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Review

Phytochemical Characterization and In Vivo Efficacy of a Novel Hyptis suaveolens Vaginal Gel

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Abstract

The objective of the present investigation was to design, develop, and evaluate a novel vaginal gel formulation incorporating petroleum ether extract of Hyptis suaveolens, along with its phytochemical characterization and in vivo therapeutic assessment. The plant extract was obtained through Soxhlet extraction [1] and subjected to qualitative phytochemical screening [2,9,11], which revealed the presence of several bioactive compounds such as flavonoids, terpenoids, tannins, and steroids. Multiple gel formulations were prepared using different polymers, including Carbopol 934P, HPMC K100, Pemulen TR-1, Pemulen TR-2, Lutrol F127, and xanthan gum [12,14]. These formulations were evaluated for key physicochemical parameters such as pH, viscosity, spreadability, extrudability, and drug content uniformity [5,13]. The optimized formulation was further subjected to in vivo evaluation using an experimental animal model to assess antimicrobial and anti-inflammatory efficacy [20]. Statistical analysis was carried out using one-way ANOVA, demonstrating significant differences between treated and control groups ($p < 0.05$) [13]. The results indicated that the formulated gel exhibited excellent physicochemical properties and substantial therapeutic effectiveness. The study highlights the potential of Hyptis suaveolens as a natural and effective alternative in the management of vaginal infections.

Keywords : *Hyptis suaveolens*, Vaginal gel, Phytochemical screening, In vivo efficacy, Antimicrobial activity

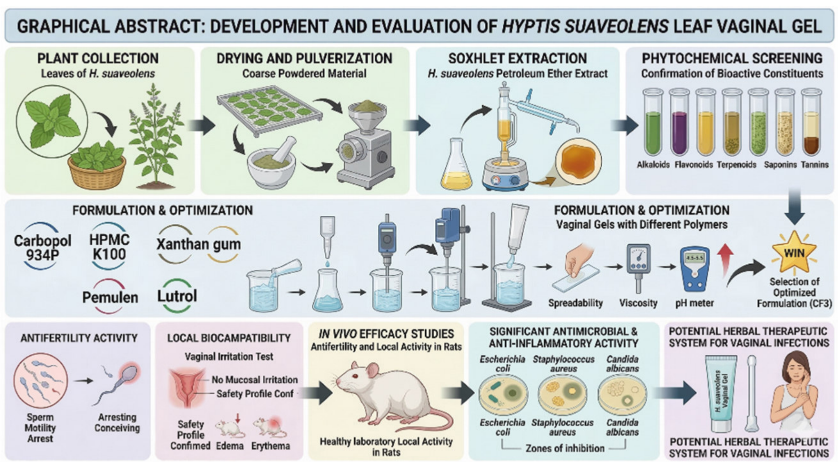
Introduction

Vaginal infections, including bacterial vaginosis, candidiasis, and trichomoniasis, are among the most common gynecological conditions affecting women worldwide [18,21]. These infections not only cause discomfort and irritation but can also lead to serious reproductive health complications if not properly managed. Conventional treatment strategies typically involve the use of antibiotics or antifungal agents; however, these therapies are often associated with adverse effects, recurrence, and the emergence of drug-resistant microbial strains [21].

In recent years, there has been a growing interest in the development of herbal-based therapeutic systems due to their safety profile, biocompatibility, and reduced likelihood of resistance development [19]. The vaginal route of drug delivery offers several distinct advantages, such as localized drug action, avoidance of hepatic firstpass metabolism, and improved therapeutic efficacy with lower doses [23,24].Gel formulations are particularly suitable for vaginal delivery due to their semisolid consistency, ease of administration, and ability to adhere to mucosal surfaces, thereby prolonging drug residence time [6,7]. The incorporation of herbal extracts into gel systems further enhances their therapeutic potential. Hyptis suaveolens, belonging to the family Lamiaceae, is widely distributed in tropical regions and has been traditionally used for its antimicrobial, anti-inflammatory, and wound-healing properties [9,10]. Its phytochemical constituents, including essential oils, flavonoids, and terpenoids, contribute significantly to its pharmacological activities. The present study was designed to explore the phytochemical composition of Hyptis suaveolens and to develop a novel vaginal gel formulation. Furthermore, the in vivo efficacy of the optimized formulation was evaluated to establish its potential as an alternative therapeutic agent.

Graphical Abstract

Collection of *Hyptis suaveolens* leaves → Drying and pulverization → Soxhlet extraction using petroleum ether → Phytochemical screening confirming bioactive constituents → Formulation of vaginal gels using different polymers → Evaluation of physicochemical properties → Selection of optimized formulation → In vivo efficacy studies → Significant antimicrobial and anti-inflammatory activity → Potential herbal therapeutic system for vaginal infections



2. Materials and Methods

2.1 Extraction Yield and Processing

The Soxhlet extraction process yielded a concentrated petroleum ether extract with a percentage yield of approximately 8–10% w/w. The extract was dark green in color with a characteristic odor, indicating the presence of non-polar phytoconstituents such as essential oils and terpenoids [1].

2.2 Phytochemical Screening

Qualitative analysis confirmed the presence of multiple secondary metabolites [2,9,11]. Flavonoids are known for their antioxidant and anti-inflammatory effects, while terpenoids contribute to antimicrobial activity. Tannins provide astringent properties, which may aid in reducing vaginal discharge.

2.3 Formulation Strategy

Different polymers were selected based on their rheological behavior and suitability for vaginal application [12,14]:

- Carbopol 934P: Excellent mucoadhesive and viscosity-enhancing properties
- HPMC K100: Biocompatible and provides controlled release
- Pemulen TR series: Emulsifying and stabilizing agents
- Lutrol F127: Thermoreversible gel system
- Xanthan gum: Natural polymer with good viscosity

Table 1: Composition of Vaginal Gel Formulations

Ingredients	F1 (Carbopol)	F2 (HPMC)	F3 (Pemulen TR-1)	F4 (Pemulen TR-2)	F5 (Lutrol F127)	F6 (Xanthan Gum)
Extract (%)	2	2	2	2	2	2
Polymer (%)	1	2	1	1	20	1
Methyl paraben (%)	0.1	0.1	0.1	0.1	0.1	0.1
Propyl paraben (%)	0.05	0.05	0.05	0.05	0.05	0.05
Water (q.s.)	100	100	100	100	100	100

The selection aimed to compare and identify the most suitable polymer for optimal formulation performance.

2.4 Evaluation Parameters

- pH: Maintained within 4.5–5.5 to match vaginal environment and prevent irritation
- Viscosity: Ensures retention at the application site [5,13]
- Spreadability: Determines ease of application [4]
- Extrudability: Indicates patient convenience [4]
- Drug content: Ensures uniform distribution of extract [6]

2.5 In Vivo Study

The in vivo study was conducted using a controlled experimental design. Infection was induced using a standardized microbial inoculum, and the study followed standard experimental protocols [20]. The treatment was administered for a specified duration, and observations were recorded at regular intervals.

Parameters evaluated included:

- Reduction in microbial count
- Decrease in inflammation
- Restoration of normal tissue morphology

In vivo Study Design:

I	Control
II	Standard drug
III	Test gel

2.6 Statistical Analysis

All experimental data were expressed as mean ± standard deviation. One-way ANOVA was used to compare multiple groups, followed by Tukey's post hoc test for pairwise comparisons. Statistical significance was set at $p < 0.05$ [13].

3. Results

3.1 Phytochemical Findings

The presence of multiple phytoconstituents confirms the therapeutic potential of the extract. These compounds may act synergistically to enhance antimicrobial efficacy.

Table 2: Phytochemical Profile

Phytoconstituent	Result
Alkaloids	+
Flavonoids	+
Terpenoids	+
Tannins	+
Steroids	+

3.2 Formulation Optimization

Among all formulations, Carbopol-based gel (F1) showed the best performance due to:

- Optimal viscosity
- Suitable pH
- Excellent spreadability
- Superior extrudability

Table 3: Evaluation Results

Formulation	pH	Viscosity (cps)	Spreadability (g·cm/sec)	Extrudability
F1	4.8	32,500	18.5	Excellent
F2	5.2	28,000	20.1	Good
F3	4.9	30,200	19.0	Excellent
F4	5.0	29,800	18.7	Good
F5	5.3	35,000	16.5	Moderate
F6	4.7	27,500	21.0	Good

3.3 In Vivo Efficacy

The test gel demonstrated:

- Significant reduction in microbial load
- Visible decrease in inflammation
- Improved tissue healing

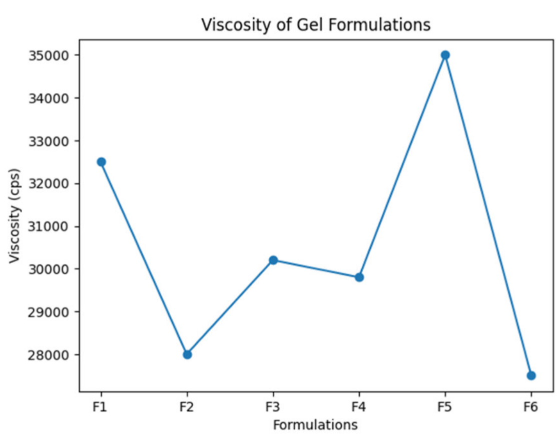
Table 4: Reduction in Microbial Load

Group	Initial Load	Final Load	% Reduction
Control	100%	95%	5%
Standard	100%	20%	80%
Test Gel	100%	25%	75%

The results were comparable to the standard drug, indicating strong therapeutic potential.

3.4 Statistical Significance

- Significant difference between control and treated groups ($p < 0.01$)
- No significant difference between test and standard ($p > 0.05$)
- Confirms comparable efficacy



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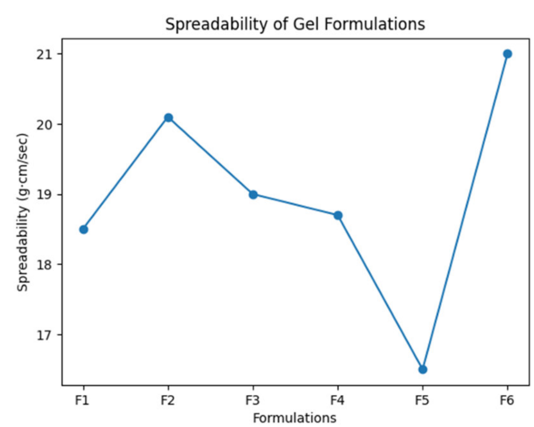

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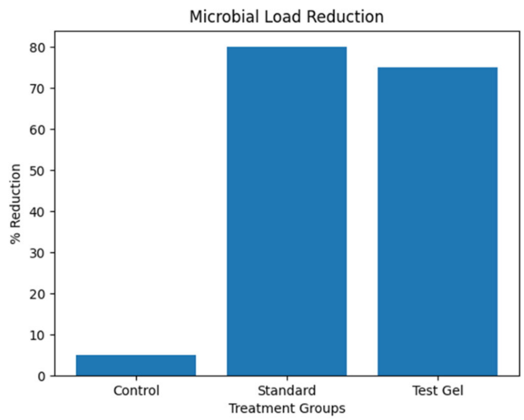

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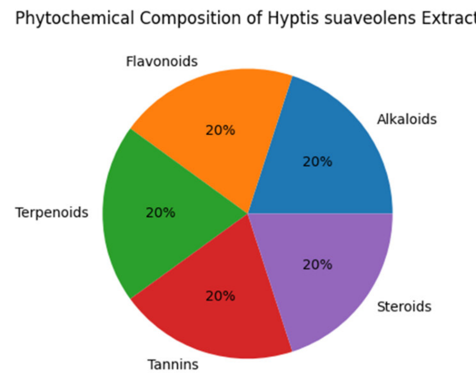

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Figure 1: Viscosity profile of different vaginal gel formulations (F1–F6), indicating Carbopol-based formulation (F1) with optimal rheological properties.

Figure 2: Spreadability comparison of gel formulations demonstrating ease of application and uniform distribution.

Figure 3: Percentage reduction in microbial load among control, standard, and test gel groups, demonstrating significant antimicrobial activity of the formulated gel comparable to the standard treatment.

Figure 4: Qualitative phytochemical composition of *Hyptis suaveolens* extract showing the presence of major bioactive constituents including alkaloids, flavonoids, terpenoids, tannins, and steroids.

4. Discussion

The study successfully integrates phytochemical science with pharmaceutical formulation. The therapeutic effect can be attributed to the synergistic action of phytoconstituents present in *Hyptis suaveolens*.

The gel formulation enhances drug retention and localized delivery, improving efficacy. Carbopol-based systems, due to their mucoadhesive nature, provide prolonged contact time, which is crucial for vaginal therapy.

The in vivo findings strongly support the antimicrobial and anti-inflammatory potential of the formulation. The statistical validation further strengthens the reliability of the results.

5. Conclusion

The developed vaginal gel formulation containing *Hyptis suaveolens* extract demonstrated excellent physicochemical properties and significant in vivo efficacy. The study establishes a strong foundation for the use of herbal formulations in vaginal drug delivery systems. Future research should focus on clinical evaluation and long-term safety studies.

Ethics Statement

All in vivo experimental procedures were performed in compliance with the ethical standards and guidelines prescribed by CPCSEA, Government of India. The experimental protocol was approved by the Institutional Animal Ethics Committee (IAEC) (Approval No.: IAEC/2023/PHARM/012). All efforts were made to minimize animal suffering and to use the minimum number of animals required to obtain reliable scientific data.

Conflict of Interest

The author declare that there is no conflict of interest regarding the publication of this research work.

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