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Formulation and Evaluation of Diclofenac Sodium Gel by Using Carbopol

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ABSTRACT

High Molecular weight water soluble homo polymer of Carbopol are reported to possess very high viscosity in low concentration, transparency, film forming properties and are useful in formation of gel. The objective of this research is to prepare and evaluate 2% 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 percentage drug release was 97.66%. It can be concluded that preparation of diclofenac sodium by using 2% carbopol 934P Grade were prepared and evaluated.

Keywords – Water soluble polymer, Diclofenac Sodium, Carbopol 934 P, Topical drug delivery.

INTRODUCTION

Topical gel Preparation is intended for skin application and to certain mucosal surfaces for local action of percutaneous penetration of medicament of or for their emollient and protective action [1]. Gel are typically formed from a liquid phase that has been thickened with other components. The continuous liquid phase allows free diffusion of molecules through the polymers and hence release should be equivalent to that from the simple solution [2]. NSAID's are non-steroidal drugs having excellent anti-inflammatory and analgesic activity but NSAID produces GIT ulceration, liver and kidney

trouble especially in case of oral administration. In view, of adverse drug reaction associated with oral formulation, diclofenac sodium is increasingly administered by topical route [3]. Carbapol 934P is used as water soluble or hydrophilic polymers topically in gel drug delivery system[4], due to their non-greasy properties; they can provide easily washable film on the skin and are non-toxic[5]

METHODOLOGY

Diclofenac sodium was received from Sahyadri scientific Islampur, Carbapol 934 P was purchased by research-lab fine chem, Mumbai, and Triethanolamine was purchased by research-lab fine chem, Mumbai. All other Ingredients were of analytical grade.

Procedure of gel preparation:

Diclofenac sodium gel was formulated by using selected concentration of 2% Carbopol 934P polymer for further formulation to getting better result.

About 1g of diclofenac sodium was weighed and dissolved in 30 ml of ethanol (95%), to this solution; specified quantity of propylene glycol was added and dissolved (solution A). Weighed quantity of polymer carbopol 934P was added to sufficient amount of water, mix uniformly by using magnetic stirrer, to that added triethanolamine while continuous stirring (solution B). Solution A and B were mixed thoroughly and the final weight was made up to 100g.

Table 1-

Sr. No.	Name of the Ingredient	Quantity Given	Quantity Taken
1.	Diclofenac Sodium	1g	1g
2.	Carbopol 934P	2g	2g
3.	Triethanolamine	1.5ml	1,5m1
4.	Glycerine	10ml	10ml
5.	Propylene Glycol	10ml	10ml
6.	Ethanol	30ml	30ml
7.	Distilled water	q.s.	Up to 100ml

Evaluation of Carbopol 934 P gel containing diclofenac sodium 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. pH: The of the gel formulations was determined by using digital pH meter(Systronic Instruments, India) by placing the glass electrode completely into the gel system and measure the pH (Table2).

B. Spreadability: It was determined by wooden block and glass slide apparatus. Weights 20g were added to pan and the time was noted for upper slide (movable) to separate completely from the fixed slides. (Table2)[6]. Spreadability was then calculated by using the formula:

$$S = M.L / T$$

Where, S = Spreadability, M = Weight tide to upper slide, L = Length of glass slide, T = Time taken to separate the slide completely from each other.

C. Viscosity: Viscosity measures the flow characteristics of topical gel formulation. Change in viscosity of the product is indicative of change in stability and effectiveness of product. The viscosity of topical gel were determined by using Brook-Field viscometer ML VT115 using Spindle no. 64, at spindle Speed 30rpm at 25˚c for 5min.

D. Homogeneity: All developed gels were tested for homogeneity by visual inspection after the gels have been set in the container. They were tested for their appearance and presence of any aggregates.

E. Skin irritation test: Test for irritation was performed on human volunteers. For each gel, 5 volunteer were selected and 1g of formulated gel was applied on the area of 2 square inch to the back of hand. The volunteers were observed for lesions or irritation. (Table 2)

F. Drug content: A specific quantity (100mg) of developed gel and marketed gel were taken and dissolved in 100 ml of phosphate buffer of pH 6.8.

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

	pH	Spreadability (g.cm/sec)	Viscosity (cp)	Homogeneity	Skin irritation test	Drug content (%)
Formulated Gel	6.8	6.0	100	Good	Nil	99.98
Marketed gel	6.8	5.5	99	Good	Nil	99.90

Table 3: In vitro diffusion studies of Formulated and marketed gel

Sr. No.	Time Interval (min)	Medium pH	% Drug Release	
			Formulated Preparation	Marketed Preparation
1	30	6.8	49.31	50.61
2	60	6.8	64.96	67.12
3	90	6.8	79.24	80.24
4	120	6.8	97.66	98.44

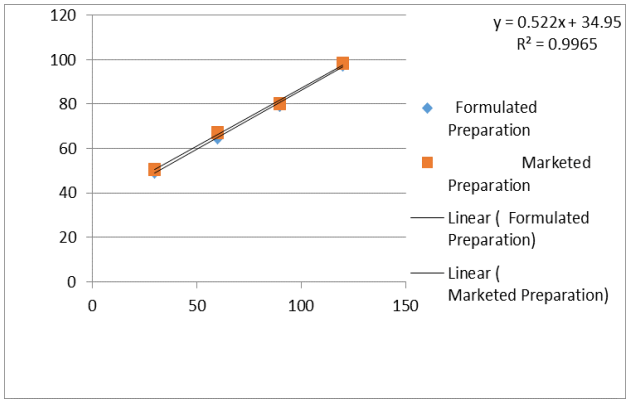

Fig: In vitro Diffusion of Diclofenac Sodium Gel

The volumetric flask containing gel solution was shaken for 2 hrs on mechanical shaker in order to get complete solubility of drug. The solution was filtered and estimated spectrophotometrically at 276.0nm using phosphate buffer pH 6.8 as blank (Table 2) [7].

G. In vitro diffusion Study : Phosphate buffer of pH 6.8 was used for in vitro release as a receptor medium. The cellophane membrane (Prepared from eggs) was used in Franz diffusion cell. The gel sample was applied on the membrane and then fixed in between donor and receptor compartment of diffusion cell. The receptor compartment content phosphate buffer (50ml) of pH 6.8. The temperature of diffusion medium was thermostatically controlled at 37± 1° by surrounding water in jacket and the medium was stirred by magnetic stirrer at 500 rpm. The sample at predetermined intervals were withdrawn and replaced by equal volume of fresh fluid. The samples withdrawn and replaced by equal volume of fresh fluid. The samples withdrawn were spectrophotometrically estimated at 276 nm against their respective blank [8].

RESULTS AND DISCUSSION

The pH values of Formulated and marketed gel was 6.8. The values of spreadability indicated that the gel is easily spreadable by small amount of shear. Spreadability of marketed gel was 5.5g.cm/sec while prepared gel was 6g.cm/sec, indicating spreadability of carbopol 934P containing diclofenac sodium was good as marketed gel.

The consistency (viscosity) reflects the capacity of the gel, to get ejected in uniform and desired quantity when the tube is squeezed. The formulated and marketed gel showed good homogeneity with absence of lumps. The formulated preparations were much clear and transparent as compared to marketed gel.
The skin irritation studies of formulated gel were carried out on human volunteers and that confirmed the absence of any irritation on the applied surface. In vitro permeability study should that permeation studies of formulated and marketed gel were comparable.

It was observed that the Diclofenac Sodium containing polymer carbopol 934P gel produced better spreadability and consistency as compared to marketed diclofenac sodium gel. The formulated gel showed good homogeneity, no skin irritation, good consistency and in vitro permeability was comparable 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.

CONCLUSION

The polymer being macromolecules of very high molecular weight remains unabsorbed from the skin and from our studies it can be concluded that carbopol 934P can be used for topical dosage forms for external application.

It has been observed that the formulated 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.

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