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## Design preparation and characterisation of polyherbal gel for bacterial infection

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### Abstract

This study focuses on the preparation and assessment of a polyherbal gel that includes extracts from Babool (*Acacia nilotica*), Tridax procumbens, and Nirgundi (*Vitex negundo*) to treat bacterial infections. Because of these plants' strong antibacterial qualities, traditional medicine holds them in high respect. In order to get the best consistency and stability for topical use, the ethanolic extracts of these herbs were combined with an appropriate gel foundation throughout the formulation process. Tests were conducted on the gel's antimicrobial activity against common harmful microorganisms, such as *Escherichia coli* and *Staphylococcus aureus*. The existence of bioactive substances with antibacterial potential, such as flavonoids, tannins, and alkaloids, was verified by phytochemical screening. The outcomes showed that the polyherbal gel had strong antibacterial properties that were on par with those of prescription antibiotics, indicating that it might be used as a natural substitute for treating bacterial skin infections. The gel's physicochemical characteristics, such as its pH, viscosity, and spreadability, were assessed to make sure it satisfies the requirements for patient compliance and application simplicity.

**Keywords:** Antibacterial gel, polyherb, nirgundi, babool, and tridax procumbens

### Introduction

#### Single herbal versus polyherbal formulation

There are two basic approaches to creating medications in Ayurveda: employing a single herb or combining many herbs (PHF). This age-old technique blends several botanicals to strengthen the medication. We call this polyherbalism <sup>[1]</sup>. This concept of mixing herbs was discussed in a text called "Sarangdhar Samhita" written some 1300 years ago. Indian medicine frequently use blends of plants rather than single ones. These mixes are mostly PHF. Though the molecular mechanisms of each plant are well understood, insufficient amounts of the active components can be detrimental. However, they may function better together than apart when combined. We refer to this as synergism <sup>[2]</sup>. Certain effects of the plant's active ingredients are only apparent when utilized in combination with other plants rather than on their alone.

#### Topical Drug Delivery System

The main goal of any drug delivery system is to make sure that the right amount of medication gets to the right place in the body at the right time in order to quickly attain and maintain the right drug levels. The drug's therapeutic effect is greatly influenced by the mode of administration selected. As the principal route for topical drug delivery systems, the skin appears as one of the most accessible organs for topical administration among the many routes <sup>[3]</sup>. Topical delivery is the process of applying a drug-containing formulation directly into the skin to treat conditions connected to the skin, like psoriasis, or disorders related to the skin, such as acne. For topical administration, semi-solid formulations in all their forms are most commonly used; however, foams, sprays, medicated powders, solutions, and medicated adhesive systems are also employed.

#### Polyherbal gel

A gel is a system comprising at least two parts that is solid or semisolid and is made up of a condensed mass that is surrounded and permeated by a liquid. Gels and jellies have more of a solid than a liquid quality while being made up of minute amounts of solids scattered throughout a huge volume of liquid. The existence of dermal structure imparting solid-like qualities is what distinguishes gel from jelly. Herbal remedies are getting increasing patient compliance as they are devoid of typical side effects of allopathic medicines.

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The present research has been undertaken with the aim to formulate and evaluate the polyherbal gel containing nirgundi, babool, and tridax procumbens Carbapol 940 was used in the construction of the gel formulation and contained nirgundi, babool, and tridax procumbens extract distilled water, propylene glycol, methyl paraben, and propyl paraben in the necessary amounts. Because allopathic treatments have adverse effects, herbal medications are thought to be safer than allopathic ones. Preparing the extract and their formulations for improved absorption and penetration of the active moiety into the systemic circulation is one strategy for ensuring its life.

A polymer is just a compound consisting of units that repeat. The structural network required for the creation of gels is provided by polymers. Clinicians and patients have access to a broad range of vehicles, including solids, semisolids, and liquid formulations, for the topical treatment of dermatological diseases as well as skin care. Transparent gels are one of the main categories of semisolid preparations, and their application in pharmaceutical and cosmetic preparations has grown. Numerous medicinal preparations that either improve or restore a skin's basic function or pharmacologically change an action in the tissues highlighted are applied to the skin or mucous membrane.

#### Advantages of Gel

- Non-greasy application
- Being easy to formulate with active ingredients
- Adhering well to the application site
- Being washable and non-toxic
- Stability over time
- Ability to target affected area for rapid treatment and relief
- Preventing unwanted side effects through bypassing the digestive system
- Easy spreading
- Skin retention
- A cooling effect on the skin

#### Disadvantages of Gel

- Some drugs aren't absorbed easily through the skin
- There's a possibility of an allergic reaction
- The effect of gels initiates slower (but lasts longer)
- Additives in the gel may irritate the skin
- Application site must be monitored for reactions
- Effectiveness may be impacted by temperature, humidity, and other environmental factor <sup>[4]</sup>

#### Experimental Methods

##### Pharmacognostic Investigation

##### Collection and Authentication

Gathering of Vitex negundo, Tridax procumbens linn, and Vachellia nilotica Fresh leaves of Vitex negundo, Vachellia nilotica, and Tridax procumbens linn.

#### Materials and Instruments

##### a) Instruments used for work

**Table 1:** List of instruments used for work

Sr. No.	Name of Instrument
1.	Soxhlet Apparatus
2.	Electronic weighing balance
3.	pH meter
4.	Brookfield viscometer (LVDV-60)
5.	Heating mantle

##### b) Chemicals used for work

**Table 2:** List of chemicals used for work

Sr. No.	Chemicals
1.	Carbopol 934
2.	Propylene glycol
3.	Methyl paraben (0.5%)
4.	Propyl paraben (0.2%)
5.	Triethanolamine
6.	Glycerine
7.	Distilled water

#### Organoleptic Characterization

The rhizomes' color, scent, form, test, and dimensions were noted.

#### Physicochemical Characters

Following a botanical assessment, the plant material that had been shade-dried underwent size reduction to produce a coarse powder, which was subsequently put through sieve number 43 to produce a homogenous powder. The consistent powder was then standardized using several factors in accordance with published research <sup>[5]</sup>.

#### Determination of Foreign Matter

When checked as described below, the sample must show no obvious symptoms of mold development, sliminess, stones, rodent excrement, insects, or any other harmful foreign matter. Spread the contents thinly in an appropriate dish or tray, taking a piece that is typical of a large container, or removing the entire contents if the quantity is 100 g or less. examined with unaided eye in daylight. If there are any suspected particles, transfer them to a petri dish and inspect them in daylight using a 10x lens.

#### Moisture Content

To check the water content and chemical quality of dried leave.

$$\text{Moisture content (\%)} = \frac{W2 - W3}{W2 - W1} \times 100$$

$$W2 - W1$$

Where, W1= weight of empty porcelain dish

W2 = weight of dish with sample before drying

W3 = weight of dish with sample after drying

#### Foaming Index

Foam index test are performed to predict the influence of concern mixture ingredients on dosage of Air Entraining Admixture (AEA) required to achieve a given air content in fresh concrete.

$$\text{Foaming index} = 1000 a$$

Where, a = volume in ml of the decoction in the test tube, showing 1 cm foam height

#### Extraction

##### Preparation of Ethanolic Extract of polyherbs

##### Steps of the Maceration Process

##### 1. Preparation of Plant Material

**Drying:** To minimize moisture content and stop mold growth and spoiling, completely dry any fresh herbs you may be utilizing.

**Grinding:** To improve extraction, increase the surface area of the dried plant material by grinding it into a coarse powder.

## 2. Solvent Selection

Depending on the type of bioactive substances to be extracted, select the right solvent. Water, ethanol, methanol, or a combination of solvents are examples of common solvents.

### Maceration

- **Weighing:** Weigh the appropriate amount of plant material (e.g., 50-100 grams).
- **Solvent Addition:** Place the plant material in a glass container and add the solvent at a ratio typically ranging from 1:5 to 1:10 (plant material to solvent). For example, 100 grams of plant material would require 500-1000 mL of solvent.
- **Soaking:** Seal the container and let the plant material soak in the solvent. Agitate or shake the mixture occasionally to enhance the extraction process.
- **Duration:** Allow the mixture to macerate for a specified period, usually ranging from 24 hours to several days (3-7 days), depending on the plant material and the solvent used.

**Filtration:** After the maceration period, filter the mixture to separate the liquid extract from the plant residue. Use filter paper and a funnel, or other filtration equipment, to ensure a clear extract. Multiple filtrations may be necessary to achieve clarity.

**Concentration (Optional):** If a more concentrated extract is desired, use an evaporator or rotary evaporator to remove excess solvent under reduced pressure. This step concentrates the active compounds in the extract.

**Storage:** Store the filtered extract in a clean, dark glass bottle to protect it from light and air exposure, which can degrade the bioactive compounds. Label the bottle with relevant information such as the plant name, solvent used, date of extraction, and concentration [6].



Fig 1: Extraction process

## Experimental Design

### Formulation of Polyherbal Gel

#### Preparation of polyherbal gel

**Selection of excipients:** The raw materials and chemicals were taken from Ashokrao mane institute of pharmacy, ambap, kolhapur.

All ingredients and excipients used are given in the Table

## Methods of preparation

For the preparation of gel formulation, firstly take carbopol 940 which was then dispersed in distilled water then methyl paraben, propyl paraben and glycerine were added and kept for overnight. Take the leaf extracts in propylene glycol which was then added in polymer dispersion. Remaining quantity of water was then added and neutralized to pH 7 with triethanolamine by constant stirring [7].

The various formulations of polyherbal gels are shown in Table

Table 3: Formulation table

Sr. No	Ingredients	Batches			Role of ingredient
		F1	F2	F3	
1	Ethanolic extract	0.3 gm	0.5 gm	0.7 gm	Therapeutic agent
2	Carbopol 934	1.0 gm	1.0 gm	1.0 gm	Thickner
3	Propylene glycol	10 ml	10 ml	10 ml	Humectant
4	Methyl paraben	0.2 gm	0.2 gm	0.2 gm	Preservative
5	Propyl paraben	0.1 gm	0.1 gm	0.1 gm	Preservative
6	Triethanolamine	qs	qs	qs	Nutralizer
7	Glycerin	1 ml	1 ml	1 ml	Vehicle
8	Distilled water	Upto 100ml	Upto 100ml	Upto 100ml	Vehicle

## Evaluation of gel

### 1. Physical appearance

The physical appearance of the gel was checked visually such as the color, odor, consistency, and greasiness. The observation was conducted for 12 days [8].

### pH determination

The pH of gel was determined using a pH meter [9].

### Homogeneity test

Observation of its homogeneity by applying a certain number of gels on a piece of transparent glass and covered with glass object, then observed. The gel must demonstrate a homogenous and there was no visible presence of grain [10].

### Viscosity

It was measured using a Brookfield viscometer with spindle no. 6 at 100 rpm [11].

### Spread Ability

It was measured by measuring the diameter of 1g of gel dispersed between two glassed slides [12].

### Skin Irritation Test:

It was performed on 10 healthy volunteers comprised of both males and females. About 1gm of gel preparation were applied to the hand of all the volunteers and held for a particular period. After 2 h, the test area was observed for any visible signs resulting from skin irritation. [12, 13]

### Antibacterial Evaluation

For the investigation, strains of Staphylococcus were employed. To ensure that the bacterial cultures were evenly distributed throughout the medium, they were added to the recently created nutritional media and thoroughly mixed. Sterilized petri dishes were filled with the medium, which was then left to stand still and harden. Next, wells measuring 6 mm in diameter were created in the petri dishes using



sterilized cork borer, to which the produced formulations were poured. This allowed the medicine to diffuse throughout media 3. It was then incubated at 37 °C for 24 hours. The zone of inhibitions' diameter was measured, and with the aid of the produced formulations were added to sterile cork borer wells, which were created in petri dishes with a 6 mm diameter apiece, allowing the drug to spread in media 3. It was then incubated at 37 °C for 24 hours. Using a ruler, the diameter of the zone of inhibitions was measured (in millimeters). The antibacterial activity of each formulation was evaluated in triplicate, and the average result was noted. Clindamycin gel was utilized in this investigation as the reference medication for comparison [14].

## Results and Discussion

### Collection and Authentication

Gathering of *Vitex negundo*, *Tridax procumbens* linn, and *Vachellia nilotica* From AMIP Botanical Garden, Amapp

### Extraction of powders

**Table 4:** Extractive values of babool, nirgundi, dagdi pala

Sample	Extraction method	Solvent used	Wt. of sample	Extraction value (%w/w)
Nirgundi	Maceration process	Ethanol	100 gm	10% w/w
Babool	Maceration process	Ethanol	100 gm	10% w/w
Tridax Procumbens	Maceration process	Ethanol	100 gm	10% w/w

### Physicochemical evaluation of Gel

#### Physical Appearance

**Table 5:** Physical appearance of gel

Sr. No.	Batch	Color	Appearance
1	F1	Light Brown	Brown
2	F2	Brown	Brown
3	F3	Dark Brown	Brown



**Fig 2:** All formulation batches were found to be homogeneous Brown gel preparations

**Homogeneity:** After the gels were placed in the container, a visual inspection was used to verify that all of the generated gels were homogenous.

**Table 6:** Homogeneity of formulation

Sr. No.	Batch	Homogeneity
1	F1	Homogeneous
2	F2	Homogeneous
3	F3	Homogeneous

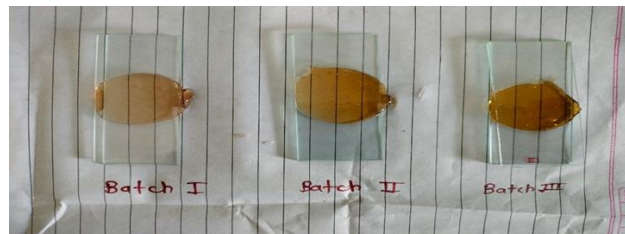
**Measurement of pH:** Since the pH of adult skin is 5, the pH values of all created formulations ranged from 6-7, which are deemed appropriate to reduce the possibility of skin irritation

upon application.

**Spreadability:** Spreadability was measured as the number of seconds needed to complete the task of separating the two slides.

**Table 7:** pH and Spreadability of leaves extracts formulation.

Sr. No.	Batch	pH	Spreadability (gm.sm/sec)
1	F1	6.8 /±0.03	14.83/±0.005
2	F2	7.0 /± 0.03	17.02/±0.005
3	F3	7.2 /± 0.03	18.17/±0.005



**Fig 3:** Spreadability test

### Viscosity

Viscosity of gel was determined by using Brookfield rotational viscometer at 5, 10, 20, rpm. Each reading was taken after equilibrium of the sample at the end of two minutes. The samples were repeated three times.

**Table 8:** Viscosity value of herbal gel

Sr. No.	rpm	Viscosity (Cps)
1	5	3614±0.11
2	10	3715±0.21
3	20	4135±0.43

### Antibacterial activity

**Table 9:** Zone of Inhibition

Sr No	Detail	Concn (%)	Zone of inhibition
1	Neomycin	100	10
2	Gel	100	20
3	Extract	100	8
4	Saline water	5	No zone

### Optimization of Batches

The batches were optimized by checking, and by studying physical evaluation to their pH, viscosity, Spreadability, greasiness, homogeneity, washability and Stability study of all formulation batches. By studying the evaluation parameters off all batches, batch F2 from leaves extract gel formulation were be optimize

### Conclusion

The creation and assessment of an antibacterial polyherbal gel including Dagdi Pala (*Tridax procumbens* linn), Nirgundi (*Vitex negundo*), and Babool (*Acacia nilotica*) has shown a great deal of promise for the treatment of bacterial infections and the promotion of wound healing.

These three herbs are well-known for their strong antibacterial, anti-inflammatory, and wound-healing qualities; this study successfully combined their synergistic effects. The strong antibacterial action and improved wound healing capacities of the gel formulation were facilitated by the presence of bioactive components such as tannins, flavonoids, alkaloids, and essential oils. The gel's appropriate pH, viscosity, and spreadability were verified by physicochemical

characterization, indicating its long-term stability and suitability for application. The formulation's resistance to different environmental conditions was further evaluated by stability experiments, indicating that it is a dependable product for long-term use. According to safety evaluations, which included skin irritation and sensitization testing, the gel is safe to apply topically and does not cause any negative side effects.

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