

A RESEARCH ON: DEVELOPMENT AND FORMULATION AND EVALUATION OF HERBAL GEL FOR THE TREATMENT OF HEMORRHOIDS

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ABSTRACT

Hemorrhoids are swollen and inflamed veins in the rectal and anal region that cause pain, bleeding, itching, and discomfort. The condition is commonly associated with chronic constipation, pregnancy, prolonged sitting, and increased intra-abdominal pressure. Conventional treatments provide symptomatic relief but may produce side effects on prolonged use. Therefore, the development of a safe and effective herbal formulation is of significant interest. The present study focuses on the formulation and evaluation of a herbal gel for the treatment of hemorrhoids using plant-based ingredients such as Aegle marmelos, Aloe vera, and Azadirachta indica, known for their anti-inflammatory, wound healing, antimicrobial, and soothing properties. The extracts were incorporated into a Carbopol 934 gel base to prepare a topical formulation suitable for rectal application. The prepared herbal gel was evaluated for various physicochemical parameters including pH, viscosity, spreadability, homogeneity, drug content, extrudability, and in-vitro diffusion study. Stability studies were also conducted to ensure formulation integrity. The results indicated that the gel possessed acceptable physical characteristics, good spreadability, skin-compatible pH, and satisfactory drug release profile. The developed herbal gel may serve as a safe, effective, and economical alternative for the management of hemorrhoids with minimal side effects and improved patient compliance. Further clinical studies are recommended to confirm its therapeutic efficacy.

KEYWORDS: Hemorrhoid, herbal gel, polyherbal formulation, phytochemical constituent, stability study.

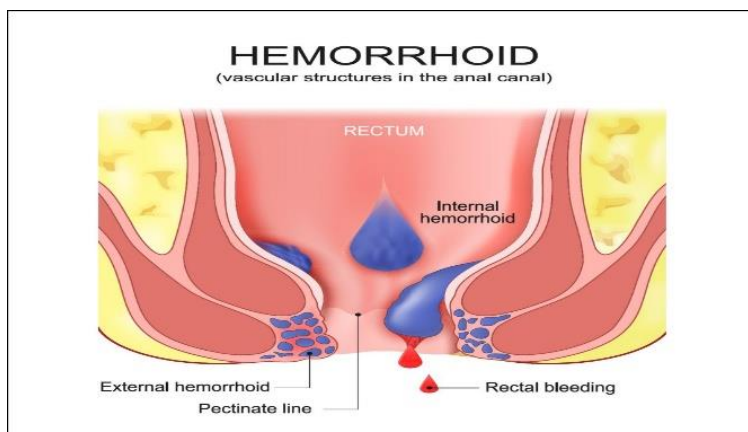


Fig: Hemorrhoid.

INTRODUCTION

Hemorrhoids, commonly known as piles, are swollen and inflamed veins in the lower rectum and anus that cause pain, itching, irritation, bleeding, and discomfort during defecation. They are classified as internal or external depending on their location. The condition is commonly associated with chronic constipation, prolonged straining, sedentary lifestyle, pregnancy, obesity, and low-fiber diet. Although not life-threatening, hemorrhoids significantly affect the quality of life. Conventional treatment options include topical corticosteroids, anesthetics, vasoconstrictors, and surgical procedures in severe cases. However, long-term use of synthetic drugs may lead to side effects such as skin thinning, irritation, and recurrence of symptoms. Therefore, there is growing interest in herbal formulations due to their safety, effectiveness, and minimal adverse effects. Medicinal plants such as *Aegle marmelos*, *Aloe vera*, and *Azadirachta indica* possess anti-inflammatory, antimicrobial, wound healing, and soothing properties that make them suitable for hemorrhoidal management. Herbal extracts can reduce inflammation, promote tissue repair, relieve pain, and prevent infection in the affected area.

Topical gel formulations are widely preferred for anorectal conditions because they provide localized action, easy application, rapid absorption, and improved patient compliance. Gels are non-greasy, easily washable, and capable of delivering active constituents directly to the site of action. The present study focuses on the development, formulation, and evaluation of a herbal gel for the treatment of hemorrhoids. The formulation is designed to ensure optimal consistency, stability, spreadability, and therapeutic effectiveness. Various physicochemical and performance parameters are evaluated to determine the quality and efficacy of the developed herbal gel.

RATIONALE FOR HERBAL GEL

1.1. Advantages

- Low side effects and safe.
- Improved feel and texture.
- Fit for skin that is sensitive.
- Antimicrobial and anti-inflammatory qualities.
- Increased stability

1.1.2. Disadvantages

- A delayed start to action
- The possibility of allergic responses or discomfort.
- The possibility of contamination
- Quality assurance and standardization
- A problem with stability

1.1.3. Scope

- The synergistic benefits of the individual qualities of turmeric, Beal, Neem and Aloe vera make a combined herbal gel containing these three plants very promising for improved anti-inflammatory activity. Although the medicinal properties of each plant are well recognized, combining them can result in a more effective and thorough treatment.
- Work on such a polyherbal gel is necessary because it has the potential to be a safe, practical, and affordable substitute for synthetic wound care solutions.
- Traditional Validation: Traditional Indian medicine has long used Aegle marmelos and Turmeric to treat anti-inflammatory and wound healing.
- Natural Alternative: This study is still relevant in the twenty-first century since there is a growing interest in creating natural, plant-based medicines to lessen the negative effects of synthetic pharmaceuticals.
- Cost-Effectiveness: Herbal remedies may be a less expensive way to treat anti inflammatory activity

AIM

To formulate and evaluate a herbal gel containing extracts of Aloe vera, Azadirachta indica, Curcuma longa, and Aegle marmelos for the effective treatment of hemorrhoids.

OBJECTIVES

1. To select suitable herbal ingredients with anti-inflammatory, antimicrobial, and healing properties.
2. To prepare herbal extracts using appropriate extraction methods.
3. To formulate the herbal gel using suitable gelling agents.
4. To evaluate physicochemical parameters.
5. To study stability of the formulation under different conditions
6. To assess safety and effectiveness of the gel
7. To develop a safe, natural, and cost-effective formulation for hemorrhoids treatment.

INTRODUCTION OF HEMORRHOIDS DISEASE

Hemorrhoids (piles) are swollen and inflamed vascular structures in the anal and rectal region. They are one of the most common anorectal disorders affecting people of all age groups. Hemorrhoids occur due to increased pressure in the lower rectum, leading to dilation of veins.

Common symptoms include

Pain and discomfort
Bleeding during defecation
Itching and irritation
Swelling around the anus

Hemorrhoids are classified into

Internal hemorrhoids (inside rectum)
External hemorrhoids (under skin around anus)
Prolapsed hemorrhoids (protruding outside)

PATHOPHYSIOLOGY OF HEMORRHOIDS

- Hemorrhoids develop due to abnormal enlargement and displacement of anal vascular cushions.
- Step-wise Mechanism:
 - Increased Pressure
 - Causes: constipation, straining, pregnancy, prolonged sitting
 - Leads to increased pressure in rectal veins
 - Venous Dilation
 - Veins in the hemorrhoidal plexus become swollen and enlarged
 - Weakening of Supporting Tissue
 - Connective tissue supporting veins becomes weak
 - Leads to prolapse of hemorrhoids
 - Inflammation
 - Swollen veins cause irritation and inflammation
 - Results in pain and itching
 - Bleeding
 - Fragile blood vessels rupture during defecation
 - Causes bright red bleeding.

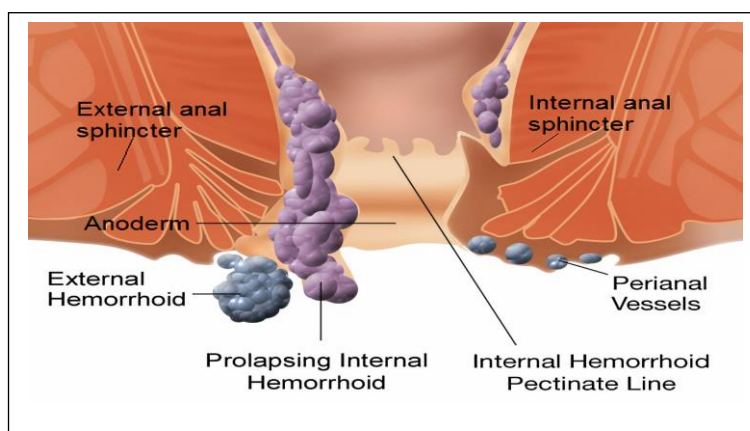


Fig: Pathophysiology of Hemorrhoids

PLANT PROFILE

Turmeric plant

Turmeric is a perennial herbaceous plant that is used extensively as a spice, dye, and medicinal herb because of its orange-yellow rhizomes. Approximately one meter (3 feet) in height, the plant has long, oblong leaves and pale-yellow flowers that emerge from a spike in the shape of a funnel.

Medicinal: Contains curcumin, known for anti-inflammatory and antioxidant properties; used in traditional medicine for digestion, skin health, and wound healing.



Fig. 1: Turmeric Rhizomes.

- * Botanical name – *curcuma longa*
- * Kingdom – plantae
- * Family- zingiberacea
- * Genus – curcuma
- * Common name – turmeric, golden spice
- * Class -Liliopsida
- * Order-zingiberales

Table 1: Characteristics and Properties of Turmeric Plant.

source	The substance was extracted from the rhizomes of the perennial plant turmeric (<i>Curcuma longa</i>).
Pharmacological properties	<ul style="list-style-type: none"> - Anti-inflammatory - Antioxidant - Anticancer (potential) - Antimicrobial - Neuroprotective
Therapeutic uses	<ul style="list-style-type: none"> - Arthritis management - Digestive disorders - Cancer prevention - Alzheimer’s disease (under study) - Wound healing
Chemical constituents	60–70% carbohydrate, 6–8% protein, 5–10% fat, 3–7% minerals (potassium, sodium, calcium, iron)

2. Aegle Marmelos

Bael is a medium-sized deciduous tree widely used in traditional medicine due to its medicinal and digestive properties. The fruit has a hard shell with aromatic pulp and is commonly used for treating gastrointestinal disorders.

Medicinal: Contains tannins and marmelosin, known for anti-inflammatory, astringent, and laxative properties; used for constipation, diarrhea, and hemorrhoids.



Fig 2: Bael Fruit.

Botanical name – *Aegle marmelos*

Kingdom – Plantae

Family – Rutaceae

Genus – *Aegle*

Common name – Bael, Bengal quince

Class – Magnoliopsida

Order – Sapindales

Table 2: Characteristics and Properties of *Aegle marmelos*.

Source	The substance is obtained from the fruit pulp, leaves, and bark of Bael plant
Pharmacological properties	Anti-inflammatory Astringent Laxative Antimicrobial
Therapeutic uses	Constipation relief Hemorrhoids treatment Diarrhea and dysentery Digestive disorder
Chemical constituents	Tannins Flavonoids Coumarins (marmelosin) Alkaloids Pectin

3 Neem Plant

Neem is a fast-growing evergreen tree known for its broad-spectrum medicinal properties. It is widely used in Ayurveda for treating infections and skin disorders.

Medicinal: Contains azadirachtin and nimbin, known for antimicrobial, antifungal, and anti-inflammatory properties; used for skin diseases and wound.



Fig 3: Neem Leaves.

Botanical name – *Azadirachta indica*

Kingdom – Plantae

Family – Meliaceae

Genus – *Azadirachta*

Common name – Neem

Class – Magnoliopsida

Order – Sapindales

Table 3: Characteristics and Properties of Neem Plant.

Source	Extracted from leaves, bark, and seeds of Neem plant
Pharmacological action	Antimicrobial Anti-inflammatory Antifungal Antioxidant
Therapeutic uses	Skin infections Wound healing Anti-acne treatment Hemorrhoids (prevents infection)
Chemical constituents	Azadirachtin Nimbin Nimbidin Flavonoids Tannins

4. Aloe vera Plant

Aloe vera is a succulent plant with thick fleshy leaves containing a clear gel, widely used in cosmetics and medicine for its soothing properties.

Medicinal: Contains aloin and acemannan, known for anti-inflammatory, moisturizing, and wound healing properties; used for burns, skin irritation, and healing.



Fig 4: Aloe vera Leaves.

Botanical name – Aloe vera

Kingdom – Plantae

Family – Liliaceae / Asphodelaceae

Genus – Aloe

Common name – Aloe vera, Ghritkumari

Class – Liliopsida

Order – Asparagales

Table 4: Characteristics and Properties of Aloe vera.

Source	Extracted from the inner gel of Aloe vera leaves
Pharmacological action	Anti-inflammatory Wound healing Antimicrobial Moisturizing
Therapeutic uses	Burns and wounds Skin irritation Hemorrhoids (soothing effect) Cosmetic applications
Chemical constituents	Aloin Aloe-emodin Anthraquinones Polysaccharides (acemannan) Vitamins and minerals

MATERIALS AND METHODS

PLANT MATERIALS

- Dried fruits of Bael
- Fresh leaves of Neem
- Fresh aloe vera gel

EXICIPIENTS

- Carbapol 934
- Triethanolamine
- Propylene glycol
- Methyl Paraben
- Distilled water

FORMULATION TABLE

SR. NO	INGREDIENT	QUANTITY(% w/w)	QUANTITY (g)	CATEGORY
1	Extract of Aegle marmelos	2%	2g	Anti-inflammatory
2	Edxtract of Azadirachta indica	2%	2g	Antimicrobial agent
3	Fresh gel of aloe vera	5%	5g	Soothing & Wound healing
4	Carbapol 934	1%	1g	Gelling agent
5	Propylene glycol	10%	10g	Humectant
6	Methyl Paraben	0.2%	0.2g	Preservatives
7	Triethanolamine	q.s	q.s	pH adjuster
8	Distilled Water	q.s to 100%	Up to 100 g	Vehicle

Development and Formulation Considerations of the Herbal Gel**Material and Methods****Plant Materials**

Aegle marmelos, turmeric, neem aloe vera

Chemicals and Reagents

Solvents for Extraction: Ethanol, methanol, distilled water etc.

Gel Base Components

- * HPMC: Gelling agent to provide viscosity and structure.
- * Propylene Glycol: Humectant and solvent to enhance spreadability.
- * Triethanolamine: pH adjuster to maintain skin-compatible pH (6.8–7.0).
- * Benzyl alcohol: Preservatives to ensure shelf stability.

Equipment

- * Maceration setup for extraction.
- * Rotary evaporator or vacuum oven for solvent removal.
- * pH meter for adjusting gel pH.
- * Magnetic stirrer for uniform gel mixing.
- * Analytical balance for precise measurements.
- * Sterile containers for gel storage.

Method of preparation**Step 1: Phase: 1**

Step1-Collection and Authentication of Plant Materials Curcuma longa rhizomes were collected from the Samarth Gurukul campus's Samarth Rural Educational Institution.

The local area, the nearby area, and our hamlet near Pune in Maharashtra were the sources of the aegle marmelos and neem and aloe vera.

Additionally, the physiochemical properties, foaming index, moisture content, and organoleptic characterisation will be examined.

Step 2: Preparation of Plant Extracts

* Drying and Pulverization The herbs are dried, cleaned, and then chopped into smaller bits to maximize the extraction surface area. It's crucial to dry the turmeric leaves and rhizomes since excessive moisture can interfere with the extraction process. The herbs should be shade-dried for two to three weeks before being ground into a fine powder.

* Extraction by Maceration:

Depending on the kind of substance, choose the right solvent for the extraction process, such as ethanol, methanol, or water. To increase surface area, cut or dry the leaves of Azadirachta indica and, as well as the turmeric, aloe vera, aegle marmelos rhizomes, into small pieces. Separately place the prepared herb in sanitized glass containers or jars. Cover the plants with enough ethanol to completely submerge them. A typical ratio is between 1:5 and 1:10. After sealing and stirring, let the maceration process run for 7–14 days, shaking the jar gently each day. After that, concentrate and filter the solution.

Step 3: Phytochemical Screening

Lastly, the phytochemical tests of the extracts of all herbs were conducted, and they were stored in an appropriate manner to ensure their stability.

Test for Alkaloids-(Mayer's Test) after adding two milliliters of concentrated HCL to around two milliliters of extract, Mayer's reagent was applied drop by drop. The presence of alkaloids is shown by the production of white precipitate.

Test for Saponin:- (Foam Test)- Mix 1 gram of the sample material with 10–20 milliliters of water, mix well, and watch for froth to form. The presence of saponins is shown by the foam's stability for a predetermined period of time, such as 60–120 seconds or more.

Test for Tannins- (Ferric Chloride Test) A brownish green or blue-black colouring, which denotes the presence of tannins, was seen when 0.1% ferric chloride solution was added to 1 milliliter of the extract.

Test for Terpenoids(Salkowski's Test) -Approximately 1 milliliter of the extract and 2 milliliters of chloroform were obtained, and then 5 milliliters of concentrated H₂SO₄ were added along the test tube sides. Terpenoids are present when a reddish-brown hue forms in the interphase.

Test for Phenolic Compounds (Bromine water Test)-. Drop by drop, add bromine water after dissolving the organic chemical in a suitable solvent, such as water or glacial acetic acid. The production of a white 2,4,6-tribromophenol precipitate and the elimination of the reddish-brown color of the bromine water suggest a successful outcome.

Test for Polysaccharides (Molisch's Test)- In a test tube with 2 mL of the sample, add a few drops of Molisch's reagent (alpha-naphthol in ethanol), stir, and then carefully add roughly 1 mL of concentrated sulfuric acid down the side to create a noticeable lower layer. When there is a purple or violet ring at the intersection of the two layers, it indicates the presence of carbs and is a favorable outcome.

Step 4: Preparation of Gel Base

To ensure effective hydration, HPMC must be dissolved in hot water, usually between 70°C and 90°C. Next, add the remaining cold water gradually while swirling constantly, as you would with a magnetic stirrer. A cooling bath, such as a water bath, is made by appropriately mixing the gel basis.

Step 5: Final Mixing and Homogenization Following the preparation of the HPMC gel basis, the remaining water was added, followed by the preservative propylene glycol and benzyl alcohol in the leaf extract. To bring the pH down to 7, triethanolamine was then added while being continuously stirred. The last preparation is complete

EVALUATION PARAMETERS FOR HERBAL GEL

➤ **Physicochemical Properties:**

- **Physical Appearance:** Through visual inspection, the color uniformity of each herbal gel formulation was verified.
- **pH:** A 1% aqueous solution of the generated gel formulations was measured using a pH meter
- **Homogeneity:** Herbal gel is examined visually. Through visual inspection, the color uniformity of each herbal gel formulation was verified. Keep an eye out for any indications of an uneven distribution of herbal extracts or additions, such as visible particles, color fluctuations, or uneven texture.
- **Spreadability:** The necessary quantity of sample is placed between two glass slides, and after five minutes, a 1-gram weight is attached to the slides, and the spreadability is examined.
- **Viscosity:** The measurements of viscosity of the gels was done with DV-I Brookfield viscometer and the corresponding reading was noted.
- **Skin Irritation Test Patch Testing:** Usually done on the back or forearm, this entails putting a tiny bit of the herbal gel to a small patch of skin and watching for any quick reactions, such as swelling, redness, or itching.
- **Washability:** Formulation was applied on skin and then ease of extent washing with water was checked.
- **Stability Test:** For weeks, the herbal gel's physical stability was assessed at different temperatures, ranging from 2 °C to 37 °C. It was discovered that the herbal gel was physically stable throughout a range of temperatures.

RESULTS AND DISCUSSION

The formulated herbal gel showed smooth texture, uniform consistency, and good homogeneity. The pH was found within the range of 5.5–6.5, which is suitable for skin application. Viscosity and spreadability were satisfactory, ensuring easy application. In-vitro diffusion studies demonstrated sustained release of active constituents. Stability studies indicated no significant change in physical characteristics, confirming formulation stability. The presence of anti-inflammatory and wound-healing phytoconstituents supports its potential therapeutic effectiveness in hemorrhoidal treatment.

CONCLUSION

The herbal gel formulated with bael, aloe vera, and neem extracts exhibited satisfactory physicochemical properties and drug release characteristics. The formulation appears to be safe, stable, and effective for the topical management of hemorrhoids. Further clinical evaluation is recommended to confirm its therapeutic efficacy.

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