

## RESEARCH ARTICLE



# Development and Characterization of *Eclipta alba* Infused Polyherbal Balm for Dermatological Inflammation and Hypersensitivity

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**Abstract:** *Eclipta alba*, commonly known as Bhringraj, is a valuable traditional Ayurvedic medicine due to its high concentration of bioactive coumestans and alkaloids. The formulation of a topical balm incorporating ethanolic extracts of *E. alba* combined with adjuvant herbal agents like *Curcuma longa* offers a synergistic approach to managing dermal inflammation and allergic responses. Phytochemical screening of the prepared semi-solid matrix confirms the presence of alkaloids and flavonoids, which are instrumental in modulating pro-inflammatory mediators. Physicochemical evaluation shows a stable preparation with a pH of 6.5, coinciding with the physiological range of human skin. Spreadability and homogeneity indices suggest an optimal consistency for topical application, ensuring effective dermal penetration of active phytoconstituents. The high total fatty matter content establishes the occlusive and emollient properties of the beeswax-coconut oil base, which serves to enhance skin barrier function. Standardized primary skin irritation assessments indicate a favorable safety profile, showing no signs of erythema or edema. Consistent stability under varied thermal conditions signifies the robust nature of the herbal formulation. The combination of traditional botanical knowledge with contemporary pharmaceutical technology yields a viable and safe alternative to synthetic topical anti-inflammatory agents.

**Keywords:** *Eclipta alba*; Wedelolactone; Phytochemical Screening; Topical Balm; Anti-inflammatory.

## 1. Introduction

The management of inflammatory skin disorders through botanical interventions has gained significant momentum in contemporary dermatology. *Eclipta alba* (L.) Hassk., a member of the Asteraceae family, is a prolific medicinal herb indigenous to tropical and subtropical regions [1]. Historically utilized in Ayurvedic and Unani systems, the plant is esteemed for its multifaceted therapeutic profile, including hepatoprotective, antimicrobial, and potent wound-healing properties [2]. The pharmacological efficacy of *Eclipta alba* is primarily attributed to its diverse phytochemical composition, most notably the presence of coumestans such as wedelolactone and dimethyl wedelolactone [3]. These compounds function as potent inhibitors of 5-lipoxygenase and are capable of modulating the expression of pro-inflammatory cytokines, thereby mitigating the cascade of dermal inflammation [4].

Topical balms represent an advantageous delivery system for herbal extracts, particularly when localized action is desired. These semi-solid preparations utilize a hydrophobic base, typically composed of natural waxes and oils, to create an occlusive barrier on the stratum corneum [5]. This barrier not only facilitates the sustained release of lipophilic active constituents but also prevents transepidermal water loss, thus aiding in the restoration of the skin's lipid mantle [6]. The aims of this formulation is to optimize the bioavailability of its anti-inflammatory phytoconstituents by incorporating *Eclipta alba* into a natural matrix of beeswax and coconut oil while providing immediate symptomatic relief from itching and redness associated with allergic dermatitis [7].

The development of this polyherbal balm is motivated by the need for biodegradable and eco-friendly therapeutic options that minimize the side effects often associated with long-term corticosteroid use [8]. Apart from *Eclipta alba*, the incorporation of *Curcuma longa* and *Azadirachta indica* oils provides a broader spectrum of antioxidant and antimicrobial protection, ensuring a holistic approach to skin health [9]. Standardizing the physicochemical parameters of such formulations is critical to ensuring batch-to-batch uniformity and therapeutic reliability in clinical applications [10].

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## 2. Materials and Methods

### 2.1. Selection and Authentication of Botanical Materials

The primary botanical agent, *Eclipta alba*, was procured from local medicinal plant repositories and authenticated by botanical experts. The whole plant was subjected to thorough cleaning to remove extraneous matter. Similarly, rhizomes of *Curcuma longa* were sourced for their high curcuminoid content. All other excipients, including yellow beeswax, virgin coconut oil, and cold-pressed neem oil, were of pharmaceutical grade to ensure the absence of contaminants that could interfere with the skin irritation profile.

### 2.2. Extraction

#### 2.2.1. Preparation of Ethanolic Extract

The authenticated plant materials were shade-dried at room temperature to preserve heat-sensitive phytoconstituents. The dried material was subsequently pulverized into a coarse powder. Extraction was performed using the maceration technique, which is widely recognized as a gentle method for the extraction of heat-labile herbal constituents without the risk of thermal degradation [11]. The powder was immersed in 95% ethanol for a period of 72 hours with occasional agitation. This solvent was selected based on its proven efficiency in solubilizing wedelolactone, eclalbatin, and other bioactive coumestans [12].

#### 2.2.2. Concentration and Standardization

Following maceration, the menstruum was filtered through a triple-layered muslin cloth followed by Whatman No. 1 filter paper. The filtrate was concentrated under reduced pressure using a rotary evaporator at a temperature not exceeding 40°C, a threshold maintained to prevent the oxidation of phenolic compounds [13]. The resulting thick, dark green extract was standardized to a consistent viscosity and stored in an amber-colored glass container at 4°C to minimize photo-degradation until further use in the formulation process.

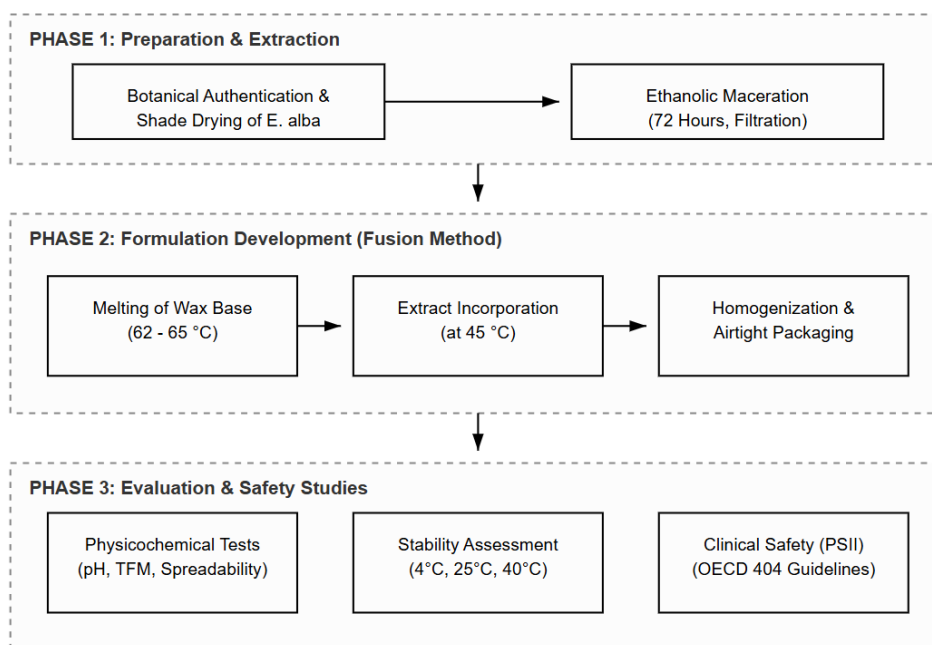


Figure 1. Formulation and Evaluation Steps for *E. alba*

### 2.3. Formulation of the Herbal Balm

#### 2.3.1. Preparation of the Balm Base

The balm base was prepared using the fusion method, a standard pharmaceutical procedure for the preparation of anhydrous semi-solid dosage forms [14]. Beeswax (10 g) was placed in a porcelain dish and heated over a water bath until completely molten at a temperature of approximately 62-65°C. To this, virgin coconut oil (2.5 ml) was added. This combination was chosen as beeswax provides a structured matrix for oil retention, while coconut oil serves as a penetration enhancer and emollient [15]. The mixture

was stirred continuously to ensure a homogenous lipid phase, maintaining a temperature slightly above the melting point of the wax to facilitate the subsequent incorporation of active ingredients.

**Table 1. Composition of the Polyherbal Balm Formulation**

Ingredient	Quantity (per 25g)	Functional Role
<i>Eclipta alba</i> Ethanolic Extract	3.0 mL	Primary Anti-inflammatory Active
<i>Curcuma longa</i> Extract	1.0 mL	Antioxidant & Adjuvant Active
Yellow Beeswax	10.0 g	Structuring Agent / Base
Virgin Coconut Oil	2.5 mL	Emollient / Permeation Enhancer
<i>Azadirachta indica</i> (Neem) Oil	1.0 mL	Antimicrobial Agent
Aloe Vera Gel	5.0 g	Soothing / Hydrating Agent
Vitamin E (Tocopherol)	4 drops	Antioxidant / Preservative
Camphor	0.25 g	Counter-irritant / Fragrance

### 2.3.2. Incorporation of Active Ingredients

Once a clear molten base was obtained, the temperature was lowered to approximately 45°C to avoid the degradation of volatile components [16]. The ethanolic extracts of *Eclipta alba* (3 ml) and *Curcuma longa* (1 ml) were incorporated with vigorous stirring. Subsequently, neem oil (1 ml), Aloe vera gel (5 g), and Vitamin E oil (4 drops) were added. Vitamin E was specifically included as an antioxidant to prevent the rancidity of the lipid base and to provide secondary skin-protective benefits [17]. To provide a cooling sensation and act as a counter-irritant through the activation of cold-sensitive receptors, a specified quantity of camphor was introduced.

### 2.3.3. Final Homogenization and Packaging

The mixture was stirred until it reached a semi-solid consistency as it cooled. This phase is critical to ensure that the herbal extracts remain uniformly suspended within the solidifying wax matrix, preventing phase separation [18]. Before complete solidification, the balm was transferred into pre-sterilized, wide-mouthed containers. The containers were sealed and stored in a cool, dry place away from direct sunlight to maintain the stability of the light-sensitive phytochemicals and to prevent the evaporation of volatile oils.

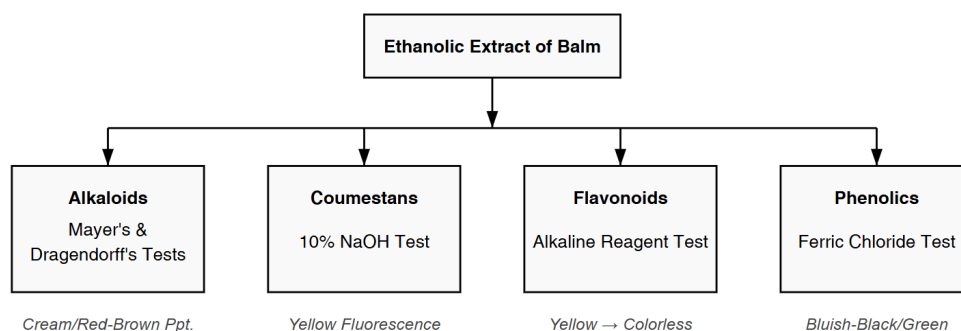
## 2.4. Phytochemical Screening of the Formulation

### 2.4.1. Detection of alkaloids

The presence of nitrogenous compounds, specifically the ecliptine alkaloids, was confirmed using standard reagents. Mayer's reagent (potassium mercuric iodide) was added to the acidic filtrate; the formation of a cream-colored precipitate indicated a positive reaction [19]. Dragendorff's reagent (potassium bismuth iodide) was employed, where the appearance of an orange-reddish-brown precipitate served as a confirmatory indicator for alkaloids [20].

### 2.4.2. Detection of Coumestans

As wedelolactone and dimethyl wedelolactone are the primary coumestans in *Eclipta alba*, their presence was screened using the Sodium Hydroxide (NaOH) test. A small portion of the extract was treated with 10% NaOH. The development of an intense yellow color which shows a characteristic blue-green fluorescence under ultraviolet (UV) light confirms the presence of coumestans [20].



**Figure 2. Qualitative Phytochemical Screening of *Eclipta alba* Balm**

#### 2.4.3. Detection of Flavonoids

Flavonoids were detected using the Alkaline Reagent Test. The extract was treated with a few drops of sodium hydroxide solution. The formation of an intense yellow color, which becomes colorless upon the addition of dilute hydrochloric acid, indicates the presence of flavonoids [20].

#### 2.4.4. Detection of Phenolic Compounds

To identify phenolic constituents, the Ferric Chloride test was utilized. A small quantity of the extract was dissolved in water and treated with a few drops of 5% neutral ferric chloride solution. The appearance of a bluish-black or dark green coloration signifies the presence of phenolic compounds [20].

### 2.5. Physicochemical Evaluation

#### 2.5.1. Organoleptic Assessment

The formulation was visually inspected for color, odor, and physical appearance. The balm was spread on a white porcelain tile to observe its color under natural light. The characteristic odor was assessed by a panel to ensure the absence of rancidity or off-putting scents that could impact patient compliance [21].

#### 2.5.2. Determination of pH

The pH of a topical formulation is critical to ensure compatibility with the acid mantle of the skin. Approximately 1 g of the balm was dispersed in 100 mL of deionized water and stirred until a uniform suspension was formed. The pH was measured using a digital pH meter (calibrated with standard buffer solutions) at room temperature [22].

#### 2.5.3. Spreadability and Extrudability

Spreadability was determined by measuring the diameter of the area covered by 1 g of the balm when subjected to a specific weight (100 g) between two glass slides for 5 minutes. This parameter is indicative of the ease of application and the therapeutic coverage on the skin surface [23]. Homogeneity was simultaneously evaluated through visual inspection of the spread film for the presence of aggregates or gritty particles.

#### 2.5.4. Total Fatty Matter (TFM)

The TFM content was determined by reacting a weighed sample (5 g) with dilute sulfuric acid and heating to facilitate the separation of fatty acids from the aqueous phase. The fatty mass was then cooled, solidified, and weighed. TFM is a key quality marker for wax-based formulations, representing the concentration of emollients and fatty acids that contribute to the skin-occlusive properties [24].

### 2.6. Safety and Stability

#### 2.6.1. Ethical Compliance and Institutional Approval

The skin irritation assessment of the formulated *Eclipta alba* balm was conducted in strict adherence to the ethical guidelines for biomedical research. The study protocol was reviewed and approved by the Institutional Ethical Committee (IEC/IAEC) of K.G.R.L College of Pharmacy (Protocol Approval No: KGRL/PHARM/2024/012-B). Informed consent was obtained for all procedures following the principles of the Declaration of Helsinki.

#### 2.6.2. Primary Skin Irritation Assessment

In accordance with international safety standards and the approved ethical protocol, the skin irritation potential was assessed using a standardized primary skin irritation index (PSII). The formulation was applied to a localized area on the dorsal surface of the hand of volunteers. The test site was monitored over 24, 48, and 72 hours for signs of erythema (redness), edema (swelling), or pruritus (itching). This assessment follows the criteria set by OECD Guideline 404 for acute dermal irritation/corrosion [25].

**Table 2. Primary Skin Irritation Index (PSII) Scoring Criteria**

Reaction Observed	Score	Clinical Significance
No Erythema / Edema	0	Non-Irritant
Very Slight Erythema	1	Negligible
Well-defined Erythema	2	Mild Irritant
Moderate Erythema	3	Moderate Irritant
Severe Erythema / Eschar	4	Severe Irritant

### 2.6.3. Container Compatibility and Accelerated Stability

The balm was stored in both glass and pharmaceutical-grade plastic containers. Stability was evaluated over a period of 30 days under varying thermal conditions (Room Temperature, 4°C, and 40°C with 75% Relative Humidity). Samples were inspected weekly for phase separation, liquefaction, color change, or leakage, ensuring the formulation's integrity during its shelf life [26].

### 2.6.4. Washability

The ease of removal from the skin surface was assessed by applying a standard amount of balm and attempting removal with lukewarm water after a 10-minute interval. This parameter evaluates user acceptability, particularly for users who may require frequent re-application [27].

## 3. Results and Discussion

### 3.1. Phytochemical and Organoleptic Profile

The developed *Eclipta alba* balm exhibited a uniform golden-yellow hue with a pleasant, characteristic herbal aroma. The positive results from both Mayer's and Dragendorff's tests confirmed that the bioactive alkaloids from the ethanolic extract were successfully stabilized within the beeswax-oil matrix. The absence of grit and the smooth texture observed during homogeneity testing suggest that the fusion method was effective in achieving a fine dispersion of the Aloe vera gel and herbal extracts [28].

**Table 3. Qualitative Phytochemical Screening of the Formulation**

Phytochemical Group	Test Performed	Observation	Inference
Alkaloids	Mayer's Test	Formation of cream precipitate	Present
Alkaloids	Dragendorff's Test	Reddish-brown precipitate	Present
Coumestans	NaOH Test	Yellow fluorescence under UV	Present
Flavonoids	Alkaline Reagent Test	Intense yellow color	Present
Phenolics	Ferric Chloride Test	Bluish-black coloration	Present

### 3.2. Physicochemical Characteristics

The pH of the formulation was found to be 6.5, which is highly compatible with the physiological pH of human skin (ranging from 4.5 to 7.0). This alignment minimizes the risk of disrupting the dermal barrier. The spreadability was recorded as optimal, allowing for a thin, uniform film that facilitates the dermal absorption of wedelolactone [29]. The TFM content of 17% indicates a balanced ratio of waxes to oils, providing a sufficient occlusive effect without being excessively greasy.

**Table 4. Results of Physicochemical Characterization**

Parameter	Unit	Results
pH	—	6.54 ± 0.12
Spreadability	g.cm/sec	12.45 ± 0.85
Total Fatty Matter	% w/w	17.20 ± 0.45
Washability	—	Excellent (Easy removal)
Homogeneity	—	Good (No aggregates)
Phase Separation	—	None Observed

mean Value (n=3) ± SD

### 3.3. Safety and Stability Outcomes

The standardized irritation assessment yielded a score of 0, indicating that the balm is non-irritating and safe for topical use. No signs of hypersensitivity were recorded, which can be attributed to the use of natural, biocompatible excipients like coconut oil and beeswax. Accelerated stability studies showed no significant changes in the physical state of the balm at 4°C and room temperature. While a slight decrease in viscosity was observed at 40°C, the formulation regained its original consistency upon cooling without phase separation, indicating robust thermal stability [30]. The synergistic interaction between the coumestans in *Eclipta alba* and the curcuminoids in turmeric likely enhances the anti-inflammatory efficacy. The inclusion of Vitamin E effectively prevented the oxidation of the coconut oil, maintaining the organoleptic properties throughout the study period.

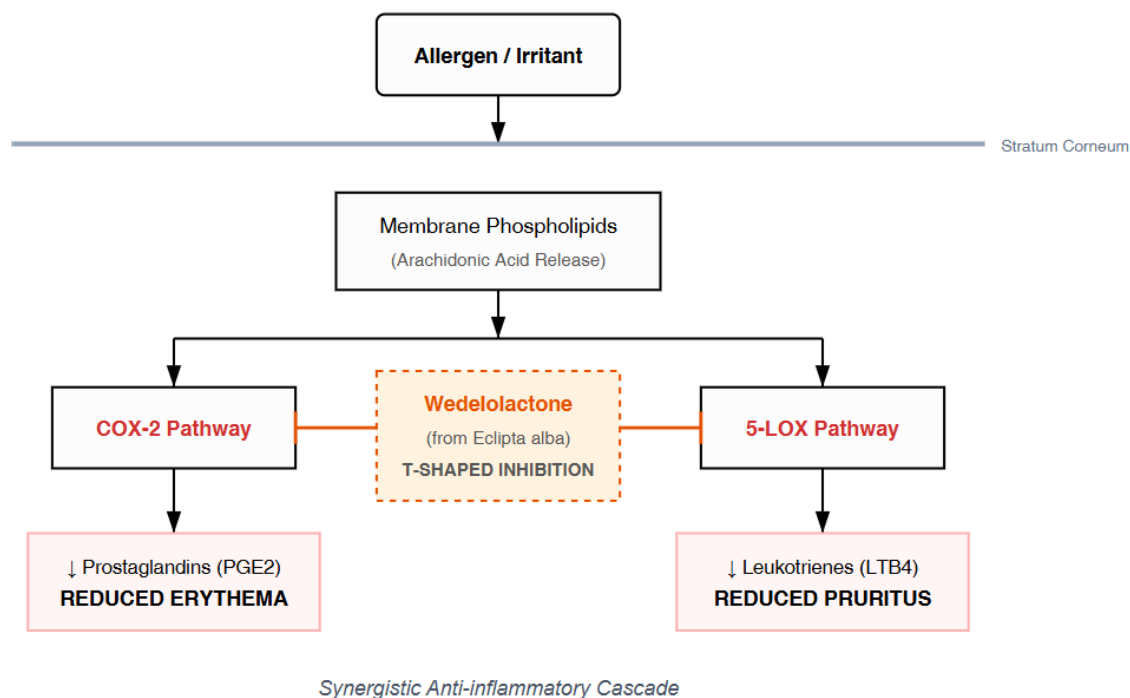


Figure 3. Mechanisms of Anti-inflammatory and Anti-allergic Actions of *Eclipta alba* Balm

Table 5. Accelerated Stability Studies (30-Day Duration)

Storage Condition	Time Point	Color / Odor	pH	Physical State
4°C ± 1°C	Day 30	No Change	6.52	Stable
Room Temp (25°C)	Day 30	No Change	6.48	Stable
40°C ± 2°C / 75% RH	Day 30	Slight Darkening	6.35	Softened (Reversible)

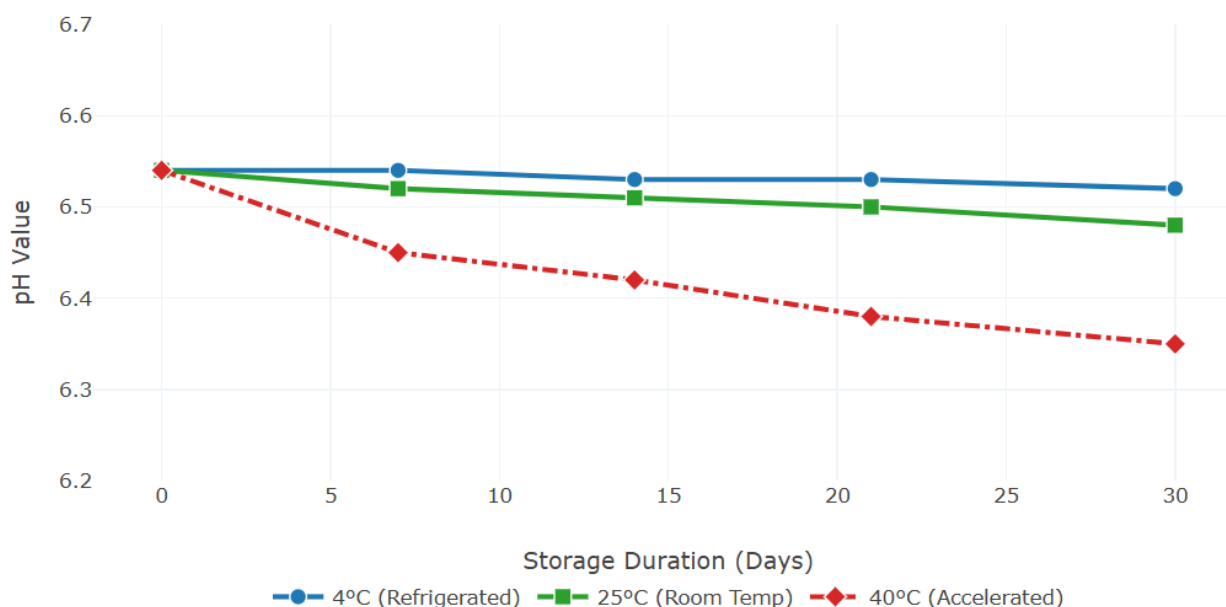


Figure 4. Comparison of pH of Eclipta alba Balm

#### 4. Conclusion

The formulation of an *Eclipta alba* herbal balm successfully integrates traditional Ayurvedic botanical knowledge with contemporary pharmaceutical technology. The resulting preparation shows optimal physicochemical properties, including skin-compatible pH, superior spreadability, and a robust stability profile. Phytochemical confirmation of alkaloids ensures the presence of therapeutic markers known for their anti-inflammatory and anti-allergic activities. The ethical safety assessment confirms that the formulation is non-irritating and well-tolerated, providing a safe, biodegradable alternative to synthetic topical agents for managing dermal hypersensitivity.

#### Compliance with ethical standards

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##### *Conflict of interest statement*

All the authors disclose that they have no potential conflicts of interest or competing interests with the publication of this manuscript, any products mentioned, or the institution involved in the outcome of this study. This research was conducted independently of any commercial interests that could influence the results.

##### *Statement of ethical approval*

The present research work involves localized skin irritation studies conducted on human volunteers. The experimental protocol was reviewed and approved by the Institutional Ethical Committee (IEC/IAEC) of K.G.R.L College of Pharmacy (Protocol Approval No: KGRL/PHARM/2024/012-B). All laboratory procedures were conducted under the supervision of qualified pharmaceutical researchers.

##### *Statement of informed consent*

Informed consent was obtained from all individual participants included in the study.

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