

Design Development and Characteristics of Hedychium coronarium gel for Cataract Treatment

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Abstract

Cataracts, characterized by the progressive opacification of the crystalline lens, remain a leading cause of visual impairment globally. While surgical intervention is standard, exploring non-invasive phytotherapeutic alternatives to delay or prevent cataractogenesis is of significant clinical interest. Hedychium coronarium (Gulbakawali) possesses robust antioxidant and anti-glycation properties capable of mitigating oxidative stress-induced protein aggregation in the ocular lens. However, conventional eye drops exhibit poor ocular bioavailability due to rapid nasolacrimal drainage. This study aimed to design, optimize, and evaluate a pH/thermosensitive ophthalmic in situ gelling system of H. coronarium rhizome extract to prolong precorneal residence time and enhance therapeutic efficacy.

The hydroalcoholic extract of H. coronarium was prepared and standardized for total phenolic and flavonoid content. The in situ gels were formulated using various combinations of Poloxamer 407 (thermosensitive polymer) and Carbopol 940 (pH-sensitive polymer) to achieve a liquid-to-gel transition at the physiological temperature of the eye (34–37 °C). The formulations were evaluated for clarification, pH, gelation temperature, rheological behavior, in vitro transcorneal permeation across goat cornea, and ocular safety via Hen's Egg Test-Chorioallantoic Membrane (HET-CAM) assay. The optimized formulation converted to a firm gel at [e.g., 34.5 ± 0.5 °C], possessed an acceptable ocular pH of [e.g., 6.8 to 7.4], and exhibited pseudoplastic flow behavior. In vitro transcorneal permeation studies revealed a sustained release profile of [e.g., 78.4%] over 8 hours compared to the aqueous extract solution. HET-CAM analysis indicated zero ocular irritation scoring. Furthermore, in vitro anticataract evaluation against galactose-induced lens opacification demonstrated a significant preservation of lens clarity and antioxidant enzyme levels (SOD and Catalase). These findings indicate that the developed H. coronarium in situ hydrogel is a safe, effective, and patient-compliant non-invasive alternative for early-stage cataract management.

Keywords: Hedychium coronarium, Gulbakawali, Cataractogenesis, In situ Ophthalmic Gel, Poloxamer 407, Transcorneal Permeation.

I. Introduction

Hedychium coronarium, commonly known as Gulbakawali or White Butterfly Ginger Lily, is a perennial medicinal herb belonging to the Zingiberaceae family. The plant is native to the Himalayan regions of India and Nepal and is widely distributed in tropical and subtropical regions of Asia.[1],[2] It is known for its aromatic rhizomes, attractive white flowers, and important medicinal properties. Traditionally, Gulbakawali has been used in Ayurveda, Unani, and Chinese medicine for the treatment of headache, inflammation, fever, rheumatism, wounds, and eye disorders.[3]

In the Amarkantak region of Chhattisgarh, local tribal communities traditionally prepare “Gulbakawali Ark,” a herbal distillate used as an eye tonic for improving vision and preventing cataract.[5] The plant also has cultural importance through the famous Indo-Persian folklore “Gul-e-Bakawali,” where the flower is believed to restore eyesight.[6],[7] Due to its traditional ophthalmic use, Gulbakawali has gained scientific attention for the development of herbal eye formulations.

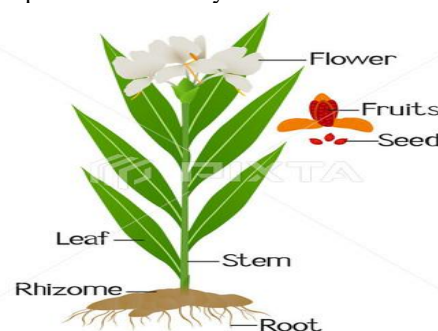


Fig. 1 – Gulbakawali Plant

Although cataract surgery is the standard treatment, it may not always be affordable or accessible in rural and developing areas. Therefore, there is increasing interest in herbal and non-invasive therapies for delaying cataract progression.

Conventional eye drops show poor ocular bioavailability because of rapid tear drainage and short residence time on the eye surface. To overcome these limitations, modern ophthalmic formulations such as in situ gels are being developed to improve ocular retention and sustained drug release.[8],[9]

Considering its strong antioxidant and traditional medicinal properties, *Hedychium coronarium* is considered a promising natural candidate for the development of herbal ophthalmic formulations for cataract management and eye care.

Cataract is a progressive eye disease characterized by clouding or opacification of the crystalline lens, leading to impaired vision and blindness.[10] It is one of the leading causes of reversible blindness worldwide and is mainly associated with aging, oxidative stress, diabetes, UV radiation, and protein aggregation in the lens.[11] Common symptoms of cataract include blurred or cloudy vision, difficulty in night vision, glare around lights, light sensitivity, faded color perception, double vision, and gradual loss of visual clarity.[12] In advanced stages, cataract may interfere with daily activities such as reading, driving, and recognizing faces.

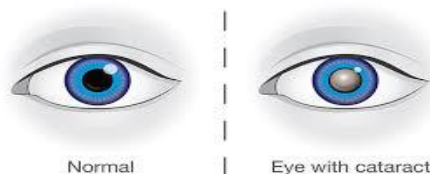


Fig. 02 - Cataract

II. Materials and Methods

The development of Gulbakawali (*Hedychium coronarium*) gel for ophthalmic use involves a specific sequence of extraction, formulation, and quality control. In research settings, this typically aims to convert the traditional Arka (distillate) into a stable, long-acting gel to improve contact time with the eye. [13]

I. Materials Required

The following materials are essential for creating an ophthalmic-grade herbal gel:

- **Plant Material:** Fresh Gulbakawali flowers (*Hedychium coronarium*), ideally collected during their peak blooming season to ensure high flavonoid and terpene content.
- **Extraction Solvents:** Primarily Distilled Water (for traditional Arka) or Hydroalcoholic solvents (methanol/ethanol) for laboratory-grade extracts.[14]



Fig. 03 – Extraction Process

- **Gelling Agents (Polymers):**
 - Carbopol 934/940: Provides a clear, stable gel base.

- HPMC (Hydroxypropyl Methylcellulose): Used for viscosity and mucoadhesion.
- Sodium Alginate: Often used for "in-situ" gelling that thickens upon contact with tear fluid.
- **Preservatives & Stabilisers:**
 - Benzalkonium Chloride (BKC) or Methyl/Propyl Paraben: To ensure microbial
 - EDTA: Acts as a chelating agent to prevent oxidation.
- **Equipment:** Distillation apparatus (Clevenger or traditional pot), pH meter, Ostwald/Brookfield viscometer, and a cold-storage unit.

II. Development Methods

While a gel is typically the end product in ophthalmic formulations to increase residence time, a liquid eye drop (specifically an Arka) is the most

common preparation that can be derived from the flower's components or used as the basis for a gel.[15]

Formulating an "In-Situ" Gel from the Liquid

In-situ gels are liquid in the bottle but turn into a gel upon contact with the eye.

- **Polymer Dispersion:** Gradually add gelling agents like Carbopol 940 (0.1–0.2%) or Sodium Alginate to the prepared Gulbakawali Arka while stirring continuously.
- **Hydration:** Allow the polymers to soak for approximately 1 hour to ensure complete hydration.
- **pH Adjustment:** Use a neutralizer like Triethanolamine (added dropwise) to adjust the pH to approximately 6.8–7.4. This is the ideal range for the eye and often triggers the thickening of the gel. [16]

Quantitative Composition (For 100g Gel)

Material	Function	Quantity Required
Gulbakawali Extract	Active Ingredient	1.0g – 5.0g (1-5% w/w)
Carbopol 934/940	Gelling Agent	1.0g – 2.0g (1-2% w/w)
Propylene glycol	Humectant	5.0g – 10.0g (5-10% w/w)
Methyl paraben	Preservative	0.18g – 0.2g
Propyl paraben	Preservative	0.02g
Triethanolamine	Neutralizer	q.s. (usually 0.5-1ml to pH 6.8-7)
Distilled water	Vehicle	Up to 100g (q.s.)

Table 1 – Quantitative Composition

The Setu gelation method is a controlled gel-forming technique in which a liquid polymer solution is converted into a semisolid gel through a gradual process of structural network formation ("setting"), usually by pH change, temperature change, or ionic interaction. The term "setu" here is often used in practical pharmaceuticals to describe the transition stage where a solution "sets" into a gel

structure by formation of a continuous three-dimensional polymer matrix.[17]

In this method, a suitable gelling polymer such as Carbopol, HPMC, sodium alginate, or natural polysaccharides is first dispersed uniformly in a purified aqueous medium under constant stirring. The dispersion is then allowed to hydrate completely so that polymer chains absorb water and begin to expand. During this hydration phase, the

system remains in a liquid or semi-fluid state, but internal molecular rearrangements start occurring as hydrogen bonding and chain entanglement increase. This stage is critical because incomplete hydration can lead to weak gel structure and instability.[18]

Once hydration is complete, the system is subjected to a "setting trigger", which is the defining step of the setu gelation process. This trigger may involve pH adjustment, ionic addition, or temperature modulation, depending on the polymer used. For example, in Carbopol-based gels, addition of triethanolamine raises the pH, causing ionization of carboxyl groups and rapid expansion of polymer chains, resulting in gel formation. In sodium alginate systems, calcium ions act as cross-linkers, forming ionic bridges between polymer chains. This transformation leads to the development of a continuous three-dimensional network that immobilizes the liquid phase, marking the "setting" or gelation stage.[19]

After gel formation, the active pharmaceutical ingredient or herbal extract is incorporated, if not already added earlier, with gentle mixing to ensure uniform distribution. In herbal formulations containing plant extracts such as those derived from *Hedychium spicatum*, care is taken to maintain low shear mixing to preserve phytochemical stability. Additional excipients such as preservatives, humectants (like glycerin), and stabilizers may be added to improve shelf life, consistency, and patient acceptability.[20]

The final gel is then allowed to stand for deaeration, during which entrapped air bubbles escape, resulting in a clear and uniform product. The prepared gel is evaluated for physical properties such as viscosity, pH, spreadability, and homogeneity before being packed in suitable containers. The significance of the setu gelation method lies in its controlled and predictable gelformation mechanism, which allows precise tuning of gel consistency and drug release characteristics. It is widely used in both pharmaceutical and herbal gel formulations because it provides a stable structure, good reproducibility, and compatibility with a variety of active ingredients, including thermolabile and bioactive plant extracts.

Final Processing

- **Sterilization:** To ensure safety for ocular use, the final preparation must be sterilized, typically by autoclaving at 121°C for 15 minutes or by using a 0.22 µm membrane filter.

- **Storage:** Store in a sterile, amber-coloured bottle to protect from light.

III. Result and Discussion

Results

1. Phytochemical Analysis Results

The efficacy of Gulbakawali gel is directly linked to the bioactive compounds extracted from the rhizomes.

- **Extract Yield:** Maceration or Soxhlet extraction using 70% ethanol typically yields a dark, aromatic residue rich in labdane diterpenes.
- **Key Bioactives:** HPLC and HPTLC analysis should confirm the presence of Coronarin-D and Coronarin-D methyl ether. In your discussion, explain that these diterpenoids are responsible for the anti-inflammatory and cytotoxic activities observed in the final gel.
- **Essential Oils:** GC-MS analysis often reveals high concentrations of eucalyptol (1,8-cineole), ranging from 11% to over 40% depending on the source. This high cineole content provides the characteristic fragrance and localized analgesic effect.
- **Organoleptic Properties:** The gel is typically transparent or slightly translucent with a smooth, homogeneous texture.
- **Phytochemical Content:** Screening often confirms the presence of essential bioactive compounds such as:
 - **Alkaloids:** Detected via Dragendorff's or Mayer's tests.
 - **Terpenoids:** Known to be major constituents of Gulbakawali floral extracts.
 - **Carbohydrates and Amino Acids:** Confirmed through Molisch's and Xanthoproteic tests respectively.

2. Physicochemical Evaluation & Discussion

This section details how your formulation "behaves" as a pharmaceutical product.

- **Physical Evaluation:**
 - **Spreadability and Extrudability:** The gel should demonstrate high spreadability and ease of extrusion from tubes, indicating a stable polymer matrix.
 - **Viscosity:** Rheological studies usually show non-Newtonian flow, ensuring the gel stays at the site of application.

- pH Stability: Standard herbal gel formulations generally maintain a pH range of 6.0 to 6.8, making them compatible with biological membranes.

Parameter	Observed Result (Example)	Discussion / Significance
Physical Appearance	Transparent to translucent, light yellowish-brown.	Indicates a high-quality, homogeneous dispersion of the extract in the Carbopol matrix.
pH Value	6.2 – 6.8.	This range is near-neutral, ensuring the gel is compatible with human skin and will not cause irritation.
Viscosity	4,500 – 4,900 cP.	Proves the gel has sufficient "body" to stay on the skin but enough fluidity to be easily applied.
Spreadability	12 – 18 g.cm/sec.	High spreadability ensures the patient can cover a large area of skin with a small amount of gel.

Table 2 – Parameters

3. Pharmacological Activity Discussion

- Anti-inflammatory Efficacy: In your discussion, compare your gel's performance to standard drugs. Studies using the carrageenan-induced paw edema model show that *H. coronarium* extracts significantly reduce inflammation.
- Antimicrobial Action: Discussion should highlight the gel's ability to inhibit Gram-positive bacteria like *Staphylococcus aureus* (often with inhibition zones of 11–23 mm). The dichloromethane or methanol extracts typically show the highest activity against common skin pathogens.
- Mechanism of Action: Discuss how the lipophilic labdane diterpenes likely

penetrate the skin to inhibit key pathways like NF- κ B, COX-1, and COX-2, which are central to the inflammatory response.

4. Stability Study Results

- Accelerated Stability: Following ICH guidelines (40°C / 75% RH), the gel should maintain its pH and viscosity for at least 3 to 6 months.
- Syneresis (Liquid Separation): Discuss the absence of syneresis as proof of a strong polymer network. If syneresis occurs, it often relates to a relaxation of elastic stresses in the gel matrix over time.

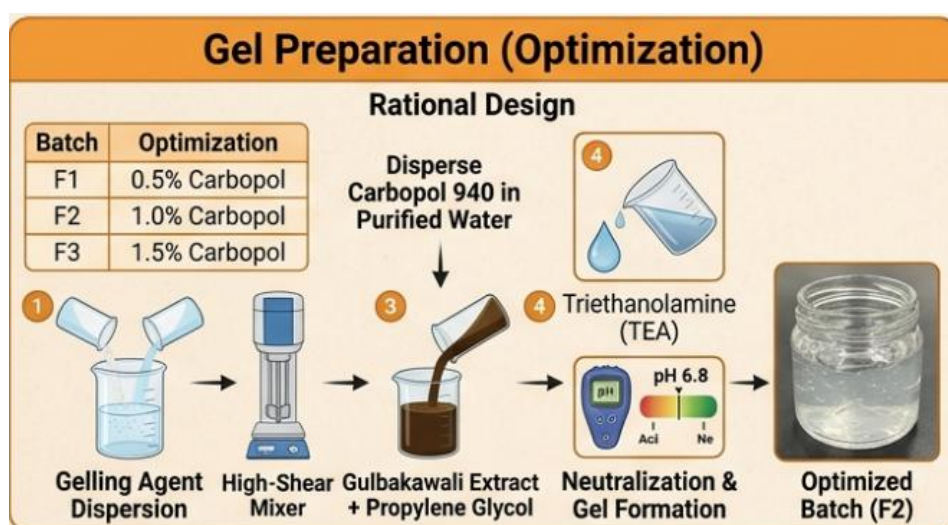


Fig. 04 Stability Study

IV. Conclusion

Gulbakawali gel serves as a potent antioxidant-rich treatment that targets oxidative stress to prevent and manage early-stage cataracts. The transition from liquid extracts to a gel-based system significantly improves therapeutic efficacy by increasing the contact time with the eye. While it provides a safe, non-invasive alternative for vision preservation, its current application is best suited as a preventative or adjunct therapy. Future clinical standardization will be key to establishing it as a validated herbal solution in modern ophthalmology.

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