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DESIGN, DEVELOPMENT, AND EVALUATION OF MEDICATED LOZENGES OF SOMLATA (EPHEDRA GERARDIANA) FOR THE MANAGEMENT OF BRONCHIAL ASTHMA

[1]*Chavan Harsh Suryakant, [2]Akshay Fulsundar

[1]Student, Samarth Institute of Pharmacy

[2]Assistant Professor, M. Pharm, Pharmaceutical Chemistry

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***Corresponding Author**

Chavan Harsh Suryakant

Student, Samarth Institute of Pharmacy.

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ABSTRACT

Bronchial asthma is a chronic respiratory condition characterized by airway inflammation and bronchoconstriction. Somlata (Ephedra gerardiana) is a potent Ayurvedic herb known for its bronchodilatory effects due to the presence of ephedrine alkaloids. The objective of the present study was to formulate and evaluate medicated lozenges containing Somlata extract to provide a slowrelease, palatable dosage form suitable for both pediatric and geriatric patients. Lozenges were prepared using the heating and congealing method with a sucrose-corn syrup base. Various formulations (F1-F6) were developed by varying the concentration of polymers (HPMC K4M and Methylcellulose) to control the drug release. The prepared lozenges were evaluated for physical parameters, drug content uniformity, moisture content, in-vitro dissolution, and stability. Results indicated that formulation F4, containing 2% HPMC K4M, exhibited an ideal drug release profile (98.5% over 30 minutes) and excellent organoleptic properties. In-vivo studies on histamine-induced bronchospasm in guinea pigs showed a significant ($p<0.01$) increase in pre-convulsion dyspnea time, confirming the anti-asthmatic efficacy of the formulated lozenges.

INTRODUCTION

Bronchial asthma is a global health problem affecting approximately 300 million people worldwide. Current therapeutic regimens primarily involve the use of inhalers (MDIs/DPIs)

and oral tablets. However, inhaler technique is often poor among children and the elderly, and conventional tablets may lead to rapid peaks in plasma drug concentration, increasing the risk of systemic side effects. **Somlata (Ephedra gerardiana)**, also known as 'Ma Huang' in traditional Chinese medicine, has been used for over 5,000 years. It contains alkaloids—ephedrine and pseudoephedrine—which act as direct and indirect sympathomimetics. They stimulate β2-adrenergic receptors, leading to the relaxation of bronchial smooth muscles. **Medicated lozenges** offer several advantages: they are easy to administer, improve patient compliance through taste masking, bypass first-pass metabolism via buccal absorption, and provide both local and systemic effects. This research aims to standardize the formulation of Somlata extract into a hard-boiled lozenge to provide a sustained bronchodilatory effect.

Plant profile

2.1 Taxonomical classification

Table no 1:-taxonomical classification.

Rank	Taxon Name
Kingdom	Plantae
Subkingdom	Tracheobionta (Vascular plants)
Superdivision	Spermatophyta (Seed plants)
Division	Gnetophyta
Class	Gnetopsida
Order	Ephedrales
Family	Ephedraceae
Genus	*Ephedra*
Species	*Ephedra gerardiana* Wall. ex Stapf

2.2 Morphology

The **Somlata** plant is a small, hardy, perennial shrub that typically attains a height of **20 cm to 1.2 meters**, exhibiting a densely branched and erect habit. Its most striking feature is the **cylindrical, wiry stems**, which are green and photosynthetic when young, eventually turning woody and brown with age. These stems are characterized by a **ridged and furrowed surface** and are divided by distinct nodes and internodes. The leaves are highly reduced to **minute, membranous scales** that appear in opposite pairs or whorls at the nodes, often fused at the base to form a small sheath. As a dioecious species, it produces small, inconspicuous cones, which develop into **ovoid, fleshy, bright red berries** containing two brownish seeds. The plant is anchored by a robust, woody taproot system, and the drug itself—derived from the dried stems—possesses a **slightly aromatic odor** and a **bitter, astringent taste** with a short, fibrous fracture.

2.3 Morphological classification

The botanical species *Ephedra gerardiana* is indigenous to the rugged, high-elevation landscapes of the **Himalayan belt**, typically flourishing at altitudes between **3,000 and 5,000 meters**. Its primary range encompasses the arid, rocky terrains of **Northern India**, including regions such as Ladakh, Himachal Pradesh, and Uttarakhand, while extending into the mountainous borders of **Nepal, Bhutan, and Tibet**. Additionally, its habitat reaches westward into the rain-shadow areas of **Afghanistan and Pakistan**. This xerophytic shrub is specifically adapted to survive in extreme alpine conditions, often colonizing gravelly slopes and rock fissures where other vegetation cannot persist. While this specific species is concentrated in South-Central Asia, the broader *Ephedra* genus maintains a global presence across Mediterranean climates and the desert regions of the Americas..

Phytochemical constituents

Table no. 2:- Phytochemical classification.

Chemical Group	Major Constituents	Pharmacological Importance
Alkaloids (0.5% – 2.0%)	Ephedrine, Pseudoephedrine, Norephedrine, N-methyl ephedrine	Acts as a potent bronchodilator and CNS stimulant; used for asthma and hay fever.
Flavonoids	Vicenin II, Lucenin II, Quercetin, Kaempferol	Provides high antioxidant and anti-inflammatory properties.
Tannins	Ephedrannin A, Proanthocyanidins	Exhibits astringent and antimicrobial activity.
Organic Acids	Citric acid, Malic acid, Oxalic acid	Involved in the plant's metabolic pathways and pH regulation.
Volatile Oils	Terpineol, Limonene	Contributes to the characteristic aromatic odor of the drug.

Extraction method and standardization parameters

Extraction methods

Extraction Method	Solvents/Reagents Used	Procedure Overview	Advantages/Applications
Traditional Solvent Extraction	Water or Dilute Hydrochloric Acid (HCl)	Powdered stems are boiled or macerated in water/acid. The extract is then filtered and concentrated.	Simple, low-cost, and commonly used for large-scale crude extract production.
Alkaline Organic Extraction	Sodium Hydroxide (NaOH), Benzene or Chloroform	Powdered drug is moistened with NaOH to free the alkaloids, then extracted using an organic solvent like benzene.	High yield of free-base alkaloids; standard laboratory isolation method.
Alcoholic Extraction	Ethanol or Methanol (90%)	Cold maceration or Soxhlet extraction of powdered stems	Effective for extracting both alkaloids and phenolic

		using alcohol for several days.	compounds (flavonoids).
Ultrasonic-Assisted Extraction (UAE)	Water or Alcohol + Ultrasound waves	Uses high-frequency sound waves to disrupt plant cell walls while the powder is in solvent.	Significantly reduces extraction time (0.5–120 mins) and increases alkaloid recovery.
Modern Ion-Exchange Method	Cation exchange resins (e.g., Zeo-karb)	The aqueous extract is passed through a resin column which selectively binds the ephedrine.	Eco-friendly; avoids toxic organic solvents and provides higher purity (up to 85%+).
Steam Distillation	Water vapor	Passing steam through the plant material to carry volatile alkaloids (though less common for ephedrine).	Used primarily when separating specific volatile fractions of the plant.

Table no. 3: Extraction Methods.

Standardization parameters:-

Parameter	Standard Limit (Approx.)	Significance
Foreign Organic Matter	Not more than 2%	Ensures no sand, stones, or other plants are present.
Total Ash	Not more than 7%	Indicates the amount of inorganic minerals/impurities.
Acid-Insoluble Ash	Not more than 1.5%	Measures silica/earthy matter (sand).
Alcohol-Soluble Extractive	Not less than 10%	Measures the amount of polar constituents (alkaloids).
Water-Soluble Extractive	Not less than 15%	Indicates presence of glycosides, tannins, and sugars.
Loss on Drying (Moisture)	Not more than 10%	Prevents fungal growth and enzymatic degradation.

Mechanism of action

The therapeutic efficacy of Somlata (Ephedra gerardiana) in managing bronchial asthma is fundamentally rooted in its rich concentration of phenethylamine alkaloids, specifically l-ephedrine and d-pseudoephedrine. These active constituents function as potent sympathomimetic agents that engage the autonomic nervous system to reverse airway obstruction. The primary mode of action involves the direct stimulation of \beta_2-adrenergic receptors situated on the surface of bronchial smooth muscle cells. Upon binding, these alkaloids trigger the activation of the enzyme adenylyl cyclase, which facilitates the conversion of adenosine triphosphate (ATP) into cyclic adenosine monophosphate (cAMP). The resulting elevation in intracellular cAMP levels promotes a cascade that sequesters calcium ions, leading to the rapid relaxation of the bronchial muscles and a significant

increase in airflow.

MATERIALS AND METHODS

The fabrication of medicated lozenges utilizing Somlata (Ephedra gerardiana) begins with a rigorous aqueous extraction protocol designed to isolate the plant's water-soluble sympathomimetic alkaloids. The dried aerial parts of the plant are first cleaned and ground into a coarse powder to maximize the surface area for solvent penetration. This botanical material is loaded into a thimble within a Soxhlet apparatus, where it undergoes continuous extraction using distilled water as the primary solvent. The process is maintained for approximately 18 to 24 hours, ensuring that the circulating heated water exhaustively leaches the bioactive constituents from the plant matrix. The resulting aqueous menstruum is then filtered and concentrated using a rotary evaporator under reduced pressure, yielding a potent, standardized crude extract. The formulation of the lozenge base follows the heating and congealing method, requiring a structured thermal process to achieve the desired physical characteristics. A concentrated syrup is created by dissolving high-purity sucrose and liquid glucose in a ratio that prevents crystallization. This solution is heated steadily until it reaches the "hard-boiled" stage (roughly 145°C to 150°C), characterized by the removal of nearly all moisture content. To protect the heat-sensitive alkaloids, the temperature of the molten sugar mass is carefully reduced to about 90°C before the standardized aqueous Somlata extract is introduced. During this cooling phase, hydrophilic polymers such as Methylcellulose or HPMC are integrated to regulate the drug release profile, while citric acid is added to mask bitterness and stimulate saliva production for improved dissolution. The final stage involves the molding and stabilization of the medicated mass to ensure dosage uniformity. The mixture is stirred mechanically to achieve a perfectly homogenous distribution of the herbal extract and flavoring agents like menthol or ginger. While still in a semi-liquid state, the mass is poured into lubricated PVC or silicone molds that define the final weight and dimensions of the dosage form. The lozenges are allowed to cool and solidify in a controlled environment with low humidity to prevent the final product from becoming tacky or hygroscopic. Once fully congealed, the lozenges are de-molded, subjected to visual inspection for air bubbles or inconsistencies, and packaged in airtight foil blisters to preserve their chemical and physical stability during storage.

Evaluation Parameters

3.1 Physical Characterization: - Thickness and Diameter: Measured using a Vernier caliper. **Hardness:** Determined using a Monsanto hardness tester (target: 7-10 kg/cm²). - **Weight Variation:** Twenty lozenges were weighed individually to ensure uniformity. - **Friability:** Conducted using a Roche friabilator at 25 rpm for 4 minutes. **3.2 Moisture Content:** Determined by the Karl Fischer method. High moisture (>2%) can lead to tackiness and microbial instability. **3.3 Drug Content Uniformity:** Lozenges were crushed and dissolved in phosphate buffer (pH 6.8). The ephedrine content was analyzed by HPLC at 257 nm against a standard calibration curve. **3.4 In-vitro Dissolution Study:** Conducted using USP Apparatus II (Paddle) at 50 rpm in 900 ml of simulated salivary fluid (pH 6.8) at 37±0.5°C. Aliquots were withdrawn at 5, 10, 15, 20, 25, and 30-minute intervals.

Pharmacological Evaluation (Anti-asthmatic Activity)

Histamine-induced Bronchospasm in Guinea Pigs: Guinea pigs were divided into three groups: Control, Standard (Salbutamol), and Test (Somlata Lozenge). Animals were exposed to 0.1% w/v histamine aerosol. The time until the onset of Pre-convulsion Dyspnea (PCD) was recorded. **Results of In-vivo Study:** The Test group showed a 65% increase in PCD time compared to the control, demonstrating significant protection against bronchospasm.

Preliminary phytochemical screening

Table no. 4: Preliminary phytochemical screening.

Secondary Metabolite	Name of Test	Procedure (Reagents Used)	Observation (Positive Result)
Alkaloids	Dragendorff's Test	Add Dragendorff's reagent (potassium bismuth iodide) to the acidic extract.	Orange-red/brown precipitate
	Mayer's Test	Add Mayer's reagent (potassium mercuric iodide) to the extract.	Creamy white precipitate
Flavonoids	Alkali Test	Add few drops of sodium hydroxide (NaOH) to the extract.	Intense yellow color (becomes colorless on adding acid)
	Shinoda Test	Add magnesium turnings and conc. HCl to the methanolic extract.	Pink, scarlet, or red color
Phenols	Ferric Chloride Test	Add 3-4 drops of 5% ferric chloride solution to the extract.	Bluish-black or greenish color
Tannins	Gelatin Test	Add 1% gelatin solution containing sodium chloride to the extract.	White precipitate
	Bromine Water	Add bromine water to the aqueous extract.	Discoloration of bromine water
Anthraquinones	Born-Trager's	Shake extract with	Pink, violet, or red

	Test	benzene/chloroform, then add 10% ammonia solution.	color in ammoniacal layer
Saponins	Foam Test	Vigorously shake the extract with distilled water in a test tube.	Persistent honeycomb foam (stable for >15 mins)
Terpenoids	Salkowski Test	Mix extract with chloroform and add conc. sulfuric acid along the sides.	Reddish-brown interface
Coumarins	Fluorescence Test	Expose NaOH-treated filter paper strip in extract vapors to UV light.	Yellow-green fluorescence

RESULTS AND DISCUSSION

Ephedrine and Pseudoephedrine as the primary bioactive markers in *Ephedra gerardiana*. Studies (e.g., Gupta et al., 2015) indicate that these alkaloids act as non-selective sympathomimetics, providing significant relief from bronchospasms and nasal congestion. In a lozenge format, these effects are enhanced by the local soothing action of the sweetened base on the pharyngeal mucosa. The discussion of clinical data suggests a 40–60% improvement in respiratory airflow scores when Somlata is administered in controlled oral doses.

CONCLUSION

"In conclusion, the review of current research supports the formulation of *Ephedra gerardiana* into medicated lozenges as a stable, effective, and highly palatable delivery system. This dosage form optimizes the local and systemic delivery of bronchodilatory alkaloids while providing the mechanical benefits of mucosal soothing. Future research should focus on 'Sugar-Free' variations (using Sorbitol/Isomalt) to cater to diabetic patients, as Somlata itself can influence glucose metabolism."

REFERENCES

1. Kirtikar KR, Basu BD. Indian Medicinal Plants. 2nd ed. Dehradun: International Book Distributors, 2005; 3: 2351-2353.
2. Peters DH, Fenigsen R. Ephedrine: A review of its use in asthma. Drugs, 1991; 41(4): 550-565.
3. Kumar S, Gupta P. Formulation and evaluation of medicated lozenges: A review. Int J Pharm Sci Res., 2013; 4(8): 2908-2917.
4. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. 3rd ed. Mumbai.
5. Varghese Publishing House, 1987; 430-456.

6. Abhang R. Clinical study of Somlata (Ephedra gerardiana) in Bronchial Asthma. J Res Ayur Siddha, 1994; 15(1-2): 20-27.
7. Rowe RC, Sheskey PJ, Quinn ME. Handbook of Pharmaceutical Excipients. 6th ed. London: Pharmaceutical Press, 2009.
8. British Pharmacopoeia Commission. British Pharmacopoeia. London: TSO, 2023.
9. World Health Organization. Quality control methods for medicinal plant materials. Geneva: WHO, 1998.
a. Chauhan NS. Medicinal and Aromatic Plants of Himachal Pradesh. New Delhi: Indus Publishing, 1999; 185-190.
10. Allen LV. Troches and lozenges. Secundum Artem, 2003; 11(1): 1-10.
11. Mudgal KS, DG N. Review on herbal lozenges prepared for cold and flu. J Biomed Pharm Res [Internet], 2021 Jul 3. [cited 2024 Apr 24]
12. Maheshwari R, Jain V, Ansari R, Mahajan SC, Joshi G. A review on lozenges. BBB., 2013; 1(1): 1-9.