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FORMULATION AND EVALUATION OF *PIMENTA DIOICA* BASED TOPICAL GEL FOR ANTI INFLAMMATORY ACTIVITY

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Abstract — The present study aims to formulate and evaluate a topical gel containing Pimenta dioica extract for anti-inflammatory activity. The extract was incorporated into a suitable gel base using polymers such as carbopol, along with necessary excipients like preservatives, humectants, and neutralizing agents. The prepared gel formulations were evaluated for various physicochemical parameters including appearance, pH, viscosity, spreadability, homogeneity, stability, anti inflammatory activity and anti oxidant activity.

Keywords: Pimenta dioica, Eugenol, Topical gel, Anti-inflammatory activity, Herbal formulation.

1. INTRODUCTION

Inflammation is a natural protective response of the body to injury, infection, or irritation. It helps in eliminating harmful stimuli and initiating the healing process. However, prolonged or excessive inflammation can lead to various chronic diseases such as arthritis, skin disorders, and cardiovascular conditions. Conventional anti-inflammatory drugs like non-steroidal anti-inflammatory drugs (NSAIDs) are widely used, but they may produce side effects such as gastric irritation, ulceration and kidney damage. Hence, there is a growing interest in the use of herbal medicines as safer alternatives.[1]

Medicinal plants have been used for centuries in traditional systems of medicine due to their therapeutic benefits and minimal side effects. Among these, Pimenta dioica, commonly known as allspice, is an important medicinal plant belonging to the family Myrtaceae. It is widely used in traditional medicine for its analgesic, anti-inflammatory, antimicrobial and antioxidant properties. The major active constituent present in Pimenta dioica is eugenol, which is responsible for its pharmacological activities. Eugenol exhibits significant anti-inflammatory effects by inhibiting the synthesis of inflammatory mediators such as prostaglandins and cytokines.[2]

2. TOPICAL GEL

Topical gels are semisolid dosage forms that are applied to the skin or mucous membranes for local or systemic effects. They consist of a liquid phase entrapped within a three-dimensional network of gelling agents, forming a clear or translucent preparation. Gels are widely used in pharmaceutical and cosmetic formulations due to their ease of application, better patient compliance and non-greasy nature. They are particularly useful for delivering drugs for conditions such as inflammation, pain, acne and infections.[3]

3. PIMENTA DIOICA LEAVE EXTRACT

Pimenta dioica, commonly known as allspice, is a medicinal plant belonging to the family Myrtaceae. The leaves of Pimenta dioica are widely used in traditional medicine due to their therapeutic properties. They contain various bioactive compounds such as eugenol, flavonoids, tannins and essential oils, which contribute to their pharmacological activities.[4]

Fig 1: pimenta dioica leaves

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4. MATERIALS AND METHODS

Table 1: Ingredients and Their Role:

S.NO	INGREDIENTS	ROLE
1	Carbopol 940	**Gelling agent**
2	Glycerine	humectant
3	Propylene glycol	Penetration enhancer
4	Ethanol	Solvent and enhancer
5	Triethanolamine	Ph adjuster
6	Distilled water	Vehicle

5. FORMULATION OF TOPICAL BASED GEL

5.1 Preparation of extract

5.2 Preparation of gel base

5.1 PREPARATION OF PLANT EXTRACT

STEP 1: Plant collection and preparation

Leaves of pimenta dioica was collected, washed, shade dried.

STEP 2: Preparation of Plant Extracts

Pimenta dioica leaves were air dried and ground into a powder. In a stopped container, 250 g of the powdered material was added to 1000 ml of solvent (ethanol) and stirred frequently for a certain amount of time until the soluble stuff was dissolved. After distillation, the extracts were concentrated and the solvents were retrieved after maceration for 72 hours.

STEP 3: Preparation of Gel Base

Carbopol-940 was added gradually by stirring in 60ml of water to avoid agglomerates. It is continuously stirred for 1 hour. 10ml of disodium edetate and 2ml of triethanolamine were added and stirred for 10 minutes. The mixture of 5 ml of propylene glycol and 12 ml of water was prepared and stirred for 10 minutes. The propylene glycol solution is added to the Carbopol solution and stirred for 10 minutes to get a clear, uniform gel base.[5]

5.2 PROCEDURE

5.2.1 Formulation of topical gel

Two batches of gel formulations were prepared each containing 5g dried powder of pimenta dioica and Carbopol 940 polymer concentration ranging from 1 to 2.5%. Carbopol is added as a gelling agent in the extract as it is bio-adhesive, non-biodegradable, irritation-free, biocompatible and non-absorbable in the body Propylene glycol is said to be one of the best permeability enhancers. Sufficient quantity of methyl paraben and propylparaben were added as preservatives. The pH of the gel is adjusted using disodium edetate and triethanolamine.[6]

S.NO	NAME OF INGREDIENT	B1	B2
1.	Carbopol 940	1%	1%
2.	Leaf powder	-	5g
3.	Propylene glycol	5ml	5ml
4.	Methyl paraben	q.s	q.s
5.	Propyl paraben	q.s	q.s
6.	Di sodium edetate	10 ml	10ml
7.	Tri ethanolamine	2ml	2ml

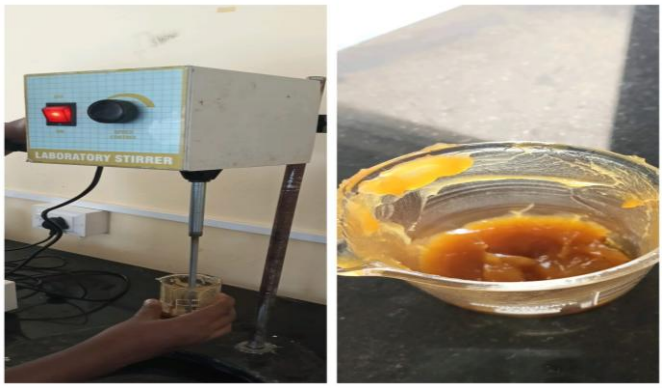

Fig 2: pimenta dioica gel

6. EVALUATION OF FORMULATED GEL

6.1 Appearance and Homogeneity

Physical appearance and homogeneity of the prepared gels were evaluated by visual perception.

6.2 Spreadability

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 the top of the gel, such that the gel was sandwiched between the two slides in an area occupied by a distance of 7.5 cm along the slides. Hundred g weight of gel was placed on the upper slides so that the gel was between the two slides was pressed uniformly to form a thin layer.

Spreadability was calculated by using the following formula:

S= m × l/t

where,

S= spread ability,

m-weight tied to upper slides (20 g),

l- length of the glass slide (7.5 cm),

t- time taken in sec.

6.3 Extrudability

A closed collapsible tube containing about 20 g of gel was pressed firmly at the crimped end and a clamp was applied to prevent any roll back. The cap was removed and the gel was extruded. The amount of the extruded gel was collected and weighed. The percentage of the extruded gel was calculated .The estimated extruded gel % was evaluated based on the following standard values:

- Excellent (Extrudability above 90%),
- good (Extrudability above 80%) and
- fair (Extrudability above 70%).

6.4 pHmeasurement

pH 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.[7]

6.5 Anti inflammatory activity

Its ability to reduce inflammation such as pain, swelling, and redness.

6.5.1 PROCETURE

1 ml of extract,1 ml of 1% egg albumin solution and add phosphate buffer Incubate the mixture at 37°C for 15 minutes.Heat the mixture at 70°C for 5 minutes.This causes protein denaturationAllow the samples to cool to room temperature[8]

6.6 ANTIOXIDANT AVTIVITY- DPPH ASSAY

DPPH (2,2-Diphenyl-1-Picryl-Hydrazyl- Hydrate) Assay

antioxidant activity by reacting DPPH free radical with a plant extract.Greater color change indicates higher antioxidant activity**.** Measure absorbance using UV spectrophotometer at 660 nm.

6.6.1 Procedure:

Prepare DPPH solution in methanol and Take 500 µl sample, Add 500 µl DPPH such as added a Mix and keep for 30 min and such as Measure absorbance at 520 nmand Use ascorbic acid as standard.Calculate % inhibition and IC_{50}. [9]

7. RESULT AND DISCUSSION

7.1 Physiochemical parameters

PARAMETERS	OBSERVATION
Formulation	Topical gel
Apperance	Smooth
Colour	Yellowish brown to dark brown
Odour	Aromatic
Homogenicity	Homogenous

7.2 Evaluation parameters

PARAMETERS	OBSERVATION
pH	6.2-6.8
Extrudability	Good(120-160g/cm^2)
Spreadability	18-25.c/sec

7.3 ANTI INFLAMATORY ACTIVITY FOR EGG ALBUMIN DENATURATION METHOD

Anti-Inflammatory Activity Ic_{50} Value (mg/ml) compared to Standard Diclofenac Sodium Ic_{50} Value (mg/ml)

S.NO	Concentration (mg)	Average (%)	$IC_{50\ (mg/ml)}$
Plain Gel			
1	50 mg	64%	120.00 mg/ml
2	100 mg	60%	
3	150 mg	50%	
Gel Extract			
1	50 mg	62%	123.07 mg/ml
2	100 mg	57%	
3	150 mg	46%	
Standard Diclofenac sodium			
1	50 mg	91%	**121.29 mg/ml**
2	100 mg	93%	
3	150 mg	85%	
4	200 mg	89%	
5	250 mg	88%	

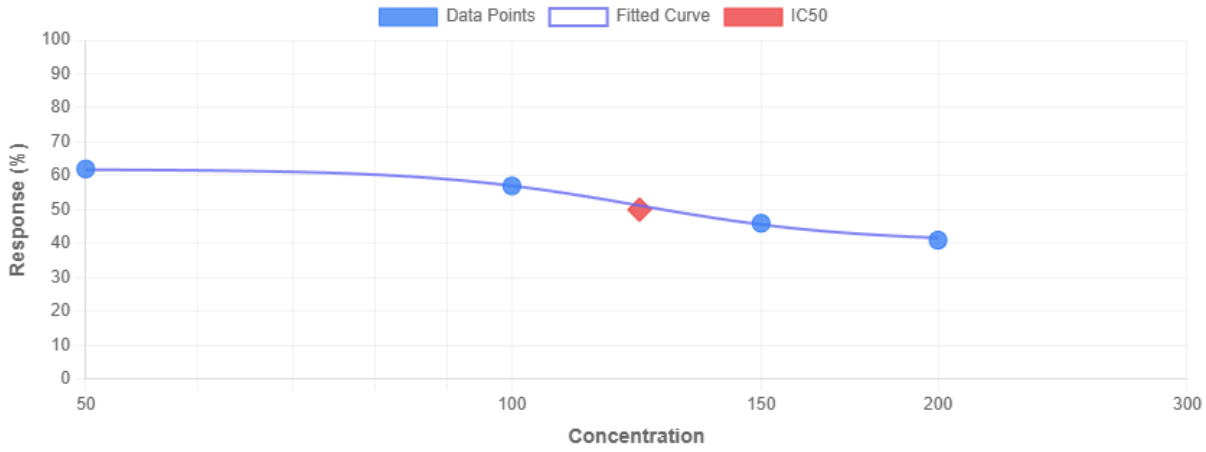

Fig 2: Gel Extract Anti-Inflammatory Activity Ic_{50} Value (mg/ml)

7.4 Antioxidant activity IC_{50} value (mg/ml) compared to standard VIT C IC_{50} value (mg/ml)

S.NO	Concentration (mg)	Average (%)	$IC_{50\ (mg/ml)}$
Plain Gel			
1	50 mg	70%	103.48 mg/ml
2	100 mg	78%	
3	150 mg	85%	
Gel Extract			
1	50 mg	77%	99.99 mg/ml
2	100 mg	83%	
3	150 mg	89%	
Standard Ascorbic acid vitamin C			
1	50 mg	91%	**33.7334 mg/ml**
2	100 mg	87%	
3	150 mg	86%	
4	200 mg	92%	
5	250 mg	84%	

8. DISCUSSION

The present study demonstrated that the formulated Pimenta dioica topical gel possessed desirable physicochemical and therapeutic properties. The gel showed good physical appearance with a homogeneous and translucent nature, indicating proper formulation. It exhibited satisfactory spreadability and extrudability, ensuring ease of application and patient compliance. The antioxidant activity confirmed the presence of active constituents capable of scavenging free radicals. Furthermore, the gel showed significant anti-inflammatory activity, supporting its effectiveness in reducing inflammation. Overall, the formulation was found to be stable, effective and suitable for topical drug delivery.

9. CONCLUSION

The formulated Pimenta dioica herbal gel showed good anti-inflammatory and antioxidant activity.All evaluation parameters like pH, spreadability and viscosity were within acceptable limits.The gel was stable, easy to apply and suitable for skin use. Hence, it can be considered as an effective herbal topical formulation.

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