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Formulation And Evaluation of Pain Reliving Gel

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Abstract: This study aims to formulate and evaluate a topical gel containing Diclofenac and Diclofenac Sodium for effective management of localized musculoskeletal pain and inflammation. The formulation was developed using Carpool 934 as the gelling agent and evaluated for its physical, chemical, and pharmacological properties. Key parameters such as pH, viscosity, spreadability, drug content, in vitro drug release, and stability were assessed. The results indicate that the gel possesses favorable physicochemical characteristics and offers significant pain-relieving potential. The combination of Diclofenac and Diclofenac provides a synergistic effect for topical pain management with enhanced patient compliance and reduced systemic side effects

KEYWORDS: Diclofenac, Pain Relieving Gel, Carpool 934, Topical Formulation, NSAIDs

I. INTRODUCTION

Transdermal medication delivery systems are self-contained, discrete dose forms of patches that, when placed to intact skin, enter the systemic circulation through the skin at a predetermined or controlled rate [1]. Most topical preparations are utilized to produce localized effects at the applicant's site since the medicine penetrates the mucous membranes or skin's underlying layers [2].Tropical gels are superior to other conventional dosage formulations in a variety of ways. Gels are more effective and less hazardous than other administration methods. Topical treatments are the best option for managing local infections, pain, and other skin conditions since they are applied directly to the skin [3].A growing number of medications have been successfully delivered via topical delivery methods for both local and systemic effects Known as non-medicalted gels, the majority of antifungal, antibacterial, anti-inflammatory, and lubricating gels have been developed recently to apply the medication topically or as lubrication for surgical instruments. By reducing gastrointestinal discomfort and counteracting the "first pass" effect, gels help raise the concentration of medications at the site of action. As one of the most accessible and widely distributed organs on the human body, the skin serves as the primary delivery system for topical medications. Greater absorption is made possible by its capacity to pierce the skin deeply [4]. A get occurs when two or more substances are combined to create a semi-solid, jelly-like substance that is unable to flow steadily. In medical applications, the most common solutions are water and hydro-alcoholic ones. A topical preparation is still one of the most widely used and significant medicinal dose forms [5]. In order to create an absolutely stiff structure that paralyzes the liquid dispersion, a get is a three-dimensional network of constituent materials that are cross-linked and dispersed in large amounts of liquid. Depending on the kind of cross-links that form, the medium inside can be divided into two types of get systems: chemical get systems are associated with strong bonding, such as covalent bonds, while the latter are associated with relatively weaker and reversible intermolecular forces, such as hydrogen bonding and dipolo-dipolo forces electores. Van der Waals forces and hydrophobic interactions are two examples of partial interactions .

A semisolid structure composed of a dispersion of either long organic molecules or tiny inorganic particles surrounded and penetrated by liquid is called a gel. Large organic particles are dissolved in the continuous phase of gels, which are known as stretchy chains, while inorganic particles are not dissolved and instead move throughout the continuous phase. [6]This efficiently achieves the therapeutic advantages of the medications while minimizing or avoiding systemic negative effects. The therapy of rheumatoid arthritis and other related conditions has made extensive use of non-steroidal anti-inflammatory medications (NSAIDS) [7] .

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PAIN

Rheumatoid arthritis, osteoarthritis, polymyositis, dermatomyositis, temporomandibular joint (TMJ) pain, spondylarthritis, ankylosing spondylitis, gout episodes, and pain treatment for kidney and gallstones are examples of inflammatory illnesses. The management of acute migraines is another indication. [1]

II. GEL PREPARATION

Gels are typically made on an industrial scale at room temperature. On the other hand, very few polymers need special care before processing. The following techniques can be used to create gels:

1.Heat Changes: Gelatin is produced when solvated polymers (lipophilic colloids) undergo heat changes. A lot of hydrogen forms dissolve better in hot water than in cold. The degree of hydration decreases, and relation occurs when the temperature is lowered. A gel will form when a concentrated hot fluid cools. For instance, cellulose derivatives, gum, gelatin, agar sodium oleate, etc. Contrarily, certain substances, such as cellulose ether, are soluble in water and form hydrogen bonds with it. Relation will result from increasing the temperature of these solutions since it will break the hydrogen bonds and make them less soluble. As a result, this technique cannot be used generally to make gels.

2. Flocculation: In this case, gelation is created by adding less salt than is necessary to cause full precipitation, but enough to cause an aged state. To prevent large precipitant concentrations in one area, rapid mixing is crucial. For example, when ethylcellulose and polystyrene solutions in benzene are rapidly combined with the appropriate amount of a non-solvent, such as petroleum ether, they can gel. Salts cause coagulation when added to hydrophobic solutions; relation is rarely seen. The flocculation process produces gels with a isotropic characteristic. Acacia, gelatin, and proteins are examples of hydrophilic colloids that are only impacted by high electrolyte concentrations; when the effect is to "salt out," the colloids and relation do not take place.

3. Chemical Reaction: In this process, the solute and solvent interact chemically to form gel. For instance, an aqueous solution of sodium carbonate and aluminum salt can combine to form aluminum hydroxide gel; a higher concentration of reactants will result in a gel structure. A few other instances are chemical reactions that cross-link the polymeric chain between PVA, cyanoacrylates and glycerol ether (Glycerol), toluene diisocyanates (TDI), and methane biphenyl isocyanate (MDI).[2]

ADVANTAGES

- When necessary, it is simple to stop taking the drugs.
- One should steer clear of the first-pass metabolism..
- avoiding incompatibility with the gastrointestinal system.
- convenient and simple to use.
- a comparatively broad application area when compared to the buccal cavity.
- prevents differences between and between patients as well as fluctuations in medication levels.
- increased adherence from patients.
- enabling the use of medications having a limited therapeutic window and a brief biological half-life.
- Make self-medication appropriate.[2]
- the capacity to more precisely administer medication to a certain location.
- It passes via the digestive system to prevent unwanted side effects.
- It is easy to distribute skin retention.
- On the skin, it provides a soothing effect.[3]

DISADVANTAGES

- The skin cannot readily absorb drugs with bigger particle sizes.
- Only applicable to medications that require extremely low plasma concentrations to function.
- The medication or agents may cause dermatitis or skin irritation. Poor skin permeability is a feature of some drugs.
- The possibility of allergic reactions..
- Drugs that cause skin irritation or sensitization should not be taken through this route. The possibility of an allergic reaction existed.
- Gels take longer to start working.
- The skin may become irritated by the gel's ingredients.
- It is necessary to monitor reactions at the application site.
- Temperature, humidity, and other environmental factors may have an effect on efficacy[2]

Gel's characteristics

- An inert, safe gelling agent that does not react with other chemicals in the formulation is ideal for medicinal or cosmetic applications.
- It must possess sufficient antibacterial defenses against microbiological assault.

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- When the gelling agent is stored, it should have a reasonable solid-like character that is easily broken by shear pressures created by squeezing the tube, shaking the bottle, or applying the gel.
- As the gel's effective cross-link density rises, so does its apparent viscosity or strength. A rise in temperature, however, may cause an increase or decrease in apparent viscosity, contingent on the molecular interactions between the solvent and the polymer.
- It should be non-staining, emollient, isotropic, and greaseless, among other qualities.
- It needs to be When stored, it ought to remain stable.
- Handling and using it should be easy.
- It is important that the topical gel not be tacky.
- The drug's biological nature should not be affected.
- The mechanical properties of the solid stage are displayed by them.
- The eye gel needs to be totally sterile.
- The gel applied topically should not be rough.[4]
- A liquid dispersed phase and a solid dispersion medium make up this colloidal system.
- It is an unyielding semi-solid.
- It has a honeycomb-like structure.
- Most gels see swelling as a result of absorbing liquids.
- Organic materials are used to make elastic gels, which solidify when heated and return to their gel form when water is added. Both reversible and lyophilize.
- Non-Elastic (Rigid) Gels: These inorganic materials produce a powder when heated, which is irreversible and biophobic and cannot be reconstituted into gel by adding water.
- Gels have the capacity to increase in bulk and absorb additional liquid.[5]

Gel are divided

According to the colloidal phase.

1.One phase gels: When macromolecules are uniformly distributed throughout a fluid in single phase gels, there is no discernible barrier between the fluid and the dispersed macromolecules.

2.Gels with two phases : In these phases, floccules of small, discrete particles known as magma are present in the gel mass.

According to the continuous phase.

1.First, hydrogels : It is a colloidal gel or a network of hydrophilic polymer chains where the dispersion medium is water. They are extremely absorbent networks of polymers, either natural or artificial.The phrase "hydrogel" was coined in 1960 by Wichterle and Lim. Reversible hydrogels, sometimes referred to as physical hydrogels, are hydrogels composed of physical cross-links. Their network of three-dimensional hydrophilic polymers expands in water and has a significant water-holding capacity.

2.**Organizers, second** :It's a non-greasy, non-crystalline thermoplastic. Solid substance composed of a liquid organic phase surrounded by a network of interconnected molecules in three dimensions. Dispersion gels known as organizers use non-polar liquids or oil as a dispersion medium.

3.The aerogels : In gels, vehicles have been eliminated, leaving behind a polymer network or film. Its surface area is enormous, its porosity is high, and its pore size is quite small (1–10 nm).

According to the rheological properties.

1.Plastic gel : The example of plastic flow is Bingham bodies, which are loculated suspensions of aluminum hydroxide.

2.Cellulose gel : The best examples of pseudoplastic gel include liquid dispersions of tragacanth, sodium alginate, Na CMC, etc.

According to physical nature.

1.Elastic gel : These are elastic gels composed of pectin, gum, agar, and alginates. At the site of contact between fibrous particles, weak interactions like hydrogen bonds and dipole attraction hold them together.

2.Stiff gel : It is present in macromolecules with a primary value bond connecting the framework.[3]

3.Pseudo-plastic gels: This type of flow is seen in liquid tragacanth , sodium alginate, Na CMC, and other dispersions. These gels have no yield value, and their viscosity falls as the rate of shear increases. The rheogram is created when the long-chain molecules of the linear polymers undergo shearing. The disorganized molecules start to align their long axis in the direction of flow as the shearing tension increases, causing the solvent to be released from the gel matrix.

4.Thixotropic gels: These gels are easily broken by shaking due to their incredibly weak particle bonds.. Because the particles collide and re-link, the resultant solution will return to gel (the reversible isothermal gel-sol-gel transformation). This happens when non-spherical particles in a colloidal system accumulate to form a scaffold-like structure.[2]

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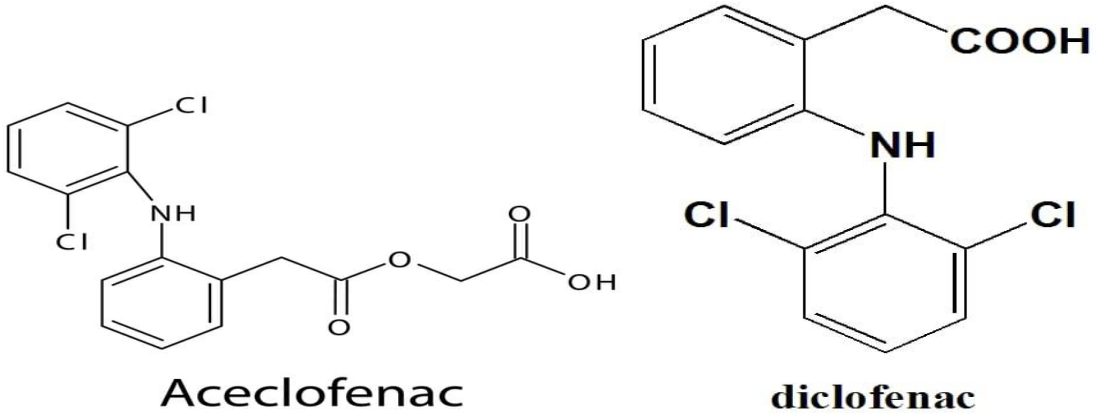
III. STRUCTURE



IV. MATERIALS AND METHODS

All materials used were of analytical grade and procured from certified pharmaceutical Laboratory from our collage.

Table 1: Ingredients and Role

Sr.No	Name Of Ingredients	Role
1	Aceclofenac and diclofenac	NSAIDs, Anti Inflammatory, Anti Analgesic
2	Carbapol 934	Gelling Agents
3	Propylene glycol	Solvent, Humactant
4	Ethanol	CO-Solvent
5	Methyl paraben	used as a preservative
6	Propyle paraben	as antimicrobial preservative
7	Triethanolamine	, pH adjuster, and surfactant
8	Purified water	Vehicle

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V. METHODS OF PREPARATION

1.First, wash and dry all glassware and tools necessary to create pain relief gel.
2. Next, precisely weigh all the active ingredients in Next, precisely weigh the medicinal components and recipients used in accordance with the table provided.
3. In After immersing the carpool 934 in purified water and letting it hydrate for a few hours or overnight, dissolve the preservatives in a tiny amount of water and mix them into the hydrated carpool.
4.Diclofenac and Diclofenac are dissolved in a solution of propylene glycol and isopropyl alcohol. To prevent air entrapment, carefully stir the medication solution above into the carpool base.
5.To start gelling, adjust the pH with triethanolamine (PH ~ 6.8-7.2).
6. If necessary, homogenize the final volume using pure water.
7.Transfer to appropriate containers after letting stand to release trapped air. And put a label on it.

VI. FORMULATION TABLE

Table 2 : Ingredients And Batches

Ingredients	F1	F2	F3	F4	F5
Aceclofenac and diclofenac	1	1	1	1	1
Carbapol 934	0.5	1	1.5	2	2.5
Propylene glycol	10	10	10	10	10
Ethanol	10	10	10	10	10
Methyl paraben	0.2	0.2	0.2	0.2	0.2
Propyl paraben	0.05	0.05	0.05	0.05	0.05
Triethanolamine	q.s	q.s	q.s	q.s	q.s
Purified water	Upto 100%	Upto 100%	Upto 100%	Upto 100%	Upto 100%

VII. EVALUTION TEST

1.Homogeneity: Homogeneity is determined by visually testing the gels for the presence of an aggregate after they have been set into the container in which they are to be inspected[6]
2.Grittiness- (Microscopic examination) - All the formulations were evaluated microscopically for the presence of particles if any appreciable particular matter was seen under a light microscope. The gel prep satisfies the desired degree of freedom for any topical preparation. "[7]
3.Extrudability study:- A good gel extrudes optimally from the gel with slight pressure, applied. Aluminum collapsible tubes were used to test compositions for extrudability utilizing universal tube filling Machine. aluminum collapsible tube filled with 10 g gel was held by two clamps. A tube was determined in terms of weight in pounds. Required to extrude a 0.5 cm. ribbon of gel in seconds.[7]
4.Spreadability:- It was determined by spreadability apparatus, which consists of a wooden block with a due alley mounted to one end. A glass slide was fixed on the wooden block. An excess of gel (about 2g) under study web was placed on this ground glide. The gel pref was then sand wicked bet" this slide having Same dimension as that of the fixed ground slide. The second goes slide is provided with the hook. Weight of 1kg was placed on the top of the two slides for 5 min to expel air & to provide a uniform film of gel on the. Two slides. The excess gel was scraped off the edges. the amount of it that was measured (50g) was placed in the pan attached to the pulley with the handle of the hook. The time taken (in sec) to cover a distance of 5 cm by slide was recorded. Less the time taken for separation of two slides, better the spreadability.
It is calculated by using the formula, SM. L/T
where,
M= wt. Tied to upper slide (gm)
L length of glass slides or-
T= time taken to separate A slides[8]
5.Consistency - The consistency of developed gel's was-examined by dropping the cone attached to a holding rad from a fixed distance of loom in the other way that it should fall down on the center of the glass cup with the gel. The cone's penetration was precisely measured from the gel's surface to the tip of its interior core. The distance traveled by cone in a port was noted down after a few seconds.[9]
6.pH measurement :- pH of the gel measured by using digital. pH DH meter should be determined IG of gel in 100ml of distilled dissolving IG water &

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kept for 2 hrs. The values are noted in triplicate of each gel & mean is calculated.[6]

7.Drug content study:- A specific amount of formulated gel & marketed gel was taken & dissolved in 100 MAL of phosphate buffer of pH 6.8. The Volumetric flask containing gel sold was left for 2 hrs on a mechanical shaker to get absolute solubility. Sol was filtered & estimated Of drug, This sol spec bop UV visible spectrophotometrically . At 276 nm using phosphate buffer pH 6.8 as a blank.[10]

8.Viscosity measurement:- The viscosity of gel was determined by using a Brookfield digital picometer (model DVI, USA) & it was equipped with a spindle for $27. The gel sample (5g) was placed in the sample holder of the picometer & allowed to set for 5 min & the viscosity measured. Templating speed of 50 rpm at some roam (25-27°C).[11]

9.Skin irritation test:- Test for invitation was performed on human Volunteers for each gel, five Volunteers were selected & IG of formulated gel was applied on an area of 2 cm^2 to the back of hand. The volunteers were observed. Lesions or imitation. OR Guinea pigs (400-500g) of both sexes were used (male & female). The animals had unrestricted access to water and were fed an ordinary diet. The animals were kept under standard conditions. Hair was shaved from back of guinea pigs & area of 4 cm^2 Cuba marked on both the side sane side served ab control while the other side was test Gal was applied (500 mg/guinea) twice a day for 7 days & the site was observed for any sensitivity & the reaction if any.[12]

10.Stability study : The stability studies for gel are regularly performed by freeze - thaw cycling. The optimized formulation ($F2/F_2$) was I subjected to a stability testing for the period of 3 months as per ICH Norma at a temp. Of 250 12 4c 120 with relative humidity RH = 45 ± 5% and 25°0 25°C 12°c with relative humidity RH = 60±5% and 90° ± 2a with relative humidity & of RH=75±5%. (for each month).For all gels, synereses is noted visually. After bringing the gels to room temperature, the liquid exudation is also seen.[6,13]

11. In-vitro drug release studies : were performed by using modified Franz diffusion cell with a receptor compartment capacity of 20 ml. The synthetic cellophane membrane was. Mounted between the donor & receptor compartment of the diffusion cell. The formulated gel was weighted up to 1g and placed over the drug release membrane and the receptor compartment of the diffusion. A phosphate buffer with a pH of 7.4 was added to the cell. The whole assembly was fixed on a Magnetic steer, and the sol in the receptor compartment was constantly & continuously Stirred using magnetic beads at 50 RPM; the temp. Was maintained at 37±0.50°C. The samples of 1 ml were withdrawn at time intervals of 15, 30, 60, 90, 120, 150, 180,210, 240, 270 & 300 min, and analyzed for dong content spectrophotometrically at 293 mm. Against blank. At each sample removal, the receptor phase was refilled with an equivalent volume of phosphate buffer. The cumulative amount of things diffused. From gal were plotted against time.[13]

FIG: PREPARED GEL

VIII. RESULTS AND DISCUSSION

Organoleptic Evaluation

Table 3.1: Organoleptic Evaluation

Organoleptic evaluation	Parameter	Observations
	Colour	White
	Odor	Mild Characteristics
	Consistency	Semi-solid

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	Uniformity	Good Uniform

PHYSICOCHEMICAL ASSESMENT

Table 3.2: PH Observation

Types Of Evaluation	Parameters	Observations
Physicochemical Evaluation	PH	6.9

EVALUATIONS OF PERFORMANCE

Table 3.3: Evaluation Performance

Types of Evaluation	Parameters	Observations
Performance Evaluation	Spreadability	Pass

IRRITATION TEST ON THE SKIN

Table 3.4 : Irritation Test On Skin

Types of Evaluation	Parameters	Observations
Skin Irritation	Irritation	No
	Etching	No
	Redness	No

STABILITY STUDIES

Table 3.6 : Stability Study

Type of Evaluation	Parameters	At Temprature Room	At Refrigerator
	Appearance	Normal	Normal
	Colour	Normal	Normal
	Odor	Normal	Normal
	Texture	Normal	Normal

IX. CONCLUSION

A stable and effective pain-relieving gel was successfully formulated using Aceclofenac and Diclofenac Sodium as active ingredients. The formulation demonstrated suitable pH, viscosity, spreadability , sustained drug release, and excellent stability. This dual-drug topical gel may serve as an effective alternative to oral NSAIDs, minimizing systemic side effects while providing targeted relief. Further in vivo studies and clinical trials are warranted to confirm its efficacy in patients.

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