INTERNATIONAL RESEARCH JOURNAL OF PHARMACY **ISSN 2230 – 8407**
Available online http://www.irjponline.com
Research Article

MARKETED PREPARATIONS: QUALITY EVALUATION OF DELAYED RELEASE ASPIRIN TABLET

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Article Received on: 17/02/2011 Revised on: 28/03/2011 Approved for publication:14/04/2011

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ABSTRACT
The main purpose of this work was quality evaluation of several delayed release marketed preparations. Extended release dosage forms are designed to achieve a prolonged therapeutic effect by continuously releasing drug over an extended period of time after administration of a single dose. Extended release dosage form allows at least two fold reduction in dosage frequency as compared to that drug presented in immediate release dosage forms. The delayed release aspirin tablets were collected from the market and evaluated for hardness, friability, weight variation, drug content, disintegration and in-vitro dissolution studies.
KEYWORDS: Delayed Release, Aspirin Tablets, Quality Evaluation

INTRODUCTION

An ideal drug delivery system should fulfill two prerequisites. The first is to deliver the drug at a rate dictated by the needs of the body over the period of treatment and the second is spatial targeting to specific sites. These prerequisites provide a need for modified release technologies, which can improve the therapeutic efficacy and safety of a drug by precise temporal and spatial placement in the body, there by reducing both the size and number of doses required (1) Modified release dosage forms can be defined as one for which the release characteristics of time course and location are chosen to accomplish therapeutic or convenience objectives, which are not offered by conventional dosage forms (2) Most modified release products are orally administered tablets and capsules. Several types of modified release dosage forms are available.

Extended release dosage forms are designed to achieve a prolonged therapeutic effect by continuously releasing drug over an extended period of time after administration of a single dose. Extended release dosage form allows at least two fold reduction in dosage frequency as compared to that drug presented in immediate release dosage forms such as controlled release or sustained release. Delayed release dosage form is designed to release the drug at a time other than promptly after administration. The delay may be time based or based on the influence of environmental conditions, like gastrointestinal pH. Repeat action forms usually contain two single doses of medication, one for immediate release and the second for delayed release**.** Targeted release describes drug release directed towards isolating or concentrating a drug in a particular body region, tissue or site for absorption or for drug action. The advantages of extended release dosage forms over conventional forms is to include the less fluctuation in drug blood levels, frequency reduction in dosing, enhanced convenience and compliance, reduction in adverse side effects and reduction in overall health care costs. The rate of drug release from solid dosage form may be modified by the technologies which in general are -1. based on modifying drug dissolution by controlling access of biologic fluids to the drug through the use of barrier coatings; 2. Controlling drug diffusion rates from dosage forms and; 3. Chemical reaction or interaction between the drug substance or its pharmaceutical barrier and site specific biological fluids.[1-4]

MATERIALS AND METHODS

Six different brands of marketed delayed release aspirin 150 mg tablets were collected and evaluated for *in-vitro* studies.

Marketed preparations

Apisafe 150 (Fiale pharmaceuticals, Indore) - PRODUCT A
Caresprin. CR (Olcare lab, Gujrat) - PRODUCT C
Delisprin 150 (Aristo pharmaceuticals Ltd. MP) - PRODUCT-D
Ecosporin 150 (Sidmak Lab, Gujrat) - PRODUCT-E
Nusprin 150 (Nucron pharmaceuticals Ltd, Pune) - PRODUCT-N
Sprintas 150 (Intas pharmaceuticals, Ahemadabad)- PRODUCT-S

Experimental design

Methodology

The delayed release aspirin tablet were collected from the market and evaluated for *in-vitro* (Hardness, disintegration, content uniformity and dissolution studies) [5,6].

In-vitro Evaluation of marketed preparation

Hardness

Hardness of the tablet was measured using Monsanto hardness tester. This was repeated for five individual tablets and mean was taken. (n = 5)

Friability

Two tablets were accurately weighed and placed in the friabilator (VEEGO- tablet Friabilator) and operated for 100 revolutions. The tablets were degusted and reweighed. The tablets that loose less than 1% weight were considered to be compliant.

Disintegration test

The apparatus was operated initially in water at room temperature for five minutes, then apparatus was operated without adding the disc using 0.1N Hydrochloric acid as the immersion liquid at $37^0 \pm 0.5^0$ c. At the end of two hours immersion liquid was replaced with phosphate buffer P^H 6.8 with adding discs.

Content uniformity

Accurately weighed about 150mg of Acetyl salicylic acid was taken in 250 ml volumetric flask, to it 30 ml of 0.5N NaOH and 20 ml methanol was added. To it 20 ml 1N HCl acid was added and volume was male up to 250 ml with water. 10 ml of filtrate was taken and diluted to 100ml with water. Again 10 ml was taken to it added 1ml ferric ammonium sulphate reagent and absorbance was taken at 530nm for drug analysis.

Dissolution study

The *in-vitro* dissolution study of delayed release aspirin tablet were carried out in USP XXIII dissolution test apparatus at 100 rpm, initially in 0.1 N HCl for 2hr and medium was replaced with 6.8 phosphate buffer for 90 minutes, Aliquot was withdrawl and analysed at 530 nm.

RESULT AND DISCUSSION

The product **A, C, D, E** and **N** shows the disintegration test, it ranges to 5-8 minutes. The product **S** fails the disintegration test as it immediately disintegrated within 1 min in acidic pH. It also fails to pass the hardness test and % friability test as per Indian and US pharmacopoeia limit.

CONCLUSION

The product A, C, D, E and N marketed preparations complies with all the pharmacopeia specifications except product '**S'**. The product **S'** fail to pass the hardness test, friability test, disintegration test and dissolution test. The product '**S'** get rapidly dispersed in 6.8 phosphate buffer and does not show any drug release pattern.

Products (A, C, D, E and N) Hardness was found to be in the range of 3.5-5kg/cm2 in all the products indicating good mechanical strength. In all the formulations the friability value is less than 1% giving an indication that tablets formulated are mechanically stable. % weight variation was within the limits. Drug content was known by performing assay and it was found to be between 90% to 110% and it was within the limits (shown in table 1). The disintegration time of various marketed preparations were found in the range of 5.2-8.1 minutes and also the dissolution profile of all the delayed release products were within the pharmacopeia specifications.

ACKNOWLEDGEMENT

The authors are thankful to principal Gurunanak college of pharmacy, Nagpur for providing all the facilities required to complete this project work.

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Table 1: Dissolution Test Conditions In 0.1N HCl

Parameter	Specificatiion
Dissolution medium	0.1N HCl
Volume of medium	900ml
Temp. medium	37± 0.5
Paddle rotation speed	50 rpm
Sampling time intervel	1hr, 2hrs
Detection wavelength	530 nm

Table 2: Dissolution Test Conditions In 6.8 Phosphate Buffer

Parameter	Specification
Dissolution medium	6.8 Phosphate buffer
Volume of medium	900ml
Temp. medium	37± 0.5
Paddle rotation speed	100 rpm
Sampling time interval	1hr, 2hrs
Detection wavelength	530 nm

Table 3: Hardness, Disintegration time and % Drug content of six different delayed release aspirin Marketed preparations

Sr. No	Product	Hardness Kg/cm^2	Friability (%)	Disintegration time in phosphate buffer (min)	% Drug content
1	**A**	4.2	0.654	6.3	99.98
2	**C**	5	0.524	8.1	99.00
3	**D**	4.1	0.629	5.3	98.80
4	**E**	3.5	0.761	5.2	98.90
5	**N**	3.9	0.789	5.2	100
6	**S**	0.7	1.5	1	75.74

Table 4: % Drug release in pH 0.1N HCl buffer

Sr. No	Product	% Drug release in 0.1N HCl (Time in hrs)	
		1 hr	2 hr
1	**A**	**3.2**	**5.6**
2	**C**	**2.0**	**5.0**
3	**D**	**3.0**	**4.8**
4	**E**	**4.0**	**7.2**
5	**N**	**3.0**	**6.2**
6	**S**	**22.02**	**56.0**

Table 5: % Drug release in pH 6.8 phosphate buffer

Sr. No	Product	% Drug release in pH 6.8 phosphate buffer (Time in min)				
		20 min	40 min	60 min	80 min	90 min
1	**A**	25	56	68	81	88
2	**C**	20	45	65	78	87
3	**D**	45	66	86	97	---
4	**E**	15	35	58	81	90
5	**N**	18	42	63	83	84
6	**S**	--		-	-	-

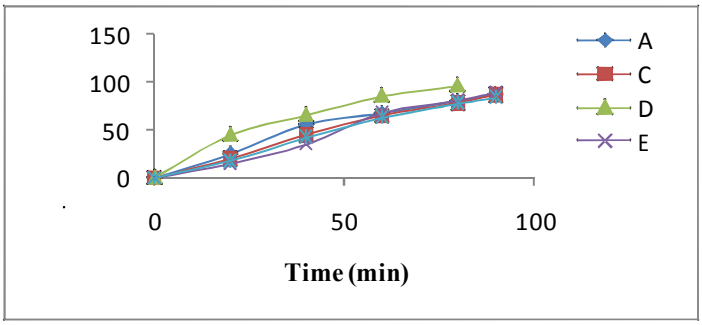

Figure 1: % Drug release in pH 6.8 Phosphate buffer

Source of support: Nil, Conflict of interest: None Declared