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DEVELOPMENT AND CHARACTERIZATION OF HERBAL VAGINAL GEL INCORPORATING POMEGRANATE EXTRACT FOR THE TREATMENT OF VAGINAL INFECTIONS

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Abstract: Vaginal infections are among the most common health issues affecting women of reproductive age, primarily caused by an imbalance in the normal vaginal microflora. Conditions such as bacterial vaginosis, candidiasis, and trichomoniasis are often associated with symptoms like itching, irritation, inflammation, and abnormal discharge. Conventional treatments, including antibiotics and antifungal agents, though effective, are frequently associated with side effects, recurrence, and the development of drug resistance. Therefore, there is a growing need for safer, more effective, and natural therapeutic alternatives.

The present study focuses on the formulation and evaluation of a herbal vaginal gel incorporating medicinal plant extracts known for their antimicrobial, anti-inflammatory, and soothing properties. Selected herbal ingredients such as Aloe vera, Azadirachta indica (Neem), Ocimum sanctum (Tulsi), Curcuma longa (Turmeric), and pomegranate peel extract were utilized due to their well-documented pharmacological activities. The extracts were prepared using suitable extraction techniques and incorporated into a gel base formulated with appropriate gelling agents to ensure optimal viscosity, spreadability, and bioadhesion.

The formulated gels were evaluated for various physicochemical parameters including pH, viscosity, homogeneity, spreadability, and extrudability to ensure suitability for vaginal application. Microbiological studies were conducted to assess antimicrobial activity against common vaginal pathogens such as Candida albicans and Escherichia coli. Stability studies were also performed under different storage conditions to determine the shelf life and consistency of the formulation.

The results indicated that the herbal vaginal gel exhibited satisfactory physicochemical characteristics and significant antimicrobial activity, suggesting its potential effectiveness in managing vaginal infections. The formulation also demonstrated good stability and compatibility of herbal constituents within the gel base. The use of herbal ingredients provides additional advantages such as reduced side effects, improved patient compliance, and enhanced therapeutic efficacy.

I. INTRODUCTION:

The vaginal environment is a highly specialized and dynamic ecosystem that plays a crucial role in maintaining women's reproductive health. It is characterized by an acidic pH (approximately 3.8–4.5), primarily maintained by Lactobacillus species, which produce lactic acid and hydrogen peroxide. This acidic environment inhibits the growth of pathogenic microorganisms and helps maintain microbial balance.

The vaginal epithelium also acts as a protective barrier against infections. Hormonal regulation, particularly estrogen, influences epithelial thickness, glycogen content, and microbial flora.

Any disruption in this balance may lead to infections and other gynecological complications.[1]

Vaginal infections (vaginitis) are among the most common gynecological problems affecting women worldwide.

These include:Bacterial vaginosis ,Vulvovaginal candidiasis ,Trichomoniasis.Among these, candidiasis caused by Candida albicans is highly prevalent. Studies show that nearly 75% of women experience vaginal candidiasis at least once in their lifetime, and recurrence occurs in ab out 40–50% of cases.

Common symptoms include: Itching and irritation ,Redness and inflammation, Abnormal discharge, Burning sensation.These infections may result from microbial imbalance, poor hygiene, antibiotic use, hormonal changes, or weakened immunity.[2]

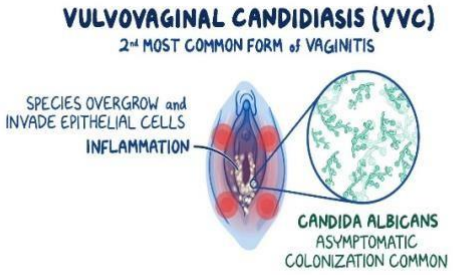

Fig 1. Vulvovaginal candidiasis

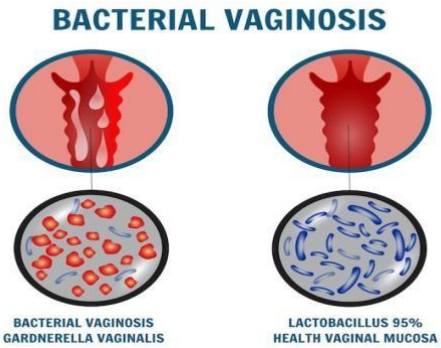

fig 2. Bacterial vaginosis

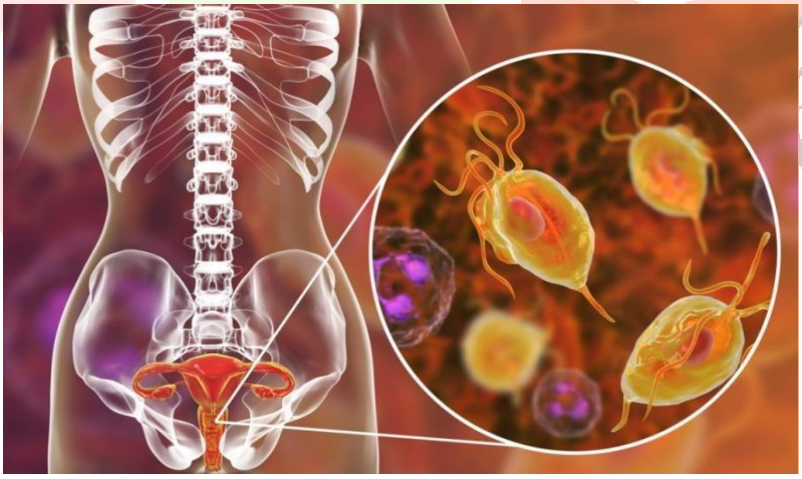

Fig 3. Trichomoniasis

Conventional treatment of vaginal infections involves synthetic drugs such as antifungal (e.g., clotrimazole), antibacterial (metronidazole), and antiseptic agents. These are commonly administered as creams, tablets, or suppositories.

However, these therapies have several limitations:Development of drug resistance

Recurrence of infection, Local irritation and side effects, Alteration of normal vaginal flora. In some cases, about 8% of patients show poor response or recurrence after treatment, highlighting the need for alternative therapies.[3]

Herbal formulations offer several advantages: Minimal side effects, Biocompatibilit, Costeffectiveness, Multi-target action (antimicrobial, anti-inflammatory, antioxidant)

Phytoconstituents such as flavonoids, tannins, alkaloids, and polyphenols exhibit strong pharmacological activities including antimicrobial and anti-inflammatory effects.

Thus, herbal formulations represent a promising alternative to synthetic drugs in the management of vaginal infections.[4]

VAGINAL DRUG DELIVERY SYSTEM:

The vaginal drug delivery system (VDDS) is an effective and well-established route of drug administration that is widely used for both local and systemic therapeutic purposes. It involves the administration of pharmaceutical formulations into the vaginal cavity for the treatment of gynecological conditions such as bacterial and fungal infections, hormonal imbalance, and contraception. The vagina is a fibromuscular organ lined with stratified squamous epithelium and covered with a mucus layer, which plays a significant role in drug absorption and protection against pathogens. The vaginal environment is maintained at an acidic pH (approximately 3.8– 4.5) due to the presence of Lactobacillus species, which produce lactic acid and help prevent microbial infections. The rich blood supply and permeable nature of the vaginal mucosa make it a suitable site for drug absorption, allowing both local and systemic effects [5].

From a pharmaceutical perspective, the vaginal route offers several advantages over conventional routes of drug administration. One of the major benefits is the avoidance of firstpass metabolism, which enhances the bioavailability of drugs that would otherwise be degraded in the liver when administered orally. Additionally, VDDS provides localized drug delivery directly to the site of infection, resulting in higher drug concentration at the target site and reduced systemic side effects. The non-invasive nature of this route also improves patient compliance, making it a preferred choice in women's healthcare. However, despite these advantages, certain limitations exist, including the self-cleansing action of the vagina, which can lead to rapid elimination of the drug formulation, as well as leakage, irritation, and variability in drug absorption due to hormonal changes and menstrual cycle variations [5].

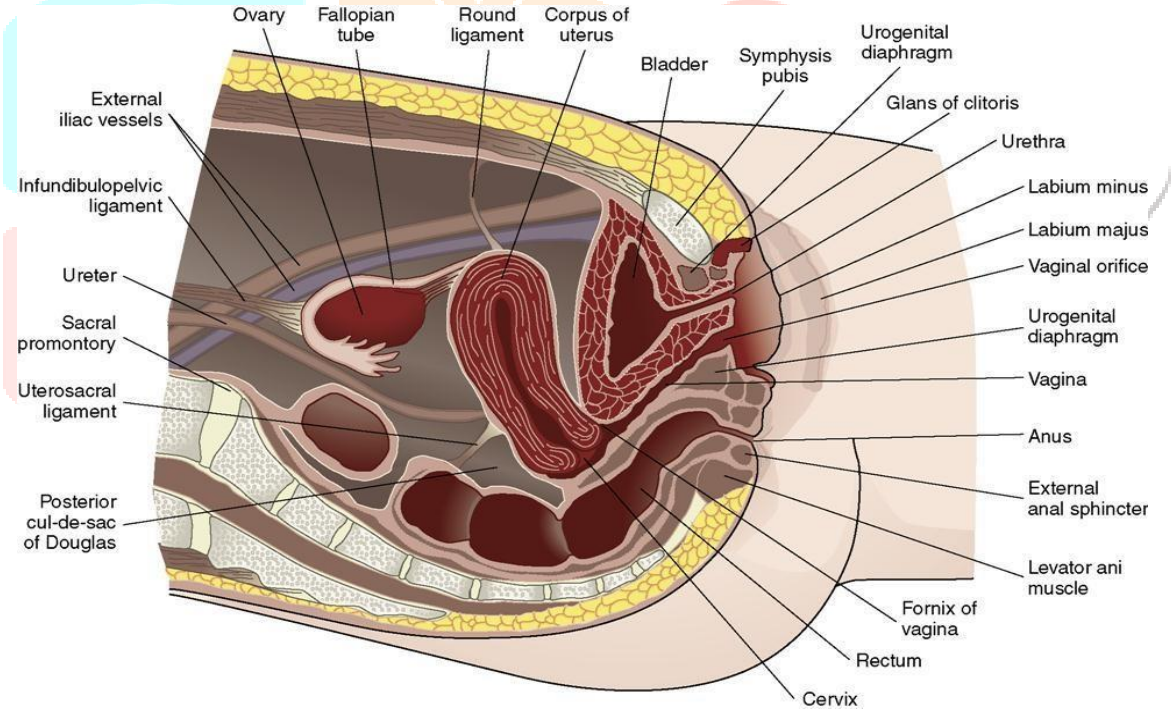

Fig 4.vaginal drug delievery system

ADVANTAGES OF HERBAL VAGINAL GEL FORMULATION:

Vaginal gel formulations have emerged as one of the most effective and patient-friendly dosage forms for vaginal drug delivery due to their unique physicochemical and biopharmaceutical properties. Unlike conventional dosage forms such as tablets or suppositories, gels provide a semi-solid system that can easily spread over the vaginal mucosa, ensuring uniform distribution of the drug. One of the major advantages of vaginal gels is their enhanced adhesion to the vaginal mucosa. This property is mainly attributed to the presence of polymers that exhibit mucoadhesive characteristics, allowing the formulation to interact with mucin present in the vaginal lining. As a result, the gel remains in close contact with the site of action, which improves drug absorption and therapeutic effectiveness.

Another significant advantage of vaginal gel formulations is their prolonged retention time. The natural self-cleansing action of the vagina often leads to rapid removal of conventional formulations; however, gels, especially those with mucoadhesive polymers, resist this clearance mechanism. This extended residence time ensures that the drug remains at the site for a longer duration, thereby enhancing its efficacy and reducing the frequency of administration. Prolonged retention also contributes to sustained therapeutic action, which is particularly beneficial in the treatment of chronic or recurrent vaginal infections.

Hydrogel-based vaginal formulations represent an advanced class of gel systems that further enhance drug delivery performance. Hydrogels are three-dimensional, hydrophilic polymeric networks capable of absorbing and retaining large amounts of water. Their high water content provides a moisturizing effect, which helps maintain vaginal hydration and soothes irritated tissues. The mucoadhesive nature of hydrogels enables strong interaction with the vaginal mucosa, leading to improved retention and bioavailability of the drug. Additionally, hydrogels protect the incorporated drug from degradation and allow for a more controlled and targeted release. Their biocompatibility and minimal toxicity make them highly suitable for sensitive vaginal tissues.[6]

RATIONALE OF THE STUDY:

In this context, herbal-based formulations have emerged as a promising approach due to their long history of use in traditional medicine systems and their relatively better safety profile. Herbal ingredients possess a wide range of pharmacological activities, including antimicrobial, anti-inflammatory, antioxidant, and wound-healing properties, which are beneficial in maintaining vaginal health. Unlike synthetic drugs that often act on a single target, herbal bioactives typically exhibit multi-targeted actions, thereby enhancing therapeutic effectiveness while minimizing adverse effects. Additionally, the natural origin and biocompatibility of herbal ingredients improve patient acceptability and compliance, especially for long-term use.

However, despite their therapeutic potential, herbal bioactive compounds face certain limitations that may hinder their clinical effectiveness. Many plant-derived compounds exhibit poor aqueous solubility, low stability, and limited retention at the site of application, which can result in inadequate drug concentration and reduced efficacy. In the vaginal environment, factors such as mucus secretion, enzymatic activity, and self-cleansing mechanisms further contribute to the rapid elimination of administered formulations. Therefore, there is a need to develop advanced delivery systems that can overcome these limitations and enhance the performance of herbal therapeutics.

The formulation of herbal vaginal gels, particularly those based on hydrogel systems, provides an effective strategy to address these challenges. Gels offer several advantages, including improved mucoadhesion, prolonged residence time, and controlled drug release, which help maintain an effective concentration of the drug at the site of action for an extended period. Hydrogels, due to their three-dimensional polymeric network and high water content, further enhance drug delivery by providing a moist environment, protecting the active compounds from degradation, and facilitating sustained release. These properties not only improve the bioavailability of herbal ingredients but also enhance their therapeutic outcomes.

Furthermore, the integration of herbal bioactives into modern pharmaceutical dosage forms represents a convergence of traditional knowledge and contemporary drug delivery technology. [7]

AIM OF THE STUDY:

To formulate and evaluate a herbal vaginal gel for the effective management of vaginal infections.

OBJECTIVE OF THE STUDY:

- To select suitable herbal ingredients with antimicrobial activity
- To formulate a stable vaginal gel
- To evaluate physicochemical properties (pH, viscosity, spreadability)
- To assess antimicrobial activity of the formulation

- To ensure safety and compatibility with vaginal mucosa[8]

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DRUG AND EXCIPIENT PROFILE:

LACTIC ACID –

1.Synonyms: 2-Hydroxypropionic acid, milk acid, α-hydroxypropionic acid
2.Chemical Formula: $C_3H_6O_3$
3.Molecular Weight: 90.08 g/mol
4.Melting Point: ~16–18 °C (pure form; commonly available as aqueous solution)
5.Solubility: Freely soluble in water, ethanol, and glycerin; miscible with many polar solvents
6.pKa Value: ~3.86
7.Role and Uses in Herbal Vaginal Gel
Lactic acid is widely used as a functional excipient in vaginal formulations due to its ability to maintain an acidic environment similar to normal vaginal pH (around 3.5–4.5). This acidic condition supports the growth of beneficial *Lactobacillus* species and helps inhibit pathogenic microorganisms.[1,2] Maintains optimal vaginal acidity, enhancing formulation stability and comfort . Creates unfavorable conditions for harmful bacteria and fungi . Contributes to microbial control within the formulation [3]

GUAR GUM –

1.Synonyms:Guaran, guarana gum, cluster bean gum
2.Source:Natural polysaccharide obtained from the endosperm of *Cyamopsis tetragonoloba* seeds

3.Chemical Nature:Galactomannan (polysaccharide)
4.Chemical Formula:$(C_6H_{10}O_5)_n$
5.Molecular Weight:High molecular weight polymer (varies widely, typically ~50,000– 8,000,000 g/mol)

6.Melting Point:Does not have a sharp melting point (decomposes on heating)
7.Solubility:Soluble in cold and hot water forming a viscous gel; insoluble in organic solvents
8.pKa Value:Not applicable (non-ionic polymer)
9.Role and Uses in Herbal Vaginal Gel
Guar gum is widely used as a natural gelling and thickening agent in vaginal formulations.[4] It hydrates rapidly in water to form a smooth, viscous gel, making it suitable for topical delivery system.Due to its biocompatibility, non-toxicity, and natural origin, guar gum is highly suitable for use in herbal vaginal gels, improving both formulation stability and effectiveness.[5]

PROPYLENE GLYCOL -

1.Synonyms: 1,2-Propanediol, propane-1,2-diol
2.Chemical Formula: $C_3H_8O_2$
3.Molecular Weight: 76.09 g/mol
4.Melting Point: ~−59 °C
5.Boiling Point: ~188 °C
6.Solubility: Miscible with water, ethanol, acetone, and chloroform
7.pKa Value: Not applicable (neutral compound)

8.Role and Gel Uses in Herbal Vaginal
Propylene glycol is a widely used excipient in pharmaceutical and topical formulations due to its multifunctional properties.Enhances the solubility of poorly water-soluble herbal constituents. Improves permeation of active compounds through vaginal mucosa. Helps maintain uniformity and stability of the formulation.[6]

GLYCERINE –

1.Synonyms: Glycerol, propane-1,2,3-triol
2.Chemical Formula: $C_3H_8O_3$
3.Molecular Weight: 92.09 g/mol
4.Melting Point: ~17–18 °C
5.Boiling Point: ~290 °C (decomposes)
6.Solubility: Miscible with water and ethanol; insoluble in non-polar solvents
7.pKa Value: Not applicable (neutral compound)
8.Role and Uses in Herbal Vaginal Gel
Glycerine is a commonly used excipient in vaginal formulations due to its moisturizing and stabilizing properties. Attracts and retains moisture, preventing dryness and irritation. Improves texture and spreadability of the gel. Provides a lubricating and calming effect on vaginal mucosa.[7] Because of its biocompatibility, non-toxicity, and ability to enhance patient comfort, glycerine is widely incorporated into herbal vaginal gels for improved formulation performance and user acceptability.

METHYLPARABEN –

1.Synonyms:Methyl p-hydroxybenzoate, para-hydroxybenzoic acid methyl ester
2.Chemical Formula:$C_8H_8O_3$
3.Molecular Weight:152.15 g/mol
4.Melting Point:~125–130 °C
5.Solubility:Slightly soluble in water, freely soluble in alcohol, propylene glycol, and ether
6.pKa Value:~8.4
7.Role and Uses in Herbal Vaginal Gel
Methylparaben is commonly used as a preservative in topical and vaginal formulations. Prevents growth of bacteria, yeast, and molds, enhancing product shelf life.[8] Protects formulation integrity over time. Works well with natural herbal actives without affecting efficacy.

TRIETHANOLAMINE –

1.Synonyms:TEA, 2,2',2"-Nitrilotriethanol
2.Chemical Formula:$C_6H_{15}NO_3$
3.Molecular Weight:149.19 g/mol
4.Melting Point:~21 °C
5.Boiling Point:~335 °C
6.Solubility:Miscible with water and ethanol
7.pKa Value:~7.8 (acts as a weak base)
8.Role and Uses in Herbal Vaginal Gel
Triethanolamine is primarily used as a pH adjuster and emulsifying agent in topical and vaginal formulations. Adjusts and maintains the gel at a physiological pH suitable for vaginal application.[9] Helps stabilize oil-in-water herbal gel formulations. Enhances solubility of certain herbal actives or other excipients. Maintains stability and consistency of the formulation.

PURIFIED WATER –

1.Synonyms:Aqua, distilled water, water for injection (depending on grade)
2.Chemical Formula:H_2O
3.Molecular Weight:18.02 g/mol
4.Melting Point:0 °C
5.Boiling Point:100 °C
6.Solubility:Completely miscible with most polar solvents; universal solvent
7.pKa Value:Not applicable (neutral solvent, pH ~7 at 25 °C)

8.Role and Uses in Herbal Vaginal Gel
Purified water is the primary solvent in herbal vaginal gels, serving as the base for formulation.Dissolves water-soluble herbal extracts, polymers, and other excipients. Provides moisture and consistency to the gel. Enables uniform distribution of active ingredients throughout the gel. Non-toxic, inert, and essential for vaginal application.[10]

ACTIVE CONSTITUENTS PROFILE:

1.ALOE VERA

Fig 5. Aloe vera

1.Biological Source:

1.Botanical name: *Aloe vera* (syn. *Aloe barbadensis Miller*)

2.Family: Asphodelaceae
3.Part used:Inner leaf gel (clear mucilaginous pulp)
Leaf latex (yellow bitter sap beneath the rind)
4.Geographical origin: Native to the Arabian Peninsula; widely cultivated in India, Africa, the Mediterranean, and the Americas.
5.Type of plant: Succulent perennial with thick, fleshy leaves arranged in a rosette.

2.Botanical & Physical Characteristics:

1.Morphology: Thick, lance-shaped leaves (30–50 cm long)**,** Serrated leaf margins**,** Gel-filled parenchymatous tissue inside**,** Yellow tubular flowers on a tall spik.

3.Chemical Constituents:

Aloe Gel contains: Polysaccharides (Acemannan – major bioactive compound)
Glucomannans, Vitamins (A, C, E, B12), Enzymes (bradykinase), Amino acids, Saponins, Sterols (lupeol, campesterol)

4.Pharmacological Properties: Anti-inflammatory**,** Antimicrobial (antibacterial & antifungal) **,** Wound-healing (promotes collagen synthesis)**,** Moisturizing & humectant Immunomodulatory, Mild estrogen-modulating activity (suggested in preliminary studies)[10,11]

5.Herbal Uses in the Female Reproductive System:

Vaginal Dryness: Aloe gel Acts as a natural lubricant**,** Hydrates vaginal mucosa**,** Supports tissue elasticity**,** Used in herbal vaginal gels for menopausal dryness.[12]

6.Mechanism of Action in Vaginal Tissue:

Polysaccharides increase moisture retention.
Stimulates fibroblast activity → enhances collagen production.
Inhibits prostaglandins → reduces inflammation.
Antimicrobial saponins help maintain healthy vaginal flora balance.

2.NEEM (Azadirachta indica)

Fig 6. Neem

1.Biological Source:

Botanical name: *Azadirachta indica* A. Juss.
Common name: Neem (family *Meliaceae*).
Origin & ecology: A tropical/subtropical evergreen native to the Indian subcontinent (India, Pakistan, Bangladesh) widely cultivated in many tropical regions. It tolerates drought and poor soils.

Plant parts used medicinally: Leaves, seeds (oil), bark, flowers, roots, and fruit are utilized in traditional medicine.

2.Chemical Characteristics & Phytochemicals:

Neem is rich in bioactive phytochemicals, including limonoids, triterpenoids, flavonoids, and other compounds: Azadirachtin – a major limonoid with insect antifeedant and biological activity. Nimbin, nimbidin, nimbidol, salannin – triterpenoids with antimicrobial and antiinflammatory properties.[13] Quercetin – a flavonoid with antioxidant effects. Fatty acids (oleic, palmitic, stearic) in seed oil. These constituents contribute to neem's broad biological and pharmacological activities.

3.General Medicinal Properties: Scientific research and traditional medicine link neem extracts to a range of bioactivities:
Anti-microbial, antibacterial, antifungal, and antiviral effects.

Anti-inflammatory & antioxidant: mitigates oxidative damage and inflammation.

Immunomodulatory & anticancer potential: shown in some cell and animal studies. Antihyperglycemic & hepatoprotective: may modulate blood sugar and liver function. Anti-ulcer and wound-healing activity: beneficial in traditional use. These properties make neem extracts a common herbal remedy across many systems of traditional medicine (Ayurveda, Unani).

4.. Contraceptive Effects: Hormonal Regulation: Some studies report decreased levels of reproductive hormones (FSH, LH) and related disruptions in reproductive physiology in treated female rats. [14]

5.Vaginal / Local Use: Vaginal Microbial Activity: Preparations derived from neem oil can exhibit antimicrobial properties against pathogens like *Candida* and bacteria, and formulations have been patented for treating abnormal vaginal discharge.

3.POMEGRANATE (*Punica granatum* L.)

Fig 7. Pomegranate

1.Biological source

Botanical name: *Punica granatum* L.
Family: Punicaceae
Plant part used: Membranous septa (the white, papery partitions inside the fruit that separate the aril chambers)
Common name: Pomegranate membrane, internal septum
Description: Thin, whitish, fibrous tissue forming the locular walls inside the fruit, derived from the mesocarp/endocarp of the pericarp. This tissue is collected from mature, ripe fruits and can be used in powdered form, dried extract, or directly in gel formulations.

2.Botanical and Anatomical Description

In a mature pomegranate fruit, the edible portion (~50% of fruit weight) consists mainly of the arils (juice-containing sacs) and seeds. The arils are arranged in compartments (locules) formed by the internal *membranous septa* — a thin, white, papery tissue that subdivides the fruit interior. These membranes are extensions of the endocarp/mesocarp (inner white tissue of the pericarp) and structurally support the locules, separating aril clusters.

3.Phytochemical Profile (General Fruit Tissues)

Although specific studies on the septal membrane alone are scarce, most parts of *Punica granatum* fruit share a rich phytochemical makeup including:
A. Polyphenols and Tannins: Ellagitannins (e.g., punicalagin, punicalin): major antioxidants present in peel and internal tissues. Hydrolysable tannins: contribute to astringency and bioactivity. These compounds have strong antioxidant, anti-inflammatory, and antimicrobial potential [15,16]

B. Flavonoids : Anthocyanins and other flavonoids are abundant in red arils and are present at lower levels in internal fruit tissues. These molecules are known for free radical scavenging and modulating inflammation and microbe-host interactions.

4.Medicinal and Functional Properties Relevant to Vaginal Gel Use

Antioxidant Effects: Polyphenols and tannins in pomegranate tissues have powerful antioxidant capacity. This may help protect vaginal mucosa from oxidative stress and support tissue resilience.

Anti-inflammatory Activity: Ellagitannins and flavonoids exhibit *anti-inflammatory modulation*, which could be beneficial in formulations aimed at soothing irritation or enhancing mucosal comfort.
Antimicrobial Potential: Studies (especially with peel extracts) have shown inhibitory effects against bacteria and fungi through disruption of microbial cell walls and key enzymes. While direct research on the septal membrane is lacking, it likely contributes similar antimicrobials due to shared phenolic content.

5.Considerations in Herbal Vaginal Gel Formulation

Bioactive carrier: antioxidant/anti-inflammatory component.
Astringent effect: may transiently tighten tissues — sometimes desirable depending on therapeutic aim.

Gelling interaction: fibers from membrane/pulp can contribute to gel viscosity and stability.

6.Safety & Sensitivity

Astringent compounds can be irritating at high concentrations.
Patch testing and formulation at appropriate concentrations is essential in sensitive mucosal applications.

4. TULSI (Ocimum sanctu

Fig 8. Tulsi

1.Biological Source

Botanical name: *Ocimum sanctum* L. (also known as *Ocimum tenuiflorum*)
Common names: Tulsi, Holy Basil, Sacred Basil
Family: Lamiaceae (mint family)
Origin & distribution: Native to the Indian subcontinent; widely cultivated across Asia and tropical regions.

Plant parts used: Leaves (most common), stems, flowers, seeds, and essential oil.

2.Phytochemistry — Key Active Compounds

Tulsi contains a wide range of bioactive compounds responsible for its therapeutic activity:
Eugenol: Major constituent (~60–70% in leaf oil), known for anti-inflammatory, analgesic, and antimicrobial effects. [17]
Rosmarinic acid, ursolic acid, flavonoids (orientin, vicenin): Potent antioxidants.
Phenolic compounds: Contribute to antioxidant and detoxification effects.
Terpenoids and essential oils: Add antimicrobial and anti-inflammatory activity.
These constituents vary depending on plant variety, growing conditions, and extraction method.

3.General Pharmacological Properties

Research supports a broad range of biological activities:
Antioxidant & Protective: Tulsi enhances antioxidant defenses (e.g., glutathione, superoxide dismutase) which help protect cells from oxidative stress.
Anti-inflammatory: Compounds like eugenol and rosmarinic acid inhibit inflammation pathways, helping with inflammatory conditions.
Antimicrobial: Tulsi extracts show activity against bacteria, viruses, and fungi in lab studies, which supports traditional use for infections.

4.Potential Vaginal / Local Effects

There is little direct clinical evidence for tulsi extracts used vaginally; most related data comes from laboratory antimicrobial studies:

5.Antimicrobial Action

Tulsi extracts show antimicrobial activity against various pathogens in lab tests, suggesting potential utility against microbes potentially implicated in vaginal infections (e.g., bacterial or fungal agents) — but this is not verified in clinical trials.
Anti-Inflammatory / Antioxidant: These actions might support vaginal tissue health indirectly, although again human data is lacking.

7.Safety & Precautions

Generally Recognized as Safe (Culinary/Moderate Use). Tulsi leaves and tea are widely consumed and generally safe at culinary doses.
8.Medicinal / High-Dose Use

Safety during pregnancy and breastfeeding is not well-established; medicinal doses should be used cautiously. Some people may experience digestive upset or allergic reactions, particularly if sensitive to Lamiaceae plants.

Hormonal effects in women are not clearly understood; high-dose use for fertility or reproductive purposes is not recommended without medical advice.

5.TURMARIC (Curcuma longa)

Fig9. Turmeric

1. Biological Source

Botanical name: *Curcuma longa* L.
Family: Zingiberaceae (ginger family)
Common names: Turmeric, Indian saffron, Haldi
Plant part used medicinally: Rhizome (underground stem)
Geographical origin: Native to South Asia, especially India; cultivated widely in tropical regions including India, Sri Lanka, China, Indonesia, and Africa.
Preparation forms: Powdered rhizome, standardized extracts (curcuminoids), essential oil, tincture, capsules, and topical preparations.

The rhizome is boiled, dried, and powdered to produce the characteristic yellow turmeric powder.

2. Phytochemical Composition

Turmeric contains several bioactive compounds:
Major Active Constituents: Curcuminoids (2–5%): Curcumin (principal compound),

Demethoxycurcumin, Bisdemethoxycurcumin
Volatile oils (2–7%): Turmerone, Atlan tone, Zingiberene
Other compounds: Polysaccharides, Proteins, Resins, Minerals

Curcumin is primarily responsible for turmeric's pharmacological activity, though whole-plant extracts may act synergistically.

3. Characteristics of Curcuma longa Extract

Physical Characteristics: Bright yellow–orange color, Warm, bitter taste, Aromatic odor
Fat-soluble (poor water solubility), Low natural bioavailability (often combined with piperine to enhance absorption)

4. Pharmacological Properties

Turmeric is one of the most extensively researched medicinal plants.
Anti-Inflammatory: Curcumin inhibits inflammatory mediators (NF-κB, COX-2, TNF-α).

Useful in chronic inflammatory conditions.
Antioxidant: Neutralizes free radicals and increases endogenous antioxidant enzymes.
Antimicrobial: Shows antibacterial, antifungal, and antiviral activity in laboratory studies.[19,20]

Immunomodulatory: Regulates immune response and inflammatory signaling.
Wound Healing: Promotes collagen synthesis and tissue repair.
Anticancer (Experimental): Demonstrates anti-proliferative and apoptosis-inducing effects in cell studies.
Hepatoprotective: Supports liver detoxification pathways. [21,22]

5. Vaginal and Local Use

Turmeric has traditional external uses but limited modern clinical validation.
A. Antimicrobial Action:Laboratory studies show activity against: Candida species, Certain bacterial pathogens. This suggests theoretical usefulness for: Vaginal candidiasis, Mild infections.

However: Clinical trials in humans are limited.Not considered a standard medical therapy
B. Anti-Inflammatory Support: Reduce inflammation, Support tissue healing, Help soothe irritation. But concentrated curcumin or essential oil may cause: Local irritation, Staining, Contact dermatitis.

C. Traditional Practices: Turmeric paste has been applied externally for vulvar irritation, Used postpartum for wound healing,

Internal vaginal insertion of raw turmeric is not medically recommended due to: Risk of irritation, Microbiome disruption, Lack of safety data

MATERIAL AND METHOD:

1.MATERIALS

Table1. List of Material

Sr.no	materials
1	Aloe Vera Extract
2	Pomegranate extract
3	Neem Extract
4	Tulsi Extract
5	Curcumin Extract
6	Lactic Acid
7	Guar Gum
8	Propylene Glycol
9	Glycerine
10	Methyl Paraben
11	Triethanolamine
12	Purified Water
13	Rose Oil

Table 2. List of equipment

Sr.no	Equipment
1	Burner
2	Ph meter
3	Water bath
4	Digital balance
5	Viscometer
6	Hot plate
7	Thermometer
8	Tube filling machine
9	Oven
10	refrigerator

METHOD:

Fig 10. Extaction process

1)Extraction of Aloe vera: [23]

Fresh, healthy, and mature leaves of Aloe vera were collected and selected based on their size, thickness, and absence of any physical damage or microbial contamination. The collected leaves were first washed thoroughly under running tap water followed by rinsing with distilled water to remove adhering dirt, dust particles, and surface impurities. After cleaning, the leaves were allowed to dry at room temperature.

The base and tip of each leaf were trimmed, and the outer green rind was carefully removed using a sterile knife under hygienic conditions. Care was taken to avoid contamination from the yellow latex layer (aloin-containing portion) present just beneath the rind, as it may cause irritation and is not required for gel extraction. The inner transparent mucilaginous gel was then gently scooped out using a sterile spatula.

The collected gel was transferred into a clean beaker and subjected to homogenization using a mechanical blender to obtain a smooth and uniform consistency. This step ensures proper breakdown of gel lumps and improves the ease of further processing. The homogenized gel was then filtered through a double-layered muslin cloth to remove fibrous material and any remaining solid impurities, resulting in a clear viscous extract.

2. **Extraction of pomogranate:[23]**

1. **PREPARATION OF POWDER**

Collection of Pomegranate Fruits

↓

Separation of Peel and Membrane

↓

Washing with Distilled Water

↓

Shade Drying (5–7 days)

↓

Grinding and Sieving

↓

Powder Ready for Extraction

2. **MACERATION** Weigh the Coarse Powder

↓

Transfer to Maceration Vessel with Suitable Solvent

↓

Allow to Stand for 24–72 hrs

With Occasional Shaking

↓

Filtration

↓

Press the Residue (Marc)

↓

Collect Filtrate (Liquid Extract)

3.FILTRATION

Take the Macerated Mixture

↓

Place Filter Paper in Funnel

↓

Pour Mixture into Funnel

↓

Liquid Passes Through

↓

Residue Remains on Filter Paper

4.**CONCENTRATION**

Take the Filtrate

↓

Transfer to Evaporating Dish

↓

Apply Gentle Heat

↓

Evaporate Solvent

↓

Thick Extract Obtained

3. Extraction of neem: [23]

1.PREPARATION OF POWDER

Collection of Fresh Neem Leaves

↓

Washing with Distilled Water

↓

Shade Drying (5–7 days)

↓

Grinding

↓

Sieving

↓

Powder Ready for Extraction

2. **MACERATION**

Weigh the Coarse Powder

↓

Transfer to Maceration Vessel

↓

Add Suitable Solvent

↓

Allow to Stand for 24–72 hrs

With Occasional Shaking

↓

Filtration

↓

Press the Residue (Marc)

↓

Collect Filtrate (Liquid Extract)

3. **FILTRATION**

Take the Macerated Mixture

↓

Place Filter Paper in Funnel

↓

Pour the Mixture into Funnel

↓

Filtrate Collected

↓

Residue Remains on Filter Paper

4.**CONCENTRATION**

Take the Filtrate

↓

Transfer to Evaporating Dish

↓

Apply Gentle Heat (Water Bath)

↓

Evaporate Solvent & Extract Obtained

4. Extraction of Tulsi: [23]

1 .PREPARATION OF POWDER

Collection of Fresh Tulsi Leaves

↓

Washing with Distilled Water

↓

Shade Drying (5–7 days)

↓

Grinding (coarse powder)

↓

Sieving

↓

Powder Ready for Extraction

2 .MACERATION

Weigh the Coarse Powder

↓

Transfer to Maceration Vessel

↓

Add Suitable Solvent

↓

Allow to Stand for 24–72 hrs

With Occasional Shaking

↓

Filtration

↓

Collect Filtrate (Liquid Extract)

3 .FILTRATION

Take the Macerated Mixture

↓

Place Filter Paper / Muslin Cloth in Funnel

↓

Pour the Mixture into Funnel

↓

Filtrate Collected

↓

Residue Remains on Filter Paper

CONCENTRATION

Take the Filtrate

↓

Transfer to Evaporating Dish

↓

Apply Gentle Heat (Water Bath)

↓

Evaporate Solvent

↓

Thick Tulsi Extract Obtained

5. EXTRACTION OF CURCUMIN: [23]

1.PREPARATION OF POWDER

Collection of Fresh Turmeric Rhizomes

↓

Washing with Water

↓

Boiling (Curing) for 30–45 min

↓

Drying (Sun drying / Hot air oven)

↓

Grinding

↓

Sieving

↓

Powder Ready for Extraction

2)

2.**MACERATION** Weigh the Turmeric Powder

↓

Transfer to Maceration Vessel

↓

Add Suitable Solvent

↓

Allow to Stand for 24–72 hrs

↓

Filtration

↓

Collect Filtrate (Liquid Extract)

3.FILTRATION

Take the Macerated Mixture

↓

Place Filter Paper in Funnel

↓

Pour the Mixture into Funnel

↓

Filtrate Collected

↓

Residue Remains on Filter Paper

4.**CONCENTRATION**

Take the Filtrate

↓

Transfer to Evaporating Dish

↓

Apply Gentle Heat (Water Bath)

↓

Evaporate Solvent

↓

Thick Yellow Extract Obtained

CHEMICAL TESTS OF ACTIVE INGREDIENTS:

Fig 11. Ferric chloride test

1)Chemical tests for pomegranate extract containing sooting and healing property: a.Ferric Chloride Test:
Procedure: Add few drops of $FeCl_3$ solution to extract
Observation: Blue-black or green coloration
Inference: Presence of tannins [24]

2) Chemical tests for neem extract containing antibacterial and antifungal property:

a. Dragendorff's Test (Antibacterial Activity):

Procedure: Add Dragendorff's reagent to extract
Observation: Orange or reddish-brown precipitate
Inference:Presence of alkaloids[25]

b. Salkowski Test (antifungal activity):

Procedure:Add chloroform and concentrated H_2SO_4
Observation:Reddish-brown coloration at interface
Inference: Presence of terpenoids[26]

3)) Chemical tests for tulsi extract containing antimicrobial property:

a.Ferric Chloride Test: Procedure: Add few drops of $FeCl_3$ solution to the extract
Observation: Deep blue, green, or violet color
Inference: Presence of phenolic compounds (eugenol) [27]

4) Chemical tests for curcumin extract containing antiinflamatory property:

a.Alkaline Reagent Test:Procedure: Add a few drops of NaOH to the extract
Observation: Reddish-brown color, which turns yellow on adding acid
Inference: Presence of curcumin (curcuminoids)[28]

5) Chemical tests for aloe vera extract containing sooting and healing property:

a.Molisch's Test: Procedure: Add few drops of α-naphthol to extract, Carefully add concentrated H_2SO_4 along the side

Observation:Formation of violet ring
Inference: Presence of polysaccharides (acemannan). [29]

FORMULATION TABLE FOR A HERBAL VAGINAL GEL:

Table 4. formulation table [f1 – f5]

Sr.no	Ingredients	F1	F2	F3	F4	F5
1	Aloe vera extract	4.5gm	5.0gm	**5.5gm**	6.0gm	6.5gm
2	Neem Extract	1.5gm	2.0gm	**2.5gm**	3.0gm	3.5gm
3	Pomegranate Extract	1.5gm	1.8gm	**2.0gm**	2.2gm	2.5gm
4	Tulsi Extract	1.0gm	1.2gm	**1.5gm**	1.8gm	2.0gm
5	Curcumin Extract	0.4gm	0.5gm	**0.5gm**	0.6gm	0.7gm
6	Lactic Acid	0.3gm	0.3gm	**0.3gm**	0.3gm	0.3gm
7	Guar Gum	1.2gm	1.2gm	**1.5gm**	1.5gm	1.8gm
8	Propylene glycol	3.0gm	3.0gm	**3.0gm**	3.0gm	3.0gm
9	Glycerine	2.0gm	2.0gm	**2.0gm**	2.0gm	2.0gm
10	Methyl Paraben	0.05gm	0.05gm	**0.05gm**	0.05gm	0.05gm
11	Triethanolamine	0.3gm	0.3gm	**0.3gm**	0.3gm	0.3gm
12	Rose oil	0.05gm	0.05gm	**0.05gm**	0.05gm	0.05gm
13	Purified Water	14.2gm	12.9gm	**10.85gm**	9.2gm	7.8gm

F1 → Mild formulation (Suitable for sensitive conditions)
F2–F3 → Balanced formulations (Best safety + efficacy balance)
F3 is usually ideal (recommended for thesis as optimized batch)

F4 → Strong antimicrobial (Higher activity but still acceptable)
F5 → Maximum concentrat (may cause mild irritation in some cases) [30, 31]

MASTER FORMULA FOR HERBAL VAGINAL GEL (30gm) : [32]

Table 5. master formula table

Sr.no	ingredients	category	quantity	property
1	Aloe vera extract	Active	5.5gm	Sooting,healing
2	Neem Extract	Active	2.5gm	Antibacterial,antifungal
3	Pomegranate Extract	Active	2.0gm	Antimicrobial
4	Tulsi Extract	Active	1.5gm	Antimicrobial
5	Curcumin Extract	Active	0.5gm	Antiinflammatory
6	Lactic Acid	Ph adjuster	0.3ml	Maintain vaginal PH
7	Guar Gum	Gelling agent	1.5gm	Gel base formation

8	Propylene glycol	Humectant	3.0ml	Moisturizer
9	Glycerine	Humectant	2.0ml	Hydration
10	Methyl Paraben	Preservative	0.05gm	Preservation
11	Triethanolamine	Nertrilizer	0.3ml	Ph adjustment
12	Rose oil	Fragrance	0.05ml	Fragrance
13	Purified Water	vehicle	10.85ml	Base

FORMULATION METHOD OF HERBAL VAGINAL GEL:

Method of Preparation:

Step 1: Preparation of Gel Base

- Accurately weigh guar gum.
- Sprinkle it slowly into a beaker containing a measured quantity of distilled water.
- Allow it to soak for 30–60 minutes for proper swelling.
- Stir continuously using a magnetic stirrer to form a uniform gel base.

Step 2: Preparation of Preservative Solution

- Dissolve methyl paraben in a small quantity of warm distilled water or propylene glycol.
- Ensure complete dissolution.

Step 3: Preparation of Herbal Extract Mixture

- Accurately weigh required quantities of: Aloe vera extract, Neem extract, Tulsi extract, Pomegranate extract, Turmeric extract
- Mix all extracts together in a separate beaker.
- Add propylene glycol and glycerine to this mixture.
- Stir well to obtain a uniform solution.

Step 4: Incorporation into Gel Base

- Slowly add the herbal extract mixture into the prepared gel base.
- Stir continuously using a mechanical stirrer or homogenizer.
- Ensure uniform distribution of all ingredients.

Step 5: Addition of Preservative

- Add the prepared methyl paraben solution to the gel.
- Mix thoroughly.

Step 6: pH Adjustment

- Add lactic acid dropwise to maintain vaginal pH (3.5–4.5).
- Add triethanolamine (TEA) slowly to adjust and stabilize pH if required.

- Check pH using a digital pH meter.

Step 7: Addition of Fragrance

- Add a small quantity of rose oil.
- Mix gently to avoid air entrapment.

Step 8: Homogenization

- Homogenize the final formulation for 5–10 minutes.
- This ensures: Smooth texture, Uniform consistence, Better stability

Step 9: Final Volume Adjustment

- Add distilled water (q.s.) to make up the final weight (e.g., 30 g).
- Mix thoroughly.

Step 10: Packaging and Storage

- Transfer the gel into sterile collapsible tubes or containers.
- Seal properly.Store in a cool and dry place or at room temperature. [33,34]

HOW TO USE HERBAL VAGINAL GEL:

A herbal vaginal gel should be used carefully to ensure safety, hygiene, and effectiveness. Before application, the user should check that the product is specifically formulated for vaginal use, within its expiry date, and free from any discoloration or unpleasant odor. Proper hygiene is essential, so hands must be washed thoroughly and nails kept short to avoid injury. The gel can be applied in a comfortable position such as lying on the back with knees bent, standing with one leg raised, or squatting. If an applicator is provided, it should be filled with the prescribed amount of gel (generally 2–5 g), gently inserted into the vagina, and the plunger pressed slowly to release the gel; alternatively, a clean finger may be used to apply the gel inside the vaginal opening. After application, the user should remain lying down for about 10– 15 minutes to prevent leakage, and it is usually recommended to apply the gel at bedtime for better retention. The applicator, if reusable, should be cleaned properly after each use.

The frequency of application depends on the condition being treated, such as once or twice daily for infections or once daily for dryness, and the duration of treatment typically ranges from 5 to 7 days or longer if advised. Certain precautions must be followed, including avoiding use during menstruation unless directed, refraining from sexual intercourse immediately after application, and not using multiple vaginal products simultaneously. The user should discontinue use if severe irritation, burning, or allergic reactions occur, or if there is no improvement within a week

EVALUATION TEST FOR A HERBAL VAGINAL GEL:

EVALUATION PARAMETER:

1.Organoleptic Evaluation Tests:

Parameters: colour , odour, appearance , homogenicity, presence of grittiness .
Procedure: Visually inspect gel against white and black background.
Smell for any unpleasant odor.
Rub small quantity between fingers to check smoothness and grittiness. [35]

2. pH Determination :The pH of the gel was determined using the pH paper by immersing the paper in the formulation. [35]

3. Appearance and homogeneity : The appearance and homogeneity were determined through visual inspection.

4. Viscosity : The viscosity of gel was measured using a Brookfield viscometer at 25oc and a viscometer spindle speed of 12 rpm with 64 No spindle. [36]

5. Spreadability - It specifies the diameter of the region that the gel can eas-ily cover when applied to skin or a damaged area. The spread-ing value has an impact on treatment effectiveness as well. Spreadability measures how long it takes two slides to sepa-rate from the gel placed in between them under a certain load direction (in seconds). The spreadability increases as the time required to divide two slides' decreases. The spreadability is calculated using the following formula. Spreadability (S) = M×L / T

Where, M= Weight tied to slide
L= Length of slide
T= Time required to separate slides. [36]

6. Washability test : The washability test was determined by applying a small amount of prepared formulation over the skin and afterward washed with water. [35]

7.Stability Study: The stability study was performed as per ICH guidelines 6. The formulated gel were filled in the collapsible tubes and stored at different temperatures and humidity conditions, viz.[37]

8.Skin Irritation test: 0.5 gm of the herbal gel was used as the test substance was applied to an area of approximately 6 cm2 of skin. At the end of the exposure period, i.e., 1 hour, residual test substance was removed, The gel was applied to the skin once a day for 7 days and observed for any sensitivity and the reaction if any was graded.[38]

9.Drug Content Uniformaty: Dissolve known quantity in suitable solvent. Analyze using UV-

Visible spectrophotometer. Compare with calibration curve. Drug content: 95–105%. [36]

10.Antimicrobial Study:

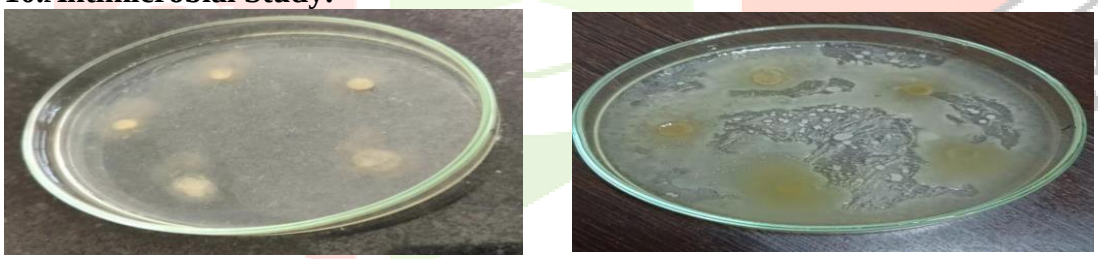

Fig.11 antimicrobial study

1.Procedure:Pour sterile Mueller-Hinton Agar (MHA) plates , Swab microbial culture evenly ,

Punch wells (6–8 mm) ,Add gel samples into wells
Incubate: Bacteria: 37°C for 24 h, Measure zone of inhibition (mm).
Result: The antimicrobial activity of the formulated herbal vaginal gel was evaluated using the agar well diffusion method. The results showed that formulation F5 exhibited the highest zone of inhibition against Staphylococcus aureus (20 mm), E. coli (18 mm), and Candida albicans (17 mm), indicating superior antimicrobial efficacy. The activity increased with increasing concentration of herbal extracts.

Table 6. Evaluation parameter

Sr no.	Evaluation parameter	F1	F2	F3

1	Colour	Yellow	Yellow	Yellow
2	Odour	Characteristics	Characteristics	Characteristics
3	Appearance	Homogeneous	Homogeneous	Homogeneous
4	Spreadability	Good Spreadability	Good Spreadability	Good Spreadability
5	Viscosity	2.55	2.75	2.85
6	pH	4.1	4.2	4.1
7	Skin irritation test	No irritation observed	No irritation observed	No irritation observed
8	Homogeneity	Uniform and free from lumps	Uniform and free from lumps	Uniform and free from lumps
9	Washability	Easy Washable	Easy Washable	Easy Washable
10	Stability Study	Stable with no change in color, PH or consistency	Stable with no change in color, PH or consistency	Stable with no change in color, PH or consistency

RESULT AND DISCUSSION:

The results typically begin with the evaluation of physical parameters such as color, odor, homogeneity, and consistency. An ideal herbal vaginal gel is usually smooth, uniform, and free from lumps, indicating proper mixing and compatibility of ingredients. The pH of the formulation is a key parameter and should be within the normal vaginal range (approximately 3.8–4.5) to maintain the natural acidic environment and support the growth of beneficial microflora. If the pH of formulations F1 to F5 falls within this range, it suggests good compatibility and reduced chances of irritation.

Viscosity and rheological behavior are also important, as they influence the spreadability and retention time of the gel in the vaginal cavity. Moderate viscosity is desirable—too high viscosity may hinder application, while too low viscosity may result in leakage and reduced residence time. The results often show that formulations containing higher concentrations of gelling agents exhibit increased viscosity.

Spreadability studies complement viscosity data, indicating how easily the gel can be applied; better spreadability ensures uniform distribution of active constituents.

A crucial part of the results includes antimicrobial activity studies, usually performed against common vaginal pathogens such as Candida albicans, Escherichia coli, or Staphylococcus aureus. The zone of inhibition observed for different formulations indicates their effectiveness. Typically, formulations with higher concentrations of herbal extracts show greater antimicrobial activity due to the synergistic effects of phytoconstituents like flavonoids, tannins, and alkaloids. The results may reveal that a particular formulation (e.g., F3 or F4) exhibits the best balance of antimicrobial activity and physicochemical properties.

Stability studies are conducted under different storage conditions (e.g., room temperature and accelerated conditions) to evaluate changes in pH, viscosity, color, and drug content over time. Minimal changes indicate good stability and shelf-life of the formulation. If the gel maintains its characteristics over a period (e.g., 1–3 months), it confirms formulation robustness.

CONCLUSION:

The present study concludes that the formulated herbal vaginal gel was successfully developed using selected plant extracts and evaluated for its physicochemical and biological properties. All formulations exhibited satisfactory characteristics such as good homogeneity, smooth texture, and acceptable appearance, indicating proper formulation techniques. The pH of the gels was found to be within the normal vaginal range, ensuring compatibility with the vaginal environment and minimizing the risk of irritation. Viscosity and spreadability results demonstrated that the gel possessed appropriate consistency for easy application and adequate retention at the site of action.

The antimicrobial studies confirmed that the herbal vaginal gel exhibited significant activity against common vaginal pathogens, which may be attributed to the synergistic effect of bioactive constituents present in the selected herbs. Among the different formulations (F1–F5), the optimized formulation showed the best balance of physicochemical properties, stability, and antimicrobial efficacy. Stability studies further indicated that the formulation remained stable under different storage conditions without significant changes in its properties.

Overall, the developed herbal vaginal gel can be considered a safe, effective, and promising alternative to conventional synthetic formulations for the management of vaginal infections. However, further in vivo and clinical studies are recommended to establish its therapeutic efficacy and safety on a larger scale.

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