Stamford Journal of Pharmaceutical Sciences *S. J. Pharm. Sci.* 3(1): 1-3

Assessment of Dissolution Profile of Aceclofenac Tablets Available in Bangladesh

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Received - 5 January 2010 *Accepted for Publication - 10 February 2010*

ABSTRACT

The objective of this work is to find out brand-to-brand variation by applying profile comparison approaches to the dissolution data of marketed aceclofenac tablet formulations. Commercially available five brands of aceclofenac tablets were studied in simulated intestinal medium (pH 6.8) for 60 minutes time period using USP reference dissolution apparatus. Four samples complied with the USP *in vitro* dissolution specifications for drug release (not less than 80% of the labeled amount of Aceclofenac should be dissolved in 60 minutes). One brand (Code: S1) failed to meet the criteria; drug release was 66.85% within the specified time period.

Key words: Bangladesh, *In vitro* dissolution, market preparations, aceclofenac, tablet.

INTRODUCTION

Prostaglandins and related compounds are produced in very small quantities by almost all tissues and they generally give local action on the tissues in which they are synthesized (Finkel et al., 2008). They are responsible for promoting various important physiological responses like inflammation, pain and fever. Prostaglandins also support the blood clotting function of platelets and protect the lining of the stomach from the damaging effects of acid. (Nelson, 2005)

Prostaglandins are produced in the physiologic system by the enzyme cyclooxygenase (COX). There are two iso forms of COX enzymes, named as COX-1 and COX-2 and both enzymes produce prostaglandins that promote inflammation, pain, and fever. However, only COX-1 enzyme produces prostaglandins that support platelets and protect the stomach. Non-steroidal anti inflammatory drugs (NSAIDs) block the COX enzymes and reduce prostaglandins throughout the body (Trevor et al., 2002).

Aceclofenac is a member of non-steroidal anti inflammatory group. It is widely used for the relief of pain and inflammation in rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. The dose is 100 mg twice daily. Aceclofenac shows comparatively higher anti-inflammatory action than conventional NSAIDS (British National Formulary 55, 2008). The drug works by blocking the action of COX that is involved in the production of prostaglandins causing pain, swelling and inflammation as discussed above (Martindale: The Complete Drug Reference, 2009).

To assess the standard of a product, *in vitro* dissolution test is widely used because, for any solid dosage forms, gastrointestinal absorption first requires dissolution of the tablet or capsule that liberates the drug into solution (Buxton, 2006). The dissolution characteristic of a drug from the dosage form depends on many factors including its formulation and manufacturing process (Augsburger et al., 1983). This study deals with the comparative *in vitro* dissolution characteristics of commonly available five brands of Aceclofenac tablet in Bangladesh in order to find out any out of compliance market preparation.

MATERIALS AND METHODS

Drug: Aceclofenac RS (Square Pharmaceuticals, Bangladesh); **Solvents and reagents:** Sodium dihydrogen phosphate monohydrate (Merck, Germany); disodium hydrogen phosphate dihydrate (Merck, Germany); Sodium hydroxide (Merck, Germany). **Equipments:** UV spectrophometer

(Hach, USA); Digital pH meter (Hach, USA); Tablet dissolution tester (Electro lab, India), Sartorius electronic balance.

Dosage forms

Five samples of different batches of marketed tablets were collected from various stores. The samples were properly checked for their manufacturing license number, batch number, manufacturing and expiry dates before purchasing. The samples were coded arbitrarily as S1, S2, S3, S4 and S5. The labeled active ingredient was Aceclofenac 100 mg and packaged in blister packing. The blister packs were stored at 25±2℃ for four weeks before the dissolution study in order to evaluate any change in organoleptic properties.

***In vitro* dissolution study**

These studies were conducted at 37±0.5℃ on an USP specification dissolution rate test type II apparatus (Paddle apparatus) with six sections assembly according to the USP 30 procedure (USP 30 and NF 25, 2007). Simulated intestinal medium (pH 6.8) was used as dissolution media.

Preparation of simulated intestinal medium (Buffer pH 6.8)

For preparing 30 liter alkaline buffer, 41.25gm sodium dihydrogen phosphate monohydrate and 34.5gm disodium hydrogen phosphate dihydrate were dissolved in distilled water and diluted to about 29.8 liter with the same solvent. Buffer pH was adjusted to 6.8 by adding dilute sodium hydroxide. Finally, the volume was diluted to 30 liter.

The water-bath temperature was fixed & confirmed to be 37±0.5℃ before starting the experiment. The medium was preheated to 37℃ and then a quantity of 900ml was added to each vessel. The apparatus was then assembled and paddle rotation was started and adjusted at 50 rpm and the system was allowed to equilibrate for 15 minutes. After that the paddle rotation was stopped and six tablets from same code were placed in the vessels (one tablet per vessel) and allowed to sink to the bottom. The apparatus was immediately operated at 50rpm. The duration of the experiment was 60 minutes for each set of sample. Six time points were selected to adequately characterize the ascending and plateau phases of the dissolution curve. 10ml of sample solution was withdrawn after each 10 minutes. The sample was filtered, diluted and analyzed at 275nm for Aceclofenac by UV spectrophotometer. The withdrawn volume was immediately replaced by dissolution medium. The amount of drug present in the samples was calculated from calibration curve constructed from the standard solution of USP reference standard test drug (Figure 1).

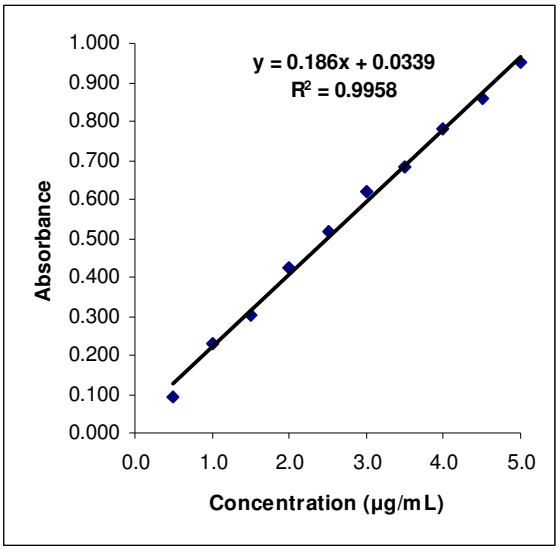

Figure 1: Standard curve of aceclofenac in alkaline buffer medium.

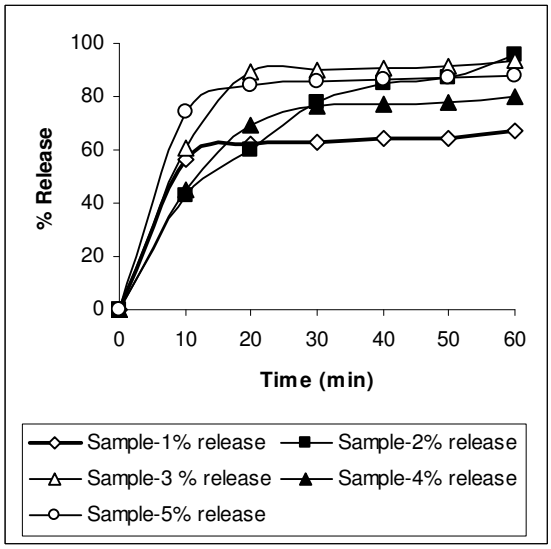

Figure 2: Comparison of release profiles of test samples.

RESULTS AND DISCUSSION

Drug release from each commercial sample was calculated by taking the average reading of all corresponding sub-samples. The drug release in the alkaline medium, which simulated intestinal pH conditions, is summarized in Table 1.

Table 1: Drug release pattern from five commercial samples under investigation.

Time (min)	Cumulative Percent Drug Release				
	S1	S2	S3	S4	S5
0	0	0	0	0	0
10	56.40	42.85	61.04	44.78	74.40
20	62.03	59.84	89.27	69.45	84.58
30	62.86	77.55	89.68	76.39	85.56
40	64.51	84.90	90.94	77.15	86.44
50	64.63	87.21	91.53	78.02	87.32
60	66.85	95.65	93.57	80.16	87.62

The *in-vitro* release data (cumulative percent drug release) have been plotted against time to get a graphical presentation of the data (Figure 2). According to USP, not less than 80% of the labeled amount of aceclofenac should be dissolved in 60 minutes. Except one brand (Code: S1), all the brands met the official standard. This brand was tested again according to BP (British Pharmacopoeia, 2003); however the results remained identical to the first one.

CONCLUSION

From this study it has been revealed that few commercially available brands of aceclofenac in Bangladesh failed to fulfill the official specification of dissolution test which might be explained by poor formulation and/or lower content of the active ingredient. This type of study should be performed more frequently and with more samples to build public awareness about the quality of marketed pharmaceutical products.

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