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Formulation and Evaluation of Diclofenac Transdermal Gel

Varsha Choudhary[1], Prerana Sahu[2], Gyanesh Kumar Sahu[3], Harish Sharma[4]

[1,2]Rungta Institute of Pharmaceutical Sciences, Kohka, Bhilai
[3,4]Rungta Institute of Pharmaceutical Sciences & Research, Kohka, Bhilai

Abstract
Diclofenac sodium gel is a widely used nonsteroidal anti-inflammatory drug (NSAID) formulation designed for topical application, primarily targeting local pain and inflammation. This wok aims to provide a comprehensive analysis of the anti-inflammatory activity of diclofenac sodium gel, focusing on its mechanism of action, efficacy, safety profile, and clinical applications. Several clinical studies have investigated the efficacy of diclofenac sodium gel in various inflammatory conditions, including osteoarthritis, rheumatoid arthritis, and soft tissue injuries. Results consistently demonstrate significant reductions in pain, swelling, and functional impairment, validating the gel's anti-inflammatory properties. The safety profile of diclofenac sodium gel is generally favorable, with local skin reactions being the most commonly reported adverse events. Systemic absorption is low, reducing the risk of gastrointestinal complications and other systemic side effects associated with oral NSAIDs. However, caution should be exercised in individuals with a history of hypersensitivity reactions or skin disorders.

Keywords: Inflammation, anti-inflammatory, diclofenac sodium, NSAID

1. Introduction

Diclofenac is generally utilized or used as a Non-steroidal anti-inflammatory drug (NSAID) that decreases irritation and torment in different circumstances, like joint pain, intense injury, and post-employable torment. One of the compelling and helpful types of diclofenac organization is through effective gels. Diclofenac gel offers restricted help by conveying the drug straightforwardly to the impacted region, limiting foundational incidental effects related with oral NSAIDs.The plan and assessment of diclofenac gel are basic cycles in drug innovative work.[1] Plan alludes to the most common way of planning a steady and powerful gel item, while assessment includes evaluating its quality, security, and viability. A few variables, including the decision of gelling specialists, entrance enhancers, and additives, impact the detailing, which thusly influences the gel's surface, solidness, and medication discharge profile.

The assessment of diclofenac gel incorporates different boundaries, for example, rheological properties, drug content consistency, in vitro drug discharge, skin saturation review, solidness, and microbiological testing. These assessments are fundamental to guarantee that the gel item fulfills administrative guidelines and conveys the ideal helpful impacts. Furthermore, understanding the gel's rheological

conduct helps in anticipating its spreadability, grip, and simplicity of utilization, which are all urgent for patient consistency and fulfillment.[2]

1.1 Disease

Diclofenac gel is normally used to manage pain (agony) and aggravation (inflammation) related with different outer muscle conditions and wounds. A portion of the particular illnesses and conditions where diclofenac gel is regularly endorsed include:

Osteoarthritis: Diclofenac gel is utilized to ease torment and irritation in joints impacted by osteoarthritis, a degenerative joint sickness that ordinarily happens with maturing.

Rheumatoid Joint pain: This is an immune system problem that causes ongoing joint irritation. Diclofenac gel can assist with dealing with the aggravation and enlarging related with rheumatoid joint pain.[3]

Bursitis: Bursitis is the aggravation of the bursae, little sacs loaded up with greasing-up liquid that pad areas of grating somewhere in the range of ligament and bone. Diclofenac gel can give alleviation from bursitis-related torment.[4]

Post-Usable Torment: Diclofenac gel is at times recommended after surgeries to oversee limited agony and expanding at the site of a medical procedure.[5]

1.2 Herbal formulation

Diclofenac gel is a synthetic medicine, there are herbal preparations and normal fixings that are accepted to have anti-inflammation and pain-relieving properties like diclofenac. These homegrown fixings are in some cases integrated into effective definitions to give help from agony (pain) and aggravation (inflammation). It's vital to take note of that the viability and well-being of these natural details might fluctuate, and counseling a medical care proficient prior to utilizing any elective treatments is fitting.[6] The following are a couple of instances of homegrown fixings regularly tracked down in normal relief from discomfort plans:

Turmeric: Curcumin, the dynamic compound in turmeric, has solid mitigating and cancer prevention agent properties. Turmeric-based creams or gels are utilized in customary medication for conditions like osteoarthritis and rheumatoid joint pain.[7,8,9]

2. Material and methods

2.1 Materials;

Diclofenac sodium, glycerin, HPMC, Carbopol 934p, Turmeric, distilled water, methyl paraben

Table no. 1: Ingredient table

Sno.	Ingredients
1	Diclofenac sodium(D)
2	Glycerin(G)
3	HPMC(H)
4	Carbopol 934p(C)
5	Distilled water(D)
6	Methyl paraben(MPS)
7	Turmeric(T)

2.2 Formulation method:

Formulation of a diclofenac gel involved a systemic steps to ensure the product is safe, effective and stable. Here is a general blueprint of the detailing strategies for making a diclofenac gel. Kindly note that particular methods and fixings could shift in view of the drug organization's restrictive strategies and the administrative prerequisites of the nation where the gel is being created. [10]

Table no. 2 Formulation table

SNO.	formulation	DS (g)	G (ml)	H (g)	C (g)		W (ml)	MPS (g)	T (g)
1	**F1**	1	15	3	-		75	0.25	1
2	**F2**	1	15	4	-		75	-	1
3	**F3**	1	15	-	0.25		75	0.25	1
4	**F4**	1	15	-	0.75		75		1

a. Selection of API:

1. Diclofenac sodium
2. Herbal ingredient: Turmeric

Other Excipients: Pick gelling specialists, entrance enhancers, additives, and stabilizers in view of their similarity with diclofenac and the ideal gel properties.[11]

b. Selection of Base and Gelling materials:

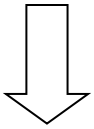
Base: This can be water-based

Gelling Specialist: Normal gelling specialists incorporate carbomer, hydroxypropyl methylcellulose (HPMC), or thickener. The decision relies upon the ideal gel consistency and rheological properties. [12]

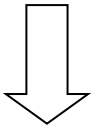
c. Preparation of Gel:

Formulation, F1 & F2:-

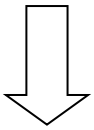
1g of Diclofenac sodium is dissolved in 15ml of Glycerin while heating turmeric and added.



3g of HPMC is dissolved in 75 ml of water with stirring then methylparaben is added.



Again 1g of Diclofenac sodium is dissolved in 15ml of Glycerin while heating.



0.25g of Carbopol 934P is dissolved in 75 ml of water with stirring then methyl paraben is added.

With proper mixing Gel is prepared.

Fig no. 1: Procedure of formulation of Diclofenac sodium gel.

d. Addition of preservatives:

Preservatives: To forestall microbial development and increment time span of usability, additives like methylparaben or propylparaben can be added. Guarantee the gel fulfills administrative guidelines for microbial substance. [14]

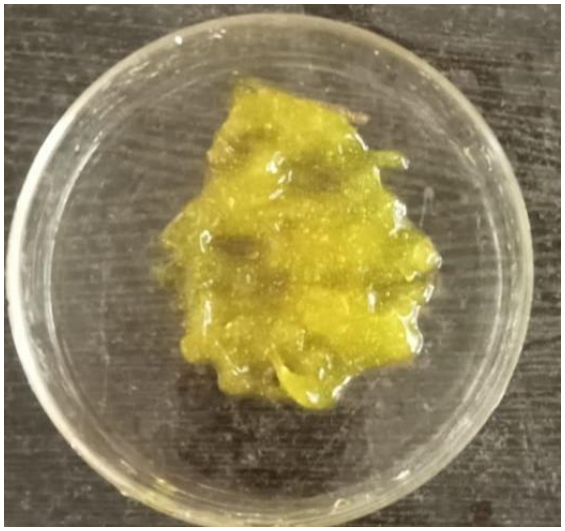


Fig no.02: Diclofenac sodium Gel using Turmeric

3. Characterization

Characterization of a diclofenac gel includes a progression of tests and examinations to survey different parts of the gel's physical, compound, and organic properties. These tests are critical to guarantee the gel's quality, security, and viability. Here are a few vital parts of portrayal for a diclofenac gel.[15]

3.1 Physical appearance:

The physical appearance was visually checked for the colour, appearance, odour, feel of application gel formulation was noted.

3.2 pH: The pH of gel formulations were determined by using the digital pH meter

3.3 Viscosity: The viscosity of the prepared gel formulations was measured by Brook field viscometer

3.4 Spreadability: Spreadability is expressed in terms of time in seconds taken by two slides to slip off from gel which is placed in between the slides under the direction of certain load. Lesser the time taken for the separation of two slides, better the spreadability

It is calculated by using the formula

S = M. L / T

where,

M = Weight tied to upper slide

L = Length of glass slide

T = Time taken to separate the slide

3.5 Homogeneity

After the gel formulations have been set in the container, all developed gels were tested for homogeneity by visual inspection. They were tested for their appearance and presence of any lumps, flocculates or aggregates

3.6 Stability testing;

The stability studies were carried out for all the prepared gel formulations by freeze – thaw cycling. Here, by subjecting the formulations to a temperature of 4o C for one month, then at 25o C for one month and then 40o C for one month and syneresis was observed

4. RESULT AND DISCUSSION

4.1 Physical appearance:

The physical appearance test Of gel is done by observing it through sensory organ and following observation is made.

Table no.3 Organoleptic properties

SNO	Physical appearance	Result
1	**Colour**	Pale yellow
2	**Odour**	Pleasant
3	**Appearance**	Translucent
4	**Texture**	Smooth

4.2 pH:

The pH of various gel formulations was determined by using digital pH meter.

Table no.04 pH of formulation

S no.	Sample	pH
1	**F1**	5.3
2	**F2**	6.1
3	**F3**	5.8
4	**F4**	5.9

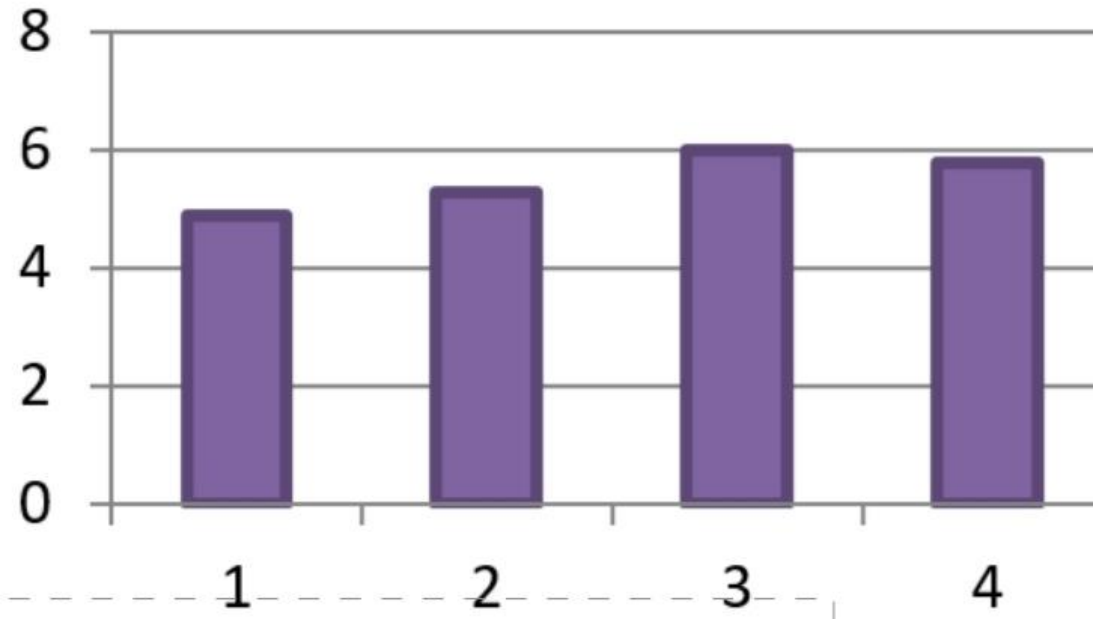


Fig no. 03 Graphical representation of pH

4.3 Viscosity;

The viscosity of the sample is measured by using Brookfield viscometer model –WDV-8.

Table no.05: Viscosity measurement

S.no	Sample	Viscosity
1	**F1**	1,50,800
2	**F2**	1,22,550
3	**F3**	50,750
4	**F4**	1,00,200

4.4 Spreadability:

Spreadability is expressed in terms of time in seconds taken by two slides to slip off from gel which is placed in between the slides under the direction of a certain load. Lesser the time taken for the separation of two slides, better the spreadability

It is calculated by using the formula

S = M. L / T

where,

M = Weight tied to upper slide

L = Length of glass slide

T = Time taken to separate the slide

4.5 Homogeneity: It is tested for their appearance and presence of lumps, flocculates or aggregates.

Table no.06 Homogeneity of Gel

S no.	Sample	Homogeneity
1	**F1**	Flocculates
2	**F2**	Aggregates

3	**F3**	Flocculates
4	**F4**	Aggregates

4.6 .*In-vivo* studies;

In-Vivo studies are performed by the help of Franz diffusion cell in the goat skin.

Fig no.04: Working of Franz diffusion cell

7. Stability data after 7 days;

The stability studies were carried out for all the prepared gel formulations by freeze – thaw cycling. Here, by subjecting the formulations to a temperature of 4o C for one month, then at 25o C for one month and then 40o C for one month and syneresis was observed.

Table no. 07 stability studies

Sno	**Sample**	**Temperature**		
		2-4C	**20-25C**	**35-40C**
1	F1	Stable	Stable	Stable
2	F2	Stable	Stable	Stable
3	F3	Stable	Un stable	Un stable
4	F4	Stable	Stable	Un stable

5. DISCUSSION:

Diclofenac sodium gel stands out as a compelling and effective option for managing inflammation through its potent anti-inflammatory activity. The topical application of diclofenac sodium allows for targeted delivery, minimizing systemic exposure and reducing the risk of adverse effects commonly associated with oral NSAIDs. It is known for anti-inflammatory action.

Maintaining the pH value is significant for determining the stability of the gel because change in pH specifies the occurrence of chemical reactions in the. The resulting pH of sample F1, F2, F3, F4 is found as 150800, 122550, 50750, 100200 respectively. The sample F1 with grater viscosity of 150800 is found to be more stable

6. CONCLUSION:

In conclusion, diclofenac sodium gel stands as a promising topical NSAID with notable anti-inflammatory activity. Its targeted and localized action, coupled with a favorable safety profile, positions it as an effective option for individuals seeking relief from localized inflammatory conditions. Ongoing research and clinical exploration continue to underscore its significance in the broader spectrum of anti-inflammatory therapeutics.

This study is further aimed to perform in vivo studies for inflammation the concentration of Diclofenac Sodium reaching into the skin and to study its effect in treatment of inflammation.

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