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Formulation And Evaluation of Diclofenac Sodium Gel By Using Carbopol 934

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ABSTRACT

The present research has been undertaken with the aim to develop a topical gel of diclofenac sodium gel (DS) 1%, evaluation of its physico chemical characteristics. The main objective of this research paper is to prepare and evaluate 1% polymer containing transdermal gel of Diclofenac Sodium. The gel was prepared and evaluated for pH, Spreadability, Consistancy, Homogeneity, Drug Content, Skin Irritation test and In vitro Diffusion Study. The carbopol is high molecular weight water soluble homo polymer ehich posses high viscoty in low concentrations, transparency, and film Forming properties these are useful for gel formation. The percentage of drug release was 97.68%. In vitro drug release was evaluated by using Inhibition of protein denaturation. The diclofenac sodium was subjected to in vitro inhibition of protein denaturation in various concentrations i.e. 100, 200, 400, 800, 1000 µg/ml. The present study suggests that the Diclofenac sodium effectively act as in vitro anti-inflammatory activity.

Keywords:- Topical Drug Delivery, Anti-inflammatory , Water Soluble Polymer ,Carbopol934

I. INTRODUCTION

Drug delivery through the skin has been a promising conception for a long time because the skin is easy to access. Diclofenac Sodium is a potent member of the nonsteroidalanti-inflammatory drugs (NSAIDs), globally used because of its strong analgesic, antipyretic andanti-inflammatory effects. Topical gel Preparation is intended for skin operation and to certain mucosal surfaces for local action of percutaneous penetration of drug of or for their emollient and defensive action. The Diclofenac sodium has a short half- life in plazma(2 hrs) and only 50 of the drug reaches the circulation. NSAID's arenon-steroidal medicaments having excellentanti-inflammatory and analgesic activity but NSAID produces GIT ulceration, liver and kidney.

Delivery of drugs to the skin is an effective and targeted treatment for local dermatological diseases. This route of drug delivery has gained acceptance because it avoids first pass effects, gastrointestinal irritation, and metabolic devolution associated with oral administration. Topical gel formulations give a

suitable delivery system for drugs because they're thixotropic, greaseless, easily spreadable, freely removable, emollient, nonstaing, compatible with several excipients and water-soluble or miscible. Percutaneous concentration of drugs from topical formulations involves the release of the drug from the formulation and permeation through skin to reach the target tissue or organ. The release of the drug from topical preparations depends on the physicochemical properties of the vehicle and the drug employed. An advanced Diclofenac formulation with a high degree of skin permeation could be useful in the treatment of not only locally inflamed skin tissues, but also inflammatory and painful states of supporting structures of the body bones, ligaments, joints, tendons and muscles.

The ideal of present study was conducted to develop a topical gel formulation of diclofenac sodium using carbopol 934 gelatinizing agnt for enhancing the skin penetration. Effect of penetration enhancer(propylene glycol) on the release has been studied. The gels were evaluated for physical appearance, rheological charasteristics, drug release and stability. The drug release from all gelatinizing agents through a standard cellophane membrane was evaluated using Franz diffusion cell.

II. METHODOLOGY

Materials

Diclofenac sodium was purchased from Yarrow Chem. Products, Mumbai, India. HPMC K100M was obtained as a gift from Colorcon, Mumbai, India. Carbopol 934P was purchased from Genuine Chemicals, Mumbai, India. All organic solvent used were of analytical grade

METHODS

Preparation of gel :

Carbopol 934 gels were formulated by first preparing a stock result of the Carbopol in distilled water and propylene glycol. Independently Diclofenac sodium(1w/ w) was dissolved in preweighted quantities of propylene glycol. Solvent mix was transferred to carbopol vessel and agitated for fresh 20 min. The dissipation was also allowed to hydrate and swell for 60 min, eventually conditioned neutral pH by sodium hydroxide result with stir. also samples was allowed to equalize for at least 24 hours at room temperature previous to performing rheological measures.

Table 1 : It shows gel formulations

Sr. No	Ingredients	Formulations		
		F1	F2	F3
1	Diclofenac Sodium	1 gm	1 gm	1 gm
2	Carbopol 934	1 gm	1.5 gm	2 gm
3	Propylene Glycol	15 ml	15 ml	15 ml
4	Methyl paraben	0.1 gm	0.1 gm	0.1 gm
5	Triethanolamine	0.30 ml	0.30 ml	0.30 ml
6	Water up to	100 ml	100 ml	100 ml

Evaluation of Carbopol 934 P gel containing diclofenac sodium gel and marketed gel :

The above formulated Diclofenac Sodium gel containing polymer carbopol 934 P and marketed gel were subjected to evaluation for the following parameter :

A. Homogeneity :

All formulated gels were tested for homogeneity by visual examination after the gels have been set in container. They were tested for their appearance and presence of any acculumations.

B. Grittiness :

All the formulated gels were evaluated microscopically for the presence of of fragments if any no detectable particulate matter was seen under light microscope.Hence obviously the gel formulation fulfils the conditions of freedom from particulate

matter and from gritiness as desired for any topical preparation.

C. Spreadability :

Spreadability is expressed in terms of time in seconds taken by two slides to slip off from gel and placed in between the slides under the direction of certain weight, Very Short the time taken for separation of two slides, better the spreadability.It's calculated by using the formula

$$S = M. L / T$$

Where M = weight tied to upper slide

L = length of glass slides

T = time taken to separate the slides

D. pH :

The pH of the gel formulations was determined by using digital pH meter(Systronic Instruments, India) by placing the glass electrode fully dipped into the gel system and measure the pH, which was calibrated before each use with standard buffer results at pH 4, 7, 9 and also Measured (Table 2)

E. Drug Content :

A specific amount (100 mg) of developed gel and marketed gel were taken and dissolved in 100 ml of phosphate buffer of pH 6.8. The volumetric beaker containing gel result was shaken for 2 hrs on mechanical shaker in order to get complete solubility of drug. The result was filtered and estimated spectrophotometrically at 276.0 nm using phosphate buffer pH6.8 as blank (Table- 2)

F. Viscosity :

The viscosity of the preparation was determined using a Brookfield digital viscometer (model DV-II, USA) and it was equipped with spindle S27.. The gel sample (5 g) was placed in the sample holder of the viscometer and allowed to settle for 5 min and the viscosity measured a rotating speed of 50 rpm at room temperature (25 - 27 °C)

In Vitro Study :

Inhibition of albumin denaturation

The below procedure was followed by evaluating the percentage of inhibition of protein denaturation :

Control Solution :

Egg albumin 2 ml , 6.4 pH phosphate buffer 14 ml and distilled water 20ml.

Standard Solution :

2 ml of fresh egg albumin & 28 ml of phosphate buffer whose pH 6.4 and 10ml of various concentration of marketed diclofenac sodium gel concentration of 100, 200, 400, 800 and 1000µg/ml.

Test Solution :

2ml of fresh egg albumin, 28 ml of phosphate buffer (pH 6.4) and 10ml various concentration of formulated gel concentration of 100, 200, 400, 800 and 1000µg/ml. All of the above solutions were adjusted to pH using a small amount of 1N HCl. The samples were incubated at 37˚ C for 15 minutes and heated at 70 ˚ C for 5 minutes. After cooling, the absorbance of turbidity was measured at 660 nm in UV-vis spectrophotometer the above solutions percentage inhibition of protein denaturation was calculated using the following formula

Percentage inhibition = [Vt/Vc -1] X 100

Where, Vt= Absorbance of test sample ,

Vc = Absorbance of control

Table 2 : Values of evaluation parameters of developed gel and marketed gel

Parameter	Formulatedgel			Marketed Gel
	F1	F2	F3	
Grittiness	-	-	-	-
Homogeneity	+++	+	+	+++
pH	6.8	6.8	6.8	6.8
Spredability	6.0 g.cm/sec	4.0 g.cm/sec	4.5 g.cm/sec	6.4 g.cm/sec
Viscocity	99	97	96	100
Drug Content	99.98	97.98	96.60	99.60

Table 3 : In vitro anti-inflammatory activity of diclofenac sodium gel on protein denaturation (Fresh egg albumin)

Treatment	Concentration (µg/ml)	Percentage of inhibition (%)
Diclofenac sodium Prepared Gel formulation	100	171.50
	200	174.00
	400	194.00
	800	222.75
	1000	225.00
Diclofenac sodium marketed gel Formulation	100	180.50
	200	198.50
	400	210.25
	800	232.13
	1000	233.37

III. RESULT AND DISCUSSION

The goal of this study was to develop suitable topical gel formulations of diclofenac sodium gel using Carbopol 934P as a gelatinizing agent and propylene glycol as permeation enhancer. The viscosity reflects the capacity of the gel, to get ejected in constant and desired volume when the tube is squeezed. The formulated and marketed gel showed good homogeneousness with absence of lumps. It was observed that the F1 formulation produces better spreadability and thickness as compared to marketed diclofenac sodium gel. The formulated F1 gel showed good homogeneousness, no skin irritation, good thickness and in vitro permeability was similar with marketed gel. The carbopol 934P forms water washable gel because of its water solubility and has wider prospects to be used as a topical drug delivery system Inhibition of egg albumin denaturation their comparison between sample and standard. From this experimental results showed significant inhibition of denaturation of egg albumin in concentration dependent manner.

IV. CONCLUSION

Diclofenac sodium is an on-steroidal anti - inflammatory medicament(NSAID) that exhibits anti - inflammatory, analgesic, and antipyretic activities. To overcome the side effects associated with oral diclofenac sodium remedy and to have the benefits associated with topical remedy; diclofenac sodium topical gels are prepared in this study. It has been observed that the formulated F1 gel produces with good consistency, homogeneity, spreadability. Since the polymer is water soluble; consequently, it forms water washable gel and has wider prospect to be used as a topical drug delivery dosage form.Protein denaturation is a process in which protein lose their tertiary structure and secondary structure by operation of external stress as strong acid, an organic solvent or heat most biological protein lose their biological function when denaturation. Denaturation of protein is a well- proved cause of inflammation. As a part of the study on the mode of the anti-inflammatory activity, ability of diclofenac sodium to inhibit protein denaturation was studied. Other anti-inflammatory drugs have showed dose dependent ability to inhibit thermally induced protein denaturation.Denaturation of protein is a well document cause of inflammation.

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