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Formulation and Evaluation of Fenugreek Gel as a Topical Anti-Inflammatory Agent

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ABSTRACT

This study focused on the development and evaluation of a topical gel containing Trigonella foenumgreacum seed extract, formulated with carbopol-934 and HPMC K4M as gelling agents, to explore its anti-inflammatory potential.

Gel formulations containing carbopol-934 and HPMC K4M were prepared, evaluated for their physicochemical properties, and subjected to in vitro permeation studies to determine the optimal formulation.

The gel formulation prepared with a combination of carbopol-934 and HPMC K4M demonstrated the highest drug release rate, with 88.02±0.06% of the drug released after 8 hours in the in vitro release study.

The anti-inflammatory efficacy of the fenugreek gel formulation containing a combination of carbopol-934 and HPMC K4M was evident from its ability to reduce paw edema by 57.78% relative to the control group 3 hours post-carrageenan injection.

The results indicate that fenugreek, when formulated as a topical gel, has considerable anti-inflammatory potential, suggesting its utility as an effective treatment for acute inflammatory disorders.

Keywords: Gels, Ethanolic extract, Anti-inflammatory activity

I. INTRODUCTION:

Anti-inflammatory topical gels work by the same process as orally taken NSAIDs. They reduced pain and inflammation by blocking the production of enzymes.That Produce inflammatory chemicals therefore pain and swelling.

Herbal gel is a semi solid ,jelly like substance that can have properties ranging from soft and weak to hard preparation.Topical drug delivery systems are gaining increased in popularity, and several drugs have been successfully delivered by this route for both local and systemic action. Gels have better potential as a vehicle to administer drug topically in comparison to the ointment because they are non-sticky, requires low energy during formulation.

Drugs is applied topically to the skin, mainly for local action. Drugs applied to the skin for local effect include anti-septic, anti-fungal and anti-inflammatory agents. Delivering of drugs through the skin can be advantageous by avoiding first pass metabolism. Topical drug delivery treats a local disorder and aims to retain the active pharmaceutical ingredient within the skin. Skin is a complex multi-layered membrane but the outermost layer, the stratum corneum, provides the principal barrier to drug delivery. Inflammation is the body's initial response to injury and involves both cellular and vascular response. The release of histamine and no. of other cell mediated factors into the wound results in vasodilation, increased capillary permeation and stimulation of pain receptors.

Aim:

To formulate and evaluate a topical Fenugreek gel as an anti-inflammatory agent for potential use in managing inflammatory skin conditions.

Objectives:

1. To extract and characterize the bioactive compounds from Fenugreek seeds.
2. To formulate a topical gel using the extracted Fenugreek bioactive compounds.
3. To evaluate the physical and chemical properties of the formulated gel, including its texture, viscosity, pH, and stability.
4. To investigate the in vitro anti-inflammatory activity of the formulated gel using relevant bioassays.
5. To assess the in vivo anti-inflammatory efficacy of the formulated gel using animal models.

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6. To evaluate the safety and tolerability of the formulated gel in terms of skin irritation and allergic reactions.

Here are the materials and requirements for the formulation and evaluation of Fenugreek gel as a topical anti-inflammatory agent:

Materials Requirements:

1. Fenugreek seeds: Dried Fenugreek seeds will be used for extraction.
2. Solvents: Ethanol, methanol, or water will be used for extraction.
3. Gelling agents: Carbomer, sodium alginate, or xanthan gum will be used to form the gel.
4. Preservatives: Parabens, phenoxyethanol, or potassium sorbate will be used to prevent microbial growth.
5. pH adjusters: Citric acid or sodium hydroxide will be used to adjust the pH of the gel.
6. Viscosity modifiers: Glycerin or propylene glycol will be used to adjust the viscosity of the gel.
7. Anti-inflammatory agents: Hydrocortisone or diclofenac will be used as reference standards.

Equipment

1. Extraction equipment: Soxhlet apparatus, rotary evaporator, or ultrasonic extractor.
2. Mixing equipment: Mixer, homogenizer, or stirrer.
3. Heating and cooling equipment: Water bath, thermometer, or heating mantle.
4. pH meter: To measure the pH of the gel.
5. Viscosity meter: To measure the viscosity of the gel.
6. Texture analyzer: To evaluate the texture of the gel.
7. Spectrophotometer: To measure the absorbance of the gel.

METHODS:

Preparation of ethanolic extract of fenugreek.

The seeds of Trigonella foenumgreacum were obtained from local
market which was identified, Seeds were, pulverized, sieved through 40 mesh to obtain a coarse powder.

Hundred grams of powdered seeds were extracted with ethanol as a
solvent by hot extraction method using soxhlet apparatus. The
resulting extract was cooled and filtered. The filtrate was evaporated
in vacuum to give a residue.

Preparation of gel formulations:(Antinflammtory Activity)

Various gel formulations were prepared from fenugreek seed extract using carbopol-934 alone, HPMC K4M alone and a mixture of
carbopol-934, HPMC K4M as gelling agents. Gels were prepared by
cold mechanical method . Required
quantity of polymer (carbapol-934, HPMC K4M) was weighed individually, and sufficient amount of distilled water were mixed in a
separate beaker, after which it was continuously stirred by
mechanical stirrer till the polymer is soaked in the water and kept
for 24 h at room temperature.
With continuous stirring, now the appropriate quantity of methyl
paraben and propyl paraben was added which acts as a preservative. Small quantities of triethanolamine were added with continuous stirring to achieve neutral pH.Finally extract was added to gel with continuous stirring till drug get dispersed
completely. The prepared gel was filled and sealed in thealuminium collapsible tube. A similar procedure was followed for base control gel without the extract.

Evaluation of gel formulations:

Prepared formulations were evaluated for various physicochemical parameters such as colour, homogeneity,pH,spreadability, viscosity and drug content (total phenolic content).

Measurement of pH:

5 gm of gel formulation was dispersed separately in 45 ml of water,and the pH of the suspension was determined using digital pH meter .Measurements of pH of all formulations were carried out in triplicate and the averages of three readings were noted 8.Homogeneity Formulations were tested for homogeneity by visual inspection after the formulations have been set in the container. They were tested for their appearance and presence of any aggregates.

Measurement of viscosity:

The viscosity of the formulation was determined by using a Brookfield viscometer .At 20 rpm at a temperature of 25’c and the determination were carried out in triplicate and the average of three readings are recorded.

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Phase separation:

The formulation gel was intact in a close container at 25-30°C not exposed to light. Phase separation was observed carefully every 24 hrs. Any change in phase separation was checked.

Spreadability:-

Take two slides to slip off from the gel, placed in between the slides, under certain load.
Lesser the time taken for separation of two slides, better the spreadability.
S = M.L / T
M = wt. Tied to upper slide
L = length of glass slide
T = time taken to separate the slides

Evaluation Table:

TEST	OBSERVED
ph	5.75 to 6.05
Viscosity	4520cp
Phase separation	No
Spreadability	22g.cm/sec

II. DISCUSSION:

All physicochemical evaluation parameter of gel formulation from the result evident that all three gelformulation having good gelling property and homogenicity. The pH of all three formulations ranged between 5.75 to 6.05 which is acceptable for topical formulation.

The extrudability of gel formulation from the collapsible tube varied from 70-76 g/cm2 whereas the results of spreadability varies from 22 to 27 g.cm/sec. A comparative study of viscosity and spreadability showed that the viscosity of the formulations increases, spreadability decreases and vice versa. From the results, it is clearly evident that all three optimized formulation showed good extrudability, homogenecity, viscocity and spreadability.

The developed gel formulations were subjected to stability study as per ICH guidelines for the period of three months. By observing that effect of aging,viscosity, pH, spreadability, extrudability, it was confirmed that thedeveloped gel posses good stability. It was observed that slight phase separation of F2 occurring at 40°C temperature. Other formulations showed good stability. The pH was constant throughout the study to about 6.5 and the gel did not produce any irritation upon application to the skin. The drug content uniformity of the gels were found in the range of 82-92%, Formulation contain more drug content as compared to other two gel formulations. Shows greater drug release 57.2% as compared with drug release which is 56.2% in 5hr.

III. CONCLUSION:

This research work is carried out to develop a new topical herbal gel formulation for topical application. The prepared herbal gel was further evaluated for pH, Viscosity and extrudability, Spreadability, Drug content uniformity, In-vitro diffusion study, and stability Studies. The pH of all the formulations was in the range compatible with normal pH range of the skin. The drug content released was also above average.The rheological behaviors of the gel formulations were studied with Brookfield viscometer. The results indicated the viscosity of gel formulations was consistant neither too thick nor too thin.

A comparative study of viscosity and Spreadability showed that with increase in viscosity of the formulation, the Spreadability decreased and vice versa. The gel formulation was found to have all the desirable properties.

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