Research Article

In-Vitro and *In-Vivo* Study of Fexofenadine Hydrochloride Transdermal Patches

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ABSTRACT
To treat allergic disorders on long term therapy needs plasma concentration of drug in better manner. This was achieved by formulating the drug in controlled release pattern. Fexofenadine hydrochloride is the only non sedative category of anti-histaminic drug available in market and formulated in transdermal drug delivery system for controlled release of drug from matrix type of patch. *In-vitro* release study of Fexofenadine hydrochloride transdermal patch shown release of drug 94 % at 23 h and also follows zero order kinetics release pattern. *In-vivo* study on rabbits proves that drug release was 99 % at 24 h.

Keywords: Fexofenadine hydrochloride, patch, *In-vitro, In-vivo*.

INTRODUCTION

Fexofenadine hydrochloride is a only non sedative category of anti-histaminic drug available in the market. Allergic diseases or disorders are difficult task for public health concern in so many countries. Fexofenadine hydrochloride is used in the treatment and management of allergic conditions with the recommended dose of 60 mg twice a day or 120. But management of allergic conditions needs the blood concentration of drug in a steady manner for better results, so alternate route of administration is adopted by prepared in transdermal therapeutic system of Fexofenadine hydrochloride.

MATERIALS AND METHODS

Fexofenadine hydrochloride was obtained as gift sample from micro labs ltd, Bangalore. HPMC K-10, PVP K-30, EC 14cps, ethanol, DBP were purchased from S.D fine chemicals Ltd, India. All other chemicals used were of analytical grade. *In-vivo* study on rabbits was done after getting approval from institutional ethical committee.

Preparation of matrix patches

Polymers of ethyl cellulose, hydroxyl propyl methyl cellulose and polyvinyl pyrolidine were accurately weighed and dissolved individually or combinations in 5 ml of ethanol. The drug was then dispersed in the polymeric solution and then plasticizer of dibutyl phthalate was added. The solution was stirred to attain semisolid like consistency and casted on a glass substrate containing ‘o’ ring, the rate of evaporation of solvent from polymeric solution was controlled by placed a inverted funnel at room temperature for a day (Samanta et al 2002; Kulkarni et al 2002; Singh et al 1993; Kanikannan1 et al 1993). The formed films were separated. Formulation of Fexofenadine hydrochloride patches was given in table. No: 1.

Preparation of rate controlling membrane

Ethyl cellulose 1% W/V was dissolved in ethanol of 5 ml, to this plasticizer of dibutyl phthalate was added, the solution was mixed to get the semisolid like consistency and casted on a glass substrate containing ‘o’ ring, the rate of evaporation of solvent from polymeric solution was controlled by placed a inverted funnel at

room temperature for a day. The drug contained patch was fixed with rate controlling membrane by ethanol, then wrapped in aluminium foil and stored in a dessicator (Sankar et al 2003).

***In-vitro* release study**

The prepared Fexofenadine patch was evaluated for release pattern using commercially available semi permeable membrane. The membrane and patch were fitted between donor & receptor compartment of self fabricated modified Franz diffusion cell (Jayaprakash S et al). The donor compartment was empty & receptor compartment was containing 50 ml of phosphate buffer pH 7.2. The samples were collected at different time intervals for analyzing the drug content in the receptor compartment for release pattern of drug and replaced with equal volume of freshly prepared phosphate buffer pH 7.2. The drug content was analyzed at 220 nm using U.V double beam spectrophotometer (Table.No:2). From the study best formulation was selected for further studies.

***In-vivo* study**

The formulation F8 was used for in-vivo study on rabbits, rabbits were selected and its hair was removed from dorsal surface with scissor. Animal dose was calculated and the patch size was reduced to 2 cm^2 to apply on the rabbit also drug free patch was formulated for control study group. Different group of animals were categorized and the patch was applied at same time to all the groups, but removed at different time intervals (Table.NO:3). The formulation F8 was studied for *in-vivo* drug release in rabbit model using remaining drug content formula (Posina Anitha et al), in that method patch was applied and removed at particular time and then analyzed for drug content in U.V spectrophotometer at 220 nm.

$$\text{Drug in blood} = \frac{\text{Amount of drug In patch before placing} - \text{Amount of drug remaining in patch after removal}}{\text{Amount of drug loaded in patch}} \times 100$$

RESULTS & DISCUSSION

The prepared Fexofenadine hydrochloride transdermal patch was evaluated for *in-vitro* release pattern. The formulation F2 shown 94 % of drug release at 15 h & further the release of drug were controlled by incorporating rate controlling membrane of ethyl cellulose 1 % this formulation F7 shown the retardation of release, but release was not completed. Because only 95 % of drug released at the end of 24 h, so rate controlling membrane of ethyl cellulose 0.5 % was incorporated to retard the release and also to release the drug completely from matrix type of Fexofenadine hydrochloride transdermal patch formulation F8 this shown the 94 % of drug release at 23 h. The kinetic study data also proves that which follows zero order kinetics for controlled release of drug to maintain drug concentration in better manner. *In-vivo* study on rabbit confirms the release of drug fexofenadine hydrochloride in transdermal patch as controlled delivery over 24 h as 99 %.

CONCLUSION

The drug selected of fexofenadine hydrochloride for transdermal therapeutic system of anti-histaminic study shown appropriate release in both *in-vitro* & *in-vivo* studies. This confirms that the formulation F8 may control the allergic disorder in better manner by achieving drug concentration in steady manner for over a day.

Table I: Formulation of Fexofenadine hydrochloride Transdermal patches

FORMULATION CODE	CUMULATIVE PERCENTAGE OF RELEASE	TIME OF RELEASE
F 1	98%	7 hrs
F 2	94%	15 hrs
F 3	92%	7 hrs
F 4	93%	12 hrs
F 5	89%	6 hrs
F 6	90%	13 hrs
F 7	72%	24 hrs
F 8	94%	23 hrs

Table II: *In-vitro* Release of Fexofenadine hydrochloride Transdermal patches

CODE	HPMC (%)	EC (%)	PVP (%)	RCM (%)	Drug	PLASTICIZER	SOLVENT
F 1	1	-	-	-	60 mg in all the patch	20 % w/v of Di-butyl phthalate in all the patch	5 ml of ethanol in all the patch
F 2	2	-	-	-			
F 3	-	1	-	-			
F 4	-	2	-	-			
F 5	-	-	1	-			
F 6	-	-	2	-			
F 7	2	-	-	1			
F 8	2	-	-	0.5			

Table III: *In-vivo* Study of Fexofenadine hydrochloride Transdermal patches

FORMULATION CODE	PERCENTAGE OF RELEASE	TIME OF RELEASE
F 8	24 %	6 hrs
	46 %	12 hrs
	75 %	18 hrs
	99 %	24 hrs

REFERENCES

1. Kanikkannan N, Jayaswal SB and Singh J. Transdermal Delivery of Indomethacin: Release Profile of Drug from Polymeric patches., Indian Drugs.1993;30(9):441-445.
2. Kulkarni RV, Mutalik S and Hiremanth D. Effect of Plasticizers on the Permeability and Mechanical Properties of Eudragit films for Transdermal application., Indian.J.Pharm.Sci. 2002;64(1):28-31.
3. Samanta MK, Wagh VD, Kavitha G, Jagadish C Pati and B.Suresh. Transdermal Drug Delivery System of Haloperidol to overcome self-induced extra pyramidal Syndrome., Indian.J.Pharm.Sci. 2002;328.
4. Sankar V, Benito Johnson D, Svanand V and Ravichandran. Design and Evaluation of Nifedipine Transdermal Patches. Indian.J.Pharm.Sci. 2003;65(5):510-515.
5. Singh UV, Pandey S and Udupa N. Preparation and Evaluation of Flurbiprofen and Diclofenac Sodium Transdermal films. Indian J Pharm.Sci. 1993;145-147.
6. Jayaprakash S, Mohamed Halith S, Mohamed Firthouse PU, Yasmin and Nagarajan M. Preparation and Evaluation of Celecoxib Transdermal Patches, Pak J Pharm Sci. 2010;23(3):2010: 279-283.
7. Posina Anitha, Sundarapandian Ramkanth, Mohamed TS Saleem.Preparation, *In-vitro* and *In-vitro* Characterization of Transdermal Patch Containing Glibenclamide and

Atenolol : A Combination Approach, Pak.J.Pharm.Sci; 2011;24(2):155-163.