IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 7, May 2025
Impact Factor: 7.67

Formulation and Evaluation of Herbal Suppositories for the Antifungal Treatment

Dr. Abhishek Kumar Sen[1], Krutika Gotarane[2], Jagruti Jadhav[3], Sujal Jadhav[4], Pranit Jadhav[5], Darshan Gurude[6], Dr. Sonali V Uppalwar[7]
Ideal Institute of Pharmacy, Posheri, Wada, Palghar

Abstract: *Background: Conventional antifungal therapies often face limitations such as resistance, adverse side effects, and narrow therapeutic range. Herbal remedies like neem (Azadirachtaindica) and turmeric (Curcuma longa) offer safer, natural alternatives with proven antifungal, anti-inflammatory, and healing properties. This study aims to explore the potential of these herbs in suppository formulations for fungal infection treatment.*
Method: Suppositories were prepared using neem extract and curcumin as active ingredients, with cocoa butter and PEG as bases. Gelatin, glycerin, and purified water were added to enhance consistency and bioavailability. The formulations were evaluated for weight uniformity, melting point, hardness, and disintegration. Antifungal activity was tested in vitro against Candida albicans.
Results: All suppositories met standard pharmaceutical criteria, displaying acceptable physical characteristics. In antifungal tests, all formulations showed significant activity against Candida albicans. PEG-based suppositories exhibited slightly better results, likely due to improved solubility and drug release.
Conclusion: Neem and curcumin-based suppositories, enhanced with gelatin, glycerin, and purified water, are effective and safe for treating fungal infections. Their strong antifungal activity and good physical stability make them suitable for rectal or vaginal use. These findings support the development of herbal alternatives to conventional antifungal treatments..

Keywords: Herbal suppositories, Antifungal, Gelatin, Glycerin, Neem, Purifiedwater, Curcumin, Natural remedies

DOI: 10.48175/IJARSCT-26836

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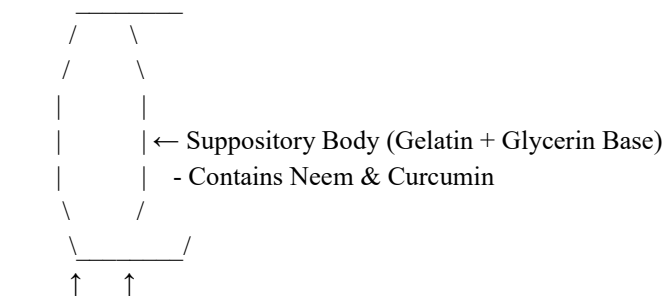
I. INTRODUCTION



Fungal infections represent a growing global health concern, particularly those caused by Candida species. These opportunistic pathogens are responsible for a wide range of infections that affect the skin, mucous membranes, and genitourinary tract. Vaginal candidiasis, oral thrush, and cutaneous candidiasis are among the most common forms, frequently affecting immunocompromised individuals, diabetic patients, and women undergoing antibiotic or hormonal therapies. Recurrent infections, patient discomfort, and treatment failures are increasingly reported, indicating a pressing need for improved therapeutic options.

Conventional antifungal agents, including azoles, polyenes, and echinocandins, have been widely employed in clinical practice. However, the effectiveness of these synthetic drugs is increasingly undermined by several limitations. The most concerning of these is the rapid emergence of antifungal resistance, particularly among non-albicans Candida species. Additionally, prolonged use of synthetic antifungals can lead to various side effects such as gastrointestinal irritation, liver toxicity, and drug interactions. These limitations not only compromise therapeutic outcomes but also reduce patient compliance and quality of life.

As a result, there has been a renewed interest in the use of herbal medicines for managing fungal infections. Herbal remedies are known for their historical use, favorable safety profiles, and diverse pharmacological actions. Among these, neem oil (Azadirachtaindica) and curcumin, the active component of turmeric (Curcuma longa), have attracted considerable attention due to their well-documented antifungal and anti-inflammatory activities.

Neem oil, derived from the seeds and fruits of the neem tree, contains potent bioactive compounds such as nimbin, nimbidin, and azadirachtin. These compounds have demonstrated broad-spectrum antimicrobial properties, including strong antifungal activity against Candida albicans and other pathogenic fungi. Neem oil also exerts anti-inflammatory and wound-healing effects, which can be particularly beneficial in managing mucosal infections where Fungal infections represent a growing global health concern, particularly those caused by Candida species. These opportunistic pathogens are responsible for a wide range of infections that affect the skin, mucous membranes, and genitourinary tract. Vaginal candidiasis, oral thrush, and cutaneous candidiasis are among the most common forms, frequently affecting immunocompromised individuals, diabetic patients, and women undergoing antibiotic or hormonal therapies. Recurrent infections, patient discomfort, and treatment failures are increasingly reported, indicating a pressing need for improved therapeutic options.

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Aim:

The aim of this project is to formulate and evaluate herbal suppositories containing curcumin and neem oil for the localized treatment of fungal infections, utilizing a suppository base composed of glycerin, gelatin, and liquid paraffin. The study focuses on harnessing the natural antifungal properties of curcumin and neem oil to develop a safe, stable, and effective dosage form intended for rectal or vaginal administration. The formulation is designed to offer targeted drug delivery, minimize systemic side effects, and improve patient compliance.

Objective

The main goal of this research is to develop and assess herbal-based suppository formulations aimed at delivering antifungal agents locally for the effective management of fungal infections. The project focuses on leveraging the medicinal value of herbal extracts known for their antifungal action, while ensuring the formulation is safe, effective, and user-friendly.

Specific Objectives:

1. To identify and select herbal extracts with established antifungal activity based on traditional use and scientific literature.
2. To develop suppository formulations utilizing an appropriate base that facilitates optimal drug release and maintains formulation stability.
3. To examine the physical characteristics of the prepared suppositories, including:
   Uniformity of weight
   Melting range
   Mechanical strength (hardness)
   Time required for disintegration
4. To conduct in vitro studies to evaluate the drug release profile of the herbal suppositories.
5. To assess the antifungal activity of the formulations through standard microbiological assays.
6. To compare the efficacy of the developed herbal suppositories with that of conventional antifungal therapies.
7. To analyze the stability and uniformity of the formulations over a specified storage duration under controlled conditions.
8. To select appropriate natural extracts recognized for their proven antifungal properties.
9. To formulate suppositories using a suitable base that ensures effective drug release and formulation stability.
10. To evaluate the physical characteristics of the formulated suppositories, including:
    Weight variation
    Melting point
    Hardness
    Disintegration time
11. To carry out in vitro drug release studies and analyze the release behavior of the herbal suppositories.
12. To determine the antifungal activity of the herbal formulations using standardized microbiological methods.
13. To compare the overall effectiveness of the herbal suppositories with that of standard antifungal treatments.
14. To monitor the stability and uniformity of the formulation over a defined period under controlled storage condition.

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Material

1. Neem (Azadirachtaindica)

Family: Meliaceae (Mahogany family)
Common Names: Neem, Indian lilac, Margosa
Native: Indian subcontinent; now grown worldwide in tropical regions

Tree Description:

- Medium to large evergreen (15–20 m tall)
- Pinnate green leaves, small fragrant white flowers
- Olive-like drupe fruit; seeds yield neem oil

Medicinal Properties:

- Rich in bioactive compounds (azadirachtin, nimbin, etc.)

Benefits:

- Antibacterial, antifungal (acne, eczema)
- Anti-inflammatory (arthritis, wounds)
- Antiviral, antimalarial, antidiabetic
- Supports oral care, liver health, and blood purification

Uses of Parts:

- Leaves: Skin care, insect repellent
- Bark: Fever, malaria, pain relief
- Seeds/Oil: Pesticide, skin/hair treatments
- Flowers: Digestive aid
- Fruit: Oil source, pest control

Non-Medicinal Uses:

- Agriculture: Natural pesticide/fertilizer
- Cosmetics: Soaps, creams, shampoos
- Personal Care: Toothpaste, mouthwash
- Environmental: Air purifier, drought-resistant

Precautions:

- Neem oil can be toxic (especially to infants, pregnant women)
- May cause skin allergies in sensitive individuals

Cultural Significance:

- Sacred in India, symbol of health and protection
- Used in Ayurveda, Siddha, Unani medicine
- Leaves used in rituals and festivals for purification

2 . Turmeric (Curcuma longa)

Botanical Profile:

- Family: Zingiberaceae (Ginger family)
- Common Names: Turmeric, Haldi, Haridra
- Part Used: Rhizome (underground stem)
- Native to: South Asia, especially India

Plant Description:

- Herbaceous perennial, ~1 meter tall
- Large green leaves; yellow-orange aromatic rhizome

Active Compounds:

- Main: Curcumin (gives color and health benefits)

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- Others: Demethoxycurcumin, turmerone, essential oils

Medicinal Properties:

- Anti-inflammatory (arthritis, injuries)
- Antioxidant (cell protection)
- Antimicrobial (fights germs)
- Supports liver, digestion, brain, heart, and wound healing
- Anticancer potential (under study)

Traditional Uses:

- Ayurveda & Unani: Skin, allergies, detox, pain relief
- Folk remedy: "Haldidoodh" (turmeric milk) for colds & coughs

Culinary Uses:

- Spice in curries, rice, pickles, drinks
- Key in golden milk, turmeric latte, mustard coloring

Cosmetic Uses:

- Skin care: Acne, brightening, pigmentation, anti-aging
- Applied with yogurt or sandalwood

Modern Research:

- Curcumin supplements for joint pain, inflammation
- Best absorbed with black pepper (piperine) or enhanced formulations

Safety:

- Safe in food amounts
- High doses may cause stomach issues or thin blood
- Avoid large doses during pregnancy or before surgery

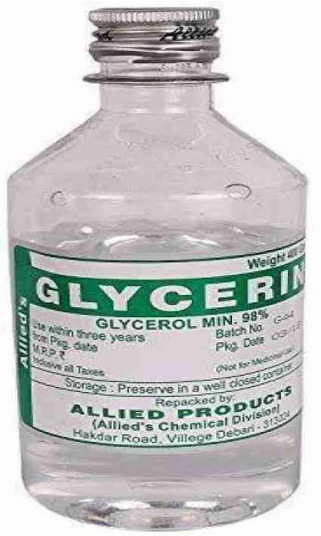
3. Glycerine (Glycerol)

Chemical Name: Glycerol

Formula: $C_3H_8O_3$

Appearance: Colorless, odorless, viscous liquid

Taste: Sweet



Sources:

- Byproduct of soap making (saponification)
- Hydrolysis of plant/animal fats
- Synthetic production from petrochemicals

Pharmaceutical Uses:

- Suppository base (with gelatin)
- Humectant (moisture retention)
- Solvent (for drugs/extracts)
- Plasticizer (adds flexibility)
- Laxative (mild, osmotic action)

Role in Suppositories:

- Combined with gelatin/paraffin
- Retains moisture, aids in slow, prolonged release
- Suitable for hydrophilic drugs and herbal actives (e.g., curcumin, neem oil)

Advantages:

- Non-toxic, non-irritating
- Stable with many actives

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- Safe for mucosal use
- Affordable and easily available

Storage:

- Keep tightly closed
- Protect from moisture and heat
- Hygroscopic (absorbs water from air)

4. Gelatin (Gelatine)

Basic Info:

- Type: Protein from animal collagen
- Source: Bovine/porcine skin, bones, cartilage
- Appearance: Colorless/light yellow, tasteless, odorless solid (powder/sheets)
- Solubility: Swells in cold water, dissolves in hot water

Composition:

- Rich in amino acids: glycine, proline, hydroxyproline, glutamic acid
- Gives it gelling, thickening, stabilizing properties

Pharmaceutical Uses:

- Suppository base (with glycerine)
- Capsule shells (hard/soft gelatin)
- Tablet coating
- Plasma expander (IV use)
- Stabilizer (vaccines, emulsions)

Role in Suppositories:

- Provides structure and firmness
- Swells with moisture, enabling slow drug release
- Ideal with glycerine and paraffin for herbal delivery (e.g., curcumin, neem oil)

Advantages:

- Biocompatible, biodegradable, non-toxic
- Safe for rectal/vaginal use
- Compatible with many herbal actives
- Forms clear, flexible, stable formulations

Storage:

- Cool, dry place
- Hygroscopic – protect from moisture
- Heat gently (below 70°C) to prevent degradation

5. Purified Water

Water that has been physically processed to remove impurities such as ions, organic matter, particulates, and microorganisms. It meets the specifications of major pharmacopeias (e.g., IP, USP, BP) and is free from chemical contaminants and biological impurities.

Appearance: Clear, colorless, odorless, and tasteless liquid

pH: Typically between 5.0 and 7.0

Production Methods

Purified water can be obtained through several purification processes, such as:

Distillation

Carbon Filtration

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In pharmaceutical industries, multi-step purification is often used to ensure high purity and consistency.
Pharmaceutical Uses
Purified water is one of the most commonly used excipients in pharmaceutical preparations due to its:High safety
Solvent properties
Universal compatibility
Role in Suppository Formulation
In your herbal suppository using glycerine, gelatin, liquid paraffin, curcumin, and neem oil:
Purified water is used to hydrate gelatin, allowing it to swell and form a smooth, gel-like matrix.
It helps dissolve or disperse hydrophilic components.
Ensures uniform consistency of the suppository base.
Aids in heat transfer and mixing during the melting and molding process.
Storage
Stored in sterile, clean, non-reactive containers (glass or pharmaceutical-grade plastic).
Should be used promptly or stored under controlled conditions to prevent microbial growth.

II. METHODOLOGY

Selection and Preparation of Herbal Actives
↓
Formulation of the Suppository Base
↓
Incorporation of Herbal Components
↓
Molding and Solidification Process
↓
Evaluation of Physical Characteristics
↓
Assessment of Antifungal Activity
↓
Stability Testing

Method

1. Selection and Preparation of Herbal Actives

Curcumin and neem oil were selected owing to their well-established antifungal activities documented in traditional and scientific sources.
Curcumin was sourced in its purified powder form, while neem oil was acquired as a cold-pressed extract.
Both ingredients underwent preliminary screening to confirm identity, assess solubility, and ensure compatibility with the base materials.

2. Formulation of the Suppository Base

The suppository base was prepared using a blend of glycerin, gelatin, and liquid paraffin in the approximate ratio:
Glycerin – 70%
Gelatin – 20%
Liquid paraffin – 10%
Gelatin was first hydrated and allowed to swell before being melted gently at 60–70°C.
Glycerin and liquid paraffin were gradually incorporated under continuous stirring to form a homogenous base.

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3. Incorporation of Herbal Components

Pre-weighed amounts of curcumin and neem oil were added to the warm, uniform base.

The mixture was stirred thoroughly to ensure uniform dispersion of the active herbal ingredients throughout the formulation.

4. Molding and Solidification Process

The final molten mixture was poured into pre-lubricated suppository molds.

Molds were allowed to cool at ambient temperature, followed by refrigeration at 2–8°C to facilitate solidification and easy demolding.

5. Evaluation of Physical Characteristics

The developed suppositories were evaluated for key physical parameters:

Weight Variation: 20 suppositories were individually weighed, and the average weight was calculated to assess uniformity.

Melting Point: Determined using a capillary melting apparatus.

Hardness: Evaluated using a hardness tester adapted for semi-solid dosage forms.

Disintegration Time: Measured using a USP disintegration apparatus in simulated rectal fluid maintained at 37°C.

6. In Vitro Drug Release Analysis

Drug release was assessed using either a Franz diffusion cell or dialysis membrane setup.

A phosphate buffer (pH 7.4) served as the release medium.

Samples were collected at scheduled intervals and analyzedspectrophotometrically to determine curcumin release over time.

7. Assessment of Antifungal Activity

The antifungal potential of the suppositories was tested using standard agar well diffusion or disc diffusion techniques.

Microbial strains such as Candida albicans and Aspergillusniger were used as test organisms.

Zones of inhibition were measured and compared with conventional antifungal standards to evaluate efficacy.

8. Stability Testing

Suppositories were stored under controlled conditions (e.g., ambient and refrigerated settings).

Evaluations were performed at regular intervals (e.g., day 0, 15, 30, and 60) to monitor changes in physical properties and drug content, ensuring formulation stability and consistency.

Suppository formulation

Ingredient	Quantity per Suppository (approx.)	Function
Neem Extract (standardized)	100 mg	Antifungal, antimicrobial
Curcumin (Turmeric extract)	50 mg	Antifungal, anti-inflammatory
Glycerin	2.0 g	Base, humectant, solubilizer
Gelatin	0.6 g	Gelling agent, gives firmness
Purified Water	0.4 g	Solvent, to hydrate gelatin

This quantity makes one suppository weighing ~3.15 g. Multiply accordingly for batch size.

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Evaluation Tests for Herbal Suppository

Test	Purpose	Method / Description
1. Physical Appearance	To check the shape, color, and surface texture	Visual inspection for uniformity, smoothness, and absence of cracks or bubbles
2. Weight Variation	Ensures dosage consistency	Weigh 20 individual suppositories, calculate average, and check for deviation (±5%)
3. Melting Point / Liquefaction Time	Determines the melting behavior in the body	Place in water bath at 37°C and record time to melt completely
4. Disintegration Time	Time taken to break down in body fluids	USP disintegration test apparatus or glass beaker with 37°C water
5. pH Measurement	Ensures safety for mucosal application	Dissolve in water and measure with a pH meter (target: ~4–5 for vaginal, ~7 for rectal)
6. Drug Content Uniformity	Ensure even distribution of actives (Neem, Curcumin)	Use UV-Vis or HPLC to quantify active ingredients in samples
7. Antifungal Activity	Confirms efficacy against fungal strains	Agar diffusion or broth dilution method against Candida albicans
8. Stability Study	Checks product integrity over time	Store at various conditions (25°C, 40°C, etc.) and evaluate appearance, weight, drug content over weeks/months
9. Irritation or Safety Test (Optional/Advanced)	For safety on mucosa (preclinical)	Patch test on animal model or in vitro mucosal model (ethically approved)

Optional Tests (if resources allow)

- Viscosity of molten base
- Microbial limit test
- Moisture content (Karl Fischer or loss on drying)

III. RESULT

Antifungal Suppository Analysis

This document outlines a comparison of the antifungal efficacy of suppositories made with neem, turmeric, and a blend of both. The analysis is based on the measurement of the zone of inhibition (in mm), which reflects antifungal effectiveness.

Batch-wise Comparison Table

Batch	Zone of Inhibition (mm)
A (Neem)	3.64
B (Turmeric)	4.84
C (Combined)	6.62

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Graphical Representation