

## FORMULATION AND EVALUATION OF (*ABUTILON INDICUM*) GEL FOR ANTI-BACTERIAL ACTIVITY IN TREATMENT OF HEMORRHOIDS

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### ABSTRACT

Plant derived substance and herbal medicines have recently attracted the great interest towards their versatile application. The present work is described about the formulation and evaluation of herbal gel which containing (thuthi leaf) *Abutilon indicum* which having the antibacterial activity. The herbal ethanolic extract was prepared by maceration method. The gel base was prepared and formulations of gel were done by incorporating the extract in the base by levigation method. The final formulation it was evaluated for its physiochemical parameters such as colour, odour, spread ability, solubility, washability. It also the formulation was evaluated for its stability at various temperature conditions which shows no change in irritancy. So, it could become a medial to use the medicinal properties of *Abutilon* effectively and easily as simple dosage form.

**KEYWORDS:** Thuthi leaf, Antibacterial activity, Maceration method, Medicinal properties, Dosage form.

### 1.1 INTRODUCTION

Haemorrhoids are the bulging veins seen in the lower anus and rectal region. This swelling may trigger localized inflammation in other tissues. Haemorrhoids are also known as piles. The Haemorrhoids are split into two types: interior and exterior heaps. Internal Haemorrhoids form within the rectum and are typically

not noticeable on external inspection. The external Haemorrhoids is fundamentally different, and it may expand to extend outside of the anus. External Haemorrhoids generate tiny bumps on the exterior margin of the anus. They are extremely irritating and can be unpleasant if a blood clot forms because it can obstruct blood flow.

Grade I	The growth doesn't protrude from the anus and doesn't create any symptoms.
Grade II	Although they may prolapse from the anus, the hemorrhoids may return on their own.
Grade III	In the anus, the hemorrhoids prolapse and only go away with manual assistance.
Grade IV	It is impossible to push the hemorrhoids back into the anus once they prolapse outside of it.

### 1.2 CLINICAL MANIFESTATIONS

- Painful lumps in and around the anus
- Itching and discomfort around the anus
- Discomfort during and after passing stools
- Bloody stools
- Excessive anal bleeding, possibly leading to anaemia
- Infection

### 1.3 CAUSES

Haemorrhoids result from increased pressure in the lower rectum.

The blood vessels around the anus becoming swell due to under pressure and may swell or bulge, forming piles. This condition leads to:

- Chronic constipation
- Chronic diarrhoea

### 1.4 DIAGNOSIS

A digital rectal exam involves inserting a gloved, lubricated finger into the rectum to detect bulging veins. An anoscope (lighted tube) is used by your provider to examine the anus and rectum linings. Sigmoidoscopy involves using a lighted tube with a camera to observe the bottom (sigmoid) section of your colon and rectum.

### 1.5 TREATMENT

#### ➤ Non-surgical treatment

Medicines. Medications are often administered to alleviate symptoms such as discomfort, irritation, edema, and stool softening.

Topical therapies include creams, ointments, gels, and suppositories to alleviate pain. These drugs should only be used for 5 to 7 days at a time since they might irritate

the delicate skin of the anus. In the case of significant irritation in the anal area, corticosteroid cream containing steroids is frequently prescribed. Common drugs can help decrease pain piles.

#### ➤ Surgical treatment

- Inability to tolerate the hospital procedures.
- Large external hemorrhoids
- Failure of non-operative procedures
- Mixed hemorrhoids with prolapse
- Grade 3 and 4 hemorrhoids
- Coagulopathic patients requiring management of hemorrhoidal bleeding

### 1.7 PLANT PROFILE



Fig. 1: *Abutilon indicum*.

#### *Abutilon indicum* leaf

*Abutilon indicum* is a medicinal plant from the Malvaceae family, sometimes known as Thuthi or Atibala. This tall, woody, and shrubby plant is extensively spread in tropical areas. Indian traditional medicinal herbs include anti-inflammatory and antibacterial properties, making them effective in treating diseases such as Haemorrhoids.

The Thuthi plant has heart-shaped leaves with pointed tips and little yellow blooms. The plant is a perennial shrub that can grow to be 2 meters tall. Thuthi leaves are said to have significant medicinal properties. Our predecessors ate a lot of green vegetables because they knew they were good for them. There are several herbs and leaves that may be used to cure a variety of conditions, one of which is 'Thuthi'.

Thuthi leaves are commonly prepared or eaten raw, especially in Tamil Nadu. Every component of the plant is helpful to human health. Be it a flower, stalk, seeds, fruits, leaves, or roots. Thuthi Keerai is a common Tamil home treatment for constipation. Thuthi is commonly planted by the beach and along roadsides. It only grows to be 2 to 3 feet tall and comes in 29 distinct types, the most popular of which is 'paniyara thuthi'. It grows in India's hot temperate zones. The plant may be found in Southern India, Sri Lanka, tropical parts of America, and Malaysia.

### 1.8 TAXONOMICAL CLASSIFICATION

Biological name	<i>Abutilon indicum</i>
Kingdom	Plantae
Clade	Tracheophytes
Clade	Angiosperms
Clade	Eudicots
Cade	Rosids
Order	Malvales
Family	Malvaceae
Genus	Abutilon
Species	Indicum
Synonym	<i>Sida indica</i>

### 1.9 CHEMICAL CONSTITUENTS

Major chemical constituents. Hescoses, n-alkane mixes, alkanols, B-sitosterol, Vanillic, p-coumaric, acceic, fumaric, and amino acids, iso-alantolactone, etc. *A. indicum* has antioxidant and antibacterial activities. *A. indicum* and *A. Indicum* were examined for their antioxidant and antibacterial properties. The total antioxidant activity of both hydrocarbons was assessed using ABTS, FRAP, DPPH, and oleic acid peroxidation techniques. These tests revealed the presence of both slow and fast-acting components in the seed oils of both plants. The seed extracts of *Abutilon Indicum* and *Abutilon indicum* shown broad spectrum efficacy, acting against bacteria of all kinds. The findings indicate seeds of *Abutilon* species, indigenous to India, as a potentially important plant for oil extraction, medication delivery, and cosmetic active components.

### 1.10 USES

*Abutilon Indicum* has been used for a variety of health advantages, including the eradication of threadworms, colds, and fever. It can also help cure piles and TB symptoms. It's a pleasant and refreshing plant. It contains antimicrobial qualities, making it effective for wound treatment. To relieve inflammation, infection, and discomfort, make a paste from their leaves and turmeric and apply it to wounds. It is a classic home remedy for a cold and fever. The earth above this plant was cooked to create an infusion.

#### ➤ Thuthi leaf for haemorrhoids

Thuthi leaf is an extremely efficient cure for piles. According to Ayurveda, eating foods with a strong sour and spicy flavour (such as chilies and tamarind) causes gas in the gastrointestinal tract and can lead to haemorrhoids.

### 1.11 MATERIALS AND METHODS

#### Collection of plant materials

The *abutilon indicum* leaves were collected from in and around virudhachalam. Dried leaves of *abutilon* were prepared. These are authenticated by botanist. Then leaves cleaned properly and shade dried at room temperature.

#### Preparation of plant extract

Making an Ethanoic Extract of *Abutilon Indicum*. In this

study, the leaves were carefully chosen, cleaned to eliminate contaminants, then shade dried. The dry material was coarsely ground in a mechanical grinder. The coarse powder was passed through sieve no. 10 and kept in an airtight container for future use. About 100 g of powdered material was extracted using the maceration technique using ethanol as a solvent. The mixture to steep and soak for 3 days. Strain the mixture and separate the liquid extract from the solid plant material. Moreover, some part of the extract was preserved for preliminary screening. For the detection of various plant constituents and rest extract was used for formulation of Gel batches.

### 1.12 PREFORMULATION STUDIES

**Solubility:** Determining the drug's solubility in various solvents is essential for selecting an appropriate gel base and ensuring optimal drug release.

**PH:** Measuring the gel's pH ensures interaction with the skin or intended region.

### 1.13 PROCEDURE FOR PREPARATION

Carbopol 934 (1 g) was distributed in 50 ml of distilled

water while swirling continuously. 5 ml of distilled water was used, and the required amounts of methyl paraben were dissolved by boiling on a water bath. Cool the solution, then add Propylene glycol 4%. A further quantity of Abutilon leaf extract was added to the previously mentioned combination, and the volume was increased to 100 ml by adding the remaining distilled water. Finally, the whole combined materials were thoroughly mixed into the Carbopol 934gel with continuous stirring, and adjust the formulation to desired pH (6.8-7) and achieve the gel's needed consistency. The same technique was used to prepare the control sample without adding any Abutilon indicum leaves extract.

### 1.14 COMPOSITION OF GEL

#### ➤ Formulation of gel base

Ingredients	Quantity to be taken
Carbopol 934	5%
Glycerine	10%
Propylene glycol	5%
Ethanol	7%
Distilled water	Q. S

#### ➤ Formulation of Abutilon indicum gel

No. Of. Trials	Carbopol %	Extract (ml)	Propylene Glycol%	Ethanol %	Methyl Paraben%	Glycerine (ml)
Formulation-1	1	4	4	3	0.2	5
Formulation-2	1	8	4	3	0.2	5

### 1.15 EVALUATION PARAMETERS FOR ABUTILON INDICUM GEL

#### Physiochemical evaluation

1. pH: Individual and Abutilon Indicum gel formulations were measured using a pH paper.
2. Appearance and Homogeneity: Individual and Abutilon Indicum gels were visually inspected for homogeneity.
3. Viscosity: The viscosity of individual and Abutilon Indicum gels was evaluated using a Brookfield Viscometer at 100 rpm with Spindle No. 6.
4. Gel Formulation Spread ability: After one minute, 1 g of gel was measured between two horizontal plates (20 cm x 20 cm) to test its spread ability.
5. Extrudability: Gel compositions were put into standard collapsible aluminium tubes and sealed with crimping at the end. The weights of the tubes were recorded. The tubes were inserted between two glass slides and clamped. 0.5 Gm was placed over the slides, and the cap was excellent, >80. Extrudability: excellent (>70%).
6. LOD: the formulation was placed in a Petri plate on a water bath and dried at 105°C. It was calculated.
7. Solubility: Soluble in water, alcohol, and chloroform.
8. Washability: The formulation was applied to the skin and the ease of washing with water was assessed.
9. Non-irritancy Test: A prepared herbal gel was applied to human skin and monitored for its effects.

10. Consistency: No greedy activity was noticed.

11. Stability study: The herbal gel physical stability was tested over four weeks at temperatures ranging from 2°C to 25°C. The herbal gel was found to be physically stable at temperatures of 2°C, 25°C, and 35°C for four weeks.

### 1.16 INVITRO ANTIBACTERIAL ACTIVITY

24h old test pathogens *Pseudomonas aeruginosa* and *Klebsiella pneumoniae* was used for disc diffusion method. To perform the assay sterile Mueller Hinton agar plates (acid Hydrolysate of Casein-17.50 g; Starch-1.50 g; Agar-17.00 g and Distilled Water 1000 ml) are prepared under aseptic condition. Using sterile swab, the plates were inoculated with appropriate bacterial cultures to obtain lawn culture. Sterile disc pre-loaded with sample at 10, 25, 50 and 100 µg was loaded on sterile disc. All the discs were placed over the test pathogen loaded MH agar plate and incubated under 37 ± 2° C for 24 h. Doxycycline (30 µg) was used as standard. Zone of inhibition around each. HKGF was measured using antibiotic zone scale.

### 1.17 RESULT AND DISCUSSION

#### Macroscopic of *Abutilon indicum*

<b>Stem</b>	The stem's transverse section has quadrangular epidermal cells that are single layered. The cortex is made up of cellulosic parenchyma with thin walls and several layers.
<b>Leaves</b>	Acuminate tips and crenate-dentate margins characterize the widely ovate to cordate leaves.
<b>Flowers</b>	Yellow to orange in colour flowers, odourless, and mucilaginous in flavour.
<b>Fruits</b>	When young, the globose schizocarps are green, but as they mature, they turn black. They have large beaks and are highly pubescent.
<b>Root</b>	The root is true, 1.2-1.5 cm in diameter, cylindrical with smooth surface, yellow in colour, with a powerful aroma, and salty flavour.

#### Maceration extract



Fig no 2: Extract of *Abutilon indicum*.

#### Pre-formulation studies

Ingredients	Solubility	PH
<b>Carbopol</b>	Soluble in water, insoluble in ethanol.	6.6
<b>Propylene Glycol</b>	Propylene glycol is highly soluble in water, ethanol, acetone, ether, and chloroform. Insoluble in fixed oils.	5.2
<b>Ethanol</b>	Ethanol is highly soluble in water. Ethanol is miscible with organic solvents	7.1
<b>Methyl Paraben</b>	Methylparaben is considered slightly soluble in water It is freely soluble in ethanol and methanol. it also dissolves in other organic solvents.	5.9
<b>Glycerine</b>	glycerine highly soluble in water and many alcohols. it is insoluble in hydrophobic solvents such as benzene, chloroform, and petroleum ether.	6.2

#### Formulation



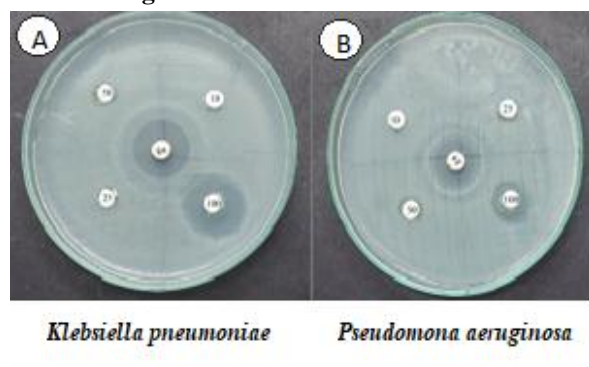
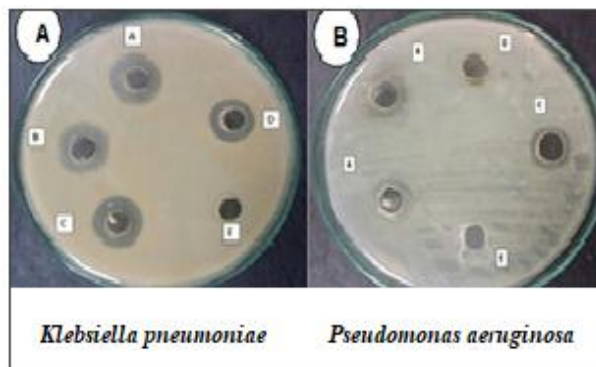
Fig no 3: Formulation-1



Fig no 4: Formulation-2

**Physiochemical evaluation**

Physiochemical parameters	Formulation 1	Formulation 2
<b>PH</b>	6.2	7.3
<b>Appearance</b>	Dark green colour	Green colour
<b>Viscosity</b>	39 cps	39 cps
<b>Spread ability</b>	3.5 sec	5 sec
<b>Extrudability</b>	0.8	0.5
<b>LOD</b>	20%	20%
<b>Solubility</b>	Soluble in water, alcohol and chloroform	Soluble in water, alcohol and chloroform
<b>Washability</b>	Good	Good
<b>Non irritancy test</b>	Non irritant	Non irritant
<b>Consistency</b>	Smooth	Smooth
<b>Stability study</b>	Stable at 25°C and 35°C	Stable at 25°C and 35°C

**Evaluation of gel****Fig no 5: Invitro activity formulation 1****Fig no 6: Invitro activity formulation 2****1.18 INVITRO ACTIVITY OF FORMULATION 1**

Concentration µg/mL	<i>Pseudomonas aeruginosa</i>	<i>Klebsiella pneumoniae</i>
10	-	-
25	-	-
50	-	-
100	20	13
Doxycycline hydrochloride	19	18

**1.19 INVITRO ACTIVITY OF FORMULATION 2**

Concentration µg/ml	<i>Pseudomonas aeruginosa</i>	<i>Klebsiella pneumoniae</i>
10	-	-
25	-	-
50	20	17
100	-	-
Doxycycline hydrochloride	19	18

**1.20 CONCLUSION**

The current study was conducted to create and assess herbal gel. The herbal extracts were made using the maceration technique, which produced a high yield of extract while causing no damage to the chemical ingredients. The levigation process was utilized to create the gel, resulting in a consistent mixing of the herbal extract with the gel foundation that remained stable throughout storage.

According to the study's findings, abutilon has antibacterial properties and may convert dosage forms into the most uncomplicated gel form. It also produced

better results in terms of physicochemical criteria like spread ability, extrudability, washability, solubility, and drying loss. Over the course of four weeks, the formulation's stability was examined at temperatures ranging from 2°C to 37°C. irritating impact, and spreading capabilities showed no modifications. The results obtained show that F2 is the ideal formulation and that it conforms to a wider zone of inhibition against *Bacillus*.

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