Iran J Pharm Res. 11*(2), 457-63.
4. Chhater, S., Praveen, K. (2013). Solid Dispersion Incorporated Microcapsules: Predictive Tools for Improve the Half Life and Dissolution Rate of Pioglitazone Hydrochloride. *American J Biomed Res*, *1*(3), 57–70.
5. Raja, S.R.P., & Chandrasekara, R.G. (2014). Formulation and Evaluation of Mouth Dissolving Tablets of Tramadol Hydrochloride. *Tropical J Pharmaceutical Research*, *13*(5), 669-675.
6. Patel, B.P., Patel, J.K., Rajput, G.C., & Thakor, R.S. (2010). Formulation and Evaluation of Mouth Dissolving Tablets of Cinnarizine, *Indian J Pharm Sci*, *72*(4), 522–525.
7. Shailendra, S.S., & Rashmi, D. (2011). Formulation and evaluation of aceclofenac mouth-dissolving tablet, *J Adv Pharm Technol Res*, *2*(2), 128–131.
8. Sudarshan, S., Dhaval, S. (2012). Development and Characterization of Mouth Dissolving Tablet of Zolmitriptan, *Asian Pacific Journal of Tropical Disease*, *2*(1), S457-464.