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Standardisation Of Nimba Lodhra Herbal Eye Drops For Infective Conjunctivitis.

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ABSTRACT
Standardizing herbal formulations is essential to ensure their safety, efficacy, and reproducibility. This study focuses on the development and standardization of Nimba-Lodhra eye drops, formulated using Nimba (Azadirachta indica) and Lodhra (Symplocos racemosa), for the treatment of infective conjunctivitis. These herbs are known for their antimicrobial, anti-inflammatory, and astringent properties in traditional Ayurvedic medicine.The formulation process involved the preparation of aqueous extracts of Nimba and Lodhra, followed by incorporation into an isotonic and sterile ophthalmic base. The standardization protocol included phytochemical analysis through qualitative and quantitative techniques such as high-performance liquid chromatography (HPTLC) to ensure consistency in active phytoconstituents.Physicochemical parameters such as pH, viscosity, and specific gravity, were evaluated to ensure compliance with ophthalmic preparation standards. The sterility and microbial limit tests confirmed the absence of harmful pathogens.The results highlight that standardized Nimba-Lodhra eye drops are a safe and effective herbal alternative for treating infective conjunctivitis. Future clinical studies are recommended to validate its therapeutic efficacy and safety profile in a clinical setting.

Keywords: Nimba, Lodhra, eye drops, infective conjunctivitis, standardization, antimicrobial, Ayurveda.

INTRODUCTION

Infective conjunctivitis is a common ocular condition characterized by inflammation of the conjunctiva. It is caused by microbial pathogens, predominantly bacteria and viruses, and is highly contagious, especially in environments where close contact occurs [(1)]. Bacterial conjunctivitis is often associated with pathogens such as *Staphylococcus aureus*, *Streptococcus pneumoniae*, and *Haemophilus influenzae*, while viral conjunctivitis is most commonly linked to adenoviruses [(2)]

The clinical symptoms of acute mucopurulent conjunctivitis and viralconjunctivitisarecharacterized by mucopurulent and watery discharge. Ayurvedic diagnostic methods relied on clinical manifestations. Features such as redness, burning sensation, watery or mucopurulent discharge, and edema suggested the involvement of vitiated Pitta. This aligns with Ayurvedic symptoms where manifestations such as purulent discharge (Prapaka), congestion (Lohitanetrata), and burning sensation (Daha) are attributed to vitiated Rakta and Pitta doshas [(4).]

The symptoms of infective conjunctivitis are similar to an eye condition described in Ayurveda as PittajaNetra abhishyanda. In conventional medicine, broad-spectrum antibiotics are commonly prescribed to speed up recovery, prevent complications, stop the spread of infection, and reduce discomfort. Antibiotics are also used in viral conjunctivitis to prevent secondary bacterial infections. However, rising antibiotic resistance, high costs, and side effects highlight the need for alternative treatments for infectious conditions. [(3)]

MATERIALS AND METHOD

Ingredients of the formulation

1. Azadirachta indica (Nimba)
2. Symplocos racemosa (Lodhra)

1. Azadirachta indica (Nimba)

Azadirachta indica, commonly known as neem. Neem is used for its broad-spectrum therapeutic properties, including anti-microbial, anti-inflammatory, and immunomodulatory effects, making it a valuable resource for managing a wide array of infections and inflammatory conditions. Among its diverse applications, neem has gained attention for its potential to treat conjunctivitis (pink eye).

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Figure1:AZADIRACHTA INDICA

Ayurvedic Properties

- Rasa (Taste):Tikta (Bitter), Kasaya(Astringent)
- Guna (Property): Laghu (Lightness), Rooksha (Dryness)
- Vipaka:Katu (Pungent)
- Veerya (Potency):Sheeta (Cold)
- Dosha Karma: Pitta Kaphahara
- Karma (Action):Krimihara, Vranahara, Kushtaharas

The rukshaguna (dryness property) of Nimba contributes to its shoshana property, which aids in absorption and drying. Its laghuguna (lightness property) is known for its shrotoshodhakaeffect [4], meaning it purifies the body channels. Additionally, Nimba's sheetaveerya (cool potency) possesses stambhana (to stop) and prasadana (soothing) effects [5], contributing to its ability to alleviate symptoms.
Nimba leaves contain potent compounds such as Nimbidin and Azadirachtin, which exhibit a broad spectrum of pharmacological activities including anti-inflammatory, antibacterial, antifungal, and antiviral effects against various pathogens [6].
The important phyto- chemical constituents present are Azadiractin, NimbolinA, Nimbin, Salannin, Gedunin, Sitosterol-responsiblefor itsactivitiesagainstStaphylococcus aureus, Escherichia coli [7].

2. Lodhra

The kashaya rasa, in particular, exhibits multiple therapeutic actions, including samshamana (alleviating effect on doshas), sangrahi (absorbing), vrana-ropana (wound healing), shoshana (moisture drying), stambhana (arresting), and Kapha-Rakta-Pitta alleviating properties [8].

Figure2:SYMPLOCOS RACEMOSA

Ayurvedic Properties

- Rasa (Taste):Kasaya (Bitter)
- Guna (Property): Laghu (Lightness), Rooksha (Dryness)

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- Vipaka:Katu (Pungent)
- Veerya (Potency):Sheeta (Cold)
- Dosha Karma: Pitta Kaphahara
- Karma (Action):Chakshushya, Vranaropana, Shotahara

The phytoconstituents present are Loturine, Gallic acid, Acetate, n acetate, Betulinic acid, Benzoylsalireposide, Symconoside A and Symconoside B, Olienic acid

Apparatus required for distillation

Distillation is the process by which liquid is vaporized and recollected by cooling and condensing the vapour.
The apparatus required for distillation is as follows:

- Boiler (Heating mantle) - which provides heat and maintains the heat.
- Vessel, in which vapours are produced by heating the liquid to its boiling point.
- Condenser - These function as a cooling device for vapours either by circulation of water or air at atmospheric temperature.
- Receiver - It is used for the collection of condensed liquid.

METHOD OF PREPARATION

The stepwise development of eye drops encompasses the preparation of distillate, making of the distillate isotonic to lacrimal fluid and adjustment of pH, addition of preservative and packing under sterile conditions.
Nimba Lodhra eye drops were prepared by using Nimba (leaves) (Fig. 1), Lodhra (bark) (Fig. 2), in equal quantities of 200 grams each. The above-mentioned plant materials were taken and made into coarse powder and the coarsely powdered herbs were taken in 2 Ltr. RB Flask and soaked in 1 Ltr. distilled water overnight.

- Next day, the distillation unit was connected to the RB flask and started the distillation process at 80 ^{0}C.
- The pH of the distillate to be checked (pH 4.5 Approx.)
- Then the pH of the eye drops was adjusted to 6.5 - 7.30 using buffer solution(0.9% NaCl)
- Benzalkonium chloride (0.01%) was added as a preservative
- Pre-filtration was done in 2- 20µm filter
- Then sterile membrane filtration in 0.2 to 2 µm
- The final pH of the drops was checked (Range 7.2 to 7.4)
- Then sterile filling of the drops was done **(10 mL Dropper)**

Figure3: APPARATUS

Precautions to be taken

- The drugs should be in coarse powder form.
- The coarsely powdered drugs should be soaked in water and then should be subjected to the distillation process.

Organoleptic parameters of the finished product

- Colour: Colourless
- Consistency: Liquid
- Smell: Specific odour
- Taste: Specific taste

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RESULTS OF STANDARDIZATION PARAMETERS OF NIMBA LODHRAEYE DROPS
Parameter Results (Indian Pharmacopia, 1996)

- PH- 7.236 – API (Part – 1) Vol 9 page 114 -115 -2016
- Viscosity - 1.017 – API part 2 Vol – 1, page 198- 2007
- Specific gravity @ 25^0 c - 1.006 - API part 2 Vol – 4, page 145- 2007

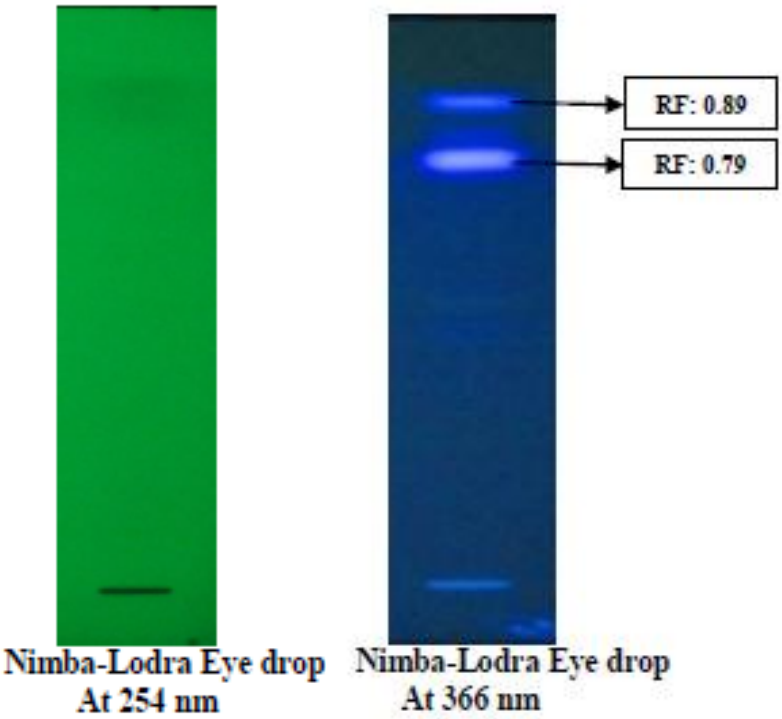

Figure4: HPTLC ANALYSIS REPORT

The Chromatography shows 2 major common bands at 366 nm in Nimba lodhra Eye drop and a few week bands at 254 nm.

Figure5: NIMBA LODHRA EYE DROP

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DISCUSSION

The Nimbadi eye drops comprise two key ingredients: Nimba (Azadirachta indica Juss.) and Lodhra (Symplocos racemose Roxb.). Nimba possesses several important properties or "Gunas" according to Ayurveda, including laghu (lightness) and ruksha (dryness). It has a tikta (bitter) taste, katu (pungent) vipaka (taste conversion after digestion), and sheet virya (coolness potency) [9]. These properties contribute to Nimba's therapeutic effects. From an Ayurvedic perspective, Nimba acts primarily through its tikta rasa (bitter taste), which serves to alleviate symptoms and destroy parasites or krimi. Nimba is also noted for its vishaghna properties, meaning it acts as a detoxifier, and dahashamaka properties, which help relieve burning sensations. Additionally, Nimba possesses kledahara properties, which decrease moisture, and puyashoshaka properties, which aid in drying up pus.

The application of phytochemicals derived from **Azadirachta indica** (Nimba) and **Symplocos racemosa** (Lodhra) exhibits antimicrobial properties, attributed to bioactive compounds like azadirachtin and nimbin, which inhibit bacterial and viral growth. Additionally, its anti-inflammatory mechanisms, mediated through the suppression of pro-inflammatory cytokines, help mitigate conjunctival swelling and redness. Lodhra, rich in alkaloids like loturine and flavonoids, demonstrates astringent and anti-inflammatory properties, promoting vascular constriction and facilitating the healing of damaged epithelial tissues.

The HPTLC report at 254 nm the phytochemical constituents found are Butonol, Benzoylsalireposide, Chloroform [9] and at 366 nm the phytochemical constituents are Palmitate, Puridin. [10]

CONCLUSION

The preparation of Nimba-Lodhra eye drops involves a standardized method to ensure safety and efficacy, including the extraction of active compounds from *Azadirachta indica* (Nimba) and *Symplocos racemosa* (Lodhra) under controlled conditions. The formulation is prepared in a sterile environment, with adjustments to pH (7.236) and viscosity to ensure ocular compatibility, and appropriate preservatives are added to maintain stability. Testing includes physicochemical evaluations (pH, specific gravity, viscosity), microbiological tests to ensure sterility and antimicrobial efficacy, and phytochemical analysis to quantify active ingredients.

Nimba-Lodhra eye drops offer a natural and effective approach to managing conjunctivitis, leveraging the synergistic benefits of their active compounds. **Nimba (Azadirachta indica)** provides potent antimicrobial and anti-inflammatory effects, helping to combat infections and reduce redness and swelling. **Lodhra (Symplocos racemosa)** complements these actions with its tissue-healing, antioxidant, and astringent properties, promoting faster recovery and soothing irritation.

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