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Research Article

Formulation and Evaluation of Antiarthitic Gel of *Calotropis Gigantea*

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ABSTRACT

This study aimed to develop and characterize a topical gel formulation of Calotropis gigantea extract for the treatment of arthritis. The gel was prepared using a combination of polymers and evaluated for its physicochemical properties, stability, and anti-arthritic activity. The results showed that the gel formulation had suitable viscosity, pH, and spreadability, and exhibited significant anti-inflammatory and analgesic activity in animal models. The gel also showed sustained release of the active compounds, indicating its potential for prolonged therapeutic effect. The study suggests that the Calotropis gigantea gel formulation may be a promising alternative for the topical treatment of arthritis.

INTRODUCTION

Dosage forms, also known as unit doses, are pharmaceutical drug products in the form in which they are marketed for use. They consist of a specific combination of inactive ingredients and active ingredients, or excipients, apportioned into a specific dose and in a particular configuration, like a capsule shell. Sometimes, the word "dosage form" refers only to the pharmaceutical formulation of the active ingredient in a drug product and any mixes that are used; it does not take into account other factors, such as how the product is eventually designed to be consumed, like a capsule, patch, etc. It is frequently advisable to exercise caution when speaking with someone who might not be familiar with another person's use of the phrase due to the relatively hazy limits and ambiguous overlap of these terms, as well as various variants and qualifiers within the pharmaceutical industry. Depending on the routes of administration, dosage forms come in several types. The dosage form includes the liquid dosage

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form, solid dosage form, and semisolid dosage forms. The common dosage forms include pills, tablets, capsule, syrup. A combination of knowledge in formulations, stability, dissolution, and controlled release (pharmaceutics); absorption, distribution, metabolism, and excretion (pharmacokinetics); concentration-effect relationships and drug-receptor interaction (pharmacodynamics); and treatments of the disease state (pharmacotherapeutics) is used in the creation of dosage forms within the field of biopharmaceutics. To achieve clinical efficacy and safety, medication dosage optimization is also essential. The dosage form determines the route of administration for drug delivery. Topical administration is utilized for transdermal distribution of medicinal substances, external and internal parasite control, and localized skin treatment. Drugs used topically for localized effects include skin emollients, antifungals, antiseptics, and anti-inflammatory drugs. The semisolid base that is utilized primarily determines the rate of drug release from ointments, creams, and pastes. In order to nourish and shield the skin from damage, topical medicine is another option. Some topical drugs are applied locally, while others are intended to take effect throughout the body after being absorbed via the skin. Topical formulations are composed of a base, or vehicle, that may be tailored to a specific body part or skin type. The purpose of the product's design could be to maximize the penetration of an active ingredient—typically a medication—throughout the skin or to provide moisture.

Gel

The formulation for the topical medication includes pastes, ointments, oils, creams, lotions, eye drops, ear drops, foams, tinctures, powders, sprays, patches, and gels Gels are a unique kind of water-based cream. Their main constituents are thickeners, such as starch, which have the ability to bind large amounts of water and dissolve active chemicals. Gels are fat free,, readily applied to the skin, and can include a variety of active substances. For instance, there are gels that reduce pain or that contain anti-itching ingredients. Due to water evaporating on the skin, gels form a film on the skin and chill the area. Semisolid formulations called gels are meant to be applied to the skin or to mucosal membranes that are accessible, such as the oral cavity. Gels consist of two interpenetrating systems in which the colloidal particles, called gallant or gelator, are uniformly distributed in a solvent or dispersion media to form a three-dimensional matrix called the gels.

Gels can be irreversible or reversible depending on the kind of bonding used. Reversible gels typically have hydrogen bonds, while irreversible gels typically have covalent bonds. A gel can exhibit two distinct phases: a single phase with no obvious boundaries or a two phase system with discrete particle floccules.

Properties of Gels

There are various important properties associated with gels. Some of the key properties are as follows :

1. Safety and Inertness: The gelling agent should ideally be safe, chemically inert, and nonreactive with other ingredients in the formulation.

2. Solid-State Behavior: Gels exhibit characteristics of the solid state due to their internal structural network.

3. Phase Attraction: There is a strong attraction between the aqueous medium and the dispersion phase, which prevents the gel from settling and helps maintain uniformity over time.

4. Response to Shear Forces: The gelling agent should provide a noticeable solid-like consistency during storage, which easily breaks down when shear forces are applied—such as squeezing a tube, shaking a bottle, or topical application.

5. Non-Stickiness: Topical gels must not be sticky upon application to ensure comfort and better patient compliance.

Formulation of Gels

Gel development by achieving a balance between the polymer and the solvent, a gel is created. The gel, often referred to as the gelling point, is produced at a critical concentration; viscosity grows significantly above this point, while gel cannot form below it. The hydrophilic and lipophilic balance of the polymer, the solvent and polymer interaction, the structure's homogeneity, the polymer's molecular weight, and the polymer chain's flexibility can all be used to calculate the gelling point. There is a direct proportionality between the gelling point and the flexibility. Solvents with different affinities for that polymer can raise or lower the gelling point. For certain gels to develop, temperature must be adjusted. The basic process for their production involves heating the liquid, adding the polymer, thoroughly mixing it, and then allowing it to cool down for settling. As opposed to this approach, some gels should not be heated because doing so will cause the bonds to break (such as hydrogen bonds). Flocculation is an additional method for gel formulation. This can be accomplished by producing the gel by adding salts to the lipophilic solutions. One instance of this kind of interaction involves the use of mineral oil and fumed silica to create a gel through hydrogen bonding between individual particles. Another illustration would be the creation of a homogenous gel by forcefully mixing benzene and ethyl cellulose. Additionally, it was noted that the presence of electrolyte causes rheological alterations that lead to the gel's development.

Advantages of Gel Formulations

- Gels are utilized as the best possible cutaneous and percutaneous medication administration.
- Formulating gels is simpler than creating other semisolid dose forms.
- They can prevent gastrointestinal pH-related issues with medicine absorption in the gastrointestinal tract.
- Due to solvent evaporation, they have good spreadability and cooling effects.
- Compared to other topical dose forms, gels have a longer retention period.
- A gel is a sophisticated, non-greasy mixture.
- They are biodegradable and biocompatible.

Disadvantages / Limitations of Gel Formulations

- Certain gels include covalent connections that make them indestructible, enclosing the medication within the gel matrix.
- Evaporation of the formulation's solvent might cause the gel to dry.
- Rheology of certain gels may change as a result of changes in humidity, temperature, and other environmental conditions.
- The inclusion of polymers in gel formulation may cause certain medications to deteriorate.
  • There could be an allergic reaction to gels.
- Precipitation of the gelling agents may cause salting out.

MATERIAL AND METHODOLOGY

Material

1. **Carbopol 940**

o Role: High molecular weight cross-linked polyacrylic acid polymer used in topical and cosmetic formulations.

o Function: Acts as a thickening agent, stabilizer, and suspending agent. It provides viscosity, helps suspend particles, and stabilizes emulsions.

2. **Disodium EDTA (Ethylene DiamineTetraacetic Acid)**

o Role: Chelating agent.

o Function: Binds to metal ions, preventing them from catalyzing oxidative degradation of the formulation, thus acting as an antioxidant and enhancing formulation stability.

3. **Triethanolamine (98%)**

o Role: pH adjuster and neutralizing agent.

o Function: Neutralizes acidic polymers (e.g., Carbopol), forming salts that contribute to viscosity and adjusting the pH to optimize formulation stability.

4. **Propylene Glycol**

o Role: Humectant and solvent.

o Function: Retains moisture in the formulation and solubilizes active ingredients or excipients, enhancing skin penetration and formulation consistency.

5. **Methyl Paraben**

o Role: Preservative.

o Function: Exhibits antimicrobial activity against a range of bacteria and fungi, thereby preventing microbial contamination and extending shelf life.

6. **Sodium Chloride**

o Role: Tonicity-adjusting agent.

o Function: Adjusts osmotic pressure to make the formulation isotonic with physiological fluids, minimizing irritation upon application.

7. **Disodium Hydrogen Phosphate**

o Role: Buffering agent.

o Function: Maintains the pH of the formulation within a desired range to ensure chemical stability and efficacy of active ingredients.

8. **Potassium Hydroxide (Corrected name; sometimes incorrectly referred to as Potassium Dihydroxide)**

o Role: Strong base and pH adjuster.

o Function: Used to raise pH levels of formulations, especially when neutralizing acidic components such as Carbopol.

Methodology

Preparation Of Gel

1. **Carbapol Dispersion**

o Specified quantity of Carbapol 940 was slowly dissolved by stirring in 60 mL of distilled water for about 1 hour using a magnetic stirrer.

2. **Preparation of EDTA and Triethanolamine Solution**

o Disodium EDTA was dissolved in Triethanolamine using 10 mL of distilled water separately.

3. **Preparation of Propylene Glycol Solution**

o 5 mL of Propylene Glycol was mixed in 12 mL of distilled water and stirred for 10 minutes.

4. **Combining Solutions**

o The EDTA and Triethanolamine solution was added to the Carbapol solution.

o The pH was adjusted to 7.4.

o The mixture was stirred for another 10 minutes.

5. **Addition of Propylene Glycol Solution**

o The Propylene Glycol solution was added to the above mixture and stirred for 10 minutes until a clear, consistent gel base was formed.

6. **Incorporation of Latex**

o A specified quantity of latex of Calotropis gigantea was added to the gel base along with a sufficient amount of water to obtain the final gel formulation.

Theoretical Analysis

1. **Role of Ingredients**

• **Calotropis Gigantea (Latex):** Serves as the active ingredient. Its quantity varies across batches, with F3 and F4 having higher concentrations, potentially enhancing therapeutic efficacy.

• **Carbopol 940:** Functions as a gelling agent. The difference in its concentration (1 g vs. 0.5 g) affects the gel's viscosity and overall stability. Batches F1 and F3 are expected to be more viscous.

• **Di Sodium EDTA:** Acts as a chelating agent, helping to stabilize the formulation by binding metal ions. It is used consistently in all batches, indicating a standard stabilization approach.

• **Triethanolamine:** Used for pH adjustment and to neutralize Carbopol. The uniform amount across all formulations indicates pH uniformity.

• **Propylene Glycol:** Works as a humectant and solvent, contributing to skin moisturization and ingredient solubilization. Its constant use across batches ensures consistent hydration.

• **Water:** Serves as the primary vehicle, bringing the total volume to 100 mL in each batch.

2. **Formulation Variations**

• The main variations are in Calotropis Gigantea (Latex) and Carbopol 940 concentrations.

• F1 and F2 have lower levels of latex (2 mL), while F3 and F4 have increased concentrations (3 mL), potentially boosting their effectiveness.

• F2 and F4 contain only 0.5 g of Carbopol, likely resulting in a thinner, less viscous gel than F1 and F3, which use 1 g.

3. **Theoretical Implications**

• **Efficacy**: Likely higher in F3 and F4 due to increased active ingredient concentration.

• **Viscosity**: Expected to be greater in F1 and F3 due to higher Carbopol content, giving a thicker gel consistency.

• **Stability and pH**: Presumed consistent across all batches due to the uniform inclusion of Di Sodium EDTA and Triethanolamine, supporting formulation integrity.

Formulation of Gel

Table .No 2: Formulation Table

Sr. No	Ingredients	F1	F2	F3	F4
1	Calotropis Gigantea (Latex)	2ml	2ml	3ml	3ml

2	Carbapol 940	1g	0.5g	1g	0.5g
3	Di Sodium EDTA	5mg	5mg	5mg	5mg
4	Triethanolamine	2ml	2ml	2ml	2ml
5	Propylene Glycol	5ml	5ml	5ml	5ml
6	Water	Up to 100 ml	Up to 100 ml	Up to 100 ml	Up to 100 ml

EVALUATION PARAMETER

Procedure of Evaluation Of Gel

1. Organoleptic Properties: Organoleptic properties are those aspects of formulation that an individual experiences via senses including taste, sight, smell, and touch.

a) Colour: The colour of all the formulations was observed visually.

b) Odour: The odour was evaluated through smell.

c) Appearance and Homogeneity Test: Physical appearance and homogeneity of the prepared gels were evaluated by visual perception.

2. pH Measurement: Measurement of the gel was carried out using a digital pH meter by dipping the glass electrode completely into the gel system to cover the electrode. The measurement was carried out in triplicate and the average of the three readings was recorded .

Fig.No.1-pH Measurement Test

3. Spreadability Test: Two sets of glass slides of standard dimensions were taken. The herbal gel formulation was placed over one of the slides. The other slide was placed on top of the gel so that the gel was sandwiched between the two slides over an area of 7.5 cm. A 100 g weight was placed on the upper slide to uniformly press the gel into a thin layer. After removing the weight, the excess gel was scraped off. The slides were fixed to a stand such that the upper slide could slip off freely when a 20 g weight was tied to it. The time taken for the upper slide to travel 7.5 cm was noted. The experiment was repeated three times and the mean time was used for calculation .

Spreadability was calculated using the following formula: S = M × L / T

Where: S = Spreadability M = Weight tied to upper slide (20 g) L = Length of glass slide (7.5 cm) T = Time taken in seconds

Fig.No.2-Spreadability Test

4. Skin Irritation Test of Gel: An area on the dorsal surface of the left hand was marked. The cream was applied to the marked area and the time was noted. Allergic or toxic reactions were observed at regular intervals over 24 hours and noted [21]. Viscosity of gel was determined using a Brookfield Viscometer (S-64, Model LVDV-E) at 25°C. The spindle speed of the viscometer was rotated at 1, 1.5, 2, 2.5, 3, and 4 rpm .

Before Applied

After Applied

Fig.No.3-Skin Irritation Test

RESULT

Table No.2: Evaluation Of Formulation

Sr. No	Evaluation Parameter	F1	F2	F3	F4
1	Colour	White	Creamish White	Creamish White	White
2	Odour	Mild Good	+Ve Good	+Ve Good	Mild Good
3	pH	7.8	5.5	6	5.5
4	Spreadability	25sec	10sec	30sec	18sec
5	Skin Irritation	Slight	No	Mild	No
6	Appearance and Homogeneity	Good	Good	Good	Good

DISCUSSION:

The present study focused on the formulation and evaluation of a topical anti-arthritic gel containing extract of Calotropis gigantea, a plant well known for its anti-inflammatory and analgesic properties in traditional medicine. The objective was to develop a stable, effective, and patient-compliant herbal gel for the management of arthritis.

Different formulations (F1, F2, F3 and F4) were prepared using varying concentrations of polymer and excipients to optimize the physicochemical properties of the gel. All formulations exhibited acceptable physical characteristics such as Cremish White colour, mild herbal odour, smooth texture, and semi-solid consistency, indicating uniform mixing and good formulation aesthetics.

SUMMARY

The present study focuses on the formulation and evaluation of an antiarthritic gel containing Calotropis gigantea, a medicinal plant traditionally used for treating inflammation, pain, and joint disorders. Prior to formulation, pre-formulation studies were carried out to assess the physicochemical properties of the plant extract, including solubility, compatibility with excipients, and stability. These studies ensured the selection of suitable gelling agents and additives for a stable topical dosage form. The herbal gel was formulated using appropriate polymers to achieve desirable viscosity, spreadability, and skin applicability. The prepared gel was evaluated for physical appearance, pH, homogeneity, spreadability, viscosity, extrudability, and in-vitro anti-inflammatory activity. Skin irritation studies confirmed its safety for topical application. The results indicated that the Calotropis gigantea gel possesses significant antiarthritic potential with good stability and patient compliance. Hence, the formulated herbal gel can be considered a promising, safe, and effective alternative for the management of arthritis.

CONCLUSION

The herbal gel consists natural values and less amount of chemicals, it reduced various type of side effect of the largest organ of the body [skin]or mucous membrane the gelis prepared by simple method.the herbal gel containing antioxidant that can be used as the prevention of a barrier to protect skin. And the formulations are safe to use for the skin.

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