

## FORMULATION AND EVALUATION OF SOMLATA PLANT LOZENGES FOR BRONCHODILATING AND ANTI ASTHAMATIC EFFECT

\*Harsh S. Chavan, Akshay Fulsundar

\*Student, Samarth Institute of Pharmacy Assistant Professor, M. Pharm, Pharmaceutical Chemistry.

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### \*Corresponding Author

**Harsh S. Chavan**

Student, Samarth Institute of  
Pharmacy Assistant Professor, M.  
Pharm, Pharmaceutical Chemistry.



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### ABSTRACT

The objective of this research was to develop and pharmaceutically evaluate herbal hard candy lozenges containing *Ephedra gerardiana* (Somlata) extract to establish a highly palatable, slow-release buccal drug delivery platform for alleviating asthmatic symptoms. Chronic asthma and associated bronchospasms present widespread clinical challenges, yet conventional treatments are frequently limited by delayed therapeutic action or poor patient compliance in pediatric and geriatric populations. In this study, a hydroalcoholic extract of Somlata stems was prepared using a continuous hot Soxhlet extraction process and standardized for its rich concentration of natural, smooth-muscle-relaxing sympathomimetic alkaloids. A series of lozenge formulations (F1–F6) were fabricated using a traditional heating and congealing technique, wherein the critical ratios of sucrose and liquid glucose were systematically

altered to optimize the sugar-glass candy matrix. The resulting lozenges were evaluated for vital physicochemical and mechanical attributes, including weight uniformity, crushing strength hardness, percentage friability, and drug content uniformity. *In vitro* dissolution profiling was performed utilizing a USP Type II apparatus in simulated saliva fluid (pH 6.8), while the *in vivo* antiasthmatic and bronchodilating efficacy was validated via a histamine-induced bronchospasm model using healthy guinea pigs. Among the evaluated batches, formulation F4 emerged as the optimized candidate, displaying excellent physical integrity

with a hardness of  $(4.5 \pm 0.23 \text{ kg/cm}^2)$ , a negligible friability of 0.28%, and an exceptionally uniform drug content of  $(99.4 \pm 0.7\%)$ . The *in vitro* dissolution data for F4 indicated a controlled, steady release pattern, successfully delivering 91.2% of the active herbal phytoconstituents across an ideal 30-minute window. Furthermore, *in vivo* preclinical testing revealed that the optimized lozenge matrix significantly delayed ( $p < 0.01$ ) the onset of pre-convulsive dyspnea in animal models, yielding a 58.94% protection rate against histamine-induced airway constriction, which closely mirrored the performance of the synthetic ephedrine reference standard. Ultimately, these findings confirm that the formulated Somlata hard candy lozenges represent a physically stable, pharmaceutically viable, and therapeutically potent alternative to traditional oral anti-asthmatic treatments, significantly improving patient compliance and localized absorption.

**KEYWORDS:** *Ephedra gerardiana*, Somlata, Lozenges, Bronchodilator, Antiasthmatic, Buccal Drug Delivery.

## 1. INTRODUCTION

Asthma is a globally recognized chronic inflammatory disease of the respiratory system that presents a substantial burden to public health systems worldwide. Characterized by airway hyperresponsiveness, chronic mucosal inflammation, and reversible bronchial constriction, this pathological condition manifests clinically as recurrent episodes of wheezing, chest tightness, severe dyspnea, and persistent coughing. The current therapeutic architecture for managing acute and chronic asthmatic episodes relies heavily on synthetic bronchodilators, including short- and long-acting  $(\beta_2)$ -adrenergic agonists, anticholinergics, and inhaled corticosteroids. Although these conventional chemical entities are highly potent in suppressing acute bronchospasms, their prolonged clinical usage is frequently limited by notable systemic adverse effects, such as muscle tremors, reflex tachycardia, cardiac palpitations, and localized oral candidiasis. Consequently, modern pharmaceutical research is increasingly directing its focus toward exploring plant-derived bioactive alternatives that can offer comparable therapeutic efficacy with an improved safety profile and minimized systemic toxicity.

Among the various botanical candidates documented in traditional Ayurvedic medicine for respiratory care, *Ephedra gerardiana*, colloquially known as **Somlata**, stands out as a highly effective natural remedy for respiratory distress. Historically utilized for centuries in indigenous treatment paradigms to treat acute breathlessness and bronchitis, the therapeutic

efficacy of Somlata is principally driven by its native sympathomimetic alkaloids, predominantly ephedrine and pseudoephedrine. At the molecular level, these active phytoconstituents act as direct and indirect agonists on the  $\beta_2$ -adrenergic receptors located on the surface of bronchial smooth muscle cells. This binding stimulates the intracellular adenylate cyclase enzyme, leading to an up-regulation of cyclic adenosine monophosphate (cAMP) levels, which subsequently triggers smooth muscle relaxation and immediate alleviation of airway constriction. However, administering raw herbal extracts in conventional liquid or large solid oral forms often leads to challenges such as an unpalatable bitter taste, poor stability, erratic absorption profiles, and reduced patient compliance.

To overcome these formulation hurdles, the hard candy lozenge has emerged as an innovative and highly advantageous solid single-dose delivery platform for targeting respiratory ailments. Lozenges are designed to dissolve slowly and continuously within the oral cavity, thereby facilitating a sustained release of the incorporated botanical extracts. This specialized route of administration offers distinct biopharmaceutical benefits: it enables a significant portion of the active alkaloids to be absorbed directly through the highly vascularized buccal mucosa into the systemic circulation. This localized mucosal absorption effectively bypasses the hepatic first-pass metabolism, potentially accelerating the onset of the bronchodilating effect while reducing gastric irritation. Furthermore, by incorporating appropriate taste-masking polymers, sweeteners, and cooling flavors, the naturally bitter profile of the Somlata extract can be successfully masked. This structural palatability is particularly beneficial for pediatric and geriatric patient demographics who frequently suffer from dysphagia or resist conventional tablet and capsule therapies.

Despite the established ethnopharmacological status of *Ephedra gerardiana* as a potent antiasthmatic agent, systematic research focusing on its integration into modern, controlled buccal delivery systems remains limited. This investigative study was designed to bridge this gap by systematically formulating and evaluating a series of standardized herbal hard candy lozenges containing bioactive Somlata extract. The research focuses on optimizing the mechanical and physical attributes of the carbohydrate matrix—specifically balancing the ratios of sucrose and liquid glucose—to achieve an ideal dissolution rate that aligns with the physiological residence time in the human mouth. By combining rigorous physicochemical characterization, *in vitro* dissolution kinetics in simulated saliva, and preclinical *in vivo* bronchodilating evaluations using established bronchospasm models, this paper aims to

present a stable, scientifically validated, and highly compliant natural alternative for the modern management of asthmatic conditions.

## 2. PLANT PROFILE

### 2.1 taxonomical classification

Table No. 1: Plant profile.

Taxonomical Rank	Classification	Common/Group Name
Kingdom	Plantae	Plants
Clade	Tracheophytes	Vascular plants
Division	Gnetophyta	Gnetophytes
Class	Gnetopsida	Gymnosperms
Order	Ephedrales	Joint-pines order
Family	Ephedraceae	Joint-pine family
Genus	<i>Ephedra</i>	Jointfirs
Species	<i>E. gerardiana</i>	Gerard's Jointfir
Binomial Name	<i>Ephedra gerardiana</i> Wall. ex Stapf	Somlata (Sanskrit/Hindi)

### 2.2 Morphology

*Ephedra gerardiana*, classically recognized as Somlata, exhibits highly specialized macromorphological adaptations characteristic of an alpine, xerophytic gymnosperm native to high-altitude mountainous terrains. In its general growth habit, the plant is a low-growing, perennial, dioecious shrub that forms dense, rigid tufts over rocky terrains and high cliffs, reaching an average height of fifteen to forty-five centimetres. The plant is anchored securely into rocky crevices by a tough, deeply penetrating, woody rhizomatous root system that protects it against severe mountain winds and prevents soil erosion.

The stem constitutes the most visually dominant and pharmaceutically valuable organ of the plant. It features a thick, grayish-brown woody base that quickly divides into numerous erect, slender, and intensely branched green twigs. These branches are distinctly cylindrical, jointed, and divided into clear nodes and short internodes ranging from one to four centimetres in length. The surface of these photosynthetic green internodes is marked by fine, parallel longitudinal ridges and furrows. Because the true foliage leaves are heavily reduced to minimize transpirational moisture loss, these green stems perform the primary photosynthetic functions for the plant.

The leaves of Somlata are non-photosynthetic, small, and scaly. They are arranged in opposite, decussate pairs at each stem node, where they fuse at their bases to form a short,

membranous, protective sheathing cup around the joint. As the season progresses, these scale leaves dry out, turning from a dull green to a dark brown or grayish hue.

As a gymnosperm, *Ephedra gerardiana* lacks true flowers and instead bears reproductive structures called strobili, or cones, which typically develop between June and August. The plant is dioecious, meaning male and female cones grow on separate individual shrubs. The male strobili are small, ovate, and sessile, appearing in dense clusters at the nodes with yellow anthers protruding past small, overlapping bracts. The female strobili are usually solitary or paired, arising on short stalks from the upper joints, and contain one or two ovules surrounded by large, overlapping, scale-like bracts.

During the fruiting season from August to September, these female bracts undergo a distinct morphological transformation, swelling to become thick, succulent, and berry-like. These pseudo-fruits turn a striking bright red or orange-red colour and have a sweetish taste, enclosing one or two small, dark brown, smooth, ovoid seeds. This colorful, fleshy adaptation attracts alpine birds and small mammals, which assists in seed dispersal across rocky terrains.

### 2.3 Geographical classification

*Ephedra gerardiana*, commonly referred to as Somlata, belongs to a highly specialized geographical classification of alpine, high-altitude xerophytic flora. Geographically, this medicinal gymnosperm is predominantly indigenous to the vast, rugged terrains of the Himalayan mountain range, spanning across southern and central Asia. Its natural habitat extends through specific mountainous zones of India, Nepal, Bhutan, northern Pakistan, western China (particularly the Tibetan Plateau), and parts of Afghanistan. The plant thrives under extreme environmental conditions, specifically occupying rocky cliffs, gravelly mountain slopes, alpine meadows, and dry stone crevices at high elevations ranging generally between 2,500 and 5,000 metres above sea level. This specific regional distribution classifies it as a classic cold-desert lithophyte, meaning it is biologically adapted to grow directly on or within the cracks of weathered rocks where soil organic matter is minimal.

Within the Indian subcontinent, the geographical distribution of Somlata is strictly restricted to the cold, arid regions of the outer and inner Northwestern Himalayas. It is commonly found growing wild in the high-altitude districts of Himachal Pradesh (such as Lahaul, Spiti, and Kinnaur), Uttarakhand (including the rocky zones of Chamoli and Pithoragarh), and across the Union Territories of Jammu & Kashmir and Ladakh. The plant's geographic

survival is heavily dependent on specific macroclimatic factors, such as intense solar radiation, prolonged exposure to sub-zero temperatures during winter, low annual rainfall, and well-drained, nutrient-poor, alkaline gravel soils. Because it occupies these sensitive alpine ecosystems, the geographical sourcing of Somlata for pharmaceutical manufacturing is often influenced by seasonal accessibility, as heavy winter snowfall blocks access to these high-altitude populations between November and April.

### 3. MATERIAL AND METHOD

#### 3.1 EXTRACTION OF SOMLATA PLANT

The extraction process begins by milling dried, authenticated stems of *Ephedra gerardiana* into a coarse powder to breach cell walls and maximize the total surface area available for solvent exposure. The pulverized plant material is transferred into a sealed glass vessel and moistened uniformly with an alkaline wetting agent, such as a 10% w/v sodium carbonate ( $\text{Na}_2\text{CO}_3$ ) solution or a 5% v/v ammonium hydroxide ( $\text{NH}_4\text{OH}$ ) solution. This basic pretreatment neutralizes the naturally occurring organic acids bound to the native ephedrine salts, converting them completely into their uncharged, highly lipophilic free-base state. The moistened plant mass is thoroughly mixed and allowed to stand at room temperature for 1 to 2 hours, ensuring full cellular penetration and complete free-base conversion.

Once the ephedrine molecules are transitioned into their free-base forms, their solubility profile shifts significantly toward non-polar organic media. The alkalized, moistened Somlata powder is packed into a Soxhlet extraction apparatus or a closed-circuit reflux system. A non-polar organic solvent, such as dichloromethane (DCM) or chloroform, is introduced as the extracting menstruum. The system is heated to the boiling point of the chosen organic solvent, allowing it to continuously cycle through the plant matrix for 12 to 18 hours. This exhaustive extraction phase dissolves and leaches out the lipophilic free-base ephedrine along with non-polar plant fats, resins, chlorophyll, and waxes, resulting in a dark, alkaloid-rich organic solution.

The organic extract is allowed to cool to ambient temperature and is subsequently processed through a Buchner funnel fitted with fine-grade filter paper under a vacuum line to remove all spent botanical debris. The clear, greenish-brown organic filtrate is then transferred into a round-bottom flask attached to a rotary vacuum evaporator. To prevent the thermal degradation of the heat-sensitive alkaloids, the water bath temperature of the evaporator is

maintained strictly between 35°C and 40°C. The organic solvent is distilled off under reduced pressure until a highly concentrated, viscous, syrupy dark residue remains at the bottom of the flask, marking the end of the primary concentration stage.

To separate the target ephedrine from co-extracted plant fats, waxes, and pigments, the concentrated syrupy residue is subjected to selective liquid-liquid partitioning. The residue is completely dissolved in 100 mL of 0.5 M hydrochloric acid (HCl). The introduced acid instantly protonates the free-base ephedrine, converting it into a highly water-soluble hydrochloride salt, while the non-polar fats and pigments remain unprotonated. This acidic mixture is transferred into a separating funnel and washed with equal volumes of petroleum ether or hexane. Upon shaking and allowing the phases to settle, the non-polar organic layer containing the unwanted plant impurities is systematically drained and discarded, while the clean, upper acidic aqueous layer containing the ephedrine salt is carefully collected.

The isolation of alkaloids from *Ephedra gerardiana* involves complex chemical transitions between salt and free-base forms to achieve high purity. These processes are foundational in pharmacognosy for studying the chemical profile of medicinal plants. The efficiency of the separation is typically monitored by observing the solubility shifts during the partitioning phases described previously.

### 3.2 Formulation

**Base Preparation (Syrup Phase):** Accurately weigh the sucrose and liquid glucose for the specific batch as per the formulation table. Dissolve the sucrose completely in a minimal amount of purified water (approximately 10–12 mL) in a stainless steel or glass heating vessel.

**Thermal Processing:** Heat the sucrose solution gently while stirring. Once boiling begins, introduce the liquid glucose. Raise the temperature of the mixture steadily to 140°C–145°C using a digital laboratory thermometer. This high temperature drives off excess water, creating a highly viscous, non-crystalline "sugar-glass" melt.

**Cooling and Incorporation:** Remove the vessel from the heat source and allow the molten candy base to cool slightly to approximately 90°C–95°C. This step prevents the thermal degradation of the active phytoconstituents. Add the pre-calculated amount of standardized Somlata free-base extract, citric acid (dissolved in 0.5 mL of warm water), and peppermint

oil flavor. Stir the mixture vigorously to ensure uniform distribution of the extract throughout the matrix.

**Molding and Solidification:** Pour the hot, uniform molten mass immediately into pre-lubricated polyvinyl chloride (PVC) or silicone lozenge molds. Ensure each cavity is filled evenly.

**Finishing and Storage:** Allow the filled molds to cool naturally at room temperature until the lozenges solidify completely. Demold the finished hard candy lozenges, wrap them individually in protective aluminum foil to shield them from atmospheric moisture

### Formulation Table for 3 Batches

This table details the exact quantities required to manufacture 10 lozenges per batch (Target weight: 3 grams per lozenge, Total batch mass: 30 grams). The three batches utilize varying ratios of sucrose to liquid glucose to evaluate structural variations.

### Formulation Matrix for Somlata Lozenges (10 Lozenges / 3g per unit)

**Table No. 2: formulation table.**

Ingredients	Role / Function	Batch A (g)	Batch B (g)	Batch C (g)
Somlata Extract	Active Pharmaceutical Ingredient	1.50	1.50	1.50
Sucrose	Bodying Agent / Sweetener	17.50	16.00	14.50
Liquid Glucose	Anti-crystallizing Polymer	10.00	11.50	13.00
Citric Acid	Salivation / Flavor Enhancer	1	1	1
Purified Water	Solvent / Processing Aid	q.s.	q.s.	q.s.
Total Weight	Batch Output Metric	30.00 g	30.00 g	30.00 g



**Image No. 1: preparation of base syrup.**



Image No. 2: Molding of lozenges.

#### 4. PHYTOCHEMICAL TESTING

Table No. 3: Phytochemical testing results.

Phytochemical Class	Diagnostic Screen / Test	Experimental Procedure	Observed Visual Indication	Inference / Result
Alkaloids	Dragendorff's Test	Treatment of the crude extract with Dragendorff's reagent (Potassium bismuth iodide solution)	Appearance of a prominent reddish-brown precipitate	Positive (+)
Flavonoids	Alkali Treatment Test	Interaction of the extract with dilute sodium hydroxide ( $\text{NaOH}$ ) solution, followed by adding dilute acid	Formation of an intense yellow colour that turns completely colourless upon adding dilute acid	Positive (+)
Phenols	Ferric Chloride Test	Addition of a few drops of freshly prepared 5% Neutral Ferric Chloride ( $\text{FeCl}_3$ ) solution to the aqueous extract	Appearance of a deep bluish-black or intense dark green coloration	Positive (+)
Saponins	Froth / Foam Test	Vigorous shaking of the diluted extract with distilled water in a graduated cylinder for 15 seconds	Formation of a stable, persistent honeycomb-like froth layer ( $>1.5 \text{ cm}$ ) that remains intact for over 15 minutes	Positive (+)



Image No. 3: Result for phytochemical screening.

## 5. Evaluation of lozenges

### 5.1 Weight variation test

Sampling: Randomly select 10 lozenges from the prepared batch.

Individual Weighing: Weigh each lozenge individually on a calibrated high-precision analytical balance and record the exact weight.

Average Calculation: Calculate the average weight by dividing the total weight of all 10 lozenges by 10.

Deviation Analysis: Compare the weight of each individual lozenge against the calculated average weight to determine the percentage deviation using the formula. Evaluation: Check if the batch passes by ensuring no more than 2 individual lozenges deviate by more than  $\pm 5\%$  from the average weight, and zero units deviate by more than  $\pm 10\%$

### 5.2 Hardness test

The hardness test for the manufactured hard candy lozenges is executed by randomly sampling ten individual units from the prepared batch to assess their overall structural durability and crushing resistance. Each selected lozenge is positioned securely between the lower fixed arm and upper moving jaw of a calibrated manual Monsanto or Pfizer hardness tester. Mechanical force is then applied steadily to the sample by turning the calibrated screw thread or compressing the instrument handle until the structural integrity of the candy matrix yields and fractures. The exact numerical value displayed on the built-in force gauge is recorded at the moment of breakage, with readings captured in either kilograms per square centimetre. This sequence is repeated uniformly for all ten sampled units, and the collected values are compiled to calculate a final mathematical average crushing strength, ensuring the batch meets the necessary physical standards to withstand handling, packaging, and shipping without breaking prematurely.

### 5.3 Friabilator test

The friability test is performed by randomly gathering a sample of ten lozenges from the prepared batch to evaluate their surface resilience against friction and mechanical shock during handling and distribution. The collected lozenges are first carefully dedusted using a soft brush to remove surface debris and are then weighed together on a high-precision digital analytical balance to record their initial collective mass. This pre-weighed sample is introduced into the drum of a standard Roche friabilator, which is programmed to rotate at a

constant speed of 25 revolutions per minute for a duration of four minutes, resulting in a total of 100 drops. Following the completion of the tumbling cycle, the lozenges are removed from the apparatus, dedusted once more to clear away any newly formed particles, and reweighed to capture their final collective mass. The percentage friability is then calculated using the mathematical relationship between the initial and final weights, where a final weight loss value of less than 1.0% signifies that the batch has successfully satisfied official pharmaceutical durability requirements.

$\% F = \frac{W_0 - W}{W_0} \times 100$  Where, % F = Friability in percentage,  $W_0$  = Initial weight of lozenges  $W$  = Final weight of lozenges after revolution.

#### 5.4 Dissolution test

The *in vitro* dissolution test for the herbal lozenges is conducted using a standard USP Type II (Paddle) dissolution apparatus to evaluate the rate of active alkaloid release. A simulated saliva medium consisting of 900 mL of phosphate buffer (pH 6.8) is introduced into the dissolution vessel and maintained at a constant physiological temperature of a paddle rotation speed set to 50 rpm. One lozenge is placed into each vessel, and the apparatus is operated continuously for a total duration of 30 minutes. At specific predetermined time intervals (such as 5, 10, 15, 20, 25, and 30 minutes), 5 mL aliquots of the dissolution medium are sampled from the vessel and immediately replaced with an equal volume of fresh, pre-warmed phosphate buffer to maintain consistent sink conditions. The collected samples are filtered, diluted appropriately, and analyzed quantitatively using a UV-Visible spectrophotometer or HPLC at the maximum absorbance wavelength of ephedrine. This process is repeated across the sampled units to calculate the final cumulative percentage of drug release over time, ensuring the lozenge matrix provides a steady and predictable therapeutic delivery.

#### 5.5 ORGANOLEPTIC TEST

The prepared lozenges were visually evaluated for clarity, color, surface texture, odor, and overall palatability via an unblinded panel test.

#### 5.6 PH TEST

The pH test for the manufactured herbal formulations is carried out to verify that the final product is compatible with the oral cavity and will not cause mucosal irritation. Ten lozenges are randomly sampled from the batch and pulverized into a fine powder using a clean mortar and pestle. A specific portion of this crushed matrix is dissolved completely in distilled water

to prepare a 10% w/v aqueous solution. A calibrated digital pH meter is then immersed directly into the resulting solution at room temperature 25 degree celcius to capture the exact electro-chemical reading. This procedure is repeated for all sampled units to calculate a final average pH value, where a resultant range falling between **6.2 and 7.2** confirms that the lozenges match the natural physiological conditions of human saliva, ensuring both safety and palatability during buccal dissolution.

## 6. RESULTS AND DISCUSSION

The physical evaluation parameters across all four developed batches are presented systematically in Table. Organoleptically, formulations displayed a superior glassy appearance, dark golden-brown aesthetic clarity, and smooth surface uniformity without any signs of crystal blooming or stickiness. The inclusion of citric acid successfully masked the inherent bitter and astringent notes of the concentrated Somlata extract, providing an appealing sweet-cooling taste.

**Table No. 4: Result for organoleptic tests.**

Test	Result
Colour	Dark brown
Odour	Sweet
Taste	Sweet

**Table No. 5: Result for evaluation tests.**

Batch Batch	Weight (kg) Weight (g)	Harsdness (kg) kg/cm <sup>2</sup> )	Friabilator	Ph rface pH	Dissolutiont time (min)
F1	2.98 ± 0.04	7.2 ± 0.3	0.24%	6.45	16.5 ± 1.2
F2	3.01 ± 0.02	7.8 ± 0.2	0.18%	6.51	19.2 ± 1.5
F3	3.00 ± 0.03	8.4 ± 0.4	0.12%	6.58	24.8 ± 1.1



**Image No. 4: Friabilator test.**



**Image No. 5: dissolution test.**



**Image No. 6: Hardness test in Monsanto hardness tester.**

**Image No. 7: Weight of lozenges.**

## 7. CONCLUSION

The current research successfully accomplished the design, development, and standard pharmaceutical optimization of hard candy herbal lozenges containing the bioactive extract of Somlata (*Ephedra gerardiana*). The selection of a 70:30 sucrose-to-glucose matrix base in formulation yielded excellent results across all physical indices including uniform weight, superior mechanical hardness (8.4 kg/cm<sup>2</sup>), low friability, and non-irritating surface pH parameters. Taste-masking strategies effectively converted a bitter botanical extract into an acceptable, palatable product. The slow, sustained in vitro release mechanism verified that this lozenge profile is capable of maintaining localized delivery of active sympathomimetic alkaloids in the oral cavity for over 20 minutes. It can be concluded that Somlata herbal lozenges represent a stable, industrially scalable, and highly viable alternative to traditional dosage forms for respiratory relief.

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