World Journal of Pharmaceutical research

Volume 2, Issue 6, 2469-2473. Research Article ISSN 2277 – 7105

THE INFLUENCE OF pH ON DRUG RELEASE FROM HYDROXYPROPYL METHYL CELLULOSE MATRICES

Masheer Ahmed Khan*

School of Pharmacy, Devi Ahilya Vishwavidyalaya, Takshshila Campus, Khandwa Road, Indore, 452001, India.

Article Received on
23 August 2013,

Revised on 30 Sept. 2013,
Accepted on 24 October 2013

***Correspondence for Author:**

Dr. Masheer Ahmed Khan
School of Pharmacy, Devi Ahilya Vishwavidyalaya, Takshshila Campus, Khandwa Road, Indore, 452001, India
masheerak@yahoo.com

ABSTRACT

The present study was focused on the effect of multimedia dissolution profile on the drug release of sustained release system of the antihistaminic agent Chlorpheniramine maleate generally used in allergic disorders, common cold and other conditions. Matrices were prepared using combination of HPMCK4M and HPMCK15M to sustain the release of the drug. Multimedia dissolution studies were performed to mimic the in-vivo condition by doing in-vitro test. The pH/buffer selection is based on the exposure of drug from stomach to intestine/colon. The study ensures the impact of pH changes on dissolution and release of drug substance for absorption. Matrices also provide quite regulated release of the drug over an extended period of time.

Keywords: Dissolution, Matrices, pH.

INRODUCTION

Chlorphenirame maleate is an alkylamine derivative with the properties and uses of the antihistamines and generally causes less sedation. It antagonizes actions of histamine at the H1 receptors. Doses – Usually 4mg, 3-4 times daily, higher doses up to 36mg daily, in sustained release preparations are given. It is used in conditions like Allergic Disorders, Renal failure ,Common Cold and others [1-5].

Multimedia dissolution is to mimic the in-vivo condition by doing in-vitro test and pH/buffer selection is based on the exposure of drug from stomach to intestine/colon and to ensure the impact of pH changes on dissolution and release of drug substance for absorption [6-9].

Sustained release drug delivery system of Chlorphenirame maleate is designed to achieve a prolonged therapeutic effect by continuously releasing medication over an extended period of time by using different grades of Hydroxy Propyl Methyl Cellulose (HPMC) viz. HPMCK4M and HPMCK15M [10-12.]

MATERIALS UNDER METHODS

Chlorphenirame maleate was obtained as a gift sample and tablets were prepared by direct compression using HPMCK4M and HPMCK15M polymer combinations. Other excipients used were Magnesium stearate, Talc, MCC and dibasic calcium phosphate. The drug was analyzed by UV spectrophotometry (UV 1601 Shimadzu, Japan) at 261nm.

Physical Characterization

The tablets were subjected to their physical characterization. Hardness, friability and weight variation and found within the probable limits, Table [1].

Dissolution Studies

In order to study the effect of the dissolution medium pH on the drug release pattern, drug release was studied in phosphate buffer of pH 2.4, 6.8 and 7.4. The dissolution mediums of different pH were prepared for the studies.

EXPERIMENTAL

Three tablets of Chlorphenirame maleate were taken into three different pH of phosphate buffer (pH2.4, pH 6.8 and pH 7.4).The USP dissolution apparatus was set at rotation 50 rpm and temperature of the assembly was set at 37^0 C. The tablets were placed in above prepared three different media of different pH. Absorbance was measured at 261 nm by collecting sample at different time interval as follows 0.5, 1, 1.5, 2, 4, 6, 8 and 12 hrs. Five milliliters aliquots were withdrawn at predefined intervals, and the volume of the dissolution medium was maintained by adding the same volume of dissolution medium. The percentage drug release was calculated at different time intervals at different pH. The graph was plotted between percent drug release and time for different dissolution media.

RESULTS AND DISCUSSION

Physical properties of the tablets were found within the probable limits as shown in Table (1). The drug content was estimated from the absorbance obtained. Three tablets of chlorpheniramine maleate were placed into three different pH of phosphate buffer (pH2.4, pH

6.8 and pH 7.4).The USP dissolution apparatus was set at rotation 50 rpm and temperature of the assembly was set at 37^0 C. Absorbance was measured at 261 nm by collecting sample at different time intervals up to 12hrs. The percentage drug release was calculated at different time intervals at different pH and shown in Table (2). The graph was plotted between percent drug release and time for different dissolution media and shown in Fig (1).

Table (1): Physical characteristics of the tablets

FORMULATION				
HPMC K4M mg	**HPMC K15M mg**	**Weight mg Mean ± SD**	**Hardness Kg Mean ± SD**	**Friability (%)**
25	15	120 ± 1.68	5.5O ± 0.14	0.50-0.09

Table (2): Result of dissolution studies with different pH

Sr. No.	Time hrs.	Absorbance (nm.)			% Drug release		
		pH 2.4	pH 6.8	pH 7.4	pH 2.4	pH 6.8	pH 7.4
1.	0.5	0.069	0.074	0.228	8.896	9.66	29.39
2.	1	0.071	0.143	0.279	9.946	16.06	33.58
3.	1.5	0.120	0.152	0.324	13.1	16.99	41.83
4.	2	0.133	0.246	0.447	14.76	31.71	46.27
5.	4	0.172	0.368	0.559	22.16	44.8	59.34
6.	6	0.194	0.380	0.670	23.53	48.96	84.1
7.	8	0.345	0.472	0.733	44.54	58.56	94.48
8.	12	0.468	0.619	0.753	58.26	79.8	94.68

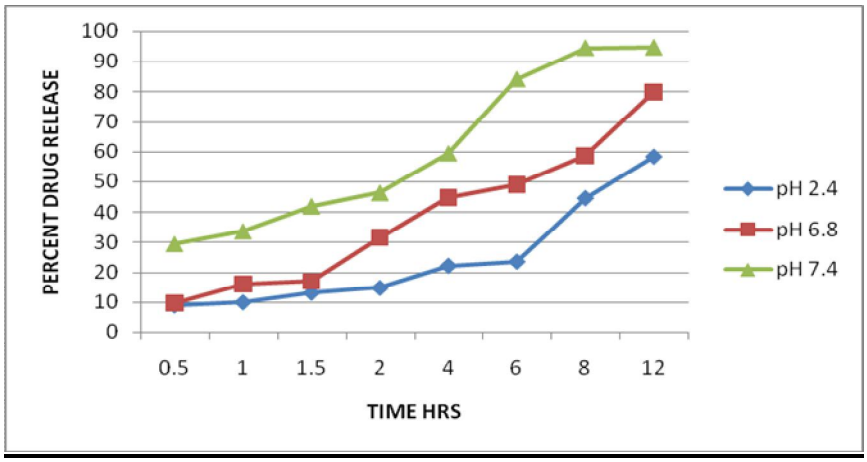

Fig (1). Percent drug release V/s Time in different pH media.

CONCLUSION

The release profile of atenolol from the matrices increased continuously with time, and the amount of drug release best seen in acidic media (pH=2.4). The cumulative amount of drug release is higher at pH 7.4 than that of pH 6.8 by 14.88 % and then that of pH 2.4 by 36.42 %. This increase in drug release at higher pH can be attributed to pH dependent solubility of chlorpheniramine maleate. As the pH increases, the solubility of chlorpheniramine maleate increases which might increase drug release from matrices.

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