SHORT COMMUNICATION

FORMULATION AND EVALUATION OF DICLOFENAC SODIUM GEL BY USING NATURAL POLYMER.

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ABSTRACT

A major problem being faced in ocular therapeutic is the attainment of an optimal concentration at the site of action[1]. The bioavailability of diclofenac sodium in the form of eye drop is very low and when the drug is administered in the form of ophthalmic suspension it lead to irritation due to particle size. So in the present study diclofenac sodium gels were developed with the aim of promoting the prolong release of drug using natural polymer. Diclofenac sodium gels were sterilized and assessed for various parameters like clarity, viscosity, pH, extrudability and sterility. In –vitro drug release determined using dialysis membrane in phosphate buffer pH 7.4. Ocular irritation studies were performed on albino rabbits.

***Key words**: gel; prolong release; ophthalmic preparation; natural polymer.*

INTRODUCTION

Preparations to the eye are usually administered in the form of eye drops. This dosage form presents inconvenience of a low bioavailability and pulse entry. The concentration of the drug available for activity decreases exponentially as a medication is diluted by tears and is estimated from eye via the lachrymal drainage system [1-2]. Due to low bioavailability of eye drops viscous liquid and semisolid prep ration were tried as alternative therapeutics system. The bioavailability of these medicines can be increased by increasing the viscosity of the preparation up to gel like consistency using various polymer like carbopol-940, sodium car boxy methyl cellulose, hydroxy propyl methyl cellulose etc. the use of such vehicles proved to enhance the ocular bioavailability or the therapeutic efficacy of applied drugs, prolong the drug duration and reduce the patient non compliance problem [3].

Diclofenac sodium is benzene acetic acid,-[(2, 6-dichlorophenyl) amino] –monosodium salt. Diclofenac sodium is an analgesic and anti-inflammatory. In acute infection, 2-4 drops of diclofenac sodium eye drop is administered for every 15 to 30 min. initially. From this it is clear that this dosage form has several drawbacks such as frequency of administration, loss of drug from tear flow, lachrymal and nasal drainage, patient non-compliance etc.

To overcome this problem, attempt has been made to formulate gel of diclofenac sodium in the present study using polymer sodium alginat[4].

EXPERIMENTAL

Materials: Diclofenac sodium was obtained as gift sample from Swiss Medicare Pvt. Ltd. Srinanganagar Rajasthan, sodium alginate polymer was obtained as gift sample from Coral Pharma Chem, Ahmadabad. other chemicals and reagents used were of analytical grade.

Method:

Preparation of Gel[5].

Potassium dihdrogen orthophosphate, diclofenac sodium, EDTA, sodium alginate were dissolved in water under agitation with mechanical stirrer, methyl paraben, propyl paraben, and PEG 400, were added to it under continous stirring polymer was slowely sprinked on the surface of purified water for uniform distribution, Three diff. Concentration of polymer is taken to get three different formulation A,B and C. The gel were buffered at pH 7.4+0.2 as given in table no. 01.

EVALUTION

pH:

The pH is determined by 2.5 gm of gel was dispersed in 25 ml of purified water and pH is measured by PH meter[1,2].

Ocular toxicity testing:

This testing was done on the healthy rabbit in eye of rabbit eye, no swelling and irritation observed.

In-vitro drug release:

In-vitro release studies were carried out using bichambered donor receiver compartment model (Franz diffusion cell). Accurately weighed 0.3 g of gel was spread uniformly on a dialysis membrane, which was in contact with receptor medium. The receptor medium was stirred continuously at 20rpm to simulate blinking action of eyelids. Samples were withdrawn at periodic intervals[4]. The drug content was analyzed using UV-Spectrophotometer at 271 nm against reference standard using distilled water as blank as given in table no.02 & Fig.no.01.

RESULTS AND DISCUSSION

Prepared controlled release gel of diclofenac sodium along with three diff. Natural polymer quantities (sod. Alginate in three formulation A, B and C in three different quantities 3, 4, 5, gm.).

On the basis of above discussed parameter formulations C,B and A have been reported to provide the release upto 9 h, 8 h and 6 h respectively. On the basis of this observation drug along with sod. alginate in formulation C has better release profile than other.

Table-1 Formulation of diclofenac gel

Ingredients	A	B	C
Diclofenac Sodium (g)	0.3	0.3	0.3
Sodium alginate (g)	3	4	5
Disodium Edetate (g)	0.01	0.01	0.01
Benzalkonium chloride (%)	0.01	0.01	0.01
Propylene glycole (%)	10	10	10
Potassium Dihydrogen O-phosphate (g)	0.908	0.908	0.908
Disodium hydrogen O-phosphate (g)	2.38	2.38	2.38
Purified water q.s. (g)	100	100	100

Table-2 Drug release study of diclofenac gel

S.No.	Time (hours)	A	B	C
1	1	44%	37%	25%
2	2	76%	55%	43%
3	3	80%	70%	59%
4	4	83%	73%	65%
5	5	82%	70%	67%
6	6	84%	74%	69%
7	7		76%	72%
8	8		84%	76%
9	9			79%
10	10			80%

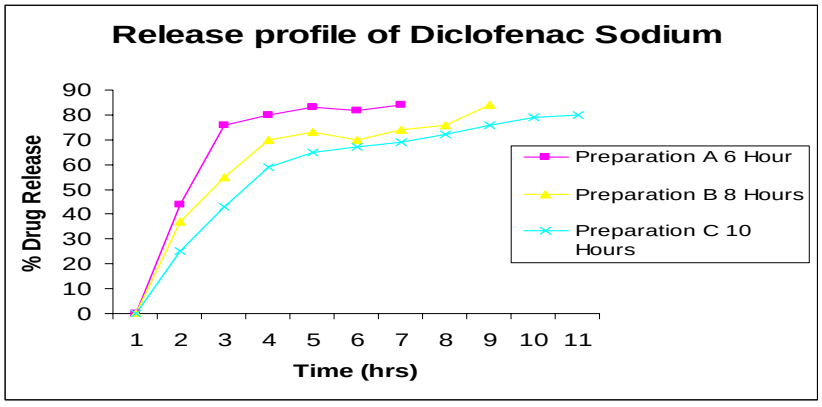

Fig.-1 Release profile of diclofenac sodium

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