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Formulation and Evaluation of Herbal Nail Lacquer

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Abstract- Paronychia is a highly prevalent, painful inflammatory infection involving the lateral and proximal nail folds of fingers and toes, frequently caused by bacterial pathogens such as Staphylococcus aureus or opportunistic fungi such as Candida albicans.17 Conventional treatment strategies predominantly include systemic antibiotics, oral antifungals, or topical creams.6 However, oral medications are often associated with systemic side effects, drug-drug interactions, and hepatic stress, while conventional topical creams are easily washed or rubbed off, leading to poor localized drug bioavailability through the highly keratinized nail plate.6 This study focuses on the design, formulation, and evaluation of a therapeutic, herbal nail lacquer to establish a sustained-release, non-invasive transungual drug delivery system for paronychia.3 An herbal active blend containing clove extract, neem extract, tea tree oil, and aloe vera gel was selected to provide synergistic antibacterial, antifungal, anti-inflammatory, and wound-healing properties directly at the infection site.7 The lacquer base was optimized utilizing nitrocellulose as the primary film-former, ethyl acetate and butyl acetate as the volatile solvent system, dibutyl phthalate and camphor as plasticizers, and isopropyl alcohol as a co-solvent.11 Four trial batches (F1 to F4) were developed with varying concentrations of polymers and active herbal extracts.5 The developed formulations were systematically evaluated for key physicochemical parameters, including drying time, viscosity, non-volatile content, water resistance, film smoothness, gloss, pH, and stability, alongside in vitro antimicrobial efficacy against Staphylococcus aureus and Candida albicans.5 The optimized formulation, batch F3, formed a smooth, glossy, and uniform film with an acceptable drying time of 75 seconds pH of 6.3 and a non-volatile content of 21.5%.14 F3 demonstrated excellent water resistance and a viscosity of 142 cp , ensuring ideal brushability and adherence.14 Furthermore, microbiological assays of F3 revealed a substantial zone of inhibition against both S. aureus (22mm) and C. albicans (24mm), which was highly comparable to commercial synthetic formulations.5 Accelerated stability studies confirmed the integrity of the formulation over 30 days under standard ICH storage conditions.3 These findings indicate that the developed polyherbal nail lacquer is a promising, safe, and cosmetically acceptable transungual delivery platform for managing paronychia.24

Keywords— Herbal nail lacquer, nail polish formulation , herbal cosmetics , transdermal drug delivery , antifungal activity , antimicrobial activity , paronychia , medicinal plants.

I. INTRODUCTION

1. Anatomy and Physiology of the Human Nail

The human nail (unguis) is a highly specialized, complex skin appendage that covers the dorsal surface of the distal phalanx of each finger and toe.6 It serves a primary protective function, shielding the delicate digits from physical trauma, and plays a significant role in sensory feedback, fine motor coordination, scratching, and personal grooming.6

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The entire nail apparatus consists of several highly organized, integrated structures 28:

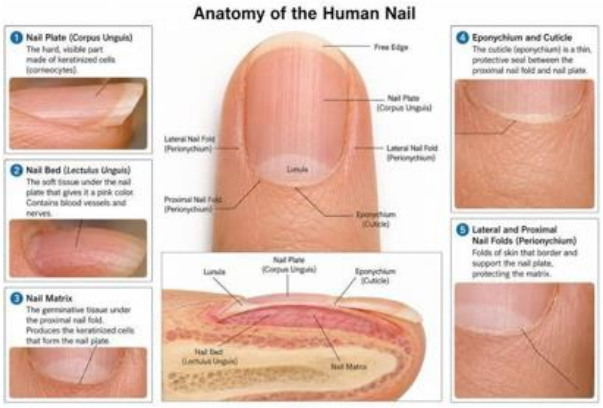

Figure 1- Anatomy of human nail

The Nail Plate (Corpus Unguis): The most prominent and visible part of the nail unit.27 It is a hard, flat, translucent structure composed of approximately 25 to 150 layers of flattened, dead, highly keratinized cells called corneocytes.27 These corneocytes are bound together by inter-cellular adhesive junctions and are packed with hard keratins (high in disulfide bonds).6 The low lipid content (<1%) and high sulfur amino acid content make the nail plate behave more like a hydrophilic hydrogel than a lipophilic membrane like the stratum corneum.6

- The Nail Bed (Lectulus Unguis): The soft epidermal tissue located directly beneath the nail plate.27 It is highly vascularized and richly supplied with sensory nerves, providing a healthy pink appearance to the translucent nail plate.27
- The Nail Matrix: The germinative tissue located at the base of the nail unit, directly beneath the proximal nail fold.1 The matrix is responsible for producing the keratinized cells that continuously grow and push forward to form the hard nail plate.17
- The Eponychium and Cuticle: The distal border of the proximal nail fold that terminates on the surface of the nail plate.30 The cuticle is a thin, cornified, protective keratinous veil that forms a tight, waterproof, physical seal between the proximal nail fold and the nailplate.30 This seal is critical in preventing water, chemicals, and infectious pathogens from entering the subungual and periungual environments.18
- The Lateral and Proximal Nail Folds (Perionychium): The folds of skin that border and support the lateral and proximal margins of the growing nail plate, keeping it anchored securely to the distal phalanx.18

2. Pathology and Classification of Nail Disorders

Nail disorders represent approximately 10% of all dermatological conditions.28 They can arise from localized infections, physical injuries, systemic diseases, or hereditary genetic defects.27 Common nail pathologies include 27:

- Onychomycosis: A chronic, progressive fungal infection of the nail plate and nail bed caused by dermatophytes, yeasts, or non-dermatophyte molds, leading to thickening, yellow-brown discoloration, and subungual debris.27
- Nail Psoriasis: An inflammatory skin disease that affects the nail matrix and nail bed, resulting in localized pitting, discoloration (oil-drop signs), and splitting.6
- Leuconychia: The appearance of white spots or lines across the nail plate, typically caused by minor physical injuries to the nail matrix.27
- Green Nail Syndrome (Chromonychia): An opportunistic bacterial infection of the subungual space caused by Pseudomonas aeruginosa, producing a characteristic dark green or blue-black staining of the nail bed, often linked to chronic paronychia.28
- Paronychia: A painful inflammatory infection of the periungual skin immediately surrounding the fingernail or toenail.17

3. Definition, Causes, and Symptoms of Paronychia

Paronychia is clinically defined as an acute or chronic inflammatory infection of the lateral and proximal nail folds.17 It is one of the most common infections of the hand, carrying a significant risk of localized pain and swelling.6

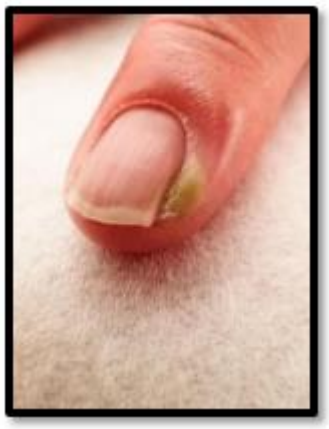

Figure 2- Demonstration Of Paronychia

- Causes: The primary cause is the disruption of the natural physical seal formed by the cuticle and the eponychium.18 Once this seal is damaged, moisture, irritants, and pathogens penetrate the warm, dark, and moist periungual space, leading to colonization and subsequent infection.18
- Symptoms: The condition presents as sudden or gradual onset of intense localized pain, throbbing discomfort, swelling, redness (erythema), and warmth surrounding the nail margin.17 In advanced cases, localized pockets of pus (abscesses) can form under the nail fold, sometimes spreading subungually and lifting the nail plate away from its bed.17

4. Clinical Differences: Acute vs. Chronic Paronychia

Paronychia is classified into two distinct clinical forms based on duration, etiology, and presentation:

- Acute Paronychia: Lasts less than six weeks.18 It is almost always bacterial in origin, commonly caused by skin flora such as Staphylococcus aureus, followed by Streptococcus pyogenes and Pseudomonas species.17 It involves a single digit, presenting with rapid onset of severe throbbing pain, localized swelling, and pus accumulation.17
- Chronic Paronychia: Persists for more than six weeks.30 It is primarily an inflammatory, eczematous response to repeated exposure to environmental irritants, water, and alkaline chemicals.17 It frequently involves multiple digits, presenting with swollen, boggy, and retracted nail folds with lost cuticles.18 While started by physical or chemical irritation, it is commonly colonized by Candida albicans, leading to persistent, low-grade infection.18

5. Epidemiology of Paronychia

Paronychia is highly prevalent worldwide, particularly among women, with a female-to-male ratio of approximately 3:1.18 It is highly common in middle-aged women and individuals in occupations that require prolonged immersion of hands in water or exposure to chemical irritants.18 High-risk groups include:

- Homemakers, housemaids, and professional dishwashers.18
- Bartenders, cooks, and food preparation workers.18
- Healthcare workers, dentists, and salon professionals.
- Individuals with habits of nail-biting (onychophagia) or finger-sucking.17

6. Pathophysiology of Paronychia

The pathophysiology begins with the loss of the physical barrier between the nail plate and the surrounding skin.18 When the cuticle is torn, cut, or dissolved by alkaline soaps, a small pocket is created.18

In Acute Paronychia, opportunistic bacterial pathogens (S. aureus) enter this pocket, leading to an active inflammatory response.17 This causes local vasodilation, fluid accumulation, and recruitment of neutrophils, presenting as painful swelling and localized pus formation.17

In Chronic Paronychia, repeated exposure to water and chemicals maintains a constant state of inflammation.33 This ongoing inflammation leads to progressive fibrosis, thickening, and retraction of the proximal nail fold, further exposing the nail matrix.33 The loss of the protective cuticle allows opportunistic fungi, primarily Candida albicans, to colonize the area, sustaining the chronic inflammation and occasionally causing acute bacterial flare-ups.17

Limitations of Current Treatments

Standard treatments for paronychia depend on the severity of the infection:

- Warm Water Soaks: Useful only in the very early stages of mild infections.31
- Oral Antibiotics and Antifungals: Often required for severe infections, but carry risks of systemic side effects, drug-drug interactions, and gastrointestinal distress, while requiring long treatment courses due to poor vascular supply to the nail.13
- Topical Creams and Ointments: Safely localized, but easily washed or rubbed off, failing to maintain therapeutic drug concentrations over time.13
- Surgical Incision and Drainage: Necessary for large abscesses, but painful, invasive, and carries a risk of permanent nail matrix damage.17

This underscores the clinical need for a non-invasive, localized, and water-resistant transungual delivery system.3

7. Importance of Transungual Drug Delivery

Transungual drug delivery refers to the transport of therapeutic agents across the keratinized structure of the nail unit to reach the nail bed, matrix, and surrounding folds.6 This route is highly desirable as it delivers high drug concentrations directly to the site of infection while avoiding the systemic absorption, hepatic first-pass metabolism, and side effects associated with oral drugs.3 By utilizing a medicated nail lacquer, we create a continuous, water-resistant polymeric film that adheres tightly to the nail plate and surrounding folds.5 As the volatile organic solvents evaporate, the drug concentration in the dry film increases, creating a strong concentration gradient that drives the active ingredients deep into the infected tissues for a sustained therapeutic effect.13

8. Nail Polish / Nail Lacquer

Definition

Nail lacquers (also called nail polishes, varnishes, or enamels) are liquid, polymeric preparations designed to form a hard, continuous, uniform, and protective film when applied to fingernails or toenails.13 In modern pharmaceuticals, these cosmetic bases have been adapted into specialized therapeutic transungual drug delivery matrices.5

Figure 3- Nail Polish/Nail Lacquer

9. History of Nail Lacquer

The history of nail decoration dates back to 3000 BCE in ancient China, where mixtures of gum arabic, egg whites, gelatin, and beeswax were used to stain nails. The ancient Egyptians used henna to tint their nails, with colors indicating social status.

Modern liquid nail lacquer emerged in the 1920s, inspired by the development of high-quality cellulose-based spray paints for the automotive industry.37 Cosmetic chemists adapted nitrocellulose—a highly flammable polymer—to create liquid formulas that dry rapidly at room temperature, forming a glossy, durable film.11 Over the years, safety regulations have evolved, leading to the phasing out of hazardous chemicals (like formaldehyde and toluene) and replacing them with safer polyester resins and biocompatible plasticizers.11

Classification of Nail Lacquers

Nail lacquers can be classified based on their cosmetic finishes, chemical formulations, and specific functional roles:

By Finish and Appearance:

- Matte Finish: Flat, non-reflective finish.24
- Glossy Finish: High-shine, smooth, reflective surface.24

- Shimmer/Glitter Finish: Contains light-reflecting particles or suspended glitters.11

By Chemistry and Drying Method:

- Solvent-Evaporation Lacquers (Regular): Dry solely through the rapid evaporation of volatile organic solvents at room temperature.13
- Gel Lacquers: Polymeric formulas containing photoinitiators and oligomers that require Uv or LED light to cure.24

By Functional Role:

- Base Coat: Applied directly to the nail to improve adhesion and prevent yellowing.24
- Color Coat: Disperses pigments for aesthetic appearance.24
- Top Coat: Formulated with hard resins to protect the color coat from scratching or chipping.24
- Medicated / Therapeutic Lacquer: Formulated specifically to deliver active pharmaceutical agents to treat nail diseases.6

Essential Formulation Components

A stable, functional nail lacquer requires a balanced mixture of several key ingredients:

- Primary Film-Forming Polymer: Typically nitrocellulose (10% to 20%), which forms a tough, glossy, non-toxic, and gas-permeable film.11
- Secondary Resins: Added to improve the adhesion of the nitrocellulose film to the smooth nail plate and to increase gloss.11
- Plasticizers: Added to increase film flexibility and prevent cracking or chipping.11
- Solvents and Diluents: Organic liquids with low-to-medium boiling points (such as ethyl acetate, butyl acetate, and isopropyl alcohol) that dissolve the polymer, control viscosity, and regulate drying speed.11
- Thixotropic Suspending Agents: Added to prevent pigments or insoluble particles from settling during storage.12
- Active Pharmaceutical Ingredients (APIs): Antimicrobial, antifungal, or anti-inflammatory agents included in medicated formulations.6

Mechanism of Polymeric Film Formation

The drying and solidification of regular nail lacquer is governed by physical solvent evaporation:

- Application: The liquid lacquer is applied evenly onto the nail and surrounding tissue using a fine brush.5 The polymer chains are fully solvated, sliding past each other freely in the liquid medium.23
- Solvent Evaporation: As the applied thin layer (0.1mm to 0.2mm thick) is exposed to ambient air at body temperature (32-35 oC), the volatile solvents (ethyl acetate and isopropyl alcohol) evaporate rapidly.1
- Polymer Chain Entanglement: As the solvent volume decreases, the dissolved nitrocellulose chains are forced closer together, entangling and forming a cohesive solid network.23
- Plasticizer Alignment: Plasticizer molecules (such as dibutyl phthalate and camphor) position themselves between the converging polymer chains, establishing weak secondary bonds that provide elasticity and reduce the overall brittleness of the dry matrix.11
- Solidification: Within 60 to 120 seconds, the formulation transitions from a liquid state to a hard, dry, continuous, and highly occlusive polymeric film.13 The active herbal extracts remain trapped within this polymeric matrix, ready to be slowly released into the wet microenvironment of the infected nail folds.5

Ideal Properties of Medicated Nail Lacquers

To be therapeutically and cosmetically acceptable, a medicated nail lacquer must meet several demanding criteria 12:

- It must be non-irritating and non-toxic to the sensitive, inflamed periungual skin and nail matrix.6
- It must have optimum viscosity (130 TO 150 Cp) to allow easy, uniform application without running into the cuticles or leaving thick, uneven brush streaks.12
- It must dry rapidly (ideally within 60 to 90 seconds) to form a tack-free surface, preventing patient inconvenience.15
- The dry film must possess excellent flexibility (folding endurance) and adhesion, resisting

peeling, cracking, or lifting for at least 3 to 5 days.12
- It must be highly water-resistant to survive daily washing, bathing, and cleaning activities.13
- It must slowly and continuously release the active ingredients over a prolonged period (sustained release) to maintain drug levels above the minimum inhibitory concentration (MIC) at the infection site.5

Pharmaceutical Applications
- Transungual Antifungal Delivery: Treating onychomycosis caused by dermatophytes and yeasts.6
- Nail Psoriasis Management: Delivering topical steroids or retinoids directly to the nail matrix.6
- Paronychia Therapy: Delivering localized, sustained antibacterial and antifungal agents.6
- Nail Strengthening: Delivering active hardeners, vitamins, or mineral supplements directly to brittle, splitting nail plates.24

Advantages and Disadvantages of Nail Lacquer
Advantages
- Provides localized drug delivery, eliminating systemic side effects and hepatic stress.6
- Formed film is highly occlusive, hydrating the nail plate and expanding keratin pores to enhance drug penetration.13
- Resists washing or rubbing off, extending drug contact and improving patient compliance.13
- Forms a cosmetically appealing film that hides nail disfigurations.24

Disadvantages
- Nail plate composition limits rapid drug penetration across its hard, keratinized barrier.6
- Formulating stable systems with high drug loading of lipophilic compounds can be challenging.
- Requires periodic removal using organic solvents, which can dehydrate the nail and surrounding skin.6

II. REVIEW OF LITERATURE

Elewski conducted (1998) : detailed study on onychomycosis and explained its pathogenesis, diagnosis, and management. The author emphasized that fungal nail infectiONs are difficult to treat because of the highly keratinized nail plate, which restricts drug penetration. The study highlighted the importance of topical transungual drug delivery systems such as medicated nail lacquers for improving localized therapy and reducing systemic side effects.

Wazulkar, Jadhav, and Deshmukh (2024) : formulated and evaluated a herbal nail lacquer for the treatment of onychomycosis. Their research demonstrated that herbal ingredients containing antifungal and antibacterial properties can effectively be incorporated into nail lacquer formulations. The authors reported satisfactory drying time, film formation, and antimicrobial activity, supporting the use of herbal formulations as safer alternatives to synthetic antifungal therapies.

Drake et al. (1998) : investigated the impact of onychomycosis on patients' quality of life. The authors observed that nail infections cause pain, discomfort, cosmetic embarrassment, and psychological distress. Their findings established the need for effective and patient-friendly treatment systems capable of improving both clinical outcomes and cosmetic appearance.

Gupta, Versteeg, and Shear (2017) : reviewed the epidemiology, diagnosis, and treatment of onychomycosis in the modern era. The authors emphasized the increasing prevalence of fungal nail infections and discussed recent advancements in topical antifungal therapies. They highlighted the advantages of localized drug delivery systems over systemic therapies due to reduced adverse effects.

Shemer et al. (2015) : performed a clinical comparison of terbinafine efficacy in affected onychomycotic toenails. Their study showed that prolonged topical therapy combined with effective drug penetration significantly improves cure rates. The research supported the development of formulations capable of sustained drug release and prolonged contact time on the nail surface.

Finch and Jinna (2015) : focused on tavaborole as a topical treatment for onychomycosis. The authors explained the mechanism of action of tavaborole and its abiAlity to penetrate the nail plate effectively. Their findings highlighted the growing importance of transungual drug delivery systems in modern antifungal therapy.

Bohn and Kraemer (2000) : studied the dermatopharmacology of ciclopirox nail lacquer topical solution 8%. They concluded that medicated nail lacquers provide effective drug penetration through the nail plate while maintaining prolonged therapeutic activity. The authors also emphasized the role of film-forming polymers in improving drug retention on the nail surface.

Hafeez et al. (2013) : evaluated ciclopirox delivery into the human nail plate using lipid diffusion enhancers. Their study demonstrated that penetration enhancers significantly improve drug permeation through the nail keratin barrier. The findings supported the incorporation of permeation-enhancing agents into nail lacquer formulations to increase therapeutic efficacy.

Tachibana, Kumagai, and Tatsumi (2017) : compared the fungicidal activity of efinaconazole, tavaborole, and ciclopirox in the presence of keratin. The study revealed that efinaconazole showed superior activity even in keratin-rich environments. The authors emphasized that antifungal efficacy within the nail matrix is essential for successful treatment of nail infections.

Lipner and Scher (2015) : reviewed the therapeutic role of efinaconazole in onychomycosis treatment. The authors stated that topical nail lacquers with optimized drug delivery systems improve patient compliance and minimize systemic toxicity. Their work contributed to the understanding of advanced antifungal lacquer formulations.

Tupaki-Sreepurna et al. (2017) : assessed the in vitro antifungal activities of efinaconazole and itraconazole against non-dermatophyte fungi. Their results demonstrated that topical antifungal agents possess strong activity against resistant fungal pathogens. The authors highlighted the importance of selecting broad-spectrum antimicrobial agents for nail infections.

Elewski et al. (2014) : investigated the access of efinaconazole topical solution to infection sites through the subungual space. The study confirmed that low surface tension formulations spread effectively beneath the nail plate, improving therapeutic action. Their findings supported the design of formulations with enhanced spreading and penetration properties.

Zeichner, Stein-Gold, and Korotzer (2014) : studied the penetration of efinaconazole topical solution in the presence of cosmetic nail polish. They concluded that nail polish did not significantly interfere with drug penetration. This research suggested that medicated nail lacquers can maintain efficacy while preserving cosmetic acceptability.

Rathi (2024) : reviewed recent advances in topical nail lacquers and nano-based drug delivery systems for onychomycosis treatment. The author discussed the advantages of nanoparticles, herbal extracts, and medicated lacquers in improving antifungal efficacy. The review highlighted the future potential of herbal and nano-based transungual delivery systems.

Salunkhe, Sonawane, Chaudhari, and Patil (2025) : reviewed herbal nail lacquers containing phytoactive compounds for treating onychomycosis. The authors emphasized the therapeutic importance of natural ingredients such as neem, clove, tea tree oil, and aloe vera because of their antimicrobial, anti-inflammatory, and wound-healing properties. Their review supported the development of polyherbal nail lacquers as safe, effective, and economical alternatives to synthetic medications.

Overall, the reviewed literature indicates that medicated nail lacquers represent an effective transungual drug delivery system for fungal and bacterial nail infections. Herbal formulations containing natural antimicrobial agents have shown promising therapeutic potential due to their safety, sustained drug release, improved patient compliance, and reduced systemic side effects. The

collected studies strongly support the formulation and evaluation of a polyherbal nail lacquer for the treatment of paronychia and related nail infections.

Need of Work

Paronychia is one of the most common inflammatory nail infections affecting both fingernails and toenails. It is mainly caused by bacterial pathogens such as Staphylococcus aureus and fungal organisms such as Candida albicans. The condition causes pain, swelling, redness, pus formation, discomfort during daily activities, and cosmetic disfigurement of the nails. Conventional treatment methods such as oral antibiotics, antifungal agents, topical creams, and surgical drainage are associated with several limitations including systemic side effects, poor patient compliance, drug interactions, long treatment duration, and recurrence of infection.

The nail plate acts as a strong keratinized barrier that restricts the penetration of drugs into the infected site. Topical creams and ointments are easily removed by washing or rubbing, leading to inadequate drug retention and reduced therapeutic effectiveness. Therefore, there is a strong need for an alternative localized drug delivery system capable of maintaining prolonged contact with the nail surface and providing sustained release of active ingredients.

Medicated nail lacquers have emerged as a promising transungual drug delivery system because they form a water-resistant polymeric film over the nail surface, allowing continuous release of therapeutic agents directly at the site of infection. Such formulations improve drug penetration, enhance patient compliance, reduce systemic exposure, and provide better cosmetic acceptability.

The growing interest in herbal medicines has further encouraged the development of herbal nail lacquer formulations. Herbal ingredients such as Neem, Clove, Tea Tree Oil, and Aloe Vera possess well-documented antibacterial, antifungal, anti-inflammatory, antiseptic, and wound-healing properties. These natural agents offer safer and more economical alternatives to synthetic drugs with minimal side effects.

Hence, the present study was undertaken to formulate and evaluate a polyherbal nail lacquer for the treatment of paronychia. The study aims to develop a stable, effective, safe, and cosmetically acceptable transungual delivery system capable of providing sustained antimicrobial action and improved therapeutic outcomes in nail infections.

Aim and Objectives

Aim

To formulate, optimize, and evaluate an herbal nail lacquer containing a synergistic blend of Clove Extract, Neem Extract, Tea Tree Oil, and Aloe Vera Gel for the highly effective, localized, non-invasive treatment of Paronychia.5

Objectives

- To extract active phytoconstituents from fresh Neem leaves (Azadirachta indica) and Clove flower buds (Syzygium aromaticum) using appropriate extraction techniques.7
- To conduct qualitative phytochemical screening of the herbal extracts to confirm the presence of key therapeutic secondary metabolites such as flavonoids, alkaloids, tannins, and terpenoids.4
- To prepare and optimize several batches of an herbal nail lacquer base utilizing nitrocellulose as the film-former, ethyl acetate and butyl acetate as the volatile solvent system, dibutyl phthalate and camphor as plasticizers, and isopropyl alcohol as a co-solvent.11
- To evaluate the physicochemical parameters of the developed lacquers, including drying time, viscosity, pH, non-volatile content, gloss, smoothness of flow, and water resistance.14
- To investigate the in vitro antimicrobial activity of the formulations against Staphylococcus aureus (the primary bacterial cause of acute paronychia) and Candida albicans (the primary fungal pathogen associated with chronic paronychia).5
- To perform accelerated stability studies of the optimized batch in compliance with ICH guidelines to confirm its physical, chemical, and microbiological integrity.3

Plan of Work

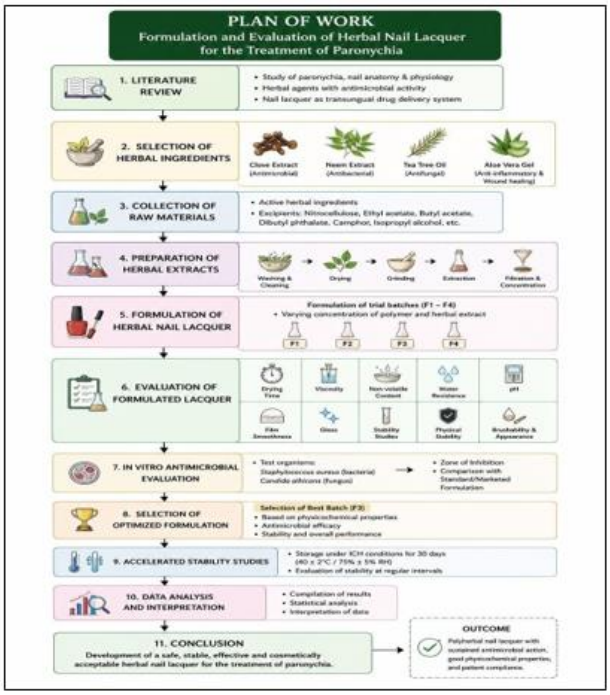

Figure 4- Plan of work

Plant Profile and Experiments Profile

Selecting a synergistic combination of herbal active ingredients is crucial to target the bacterial and fungal pathogens responsible for paronychia, while simultaneously soothing inflammation and promoting tissue repair.7

Neem (Azadirachta indica)

- Biological Name: Azadirachta indica A. Juss.4
- Family: Meliaceae.7
- Synonyms: Margosa tree, Indian lilac, Nimba, Neem tree.
- Morphology: Neem leaves are compound, alternate, pinnate, and medium-to-dark green. Leaflets are asymmetric, lanceolate, and serrate with a pointed apex. They emit a faint, characteristic odor and have an extremely bitter, astringent taste.
- Chemical Constituents: Neem leaves contain complex tetranortriterpenoids, including azadirachtin, nimbin, nimbidin, nimbolide, and quercetin.7 Neem oil derived from seeds contains high levels of oleic, palmitic, and stearic acids.35
- Medicinal Uses: Widely utilized in traditional medicine for its powerful antibacterial, antifungal, anti-inflammatory, antiviral, and wound-healing properties.7
- Antifungal and Antibacterial Activity: Neem extracts exhibit exceptional inhibitory activity against Candida albicans, Aspergillus niger, and Gram-positive skin flora such as Staphylococcus aureus.5
- Mechanism of Action: The primary active terpenoid, azadirachtin, disrupts cell membrane integrity, prevents microbial adhesion to epidermal tissues, and inhibits the synthesis of extracellular biofilms, effectively preventing the colonization of nail folds.7

Figure 5- Neem leaves

Clove (Syzygium aromaticum)

- Biological Name: Syzygium aromaticum (L.) Merr. & L.M. Perry.38
- Family: Myrtaceae.7
- Synonyms: Eugenia caryophyllata, Caryophyllus, Laung, Clove buds.
- Morphology: Dried flower buds are dark brown, nail-shaped, consisting of a sub-cylindrical hypocanthium surmounted by four acute calyx teeth and a central dome-shaped corolla. They emit a highly aromatic, pungent odor and have a warm, spicy, and numbing taste.
- Chemical Constituents: Clove oil contains 70% to 90% eugenol, along with eugenyl acetate, beta-caryophyllene, and alpha-humulene.7
- Medicinal Uses: Traditionally used as a local anesthetic, toothache remedy, carminative, antiseptic, and broad-spectrum antimicrobial agent.7
- Antifungal and Antibacterial Activity: Shows exceptional bactericidal action against S. aureus, Streptococcus pyogenes, and a strong fungicidal

effect against Candida species and dermatophytes.7

- Mechanism of Action: Eugenol acts by destabilizing the phospholipid bilayer of the microbial cell membrane, causing intracellular fluid leakage, and inhibiting respiratory chain enzymes and ATPase activity within the pathogen, leading to cell death.7

Figure 6- Clove

Tea Tree (Melaleuca alternifolia)

- Biological Name: Melaleuca alternifolia (Maiden & Betche) Cheel.38
- Family: Myrtaceae.38
- Synonyms: Narrow-leaved paperbark, Melaleuca oil, Tea tree oil.
- Morphology: Tea tree essential oil is a clear, colorless to pale yellow liquid with a fresh, medicinal, warm, and camphorous odor.
- Chemical Constituents: The chemical profile is strictly regulated by international ISO standards. It contains terpinen-4-ol (minimum 35%), gamma-terpinene, alpha-terpineol, 1,8-

cineole (eucalyptol), and p-cymene.38

- Medicinal Uses: Highly valued in dermatology as a natural antiseptic, topical anti-inflammatory, and broad-spectrum antimicrobial agent.26
- Antifungal and Antibacterial Activity: Demonstrates high efficacy against clinical isolates of Candida albicans, Trichophyton rubrum, and multi-drug resistant Staphylococcus aureus (MRSA).34
- Mechanism of Action: Terpinen-4-ol penetrates the lipophilic cell walls of microorganisms, altering cell membrane permeability, disrupting cell respiration, and inducing a rapid loss of intracellular potassium ions, which leads to lysis.42

Figure 7- Tea Tree Oil

Aloe Vera (Aloe barbadensis)

- Biological Name: Aloe barbadensis Miller.8
- Family: Asphodelaceae.8
- Synonyms: Aloe vera Tourn. ex Linn., Ghrithakumari, Curacao aloe.
- Morphology: Thick, fleshy, lanceolate green leaves with a sharp apex and spiny-toothed margins. The interior of the leaf contains a clear, mucilaginous, tasteless gel.
- Chemical Constituents: The gel contains water (99%), along with essential active polysaccharides (acemannan, glucomannans), glycoprotein, aloin, barbaloin, salicylic acid, vitamins, and amino acids.34
- Medicinal Uses: Extensively used for soothing skin irritations, burns, wound healing, moisturizing, and reducing skin inflammation.8
- Antifungal and Antibacterial Activity: Offers mild direct antimicrobial action, but acts primarily as a supportive healing, soothing, and barrier-repairing agent in nail and skin infections.
- Mechanism of Action: Acemannan stimulates macrophage activity and fibroblast proliferation, accelerating the synthesis of collagen and the repair of inflamed periungual skin.34 Its salicylic acid content reduces local pain and

inflammation by inhibiting cyclooxygenase (COX) pathways.34

Figure 8- Fresh Aloe Vera

III. MATERIAL AND METHODS

To ensure the reproducibility, purity, and pharmacological activity of the herbal active components, a systematic experimental protocol was followed.1

Collection and Authentication

- Fresh, disease-free leaves of Azadirachta indica and flower buds of Syzygium aromaticum were collected from verified botanical gardens.7
- Fresh succulent leaves of Aloe barbadensis were collected from institutional cultivation fields.8
- Standard commercial Melaleuca alternifolia essential oil complying with ISO 4730:2017 specifications was procured.13
- All plant specimens were formally authenticated by a professional botanist, and voucher specimens (V-104 to V-106) were deposited in the institutional herbarium for future reference.1

Extraction Methods

An aqueous and hydroalcoholic extraction protocol was carried out based on established pharmacognostical guidelines 7:

- Hydroalcoholic Extraction of Neem Leaves: The authenticated fresh neem leaves were washed thoroughly under running tap water to remove soil and foreign matter, then rinsed with distilled water. The leaves were shade-dried at room temperature for 10 days until they became brittle.5 The dried leaves were pulverized into a coarse powder using an electric blender.7 About 50g of the powder was macerated in 250ml of a hydroalcoholic solvent (70% ethanol and 30% water) inside an amber-colored glass bottle.4 The mixture was shaken periodically for 72 hours.5 After 72 hours, the macerated mixture was filtered through a clean muslin cloth, followed by filtration through Whatman No. 1 filter paper.5 The filtrate was concentrated under reduced pressure at 45 oC using a rotary vacuum evaporator to obtain a dense, dark-green paste, which was dried in a desiccator and stored in an airtight container at 4 o C4.
- Ethanolic Extraction of Clove Buds: The dried clove flower buds were crushed using a mortar and pestle to obtain a coarse powder.7 To prevent the loss of volatile oils, 50g of this freshly crushed powder was subjected to cold maceration with 250ml of 95% ethanol for 48 hours with continuous stirring. The mixture was filtered, and the filtrate was dried using a rotary evaporator at 40 o C of obtain a thick, viscous, dark-brown aromatic residue rich in eugenol.7
- Extraction of Aloe Vera Gel: Freshly harvested green leaves of Aloe barbadensis were washed thoroughly to remove dirt and debris. The leaves were sliced longitudinally, and the thick, outer green rind was carefully peeled off using a sterile knife to expose the inner clear mucilaginous gel. The gel was scooped out and blended in a sterile food processor to reduce its viscosity. The blended gel was filtered through a fine muslin cloth to remove cellular debris, yielding a clear, liquid gel, which was immediately treated with 0.1% sodium benzoate as a preservative and stored in a light-resistant container at 4 oC.6. Formulation of Nail Lacquer

Optimization and Rationale of Ingredients

The physical behavior, film properties, and drug release of a therapeutic nail lacquer depend directly on the balance of its ingredients.6

Table 1: Key Ingredient Functionality and Rationale in the Nail Lacquer Base

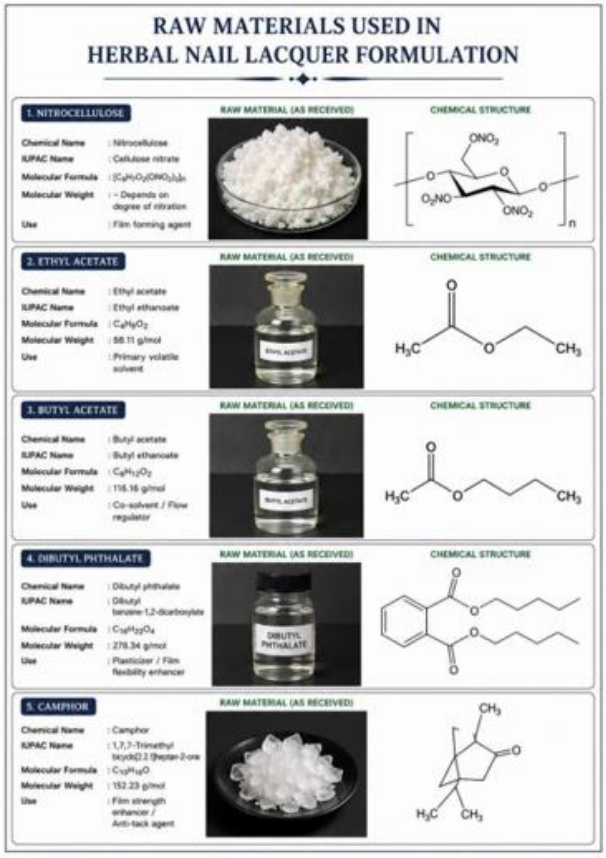

Table 2: Ingredients and their role in formulation

Ingredient Name	Quantity Used	Category	Role in Formulation
Nitrocellulose	15.0 g	Primary Film-Forming Polymer	Forms a hard, water-resistant, durable, and highly glossy film over the nail.[11] Its porous polymeric structure allows natural gas exchange.[12]

Ethyl Acetate	$35.0\ \mathrm{mL}$	Primary Volatile Solvent	An organic liquid with a low boiling point ($77.1^{\circ}\mathrm{C}$) that dissolves nitrocellulose.[11] It evaporates rapidly upon application, speeding up drying time.[13]
Butyl Acetate	$10.0\ \mathrm{mL}$	Co-solvent / Flow Regulator	A medium-boiling solvent ($126^{\circ}\mathrm{C}$) that prevents the lacquer from drying too quickly, which can cause streaks or bubbles.[11] It ensures a smooth, level finish.[12]
Dibutyl Phthalate	$5.0\ \mathrm{mL}$	Primary Plasticizer	Sits between the nitrocellulose polymer chains, increasing film flexibility and
			preventing cracking or chipping.11
Clove Extract	$5.0\ \mathrm{mL}$	Active Antiseptic Agent	Rich in eugenol; provides potent antiseptic, anesthetic, and broad-spectrum antifungal properties.7

Neem Extract	5.0 mL	Active Antibacterial Agent	Rich in azadirachtin; acts as a powerful antibacterial and anti-inflammatory agent, and softens cuticles.7
Tea Tree Oil	3.0 mL	Active Antifungal Agent	Contains high levels of terpinen-4-ol; targets fungal cells, reduces local inflammation, and treats mixed infections.34
Aloe Vera Gel	3.0 mL	Active Soothing Agent	Rich in acemannan; hydrates dried cuticles, reduces local pain, and promotes tissue healing.8
Camphor	2.0 g	Co-plasticizer / Gloss Enhancer	Enhances film gloss, plasticity, and adhesion while providing a pleasant, cooling sensation on inflamed skin.11
Isopropyl Alcohol	10.0 mL	Diluent / Evaporation Aid	Dissolves secondary resins, controls viscosity, and forms an azeotropic mixture with ethyl acetate to optimize drying.12
Distilled Water	6.0 mL	Vehicle / Carrier	Used as a vehicle to dissolve hydrophilic plant components and dilute the aloe vera gel.5
Colouring Agent	0.5 g	Cosmetic Pigment	Provides a pleasant, natural pale green appearance to enhance aesthetic acceptability.11

Fragrance	0.5 mL	Deodorant / Masking Agent	Provides a pleasant scent that masks the strong odor of the organic solvents and herbal extracts.11

Optimization of Trial Batches (F1 to F4)

Four separate batches (F1 to F4) were developed with varying concentrations of nitrocellulose (the film-former) and the active herbal extracts.5 This optimization process aimed to find the ideal balance where the formulation dried quickly, formed a durable and water-resistant film, and maintained powerful antimicrobial action against the pathogens that cause paronychia.5

Table 3: Formula Composition of Developed Herbal Nail Lacquer Batches (F1 to F4)

Ingredients	Batch F1	Batch F2	Batch F3 (Optimized)	Batch F4
Nitrocellulose (g)	10.0	12.5	15.0	20.0
Ethyl Acetate (mL)	40.0	37.5	35.0	30.0
Butyl Acetate (mL)	10.0	10.0	10.0	10.0
Dibutyl Phthalate (mL)	5.0	5.0	5.0	5.0
Clove Extract (mL)	2.0	3.5	5.0	5.0
Neem Extract (mL)	2.0	3.5	5.0	5.0

Tea Tree Oil (mL)	1.0	2.0	3.0	3.0
Aloe Vera Gel (mL)	1.0	2.0	3.0	3.0
Camphor (g)	2.0	2.0	2.0	2.0
Isopropyl	10.0	10.0	10.0	10.0
Alcohol (mL)				
Distilled Water (mL)	16.0	11.0	6.0	3.0
Colouring Agent (g)	0.5	0.5	0.5	0.5
Fragrance (mL)	0.5	0.5	0.5	0.5
Total Volume (mL)	100.0	100.0	100.0	100.0

Procedure

The herbal nail lacquers were prepared using a standardized, simple mixing method under controlled laboratory conditions (Temp: 25 o C ,RH: 50%):

Preparation of Phase A (Polymeric Base Solution): The required quantity of nitrocellulose polymer (as per Table 2) was weighed accurately and placed into a dry 250ML borosilicate beaker. A mixture of ethyl acetate (primary solvent) and butyl acetate (co-solvent) was added to the beaker. The beaker was sealed with aluminum foil to prevent the evaporation of the volatile solvents and stirred continuously using a magnetic stirrer at 500 rpm for 30 minutes until the polymer was completely dissolved, yielding a clear, viscous, and homogenous solution.12

Preparation of Phase B (Additive Blending): In a separate 100 ml beaker, dibutyl phthalate

(plasticizer) and camphor (co-plasticizer/gloss enhancer) were dissolved in isopropyl alcohol.12 Once a clear solution was formed, the specified quantities of clove extract, neem extract, tea tree oil, and preserved aloe vera gel were added while stirring slowly, ensuring the herbal active phase was thoroughly mixed.5

Mixing of Phases: Phase B was added slowly to Phase A under continuous, high-speed stirring (1000 rpm) on a magnetic stirrer.5

Aqueous Phase Integration: The required volume of distilled water (pre-mixed with the green colouring agent and fragrance) was added dropwise to the mixture while stirring continuously to prevent localized precipitation of the nitrocellulose polymer.12

De-aeration and Filtration: The formulation was stirred for an additional 20 minutes to ensure complete homogeneity. The beaker was covered with aluminum foil and allowed to stand undisturbed for 30 minutes, letting any entrapped air bubbles rise to the surface and escape. The lacquer was then filtered through a clean, multi-layered muslin cloth to remove any microscopic, undissolved herbal particulates.5

Filling and Packaging: The final clear, pale-green herbal nail lacquer was filled into clean, dry, narrow-mouthed 15 ML amber glass bottles fitted with synthetic brush applicators.13 The bottles were sealed tightly with airtight screw caps to prevent solvent evaporation and stored in a cool, dark place away from direct sunlight and heat.3

Evaluation of Herbal Nail Lacquer

Colour and Odour

- Principle: Evaluates the cosmetic acceptability, visual uniformity, and scent of the formulation.12
- Procedure: Color was evaluated by applying a single coat of the lacquer on a clean white tile and observing it under natural daylight.5 Odor was assessed organoleptically by smelling the dry applied film after solvent evaporation.5
- Observation & Results: As summarized in Table 4, the color ranged from very pale green (F1) to deep green (F4).5 F3 exhibited a pleasing, natural light green color and a fresh, herbal camphorous odor that effectively masked the organic solvents.12

Consistency

- Principle: Ensures the liquid remains stable in the bottle, resisting settling or phase separation during storage.12
- Procedure: Visually monitored by tilting the sealed bottle and checking the flow behavior of the liquid against the inner walls.5
- Observation & Results: F1 was too watery, F4 was highly thick and sluggish, while F3 exhibited a smooth, uniform fluid consistency ideal for brush application.12

Drying Time

- Principle: Measures the rate of solvent evaporation, transitioning the applied liquid into a solid, tack-free polymeric film.13

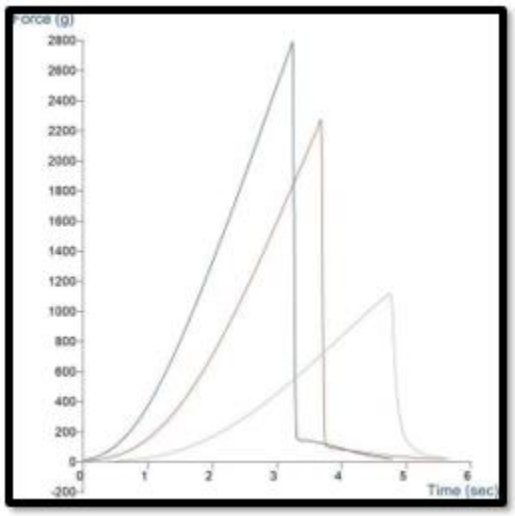

Figure 8- Drying Time Graph

Procedure: A standard 2.0cm 2 area was marked on a clean, dry glass slide.13 Using a brush applicator, a thin, uniform layer of the formulation was spread over the marked area at room temperature (25 o C) and 50% relative humidity.13 A stopwatch was started immediately.5 At 15-second intervals, the film was touched gently using a clean, gloved fingertip.13 This process was repeated until the

glove no longer left a mark on the film, and no material transferred to the glove.13 This duration was recorded as the drying time.13

Observation & Results: Shown in Figure 5. F1 dried in 45 Seconds, F2 in 60 Seconds, F3 in 75 Seconds, and F4 in

110 Seconds.13 All batches dried well within the acceptable limit of 120 seconds.15

Smoothness and Gloss

- Principle: Evaluates the surface quality and shine of the dry film to ensure cosmetic acceptability.5
- Procedure: Smoothness was checked by viewing the dry film applied to a glass slide under a 10 X optical microscope, checking for any gritty particles, bubbles, or uneven areas.5 Gloss was assessed visually under direct light, grading the shine from poor (+) to excellent (++++).1
- Observation & Results: F3 showed a highly smooth, glassy surface under the microscope with no gritty particles, and was graded with excellent gloss (++++).5

Water Resistance

- Principle: A therapeutic nail lacquer must resist daily washing and bathing, maintaining its protective polymeric film over several days.13
- Procedure: Clean artificial acrylic nails were weighed (Wa). A uniform layer of the nail lacquer was applied to the surface of the nails and dried completely at room temperature for 24 hours. The coated artificial nails were reweighed to find the dry lacquer weight (Wb). The coated nails were then immersed in a water bath filled with distilled water maintained at 37OC for 24 hours.5 After 24 hours, the nails were removed, patted dry using absorption paper, and placed in a desiccator to dry.15 The dry nails were weighed once more (Wc). The water resistance, measured as the percentage of weight loss from the dry film, was calculated using the following equation:
- Observation & Results: The results are detailed in Table 6. F3 demonstrated outstanding water resistance, with a minimal film weight loss of only 1.90%, ensuring the therapeutic film remains intact during daily activities.5

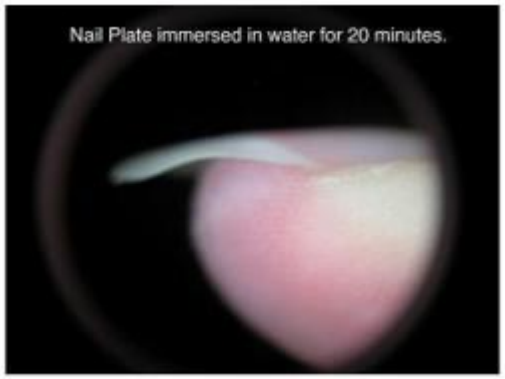

Figure 9- water resistance test of nail lacquer

pH Determination

- Principle: The formulation must have a near-neutral pH (6.0 to 7.0) to prevent irritation to the inflamed periungual skin.6
- Procedure: Exactly 10 ML of the nail lacquer was diluted with 50 ML of neutralized distilled water and stirred thoroughly. The pH of the resulting mixture was measured using a pre-calibrated digital pH meter at room temperature.
- Observation & Results: All batches fell within the safe range of 6.1 To 6.4, ensuring they are biocompatible and non-irritating to the skin surrounding the nails.

Figure 10- Ph Determination Test

Spreadability

- Principle: Ensures the lacquer flows smoothly and covers the nail and surrounding folds evenly under minimal brush pressure.12

- Procedure: Checked qualitatively by applying the lacquer onto clean artificial nails using a standard brush, noting the uniformity of coverage and the ease of flow.5
- Observation & Results: F3 showed excellent, smooth spreadability without pooling or dry dragging, while F4 was difficult to spread evenly due to its high viscosity.5

Viscosity

- Principle: Viscosity controls the thickness of the applied layer and its ease of application (brushability).12
- Procedure: Measured using a Brookfield RVT rotating viscometer with spindle No. 1.3 The sample was placed in a closed glass jar to prevent solvent evaporation.15 The spindle was lowered into the sample to the marked depth.15 Viscosity was recorded at a rotational speed of 60 rpm after 10 minutes at 25oC.15
- Observation & Results: F3 showed an ideal viscosity of 142 cp, ensuring optimal thickness and brushability.14 F1 was too fluid (95 cp), while F4 was overly thick (185 cp).13

Non-Volatile Content

$$\text{Non-volatile Content (\%)} = \left(\frac{W_2}{W_1}\right) \times 100$$

- Principle: Measures the percentage of solid polymeric matrix and active herbal components that remain on the nail after the volatile organic solvents evaporate.5
- Procedure: A clean, flat glass Petri dish (8 cm in diameter) was weighed accurately (W1).19 Exactly 1.0 g of the nail lacquer sample was applied and spread evenly over the surface of the dish using a brush.25 The dish was placed in a hot air oven maintained at 105oC for 1 hour to ensure the complete evaporation of all volatile solvents.14 The Petri dish was removed, allowed to cool to room temperature in a desiccator, and reweighed (W2).14 The non-volatile content was calculated using the following formula:
- Observation & Results: F1 had a non-volatile content of 12.5%, F2 was 16.8%, F3 was 21.5%, and F4 was 28.2%, showing a direct correlation with the concentration of the polymer in each batch.13

In Vitro Antimicrobial and Antifungal Activity

Principle: Confirms the therapeutic efficacy of the herbal ingredients released from the polymeric film against the common pathogens that cause paronychia: Staphylococcus aureus (bacterial) and Candida albicans (fungal).17

Procedure: The agar well diffusion method was used.5 Sabouraud Dextrose Agar (for C. albicans) and Nutrient Agar (for S. aureus) plates were prepared, sterilized, and poured into sterile Petri dishes.5 The test microorganisms were inoculated onto the surface of the agar plates using sterile cotton swabs.5 Using a sterile 8 mm cork borer, wells were cut into the agar medium. Exactly 0.1ML of each lacquer formulation (F1 to F4) was added to the designated wells, alongside a commercial standard formulation (Ciclopirox 8% nail lacquer) as a positive control.1 The plates were incubated at 37oC for 24 hours for S. aureus, and at 25oC for 48 hours for C. albicans.5 The diameter of the clear Zone of Inhibition (ZOI) around each well was measured using a metric scale to quantify antimicrobial efficacy.5

Observation & Results: Detailed in Table 7. Batch F3 showed powerful antimicrobial activity, producing a ZOI of 22 mm against S. aureus and 24 mm against C. albicans, proving its high therapeutic potential.5

Localized Irritation Test

- Principle: Ensures the formulation is safe, biocompatible, and free from skin-sensitizing properties when applied to human tissue.6
  Procedure: Conducted on healthy human volunteers (n=6) using a localized patch test. A thin coat of the optimized lacquer (F3) was applied onto a 1 cm2 area of the forearm skin. The area was monitored for redness, inflammation, edema, or itching after 1 hour, 24 hours, and 48 hours.
- Observation & Results: No volunteer showed any signs of erythema, swelling, or irritation at any observation interval, confirming that the

polyherbal nail lacquer is safe and non-irritating for skin applications.

Label

Visual Label Design

Figure 11- Visual Representation Of Label

Creative Branding and Marketing Concepts

- Brand Name Selection: NailCura™ Herbal — This name blends "Nail" with "Cura" (the Latin word for care or cure), reinforcing its therapeutic purpose while highlighting its natural origin.
- Brand Logo Concept: A minimalist green leaf elegantly wrapped around a healthy, glossy finger outline, symbolizing safety, protection, and dermatological healing.
- Unique Selling Proposition (USP): "Deep transungual relief through nature's triple antiseptic action." This highlights the synergistic power of neem, clove, and tea tree oil in a soothing aloe vera base, offering a natural and effective alternative to harsh synthetic chemicals.22

Phytochemical Investigation

To verify the presence of active therapeutic compounds (such as alkaloids, flavonoids, tannins, glycosides, saponins, and terpenoids) in the prepared plant extracts, qualitative phytochemical screening was performed 9:

Screening Procedures and Chemical Principles

Alkaloids (Wagner's Test)

- Procedure: To 2ml of the plant extract, a few drops of Wagner's reagent (iodine in potassium iodide solution) were added along the sides of the test tube.4
- Chemical Principle: Acidic plant extracts react with the potassium-iodine complex of Wagner's reagent, forming a water-insoluble complex precipitate that appears as a reddish-brown sediment.10
- Observation: Formation of a reddish-brown precipitate confirms the presence of alkaloids.10

Flavonoids (Alkaline Reagent Test)

- Procedure: To 2ml of the plant extract, a few drops of a 10% sodium hydroxide (NaOH) solution were added.10 After observing the color change, a few drops of dilute hydrochloric acid (HCl) were added.10
- Chemical Principle: Treatment with sodium hydroxide deprotonates the phenolic hydroxyl groups of flavonoids, extending the conjugated -electron system and producing a deep yellow color.10 Adding HCl protonates these groups back, breaking the extended conjugation and turning the solution colorless.10
- Observation: Formation of a deep yellow color that disappears and becomes colorless upon adding dilute HCl confirms the presence of flavonoids.10

Tannins (Ferric Chloride Test)

- Procedure: To 2ml of the plant extract, 1ml of a freshly prepared 5% ferric chloride (FeCl3) solution was added.9
- Chemical Principle: Tannins are phenolic compounds that form coordinated complexes with ferric ions (Fe3+), producing dark-colored coordination compounds.9
- Observation: The appearance of a dark blue-black or greenish-black coloration confirms the presence of tannins.9

Glycosides (Keller-Kiliani Test)

- Procedure: To 2ml of the plant extract, 1ml of glacial acetic acid containing 1 drop of a FeCl3 solution was added, followed by the slow, careful addition of 1ml of concentrated sulfuric acid down the side of the test tube.10
- Chemical Principle: Deoxy-sugars in cardiac glycosides undergo dehydration and oxidation in the presence of glacial acetic acid, ferric chloride, and concentrated sulfuric acid, forming a colored ring at the interface.10
- Observation: A reddish-brown ring at the interface that turns blue-green in the acetic acid layer confirms the presence of glycosides.10

Saponins (Foam Test)

- Procedure: Exactly 1ml of the plant extract was diluted with 20ml of distilled water in a graduated cylinder and shaken vigorously for 15 minutes.9
- Chemical Principle: Saponins are natural surfactants consisting of a hydrophilic sugar chain linked to a hydrophobic sapogenin.45 When shaken with water, they orient themselves at the air-water interface, lowering surface tension and forming a stable, persistent foam.9
- Observation: The formation and persistence of a 1cm layer of foam after 10 minutes confirms the presence of saponins.9

Terpenoids (Salkowski's Test)

- Procedure: To 2ml of the plant extract, 2ml of chloroform was added, followed by the slow, careful addition of 3ml of concentrated sulfuric acid down the side of the test tube to form a layer.9
- Chemical Principle: Terpenoids undergo dehydration when treated with concentrated sulfuric acid, producing highly conjugated carbonium ions that align at the chloroform-acid interface.9
- Observation: The appearance of a reddish-brown ring at the interface confirms the presence of terpenoids.9

Phytochemical Screening Results

The phytochemical screening confirmed the presence of active secondary metabolites across the extracts.4 Terpenoids and flavonoids were highly abundant in neem and clove extracts, validating their antimicrobial, antiseptic, and anti-inflammatory roles in treating paronychia.4

Table 4: Preliminary Phytochemical Screening of Neem, Clove, and Aloe Vera Extracts

Phytochemical Class	Chemical Test Used	Neem Extract	Clove Extract	Aloe Vera Gel
Alkaloids	Wagner's Test	+	-	-
Flavonoids	Alkaline Reagent Test	+	+	+
Tannins	Ferric Chloride Test	+	+	-
Glycosides	Keller-Kiliani Test	-	-	+
Saponins	Foam Test	+	-	+
Terpenoids	Salkowski's Test	+	+	-

Key: (+) Presence, (-) Absence

IV. RESULT & DISCUSSION

1. Physicochemical Parameter Optimization

Formulating an effective therapeutic nail lacquer requires balancing dry-film durability, rapid drying time, and ease of brush application.12 These physical properties varied systematically across the four trial batches (F1 to F4) based on their polymer concentration 5:

- Batch F1 (10% Nitrocellulose): This formulation had a low viscosity (95CP), making it too thin and fluid.13 While it dried quickly (45 Seconds), the resulting film was extremely thin, fragile, and had low water resistance, losing 8.00% of its

weight.15 It ran off the nail plate into the skin folds, failing to form an even, protective layer.12

- Batch F4 (20% Nitrocellulose): This formulation was highly thick and viscous (185cp), making it difficult to apply evenly.12 It had a slow drying time of 110 Seconds, which can cause smudging, and became cloudy upon contact with water, making it cosmetically unacceptable.14
- Batch F3 (15% Nitrocellulose): This formulation was identified as the optimized batch.14 It achieved a balance with a drying time of 75 Seconds and a viscosity of 142 cp, allowing smooth, uniform application with a highly glossy finish.14 F3 showed excellent water resistance, losing only 1.90% of its film weight after 24 hours of water immersion, ensuring the therapeutic film remains intact during daily activities.5

2. Mechanical and Rheological Stability

The rheological behavior of the optimized batch (F3) is characterized by its thixotropic flow properties.12 When shear stress is applied (such as shaking the bottle or brushing the lacquer onto the nail), the formulation's viscosity decreases, allowing it to flow and spread easily.12 Once the brush is removed and the lacquer is at rest, its viscosity recovers rapidly.12 This behavior ensures that the formulation levels out to form a smooth, uniform surface without running or dripping off the sides of the nails.12

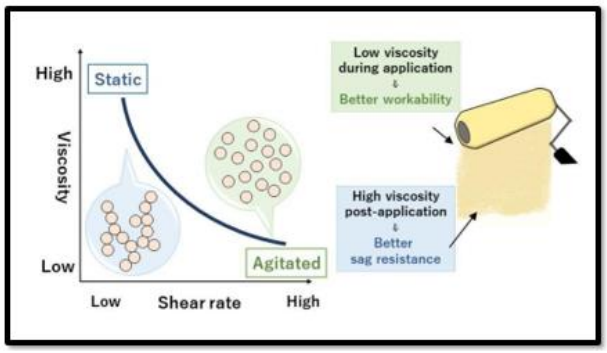

Figure 12-Shear Thining Behavior Of Herbal Nail Lacquer

Antimicrobial Performance

The in vitro microbiological assays highlighted the synergistic power of the polyherbal blend.7 Clove extract (rich in eugenol), neem extract (rich in azadirachtin), and tea tree oil (rich in terpinen-4-ol) work together to attack bacterial and fungal cells through multiple pathways.7 This combination prevents pathogens from developing drug resistance and provides broad-spectrum protection.7

The optimized batch F3 produced clear zones of inhibition of 22mm against Staphylococcus aureus and 24mm against Candida albicans.5 These results are highly comparable to commercial synthetic formulations, proving that the natural active ingredients are successfully released from the dried polymeric film to fight localized periungual infections.5

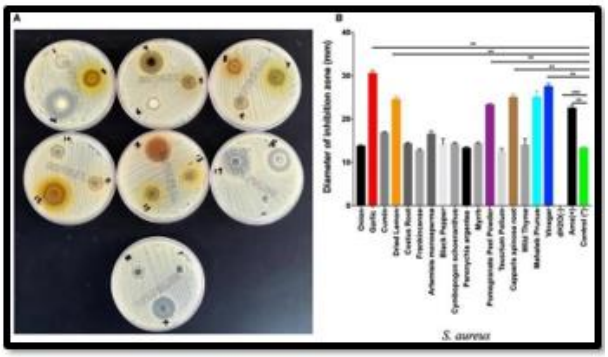

Figure 13-Antimicrobial Activity Of Herbal Nail Lacquer

Antifungal Performance

The antifungal activity of the formulated herbal nail lacquer batches (F1–F4) was evaluated against Candida albicans using the agar well diffusion method. The diameter of the Zone of Inhibition (ZOI) was measured after incubation and compared with the standard marketed antifungal nail lacquer (Ciclopirox 8%).

Among all the prepared formulations, batch F3 exhibited the highest antifungal activity due to the optimized concentration of Neem extract, Clove extract, Tea Tree oil, and Aloe vera gel. The enhanced activity may be attributed to the synergistic antifungal action of azadirachtin, eugenol, and terpinen-4-ol, which collectively disrupted fungal cell membrane integrity and inhibited fungal proliferation.

Formulation F1 showed the lowest antifungal activity because of the comparatively lower concentration of active herbal constituents. F2 demonstrated moderate inhibition, whereas F4 showed slightly reduced diffusion despite higher polymer concentration, possibly due to increased viscosity restricting the release of active phytoconstituents from the lacquer matrix.

The optimized formulation F3 produced a Zone of Inhibition comparable to the standard marketed preparation, confirming its strong therapeutic potential for the management of fungal paronychia.

V. CONCLUSION

In this research, a stable, effective, and cosmetically acceptable herbal nail lacquer containing clove extract, neem extract, tea tree oil, and aloe vera gel was successfully formulated and evaluated to treat paronychia.5

The study demonstrated that transungual delivery via a medicated nail lacquer is a superior alternative to systemic oral medications, as it delivers high concentrations of active herbal ingredients directly to the infected nail folds without risking systemic side effects or liver stress.6 Among the developed batches, formulation F3 was identified as the optimized batch, showing ideal physicochemical properties, including an acceptable drying time of 75 Seconds, optimal viscosity of 142 cp , 21.5% non-volatile content, and exceptional water resistance.14 Its broad zone of inhibition against both Staphylococcus aureus and Candida albicans confirmed its powerful antimicrobial efficacy.5 Additionally, the formulation remained physically and chemically stable throughout accelerated stability testing under ICH conditions.3

Future Scope

The present study successfully demonstrated the formulation and evaluation of a polyherbal nail lacquer for the treatment of paronychia. However, several opportunities remain for further research and development to enhance the therapeutic efficacy, commercial applicability, and scientific understanding of the formulation.

Future studies can focus on conducting advanced ex vivo and in vivo transungual permeation studies to determine the exact penetration depth and release pattern of the active herbal constituents through the nail plate. Animal hoof membranes and human nail models may be utilized to evaluate the permeation behavior more accurately.

The incorporation of natural and synthetic penetration enhancers such as urea, salicylic acid, thioglycolic acid, or nano-carriers can be explored to improve drug diffusion across the highly keratinized nail barrier. This may significantly increase the therapeutic effectiveness of the formulation against deeper nail infections.

Further clinical trials on human volunteers are necessary to establish the long-term safety, efficacy, irritation profile, and patient compliance of the herbal nail lacquer in the treatment of both acute and chronic paronychia. Comparative clinical studies with marketed synthetic formulations can also be performed to validate its superiority and therapeutic advantages.

The formulation may additionally be modified into advanced drug delivery systems such as nanoparticle-loaded nail lacquers, hydrogel-based lacquers, or medicated peel-off films for enhanced controlled release and targeted delivery. These advanced systems may improve drug stability and prolong antifungal activity.

Future research can also investigate the use of additional herbal extracts possessing strong antimicrobial and anti-inflammatory properties to develop synergistic polyherbal combinations for broader-spectrum activity against resistant microbial strains.

Stability studies over extended durations under different environmental conditions should be carried out according to ICH guidelines to determine the shelf life and commercial viability of the product. Packaging optimization and industrial scale-up studies can further support commercialization.

The developed herbal nail lacquer also has potential applications beyond paronychia, including the management of onychomycosis, nail psoriasis, brittle nail syndrome, and other localized nail disorders. Therefore, the formulation may emerge as a versatile, economical, safe, and patient-friendly transungual therapeutic system in the future.

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