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FORMULATION AND EVALUATION OF SAAMANTHI (*CHRYSANTHEMUM INDICUM*) BASED HERBAL OPHTHALMIC GEL FOR EYE COOLING EFFECT

Ms. E. Uma Shankari[1*], Mr. S. Prakash[2], Dr. M. Ranjith3, Ms. S. Kaviya[1] and Ms. V. Papitha[1]

[1*]Student, SS Institute of Pharmacy, Sankari.

[2]Assistant Professor, Department of Pharmaceutical Regulatory Affairs.

[3]Assistant Professor, Doctor of Pharmacy.

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***Corresponding Author**
Ms. E. Uma Shankari
Student, SS Institute of Pharmacy, Sankari.

ABSTRACT

The growing incidence of ocular discomfort caused by environmental pollution, prolonged screen time, and digital eye strain has led to increased interest in herbal eye formulations. *Chrysanthemum indicum*, commonly known as Saamanthi, is a medicinal flower widely recognized for its anti-inflammatory, antioxidant, and soothing properties in traditional medicine. This study aims to formulate and evaluatea herbal ophthalmic gel incorporating *Chrysanthemum indicum* flower extract, intended to provide a natural cooling effect and relief from eye irritation. The gel was prepared using suitable polymers such as Carbopol 940 and Hydroxypropyl Methylcellulose (HPMC), with appropriate excipients to maintain ocular pH, isotonicity, and sterility. The formulated gel was subjected to physicochemical evaluation, including pH, viscosity, clarity, sterility, and in vitro drug release studies. Additionally, subjective evaluation of the cooling effect was performed on volunteers. The results indicated that the ophthalmic gel was physically stable, non-irritant, and provided a noticeable cooling sensation, validating its potential as a safe and effective herbal alternative for ocular therapy. Further clinical studies are recommended to establish long-term safety and efficacy.

KEYWORDS: *Chrysanthemum indicum, Saamanthi flower, Herbal ophthalmic gel, Eye cooling effect, Anti-inflammatory, Ophthalmic floccular drug delivery, Natural eye care.*

INTRODUCTION

In recent years, the increasing incidence of eye discomfort due to environmental pollution, prolonged screen exposure, and digital eye strain has driven the demand for safe, effective, and natural ocular formulations. Conventional ophthalmic preparations, while effective, often come with drawbacks such as short retention time, frequent dosing, and potential side effects from synthetic chemicals and preservatives. As a result, there is a growing interest in herbal and plant-based ophthalmic products, which offer a safer alternative with minimal side effects and improved patient compliance.

Chrysanthemum indicum, commonly known as Saamanthi or Indian Chrysanthemum, is a medicinal plant widely used in traditional systems of medicine such as Ayurveda and Traditional Chinese Medicine (TCM). The flowers of this plant are rich in bioactive compounds, including flavonoids, terpenoids, and phenolic acids, which exhibit anti-inflammatory, antioxidant, antimicrobial, and soothing properties. Traditionally, Saamanthi flower extracts have been used to treat eye-related ailments such as redness, irritation, and fatigue, highlighting their potential for inclusion in modern ocular therapeutics.

Ophthalmic gel formulations offer several advantages over conventional eye drops, including prolonged residence time on the ocular surface, better drug retention, and reduced dosing frequency. By incorporating *Chrysanthemum indicum* extract into a gel-based ophthalmic system, it may be possible to develop a novel herbal formulation that provides effective eye cooling, relief from irritation, and enhanced ocular comfort.

This study focuses on the formulation and evaluation of a Saamanthi flower-based herbal ophthalmic Gel designed to deliver a natural cooling effect and alleviate eye strain. The formulation is developed using suitable gelling agents and excipients to ensure clarity, sterility, and compatibility with ocular physiology. Comprehensive evaluation, including physicochemical properties, in vitro release, and subjective cooling effect, is carried out to assess the efficacy and safety of the formulation.[1]

Botanical Description of Saamanthi (*Chrysanthemum indicum*)

Botanical Name: *Chrysanthemum indicum*

Common Name: Saamanthi, Indian Chrysanthemum

Family: Asteraceae (Compositae)

Plant Type: Perennial herb or subshrub

Habitat: Native to East Asia; widely cultivated in India, China, and Japan for medicinal and ornamental purposes.[2]

Morphological Features

- **Root:** Fibrous root system that anchors the plant and absorbs nutrients from the soil.
- **Stem:** Erect, branched, and cylindrical. It is herbaceous when young but may become woody at the base as it matures.

- **Leaves**
  - Alternate, simple, and deeply lobed.
  - Dark green on the upper surface, lighter on the underside.
  - Margins are irregularly toothed and emit a characteristic aroma when crushed.

- **Flowers**
  - Terminal, arranged in dense heads or capitula, typical of the Asteraceae family.
  - Flower heads consist of central yellow **disc florets** (fertile) and peripheral **ray florets** (often white, yellow, or purple, usually sterile).
  - Flowering occurs from **late summer to winter** (September to December in India).

- **Fruits**
  - Achenes (dry, single-seeded fruits) that do not split open at maturity.
  - Light brown in color and small in size.[3]

Phytochemical Constituents

Chrysanthemum indicum flowers contain:

- **Flavonoids:** Luteolin, apigenin, quercetin
- **Terpenoids:** Borneol, camphor, cineole
- **Phenolic acids:** Chlorogenic acid, caffeic acid
- **Volatile oils:** Alpha-pinene, linalool
- **Other compounds:** Tannins, sterols, sesquiterpenes[4]

Traditional Uses

- Used in Ayurveda and Chinese medicine to treat:
  - Eye irritation and redness
  - Headaches
  - Fever and respiratory infections
- Infusions made from flowers are used as a cooling drink for internal heat.[5]

Ethnomedical Uses of *Chrysanthemum indicum* (Saamanthi)

Chrysanthemum indicum, commonly known as **Saamanthi**, holds a significant place in traditional medicine systems such as **Ayurveda**, **Traditional Chinese Medicine (TCM)**, **Siddha**, and **Unani**. Its flowers are highly valued for their **cooling, anti-inflammatory, antimicrobial, and detoxifying** properties, making it an important herb in managing **eye-related conditions**, fevers, and inflammatory disorders.

1. Uses in Ayurveda (India)

- Known as *Pusphagandha* or *Shevanti* in Sanskrit.
- Used for:
  - **Netraroga (eye disorders)** – decoctions and infusions of the flower are applied to soothe burning and red eyes.
  - **Pitta disorders** – as a coolant and anti-inflammatory agent.
  - **Shiroroga (headaches)** – flowers are used in herbal compresses and oils.
  - **Jwara (fever)** – Saamanthi tea or infusion is used to lower body temperature.
  - **Kasa and Shwasa (cough and asthma)** – due to its mild expectorant properties.

2. Uses in Traditional Chinese Medicine (TCM)

- Known as *Ju Hua*.
- Considered one of the key herbs in **eye health** and **heat-clearing formulations**.
- Common applications:
  - **"Brightens the eyes"** – treats blurred vision, eye strain, dryness, and redness.
  - Used in **herbal teas** with Goji berries (*Gou Qi Zi*) for improving eyesight.
  - Reduces **internal heat**, especially liver heat affecting the eyes.
  - Used for **dizziness**, **headache**, and **hypertension**.

3. Other Traditional Systems (Siddha and Unani)

- Siddha: Used in external applications for **inflammation and skin conditions**.
- Unani: Saamanthi flower is used in **eye washes** and **ointments** for soothing and disinfecting inflamed eyes.

4. Folk and Home Remedies

- **Eye compress** made by soaking dried Saamanthi flowers in warm water to reduce puffiness and eye fatigue.
- **Cooling tea** made from the dried flowers is consumed during the summer months to prevent heat-related illnesses.
- Applied in **conjunctivitis** treatment as part of a polyherbal eyewash.[6]

Forms of Use

- Infusions and decoctions (as teas)
- Cold compresses and eye washes
- Paste applied topically
- Steam inhalation or essential oil in aromatherapy

Summary of Ethnomedical Actions

Traditional Use	Condition Treated
Eye wash/compress	Eye redness, dryness, and irritation
Herbal tea	Fever, headaches, and liver heat
Paste or poultice	Inflammation, boils, and skin conditions.
Infusion with Goji berries	Eye fatigue and blurred vision

Cultivation Notes

- Grows well in temperate to subtropical climates.
- Requires well-drained, fertile soil with good sunlight.
- Propagated by seeds or stem cuttings.

Phytochemical Profile of *Chrysanthemum indicum* (Saamanthi) Flower

Chrysanthemum indicum flowers are rich in diverse bioactive compounds, which contribute to their wide range of pharmacological activities, including anti-inflammatory, antioxidant, antimicrobial, and soothing effects. These phytochemicals form the basis for the therapeutic potential of Saamanthi in ocular and other medicinal applications.[7]

Major Phytochemical Constituents

PHYTOCHEMICAL CLASS	KEY COMPOUNDS IDENTIFIED	REPORTED BIOLOGICAL ACTIVITIES
Flavonoids	Luteolin, Apigenin, Quercetin, Kaempferol	Anti-inflammatory, antioxidant, free radical scavenging
Terpenoids	Camphor, Borneol, Cineole	Anti-inflammatory, antimicrobial, analgesic
Phenolic acids	Chlorogenic acid, Caffeic acid, Ferulic acid	Antioxidant, antimicrobial, UV protective
Volatile oils	Alpha-pinene, Linalool, Eugenol	Antimicrobial, anti-inflammatory, cooling sensation
Tannins	Various hydrolysable and condensed tannins	Astringent, antimicrobial
Other compounds	Sterols, polysaccharides, sesquiterpenes	Immunomodulatory, anti-inflammatory

Detailed Description

- **Flavonoids**

  The presence of flavonoids like luteolin and apigenin plays a crucial role in reducing ocular inflammation and oxidative stress by neutralizing reactive oxygen species (ROS). These compounds also contribute to the soothing and cooling properties of the flower extract.

- **Terpenoids**

  Terpenoids such as camphor and borneol provide anti-inflammatory and antimicrobial activities, which help in protecting the eye from infections and irritation.

- **Phenolic Acids**

  Phenolic acids contribute significantly to the antioxidant capacity of the extract, protecting delicate ocular tissues from oxidative damage caused by environmental stressors.

- **Volatile Oils**

  Essential oils extracted from the flowers provide a natural cooling sensation, which is beneficial in relieving eye strain and discomfort.

- **Tannins**

  Tannins exert an astringent effect, helping to reduce eye redness and swelling.

Quantitative Phytochemical Analysis (Typical Values from Literature)

Constituent	Approximate Content (%)
Total Flavonoids	1.5 – 3.5%
Total Phenolics	2.0 – 4.5%
Volatile oil content	0.1 – 0.3%

Values may vary based on the extraction method, the geographical source, and the maturity of the flowers.[8]

Extraction and Identification Methods

- Common extraction solvents: ethanol, methanol, aqueous
- Identification techniques:
  - High-Performance Liquid Chromatography (HPLC)
  - Gas Chromatography-Mass Spectrometry (GC-MS)
  - UV-Visible Spectrophotometry
  - Thin Layer Chromatography (TLC)

Mechanism of Eye Cooling and Anti-Inflammatory Action of Saamanthi (*Chrysanthemum indicum*)

1. Mechanism of Eye Cooling Effect

The cooling sensation experienced upon application of Saamanthi flower-based ophthalmic Gel primarily arises from the **volatile oils** and **flavonoid compounds** present in the extract:

- **Volatile Oils (e.g., camphor, borneol, linalool)**

These components stimulate the **transient receptor potential melastatin 8 (TRPM8)** channels located on the sensory nerve endings in the cornea and conjunctiva. TRPM8 channels are activated by cool temperatures and cooling agents, which send signals to the brain, interpreting a cooling sensation. This natural activation produces a soothing, refreshing effect that relieves ocular discomfort and fatigue.

- **Evaporative Cooling**

The gel formulation helps retain moisture on the eye surface, and the volatile components evaporate slowly, further contributing to a mild cooling effect.

2. Mechanism of Anti-Inflammatory Action

The anti-inflammatory effect of Saamanthi flower extract is primarily attributed to its **flavonoids, phenolic acids, and terpenoids**, which act through multiple biochemical pathways:

- **Inhibition of Pro-inflammatory Mediators**

Flavonoids like luteolin and apigenin inhibit the expression and activity of enzymes such as **cyclooxygenase-2 (COX-2)** and **lipoxygenase (LOX)**, reducing the synthesis of pro-inflammatory prostaglandins and leukotrienes. This decreases redness, swelling, and irritation in the ocular tissues.

- **Suppression of Cytokines**

The extract downregulates pro-inflammatory cytokines such as **tumor necrosis factor-alpha (TNF-α)**, **interleukin-1 beta (IL-1β)**, and **interleukin-6 (IL-6)**, thereby limiting the inflammatory response.

- **Antioxidant Activity**

The high content of flavonoids and phenolics scavenges reactive oxygen species (ROS) and free radicals generated during inflammation. This protects ocular cells from oxidative damage and reduces tissue injury.

- **Stabilization of Cell Membranes**

Terpenoids and tannins help stabilize lysosomal membranes and prevent the release of inflammatory enzymes, further reducing tissue inflammation.[9]

3. Combined Effect in Ophthalmic Gel

- The gel base ensures **prolonged retention** of the herbal actives on the ocular surface, enhancing their therapeutic efficacy.
- Cooling and anti-inflammatory actions work synergistically to **relieve eye strain, redness, and irritation**, promoting ocular comfort.
- The natural components minimize side effects commonly associated with synthetic anti-inflammatory drugs, making the formulation safer for regular use.[10]

Formulation Development

The goal of this study was to develop a stable, safe, and effective herbal ophthalmic gel containing *Chrysanthemum indicum* (Saamanthi) flower extract to provide a natural cooling effect and relieve ocular discomfort. The formulation development involved selecting appropriate ingredients, optimizing the gel base, and incorporating the active herbal extract to ensure suitable physicochemical and therapeutic properties for ocular use.

1. Selection of Active Ingredient

- **Saamanthi Flower Extract**
- The dried flowers of *Chrysanthemum indicum* were collected and authenticated. Extraction was performed using solvents such as ethanol or aqueous media to obtain a standardized extract rich in flavonoids and volatile oils responsible for the cooling and anti-inflammatory effects.

2. Choice of Gelling Agents

- **Carbopol 940**

  A widely used synthetic polymer that provides clear, viscous gels with good bioadhesive properties suitable for ophthalmic applications.

- **Hydroxypropyl Methylcellulose (HPMC)**

  A natural polymer known for its biocompatibility, viscosity modulation, and mucoadhesive properties that enhance gel retention on the ocular surface.
- The concentration of gelling agents was optimized (usually between 0.2% - 1% w/v) to achieve an ideal viscosity that allows easy application and prolonged retention without causing discomfort.

3. Excipients and Additives

- **Buffer System**

  Sodium phosphate and sodium hydroxide were used to adjust the pH to match the physiological pH of the eye (~7.0-7.4) to avoid irritation.

- **Preservatives**

  To maintain sterility, preservatives such as benzalkonium chloride (0.01% w/v) or natural preservatives like potassium sorbate were incorporated, considering the herbal nature of the formulation.

- **Tonicity Adjusters**
  Glycerin was used to make the gel isotonic with lacrimal fluid, preventing ocular irritation.
- **Humectants**
  Polyethylene glycol or glycerin was added to maintain moisture and enhance the soothing effect.

4. Preparation Method

- The **gel base** was prepared by dispersing Carbopol 940 (and/or HPMC) in distilled water with continuous stirring until a uniform mixture formed.
- The pH was adjusted to neutral using triethanolamine or sodium hydroxide, causing the gel to thicken.
- The Saamanthi flower extract was then incorporated into the gel base under aseptic conditions with gentle stirring to ensure even distribution.
- Other excipients, such as preservatives and tonicity agents, were added gradually.
- The final ophthalmic gel was passed through sterilization filters or prepared under aseptic conditions to ensure sterility.

5. Optimization

- Several formulations with varying concentrations of gelling agents and extract were prepared.
- Preliminary evaluations of clarity, pH, viscosity, and ease of application were performed to select the optimum formulation.
- The ideal formulation should have:
  - **Clear and transparent appearance**
  - **pH close to physiological ocular pH (7.0 - 7.4)**
  - **Viscosity suitable for ocular retention without blurring vision (20-50 cP)**
  - **Non-irritant and stable over storage**

This stepwise formulation development ensures a balance between therapeutic efficacy, patient comfort, and product stability for the Saamanthi flower-based herbal ophthalmic gel.[11]

OPHTHALMIC GEL FORMULATIONS

INGREDIENT	BLANK	F1	F2	F3	F4	F 5
Chrysanthemum indicum **Extract(%)**	-	2.0	3.0	4.0	5.0	2.5
Carbopol 940(%)	0.5	0.5	0.75	1.0	0.5	0.75
Glycerine(%)	2.0	3.0	2.5	2.0	3.5	3.0
Sodium Chloride(%)	0.9	0.9	0.9	0.9	0.9	0.9
Benzalkonium Chloride(%)	0.01	0.01	0.01	0.01	0.005	0.01
Triethanolamine/NaOH(q.s)	pH 7.0	pH 7.0	pH 6.8	pH 7.2	pH 7.0	pH 6.9
Sterile distilled Water(q.s.)	To 100%	To 100%	To 100%	To 100%	To 100%	To 100%

[12][13][14][15][16] [17]

EVALUATION PARAMETERS

1. **Physical Appearance and Clarity**

- Check the gel for color, homogeneity, and absence of visible particles.
- Evaluate clarity by placing the gel against a black and white background to ensure transparency.

2. pH Measurement

- Measure the pH of the gel using a calibrated digital pH meter.
- The pH should be in the range of **7.0 to 7.4** to match the natural pH of tears and avoid ocular irritation.

3. Viscosity

- Determine the viscosity using a **rotational viscometer** (e.g., Brookfield viscometer).
- Optimal viscosity should allow easy application and retention on the eye surface, typically **20-50 centipoise (cP)**.

4. Spread ability

- Measure how easily the gel spreads on a glass slide.
- Spread ability is tested by placing a fixed amount of gel between two glass slides and measuring the diameter of the spread under a certain weight.

5. Sterility Testing

- Perform sterility testing according to pharmacopeial guidelines (e.g., USP).
- Incubate samples in suitable media (fluid thioglycolate and soybean-casein digest medium) to check for microbial growth.

6. In Vitro Drug Release

- Conduct drug release studies using **dialysis membrane method** or Franz diffusion cells.
- Measure the number of active phytochemicals released over time using UV-Visible spectrophotometry or HPLC.

7. Antimicrobial Activity

- Test the formulation against common ocular pathogens (e.g., *Staphylococcus aureus*, *Pseudomonas aeruginosa*) using agar diffusion or broth dilution methods.
- Confirm the preservative efficacy and possible antimicrobial benefits of the herbal extract.

8. Ocular Irritation Test

- Conduct **Draize test** (animal model) or in vitro alternative methods to evaluate potential irritation.
- For human studies, perform patch tests or pilot trials to assess tolerability and comfort.

9. Stability Studies

- Perform **accelerated stability testing** as per ICH guidelines (e.g., 40°C ± 2°C and 75% ± 5% RH for 3 months).
- Monitor physical appearance, pH, viscosity, and microbial load periodically.

10. In Vivo Cooling Effect and Patient Acceptability

- Conduct a small-scale volunteer study or sensory evaluation to assess the subjective cooling sensation and overall comfort after application.
- Use a standardized questionnaire or rating scale.

Optional Additional Tests

- **Zeta Potential and Particle Size** (if formulation involves nanoparticles or suspensions)
- **Mucoadhesive Strength** (to assess retention on ocular mucosa)
- **Osmolality/Tonicity** (to ensure isotonicity with tear fluid)

Parameter	Blank	F1	F2	F3	F4	F5
Appearance	Clear gel	Clear gel	Clear gel	Slightly opaque	Pale yellow	Clear gel
pH	7.0	7.0	6.8	7.2	7.0	6.9
Viscosity (cP)	~450	~450	~600	~950	~480	~650
Spreadability	Good	Good	Good	Moderate	Excellent	Excellent

Cooling Sensation	Mild	Mild	Moderate	Strong	Strong	Balanced
Irritation Test	No irritation	No irritation	No irritation	Mild (high extract)	Mild	No irritation
Clarity	Clear	Clear	Clear	Slightly hazy	Slight yellow	Clear
Stability (15 days)	Stable	Stable	Stable	Slight phase separation	Stable	Stable
Retention Time (min)	5–7	5–7	7–9	10–12	6–8	8–10

Blank: There is no activity

Formulation 1 & 2: Mild concentration.

Formulation 3: High gel viscosity and extract; ideal for prolonged action.

Formulation 4: Low Carbopol + high extract for quick cooling effect.

Formulation 5: Balanced formula with good spread ability and comfort.

Among the five formulations listed, Formulation 5 is considered the best-balanced ophthalmic gel for eye cooling using Saamanthi flower extract.

Reason for Selecting Formulation 5

Moderate extract concentration (2.5%) avoids excessive irritation while still delivering active benefits.

Carbopol at 0.75% provides suitable viscosity for longer ocular retention without blurring vision.

Glycerine at 3% acts as a lubricant and reduces eye strain and dryness.

Maintains clarity, spreadability, and comfort, which is critical for ophthalmic use.

Comparison with Other Eye Formulations

The development of a Saamanthi (*Chrysanthemum indicum*) flower-based herbal ophthalmic gel aims to combine the advantages of herbal therapy with modern ocular drug delivery systems. Below is a comparative analysis of this herbal gel with commonly used ophthalmic formulations such as eye drops, ointments, and other gels.

Parameter	Saamanthi Herbal Ophthalmic Gel	Conventional Eye Drops	Ophthalmic Ointments	Other Herbal Ophthalmic Gels
Formulation Type	Gel (semi-solid) with herbal extract	Liquid solution or suspension	Semi-solid greasy base	Gel or gel-like formulations with herbal extracts
Retention Time on Eye	Prolonged retention due to viscosity and mucoadhesion	Short residence time, rapidly washed away by tears	Long retention, but may blur vision	Variable, depending on polymer and herbal load
Cooling Effect	Natural cooling from Saamanthi volatile oils and flavonoids	Usually, none or minimal	Usually none	Depends on the herbs used; Saamanthi is known for its strong cooling
Anti-inflammatory Action	Herbal flavonoids and phenolics provide natural anti-inflammatory effects	Synthetic NSAIDs or corticosteroids may cause side effects	Often steroid-based, risk of side effects	Similarly, depending on the herbal constituents
Patient Comfort	Generally good; non-greasy, less blurring	Good comfort, but frequent dosing is needed	May cause blurred vision and discomfort	Varies; gels tend to be more comfortable than ointments
Sterility & Preservation	Preserved with mild preservatives, natural alternatives are possible	Often require preservatives like benzalkonium chloride	Usually sterile, preservatives are less common	Similar challenges; natural preservatives preferred
Ease of Administration	Easy to apply with a dropper or tube	Easy, drops are most common	Difficult, ointments are greasy and can blur vision	Easy, similar to conventional gels
Stability	Generally stable if formulated properly	Stable but sensitive to contamination	Stable, long shelf life	Variable, depending on the herbal extract stability
Therapeutic Uses	Eye cooling, relief of redness and irritation, and eye fatigue	Wide range, including infection, inflammation, and dryness	Usually for lubrication or severe dryness	Eye cooling, anti-inflammatory, antimicrobial, depending on the herbs
Side Effects	Minimal, natural ingredients reduce risk	Possible irritation, allergy, or toxicity	Blurring of vision, discomfort	Minimal, but depends on the herbal safety profile

[18]

Summary

- **Saamanthi-based herbal gel** offers a natural, soothing alternative with added benefits of cooling and anti-inflammatory effects derived from its phytochemicals, which are generally absent in synthetic eye drops.
- Compared to **eye drops**, gels have longer ocular residence time, reducing the need for frequent application.
- Compared to **ointment**, the gel is less greasy and less likely to blur vision, improving patient compliance.
- Compared to other **herbal ophthalmic gels**, Saamanthi provides a distinct cooling effect due to its unique volatile oils and flavonoids, making it especially beneficial for eye strain and heat-related irritation.

Challenges and Limitations

While the development of a Saamanthi (*Chrysanthemum indicum*) flower-based herbal ophthalmic gel offers promising therapeutic benefits, several challenges and limitations must be considered:

1. Standardization of Herbal Extract

- **Variability in Phytochemical Content**
- The concentration of active compounds such as flavonoids and volatile oils can vary due to differences in plant origin, harvesting time, extraction methods, and storage conditions, making it difficult to ensure batch-to-batch consistency.

- **Need for Standardized Extracts**
- Precise standardization protocols and quality control measures are essential but can be resource-intensive.

2. Stability Issues

- **Degradation of Active Constituents**
- Flavonoids and volatile oils are sensitive to light, heat, and oxidation, which may reduce the efficacy of the formulation over time.

- **Microbial Contamination**
- Herbal formulations are prone to microbial contamination due to their natural origin, necessitating the use of effective, yet non-irritating preservatives compatible with ocular use.

3. Formulation Challenges

- **Achieving Optimal Viscosity**

  Balancing gel viscosity to ensure easy application while maintaining sufficient ocular retention is critical and can be challenging.

- **Compatibility of Herbal Extract with Gel Base**

  Interaction between extract components and polymers may affect gel clarity, stability, or drug release.

4. Safety and Toxicity Concerns

- **Ocular Irritation Potential:**

  Despite being natural, certain phytochemicals or residual solvents may cause irritation or allergic reactions in sensitive individuals.

- **Lack of Extensive Toxicological Data**

  Comprehensive ocular toxicity studies and long-term safety data are often limited for herbal ophthalmic products.

5. Regulatory and Commercialization Barriers

- **Regulatory Approval**

  Herbal ophthalmic formulations face stringent regulatory scrutiny for safety, efficacy, and sterility, which can be costly and time-consuming.

- **Market Acceptance**

  Patient and physician acceptance may be limited due to unfamiliarity with herbal ophthalmic gels compared to conventional synthetic drugs.

6. In Vivo Efficacy Evaluation

- **Limited Clinical Data**

  Robust clinical trials demonstrating efficacy and safety in humans are often lacking, hindering wide adoption.

- **Subjective Nature of Cooling Effect**

  Measuring and standardizing the cooling sensation objectively can be challenging.[19]

Future Scope

The development of a Saamanthi (*Chrysanthemum indicum*) flower-based herbal ophthalmic gel presents numerous promising avenues for further research and application:

1. Advanced Formulation Technologies

- Incorporation of **nanocarriers** (like nanoparticles, liposomes, or nanoemulsions) to enhance the **bioavailability**, **ocular penetration**, and **controlled release** of active phytochemicals.
- Development of **mucoadhesive and stimuli-responsive gels** that respond to pH or temperature changes for improved retention and therapeutic efficacy.

2. Comprehensive Pharmacological Studies

- Detailed **mechanistic studies** at the molecular and cellular levels to better understand the anti-inflammatory and cooling effects.
- Exploration of synergistic effects by combining Saamanthi extract with other complementary herbal extracts known for ocular benefits.

3. Clinical Trials and Safety Evaluation

- Conducting well-designed **clinical trials** to establish safety, efficacy, dosage, and patient compliance.
- Long-term **toxicological and allergenicity studies** to ensure the formulation's safety for widespread clinical use.

4. Expanded Therapeutic Applications

- Investigating the potential of Saamanthi-based formulations for other ocular conditions such as **dry eye syndrome**, **conjunctivitis**, or **ocular allergies**.
- Exploring its use as an adjunct therapy to conventional drugs to reduce side effects or enhance therapeutic outcomes.

5. Commercialization and Product Development

- Development of **ready-to-market sterile herbal ophthalmic products** with standardized extracts and validated quality parameters.
- Exploration of **preservative-free formulations** or use of natural preservatives to reduce ocular toxicity risks.

6. Integration with Digital Health

- Incorporating **patient feedback and digital monitoring** for personalized ophthalmic care using herbal gels.
- Development of **smart packaging** that indicates sterility or product expiration to ensure safety.[20]

CONCLUSION

The formulation and evaluation of a Saamanthi (*Chrysanthemum indicum*) {F5} flower-based herbal ophthalmic gel demonstrates the promising potential of this natural extract as a safe and effective agent for eye cooling and relief from ocular irritation. Rich in bioactive phytochemicals such as flavonoids and volatile oils, the gel provides both anti-inflammatory and soothing effects, addressing common eye discomforts naturally. The optimized gel formulation ensures appropriate viscosity, pH, and sterility, making it suitable for ocular application with good patient compliance. Despite certain challenges related to standardization and stability, the herbal ophthalmic gel represents a valuable alternative to conventional synthetic eye products. Further clinical studies and advanced formulation approaches can pave the way for its development as a commercially viable and widely accepted natural eye care solution.

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