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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

The development of a topical gel formulation for Diclofenac Sodium using Carbopol 934 and the inclusion of propylene glycol as a penetration enhancer presents a unique and valuable approach for delivering this potent NSAID. Here are some aspects that make this study unique and noteworthy :

**1.Importance of Skin as a Drug Delivery Route:** Your study recognizes the significance of the skin as an accessible and effective route for drug delivery. This aligns with the growing interest in transdermal drug delivery due to its advantages over oral administration.

**2.Diclofenac Sodium's Therapeutic Potenial:** Diclofenac Sodium's potent anti-inflammatory, analgesic, and antipyretic effects are highlighted, emphasizing its therapeutic potential for various

medical conditions. This information is valuable for clinicians and researchers looking for effective treatments.

**3.Targeted Local Action:** Your study focuses on local action and percutaneous penetration of drugs for skin and certain mucosal surfaces. This targeted approach can minimize systemic side effects associated with oral NSAID administration, making it a safer option for localized treatment.

**4.Advantages of Topical Gel Formulations:** The advantages of topical gel formulations, such as being thixotropic, easily spreadable, and non-greasy, are emphasized. This promotes patient compliance and comfort, which is essential for long-term medication adherence.

**5.Unique Penetration Enhancer:** Your investigation of propylene glycol as a penetration enhancer sets your study apart. Understanding the impact of this enhancer on drug release is crucial for optimizing the formulation's efficacy.

**6.Comprehensive Evaluation:** Your study evaluates various aspects of the topical gel formulation, including physical appearance, rheological characteristics, drug release, and stability. This comprehensive assessment ensures that the formulation meets quality and performance standards.

**7.Transdermal Drug Delivery Potential:** You discuss the potential for your advanced Diclofenac formulation to not only treat inflamed skin tissues but also address inflammatory and painful conditions in supporting structures of the body, including bones, ligaments, joints, tendons, and muscles. This highlights the versatility and broader therapeutic potential of your formulation.

**8.Application of Franz Diffusion Cell:** The use of a standard cellophane membrane and Franz diffusion cell to evaluate drug release provides a scientifically rigorous approach, ensuring that your results are reliable and suitable for application in clinical settings.

## II. METHODOLOGY

### MATERIAL :

Diclofenac sodium was sourced from Yarrow Chem. Products in Mumbai, India, while HPMC K100M was graciously provided by Colorcon, also based in Mumbai, India. Carbopol 934P was procured from Genuine Chemicals in the vibrant city of Mumbai, India. Our organic solvents, meticulously selected for quality, were all of high-grade analytical purity.

### METHODS

### PREPARATION OF GEL :

Carbopol 934 gels were meticulously crafted through a well-orchestrated process. To start, a Carbopol stock solution was prepared b y dissolving it in a combination of distilled water and propylene glycol, ensuring precision in every measurement. In parallel, Diclofenac sodium (1% w/w) was skillfully dissolved in accurately pre-weighed amounts of propylene glycol. The two solvent mixtures were harmoniously combined in the Carbopol vessel, where they were gently agitated for a fresh 20-minute cycle.

Subsequently, the Carbopol compound was given ample time to hydrate and swell, allowing it to reach its optimal consistency over a period of 60 minutes. This was achieved by conditioning the gel to a neutral pH through the judicious addition of sodium hydroxide, all while maintaining a gentle stirring motion.

To ensure the gel's stability and readiness for rheological analysis, samples were diligently left to equilibrate for a minimum of 24 hours at room temperature. This patient waiting period allowed for any potential fluctuations in the gel's properties to settle, ensuring that the subsequent rheological measurements were carried out under the most reliable and consistent conditions.

**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 :

### i.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.

### ii. 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.

### iii. 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

### iv.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)

### v.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)

### vi.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 objective of this research was to develop effective topical gel formulations of diclofenac sodium using Carbopol 934P as the gelatinizing agent and propylene glycol as a permeation enhancer. The viscosity of the gel is a crucial factor, indicating its ability to be consistently dispensed in the desired volume when the tube is squeezed. Both the formulated and commercially available gels exhibited homogeneity, with no lumps present.

Comparative analysis revealed that the formulation offered superior spreadability and thickness when compared to the marketed diclofenac sodium gel. The gel exhibited uniformity, causing no skin irritation, and maintained a desirable thickness. Furthermore, in vitro permeability was found to be comparable to the marketed gel. This suggests that Carbopol 934P, known for its water solubility, holds promise as a water-washable gel and has significant potential as a topical drug delivery system.

In the context of inhibiting egg albumin denaturation, the study observed a concentration-dependent reduction in denaturation, as evidenced by a comparison between the sample and the standard. These experimental results underscore the significant

capacity of the developed gel to inhibit egg albumin denaturation.

## IV. CONCLUSION

Diclofenac sodium is non-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 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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