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FORMULATION AND EVALUATION OF HERBAL VEGINAL SUPPOSITORY

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Abstract:
Formulation and Evaluation of Herbal Vaginal Suppository Using Neem Herbal drug delivery systems have gained increasing attention due to their safety, efficacy, and reduced side effects compared to synthetic formulations. Among various medicinal plants, neem (Azadirachta indica) is widely recognized for its potent antimicrobial, antifungal, anti-inflammatory, and antiseptic properties. The present study focuses on the formulation and evaluation of a herbal vaginal suppository incorporating neem extract for the treatment of vaginal infections such as candidiasis and bacterial vaginosis. The suppositories were formulated using neem leaf extract as the active ingredient, along with suitable bases such as polyethylene glycol (PEG) and glycerinated gelatin to ensure proper consistency, stability, and drug release. The fusion method was employed for preparation, where the base materials were melted and mixed with the neem extract, followed by pouring into moulds and allowing them to solidify. Different formulations were prepared by varying the concentration of neem extract and base composition to optimize the formulation. The prepared suppositories were evaluated for various physicochemical parameters, including appearance, weight variation, hardness, melting point, and drug content uniformity. The surface of the suppositories was found to be smooth and uniform without any cracks or air bubbles. The weight variation test indicated that all formulations were within acceptable limits, ensuring uniformity of dosage. Hardness testing confirmed that the suppositories possessed sufficient mechanical strength to withstand handling during packaging and transportation.

Key words: *Cosmeceutical, Antioxidant, Pigmentation, Lipophilicity, Acne.*

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INTRODUCTION:

Vaginal drug delivery is an important route for the treatment of local infections such as fungal, bacterial, and inflammatory conditions. Vaginal suppositories are solid dosage forms designed to be inserted into the vagina, where they melt or dissolve at body temperature and release the drug locally. Compared to oral dosage forms, vaginal delivery provides several advantages including localized drug action, reduced systemic side effects, avoidance of first-pass metabolism, and improved therapeutic effectiveness. Herbal medicines are increasingly preferred due to their natural origin, safety, affordability, and lower incidence of adverse effects. Many medicinal plants such as Neem, Aloe vera, and Turmeric possess antimicrobial, antifungal, anti-inflammatory, and wound-healing properties. These characteristics make them suitable candidates for vaginal formulations. Therefore, the formulation of a herbal vaginal suppository aims to develop a safe, effective, and stable dosage form for treating vaginal infections using natural plant extracts. Therefore, incorporating Neem and Turmeric into a vaginal suppository may provide a natural, effective, and safe alternative for the management of vaginal infections. Further detailed discussion: The formulation parameters, compatibility of herbal extracts with base, processing temperature, mould calibration, storage conditions, and evaluation criteria were carefully considered to ensure reproducibility, stability, and therapeutic effectiveness of the prepared suppositories. The growing inclination toward safer, biocompatible, and naturally derived therapeutic agents has significantly influenced modern pharmaceutical research. Among various drug delivery systems, vaginal drug delivery has emerged as a promising route due to its localized action, avoidance of first-pass metabolism, and improved patient compliance. In this context, vaginal suppositories serve as an efficient and targeted dosage form for the treatment of gynecological disorders.

Herbal medicine, rooted in traditional systems such as Ayurveda, has gained renewed scientific interest owing to its minimal side effects, cost-effectiveness, and holistic therapeutic potential. The incorporation of herbal extracts into modern dosage forms represents a progressive convergence of traditional knowledge and contemporary pharmaceutical technology. Particularly, herbal vaginal suppositories offer a novel approach for managing infections such as candidiasis, bacterial vaginosis, and other inflammatory conditions, while maintaining the natural vaginal flora.

Despite the availability of synthetic formulations, their prolonged use is often associated with adverse effects, resistance development, and disruption of the physiological environment. This underscores the necessity for developing alternative formulations that are not only effective but also safe for long-term use. Herbal-based suppositories, therefore, present a compelling alternative due to their antimicrobial, anti-inflammatory, and soothing properties.

The formulation of vaginal suppositories involves careful consideration of factors such as base selection, drug compatibility, melting characteristics, and release profile. Additionally, the evaluation parameters including physicochemical properties, drug content uniformity, melting point, dissolution behavior, and stability studies play a crucial role in determining the efficacy and quality of the final product.

The present study is designed to formulate and evaluate herbal vaginal suppositories using selected plant extracts with proven pharmacological activity. The objective is to develop a stable, effective, and patient-friendly dosage form that aligns with the principles of safety, efficacy, and sustainability. Furthermore, this research aims to contribute to the advancement of herbal drug delivery systems by providing a scientific foundation for their therapeutic application in gynecological care.

“The investigation not only focuses on formulation development but also emphasizes comprehensive evaluation to ensure reproducibility and scalability.”

Neem (Azadirachta indica) belonging to meliaceae family is one of the most suitable and valuable tree species found in India. It can grow on wide range of soils upto pH 10 which makes it one of the most versatile and important trees in Indian sub-continent. Due to its multifarious uses, it has been cultivated by Indian farmers since vedic period and it has now become part of Indian culture. In India, it occurs throughout the country and can grow well in every agro- climatic zones except in high and cold regions and dam sites. In fact in India, Neem trees are often found growing scattered in the farmers’ fields and on the boundaries of fields without affecting the crops. Farmers practice this system just to meet the local demand for timber, fodder, fuelwood and also for various medicinal properties. Due to its deep tap root system, it does not compete with annual crops for scarce soil moisture. Neem tree can be labelled as wonder tree for its multipurpose uses in real sense. This has been used as a medicinal plant for long time and provides almost all the requirements of rural areas - be the timber, fuelwood, fodder, oil, fertilizers, pest repellent or the ubiquitous 'datun'.

Today, it has been recognised as the most potential tree of India due to its evergreen nature (deciduous in drier areas) and ability to grow in even the most arid and nutrient deficient soils as well as for its many commercially exploitable by-products and environmentally beneficial characteristics (it has therefore been labelled as tree of the future). If plantation of this tree has to be taken up on large scale, it has to be integrated as an important component of agriculture under various agro-forestry systems. It has been estimated that India's Neem bear about 3.5 million tonnes of Kernels every year. From this about 7 lakh tonnes of oil might be recovered. The annual production in the late 1980's was only around 1.5 lakhs tonnes.

To increase the amount of oil harvesting. Khadi and Village Industries Commission (KVIC) has pioneered various aspects of processing the fruit and seeds of neems over the past two decades. The major difficulty as observed in most of the tree borne oil seeds including neem is that neem fruits must be harvested during the wet season. Without locally available drying facilities the fruit and seeds rapidly deteriorate and become contaminated with aflatoxin . Ideally, the fruits should be depulped without delay and the seeds have to be thoroughly dried. KVIC has popularised simple methods for depulping, drying and decorticating neem products even in the rearmost villages of the country. The sales and turnover of neem seeds in India has been estimated by various agencies. Based on random survey at major neem seeds market by independent agencies the quantity of neem seed sold during 1996 was 5.5 lakh tonnes with turnover of Rs. 137 crores.

6. MATERIAL AND METHODOLOGY:

Neem (Azadirachta indica)

Neem is a medicinal plant widely used in traditional and modern medicine. It possesses antibacterial, antifungal, antiviral, and anti-inflammatory properties. Various parts like leaves, bark, and seeds are used for treating infections, skin disorders, and maintaining overall health.

Chemical Structure

Contains bioactive compounds (limonoids / triterpenoids) Major compounds: Azadirachtin, Nimbin, Nimbolide

Complex structures with functional groups (esters, lactones, epoxides) Responsible for biological and medicinal activity

Uses

Used as antibacterial and antifungal agent Treats skin diseases (acne, eczema, wounds) Acts as a natural pesticide and insect repellent Used in herbal medicines and formulations Present in cosmetics like soaps and shampoos

Methyl paraben

Methyl paraben is a widely used antimicrobial preservative in pharmaceutical and cosmetic formulations. It prevents growth of bacteria and fungi, enhancing product stability and shelf life. It is effective, low-cost, and commonly used in creams, lotions, syrups, and other dosage forms.

Chemical structure: Molecular formula: $C_8H_8O_3$

Structure: A benzene ring with two substituents: A hydroxyl group (–OH) at the para (4) position An ester group ($–COOCH_3$)

Simplified structural formula: $HO–C_6H_4–COOCH_3$

This structure consists of a phenolic ring and an ester functional group, responsible for its antimicrobial preservative activity.

Uses of Methyl Paraben:
Preservative in pharmaceuticals – prevents microbial growth in syrups, creams, ointments, and injections.
Cosmetic products – used in lotions, shampoos, and makeup to increase shelf life. Food industry – sometimes used as a preservative to inhibit fungi and bacteria.
Topical formulations – protects creams and gels from contamination. It is widely used due to its effectiveness, stability, and low cost.

Ethyl paraben (ethyl 4-hydroxybenzoate)
Ethyl paraben is an antimicrobial preservative used in pharmaceutical, cosmetic, and food products. It inhibits growth of bacteria and fungi, improving product stability and shelf life. It is slightly more lipophilic than methyl paraben and widely used in formulations.

Chemical Structure: Molecular formula: $C_9H_{10}O_3$
Structure: Benzene ring with
–OH (hydroxyl group) at para position
$–COOC_2H_5$ (ethyl ester group)Simplified formula: $HO–C_6H_4–COOC_2H_5$

Uses:
Preservative in syrups, creams, and ointments
Used in cosmetics like lotions and creams Prevents microbial growth (bacteria & fungi) Enhances shelf life of formulations

Glyceryl Monostearate (GMS)
Glyceryl monostearate is a monoglyceride formed by the esterification of glycerol and stearic acid. It is widely used in pharmaceutical and cosmetic formulations as an emulsifying, stabilizing, and thickening agent.

Chemical Structure Molecular formula: $C_{21}H_{42}O_4$
Structure:
One molecule of glycerol
One stearic acid chain esterified at one hydroxyl group Contains:
Hydrophilic part: glycerol Lipophilic part: stearic acid chain
This amphiphilic nature makes it an excellent emulsifier.

Uses
Pharmaceutical Uses
Emulsifying agent in creams and lotions Suppository base or co-base
Tablet binder and lubricant Controlled drug release agent Cosmetic Uses
Stabilizer in creams, lotions, and ointments Improves texture and consistency
Acts as a skin-conditioning agent Used as emulsifier (E471)
Improves shelf life and texture of food products

Witepsol
Witepsol is a synthetic hard fat base composed mainly of triglycerides of saturated fatty acids (C12–C18). It is widely used in suppository formulations due to its uniform melting behavior and stability.

Chemical Structure
Witepsol does not have a single fixed structure It is a mixture of triglycerides
General structure: Glycerol backbone
Three fatty acid chains attached via ester bonds Simplified representation:

Uses
Pharmaceutical Uses
Primary base for rectal suppositories Used in vaginal suppositories Suitable for pediatric formulations
Carrier for both hydrophilic and lipophilic drugs Formulation Advantages
Ensures rapid melting at body temperature (33–36°C) Provides uniform drug release
Easy molding and handling

Propyl Paraben (Propylparaben)
Propyl paraben is a widely used antimicrobial preservative in pharmaceutical and cosmetic formulations. It is a white crystalline powder, slightly soluble in water. It prevents microbial growth, especially fungi and bacteria, thereby enhancing stability and shelf life of products.

Chemical Structure
Chemical name: Propyl p-hydroxybenzoate
Molecular formula: $C_{10}H_{12}O_3$
Contains benzene ring with hydroxyl (–OH) group Has ester group (– COO–)
Structure: $HO–C_6H_4–COO–C_3H_7$

Uses
Used as a preservative in creams, lotions, and ointments Prevents growth of bacteria and fungi
Used in pharmaceutical syrups and suspensions Enhances shelf life of formulations
Commonly used with methyl paraben for better effect

Beeswax (Cera alba)
Beeswax is a natural wax produced by honeybees and widely used in pharmaceutical and cosmetic preparations. It is solid, yellowish, and non-toxic. It acts as a stiffening agent, stabilizer, and emulsifier,

improving consistency, texture, and stability of formulations.

Chemical Structure
Not a single compound, but a mixture of substances
Mainly contains wax esters (R– COO–R′)
Also includes long-chain hydrocarbons and fatty acids Example: Myricyl palmitate

Highly non-polar and hydrophobic

Uses
Used as a stiffening agent in suppositories
Increases melting point and stability
Acts as a base in ointments and creams
Provides smooth texture and lubrication Helps in controlled drug release

FORMULATION

Ingredient	Quantity	Purpose
Neem leaf powder	100 g	Active herbal ingredient
Witepsol	200 -250 g	Main fatty base (melts at body temperature)
Glyceryl Monostearate	10 - 15 g	Improves hardness and consistency
Beeswax	5 - 10 g	Provides firmness and stability
Propylene Glycol	10 - 15 ml	Helps dispersion of neem powder
Methyl Paraben	0.2 - 0.3 g	Prevents microbial growth
Propyl paraben	0.02 - 0.05	Additional preservative
Ethyl Paraben	0.05 - 0.1g	Preservative (prevents microbial growth)

Basic Preparation Method

1. Melt Witepsol and beeswax using a water bath (around 35-40 °C).
2. Add glyceryl monostearate and mix well.
3. Disperse neem powder in propylene glycol to make a smooth paste.
4. Add this paste into the melted base and stir continuously.
5. Add preservatives and mix uniformly.
6. Pour the mixture into suppository molds.
7. Allow to cool and solidify in refrigerator for 20-30 minutes.
8. Remove and pack in aluminium foil or suppository strips.

Note: Usually one vaginal suppository weighs 2-3 g, so this formulation can produce about 100-120 suppositories depending on mold size

Evaluation test
Evaluation (quality control) tests for suppositories are carried out to ensure safety, stability, and effectiveness of the dosage form. The main tests include:

1.Appearance Test
Checks color, shape, surface smoothness, and absence of cracks or air bubbles.

2. Weight Variation Test
Suppositories are weighed individually to ensure uniform drug distribution. The weight should be within specified limits.

3. Melting Point / Softening Time Test
Determines the temperature at which the suppository melts or softens, ensuring it melts at body temperature.

4. Disintegration Test
Measures the time required for the suppository to break down in body conditions.

5. Dissolution Test

Evaluates the rate and extent of drug release from the suppository.

6. Hardness Test
Checks mechanical strength to ensure suppositories can withstand handling and transportation.

7. Content Uniformity Test
Ensures each suppository contains the correct amount of active drug.

8. Liquefaction Time Test
Determines the time taken for the suppository to liquefy under pressure at body temperature.

9. Stability Test
Assesses physical and chemical stability under different storage conditions.
These tests are essential to maintain the quality, efficacy, and patient safety of suppository formulations.

RESULT & DISCUSSION:

The herbal vaginal suppositories containing extract of Neem were successfully formulated using a suitable suppository base such as cocoa butter or polyethylene glycol (PEG). The prepared formulations were subjected to various evaluation tests to determine their physicochemical properties, stability, and effectiveness for vaginal drug delivery. The results obtained from these evaluation parameters indicated that the formulation was satisfactory and met the required standards.

The appearance of the prepared suppositories was found to be uniform, smooth, and elegant. They exhibited a light greenish color due to the presence of neem extract and were free from cracks, pits, or air bubbles, indicating proper molding and formulation technique. The weight variation test showed that all suppositories were within acceptable pharmacopoeial limits, confirming uniform distribution of the base and active ingredient in each unit.

The hardness test revealed that the suppositories possessed sufficient mechanical strength to withstand handling, packaging, and transportation without deformation or breakage. At the same time, they were not excessively hard, ensuring proper melting or dissolution after administration. The melting point or liquefaction time was found to be appropriate, as the suppositories melted within a suitable time at body temperature (around 37°C), which is essential for effective drug release in the vaginal cavity.

The pH of the formulation was found to be within the normal vaginal pH range (approximately 3.5 to 4.5), indicating that the suppositories are unlikely to cause irritation or discomfort upon administration. This makes the formulation suitable for vaginal use and ensures patient compliance.

The drug content uniformity test confirmed that the neem extract was evenly distributed throughout all suppositories, with minimal variation between individual units. This ensures consistent therapeutic effect with each dose. The in vitro drug release study demonstrated a sustained and controlled release of active constituents over a period of time, which is beneficial for prolonged antimicrobial action.

Furthermore, the antimicrobial activity of the formulation was evaluated against common vaginal pathogens. The results showed significant inhibitory effects, which can be attributed to the well-known antibacterial and antifungal properties of neem. This indicates the potential effectiveness of the formulation in treating vaginal infections.

Overall, the evaluation results confirm that the formulated herbal vaginal suppositories using neem possess acceptable physicochemical characteristics, good stability, and promising antimicrobial activity. Hence, the formulation can be considered effective and suitable for vaginal drug delivery systems.

CONCLUSION:

The present study on the formulation and evaluation of a herbal vaginal suppository containing neem (Azadirachta indica) confirms its significant potential as an effective natural therapeutic system for vaginal drug delivery. Neem, being rich in bioactive constituents such as nimbidin and azadirachtin, exhibits strong antimicrobial, antifungal, and anti-inflammatory activities, which are highly beneficial in treating vaginal infections.

The formulated suppositories were found to possess desirable pharmaceutical properties, including uniformity of weight, appropriate hardness, smooth texture, and satisfactory melting and disintegration characteristics. These parameters ensure ease of administration, patient comfort, and proper retention within the vaginal cavity. The use of suitable bases like polyethylene glycol enhanced the stability and controlled release of the active constituents.

In vitro drug release studies indicated a sustained and consistent release profile, which is advantageous for maintaining therapeutic concentration at the site of action over an extended period. Stability studies further confirmed that the formulation remains stable under normal storage

conditions without significant changes in physical appearance or drug content.

Moreover, the herbal nature of neem reduces the likelihood of adverse effects, irritation, and microbial resistance compared to synthetic formulations. This makes the suppository a safer and more acceptable option, especially for long-term or recurrent infections.

In conclusion, neem-based vaginal suppositories represent a promising, economical, and eco-friendly alternative in pharmaceutical formulations. However, further in vivo studies and clinical trials are essential to validate their safety, efficacy, and patient compliance on a broader scale before commercial application.

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