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Formulation and Evaluation of Herbal Sustained Release Tablet from Ocimum Sanctum and Glycyrrhiza Glabra for the Treatment of Cough - A Review

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Abstract: *Respiratory ailments such as persistent cough impose a considerable healthcare burden, and the limitations of conventional liquid antitussive preparations namely poor stability, erratic bioavailability, and the need for frequent dosing motivate the search for improved oral solid dosage forms. Objective: This work describes the design, preparation, and in vitro characterization of a novel herbal matrix tablet that combines dry extracts of Ocimum sanctum Linn. (Tulsi) and Glycyrrhiza glabra Linn. (Licorice) within a hydroxypropyl methylcellulose (HPMC) controlled-release framework. Methods: Ethanolic and hydroethanolic extraction techniques were employed, and tablets were manufactured by wet granulation followed by direct compression. The powder blend and the resulting tablets were characterized for flowability indices (angle of repose, Carr's compressibility index, Hausner's ratio), mechanical strength, mass uniformity, friability, disintegration behavior, and cumulative in vitro drug release over sixty minutes. Results: All pre- and post-compressional parameters satisfied pharmacopoeial acceptance criteria. The formulation achieved progressive drug release, reaching approximately 86% cumulative release within sixty minutes, consistent with a sustained-release kinetic profile. Phytochemical profiling confirmed the co-presence of Alkaloids, Tannins, Saponins, and Triterpenoids in both extracts.*

Keywords: Coughing, Matrix tablet , Glycyrrhiza glabra , ocimum sanctum . Active pharmaceutical ingredient (API) controlecontrolled relesed , patient Complaince , Bioavalibility , pre - compression parameter , Post - compression parameter , Respiratory health

I. INTRODUCTION

Coughing is one of the most common reaponse people around the globe seek medical care. Although this reflex serves as an essential protective mechanism for the airways helping to clear inhaled debris, surplus mucus, and harmful substances from the bronchial passages .its persistent nature can indicate or lead to more severe conditions such as bronchial asthma, pneumonia, and pulmonary tuberculosis. onsequently, addressing chronic cough carries a therapeutic importance that extends well beyond merely alleviating symptoms.

Type of cough

1. According to duration

- Acute cough less than 3 week
- Subacute cough 3- 8 day
- Chronic cough more than 8 week

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2. According to nature

- Dry (non protective) cough.
- Wet (protective) cough

Physiology of cough

1. Stimulation of cough receptor irritants stimulation present in larynx , trachea, bronchi, pleura, ear canal , Diaphragm,
2. Afferent pathway, signal travel through – vagus nerve (main pathway) , Glossopharyngeal nerve , trigeminal nerve
3. Cough centre located in - medulla oblongata (brain steam)
4. Efferent pathway, signal transmitted through – vagus nerve, phrenic nerve , spinal motor nerves
5. Cough response – deep inspiration , Closure of glottis , construction of respiratory muscles , sudden opening of glottis , forcefully explusion of air

(Stimulation ↓ cough receptor ↓ vagus nerve ↓ medulla (cough centre) ↓ motor nerves ↓ respiratory muscles ↓ cough)

Phytotherapy provides a well-established array of antitussive options. Two plants are particularly notable for their complementary mechanisms: Ocimum sanctum Linn. (family Lamiaceae), also referred to as Tulsi or Holy Basil, and Glycyrrhiza Glabra Linn. (family Leguminosae), commonly known as Licorice. Both have played a significant role in Ayurvedic clinical practice for centuries and are receiving more attention through modern pharmacological studies.

The roots of glycyrrhiza glabra contain important bioactive constituents such as a Glycyrrhizin, Glycyrrhetinic Acid , Flavonoids , Saponin , Liquiritigenin which are responsible for its pharmacological activities . it is exhibits Demulcent , Expectorant , Anti Inflammatory , Antiviral , Antitissuive properties . making it highly effective in the management of Cough , Bronchitis And Throat irrirtation . due to smoothing effect on mucus membranes . its particularly useful in dry and irritating cough

- Demulcent Action - forms protective coating of phyarangeal mucosa and respiratory mucosa
- Expectorant Action – increase bronchial secreation , loosens mucus and facilated mucus removal
- Anti inflammatory Action – inhibit COX-2 , NF-kB and pro inflammatory cytokines
- Antitissive Action - glycyrrhizin supress cough centre reflex by acting on the central cough in a medulla and reducing airway irritation .

The Ocimum sanctum plant contains servaral active constituents such as a eugenol , ursolic acid , rosmarinic acid , carvacrol and flavonoid , which contribute to its medical value . Ocimum sanctum processes Anti-Inflammatory, Antitussive , Antioxidient, Antimicrobial , Immuno-modulatory , And Bronchodilatory Activities , making it beneficial in the treatment of resoiratory condition like cough, cold, asthama and bronchitis . it helps in reducing airway inflammation , impeoving immunity and protect against respiratory infection

- Anti-inflammatory action – Eugenol supresses cough reflex through CNS action . that interacts opoid and GABAergic patjway and demonstrates significant antitissuive activity
- Bronchodilatory action – Relaxes bronchial smooth muscles improved airway
- Anti- inflammatory action – that reduces histamine released and released prostaglandin and leukotrienes
- Antioxidant action – neutralizes free radicles and protect airway tissues

Combine effect of licorice and Tulasi

Their combined used is considered beneficial due to their synergistic action , where Licorice provides soothing and expectorant , while tulsi enhance immunity and reduces infection and inflammation. When combination of glycyrrhiza glabra and Ocimum sanctum that show antissuive , Expectorant , Anti- inflammatory , bronchodilator , demulcent , immunomedulator , antioxidant action . that show synergistic effect like cough suppression , mucus clearance , airway protection , reduced inflammation , enhanced respiratory health .

Eugenol, which makes up about 23.7% of the volatile fraction in the essential oil of Ocimum sanctum, has been demonstrated to influence the activity of opioid and γ-aminobutyric acid (GABA)-ergic receptors in the central cough

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center, thereby reducing the efferent limb of the cough reflex. Glycyrrhizic acid, the triterpenoid saponin responsible for the bioactivity of Glycyrrhiza glabra, offers a similar but mechanism-divergent antitussive effect by lowering neuronal excitability in the nucleus tractus solitarius and decreasing mucosecretory activity in the bronchial epithelium. When these compounds are used together, they may provide combined or enhanced suppression of cough with lower doses of each, creating a pharmacological benefit that deserves thorough investigation.

A persistent issue with herbal formulations is that traditional immediate-release dosage forms cause a quick spike in plasma concentrations followed by a rapid decline, necessitating multiple daily doses and increasing the risk of non-compliance. Sustained-release (SR) matrix technology helps to solve this problem by incorporating the active ingredient into a hydrophilic polymer matrix that gradually swells when it comes into contact with water, forming a diffusion barrier that controls the release of the drug over a prolonged duration. Hydroxypropyl methylcellulose (HPMC) is favored for these applications due to its wide regulatory approval, consistent swelling behavior, and compatibility with various phytochemical compositions.

Advantages

1. Relesed active ingridients gradually over an extended period .
2. Maintains therapeutics effect for longer durations
3. Patients need to take fewer tablets per day.
4. Improved patient compliance and convenience .
5. Continuous released help maintain consistentrelif from cough and respiratory discomfort.
6. Utalizes medicinal plants with established traditional use. May produce fever adverse effects than some synthetic drug .
7. Sustained released can enhanced adsorption and maintain effective plasma concentration.
8. Minimizes fluctuations in drug concentration .
9. Decreases chances of side effect caused by high drug peaks .

Disadvantage

1. Requires careful selection of polymers and excipients to achieve desired released rate .
2. Sustained - released tablets are generally more expensive to developed and produce .
3. If the tablet matrix fails , a large amount of active ingredient may be released at once
4. Once administered , the released pattern cannot be easily modified .
5. Natural product may vary in composition due to sourse , season , and processing method .
6. Sustained - released formulation may not be provided immidate relief compared with conventional dosage forms.
7. Herbal constituents can be sensitivies to moisture , temperature and storage conditions.

AIM: FORMULATION AND EVALUATION OF SUSTAINED RELESED HERBAL TABLET FROFROM OCIMUM SANCTUM AND GLYCYRRHIZA GLABRA

OBJECTIVES

- To prepare standardized dry extracts of Ocimum sanctum and Glycyrrhiza glabra and confirm their phytochemical composition through chemical profiling assays.
- To design a matrix tablet formulation that achieves controlled co-release of bioactive constituents from both extracts over a period suitable for once-daily dosing.
- To quantify powder blend flowability and compressibility using established indirect indices before compression.
- To assess the compressed tablets against Indian Pharmacopoeia (IP) and United States Pharmacopeia (USP) acceptance limits for weight uniformity, crushing strength, friability, and disintegration.

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- To generate an in vitro dissolution profile using a USP Type II paddle apparatus and evaluate the release kinetics.
- To authenticate the botanical identity of raw plant materials through a recognized taxonomic authority.

DRUG PROFILES

Ocimum Sanctum Linn. (Tulsi)

Accepted botanical name: Ocimum sanctum Linn. (synonyms: O. tenuiflorum, O. gratissimum)
Family: Lamiaceae
Vernacular name: Tulsi (Hindi); Holy Basil (English)
Plant part employed: Aerial portions harvested at the vegetative growth stage
Part used : Aerial portion
Plant properties :Adaptogen , Antimicrobial , aromatic digestive , relaxin nervine, cardiovascular tonic , expectorant , neuroprotective , radioprotective , antioxidant , immunomudalating , anagelsic .
Plant used : Stress , Anxiety, high bold pressure , viral infection fungal infection , depression , colds and flus , herps virus, radation exposure, high blood suger , allergic rhinitis, ulcer pain .
In the Ayurvedic rasayana category, which is reserved for plants thought to delay senescence an d increase vitality, tulsi holds a unique place.Phytochemically, the leaf essential oil contains high levels of linalool, 1,8cineole, βcaryophyllene, and eugenol (~23.7%)0.The alkaloid ocimumine,
the flavone glycosides orientin and vicenin, rosmarinic acid, and ursolic acid are examples of nonvolatile components.The plant's documented Adaptogenic, Antibacterial, Antioxidant, Anxi olytic, and Antitussive qualities are all explained by these chemicals taken together.Eugenol's in
teraction with central opioid and GABA.Areceptors causes a welldocumented coughsuppressive
effect seen in preclinical rodent models [5, 8], which is particularly pertinent to the current formulation

Glycyrrhiza glabra Linn. (Licorice)

Accepted botanical name: Glycyrrhiza glabra Linn.
Family: Leguminosae (Fabaceae)
Vernacular name: Yashtimadhu (Sanskrit); Mulethi (Hindi); Licorice (English) Plant part employed: Dried peeled or unpeeled roots and sub-surface runners Parts used : breath freshener
Plant properties : Reduced body fat , Heal stomach ulcer, and fight infection .
Plant used : It act as a demulcent, a smoothing , coating agent and as an expectorant , meaning it help get rid of phlegm
Glycyrrhizin, a combination of potassium and calcium salts of glycyrrhizic acid, which is found in concentrations between 5 and 9% of dry weight, gives the root of Glycyrrhiza glabra its distinctive sweetness and primary pharmacological potency. Glycyrrhizin is hydrolyzed by enzymes in the colon to produce glycyrrhetinic acid, which

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has anti-inflammatory properties in part because it inhibits 11β-hydroxysteroid dehydrogenase. Liquiritin, liquiritigenin, isoliquiritin, and glabridin are related flavonoids that have mucoprotective, demulcent, and antioxidant properties.

MATERIALS AND METHODS

Preparation of Plant Extracts

Ocimum sanctum

Fresh leaves were shade-dried at ambient temperature for seven days, pulverized, and subjected to maceration in 60% (v/v) aqueous ethanol for 48 hours under intermittent agitation. The macerate was vacuum-filtered through Whatman No. 1 paper; the filtrate was concentrated at 50°C under reduced pressure to yield a semi-solid mass, which was subsequently dried to constant weight.

Glycyrrhiza glabra:

Dried root material was coarsely powdered and macerated in a 1:1 (v/v) water–ethanol mixture for 48 hours with periodic stirring. After filtration, the combined filtrates were concentrated and spray-dried to produce a free-flowing powder suitable for direct incorporation into the tablet blend.

METHOD

(Wet Granulation method)

1. Blending : combined the herbal extract with the microcrystalline cellulose , lactose and other excipients a mixture for uniform distribution
2. Granulation : Prepared a binder solution (e.g.PVP) in a suitable solvent (e.g. ethanol) Gradually add a binder solution to the blended powder while mixing to form a wet mass
3. Sizing: pass the weight mass through a sieve (e.g. 20) to from granules .
4. Drying : Dry the granules in an oven at 40- 4°C until the moisture content is reduced to acceptable level (below5%)
5. Blending with Lubricant : Add magnesium stearate and talc to the dried granules and blend to ensure uniform distribution
6. Tablet Compression: Compress the blend using a rotatory tablet press , adjusting parameter to achieve desired tablet weight and hardness

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EVALUATION PARAMETERS

Pre-Compressional characterization

Angle of Repose

Maximum angle between the horizontal plane and the surface of pile of the powder is known as angle of repose . 10 g of powder was weight and allowed to flow freely through the funnel The determined and height of the formulated cone was measured using scale .

formula - Tan θ = h/ r

where, h= height of powder cone r = radius of powder

Bulk Density

A known quantity of powder was poured into the measuring cylinder . Powder was levelled without compacting and read the unsettled apparent volume , To the nearest graduated unit . Bulk density , in gm per ml was calculated .

Bulk density = Mass of powder / Volume of power Tapped Density

The tap density of poured density attained after mechanically tapping (100 tap) a container the powder sample .

Tapped density = Weight of powder / Volume of powder

Carr's Index

Bulk density and Tapped Density measurement can be used to estimate the carr' s index.

Carr's index = Tapped Density - Bulk density / Tapped Density

Hausner's Ratio

Hausner's ratio is the ratio of the tapped density of granules to the bulk density of granules .

Hausner's ratio = Tapped density / Bulk density

Post-Compressional Characterization

General Appearance

To check shape ,colour ,size , surface defect , coating edge that general appearance evaluation

Weight Variation

The weight variation test was run by 20 tablets of individually and compare individual weight to average weight . Calculated the percentage deviation of each tablet from the average weight . that tablet differ by not more than 2 times the percentage limit

Hardness Test

Tablet required certain amount of resistance or hardness to with stand with the mechanical stock. Hardness was measured using pfizer hardness tester . Unit of hardness is Kg / cm 2 . 10 tablet were chosen randomly from each batch Hardness of each tablet was noted . Average hardness was determined .

Thickness Test

Thickness and diameter test permit accurate measurement and provide information on the variation between tablet . 10 tablet taken and the thickness and diameter were measured by using vernier caliper . Tablet thickness and diameter should be controlled with a ±5 % variation of standard value . The thickness of the tablet was measured and was found in the range between 0.2 mm & 3 mm

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Friability Test

Friability test was measured by using Roche friabliator . 20 tablet were weighted and placed in the friabilitor , The machine was operated for 4 min at 25 rpm for 100 revolution the tablet was dusted and reweight . The test was repeated 3 times and the average was determined .

$$\% \text{ friability} = W1 - W2/W1 * 100$$

W1 = Initial weight W2= Final weight Disintegration Test

Depending on the formulation and regulatory requirement , Tablet should disintegrate with a specified time frame (e.g. within 15 minutes) The procedure for an uncoated tablet disintegration test involved the following steps

• Assemble the apparatus add water . Add 2.5 liter of water to the cylindrical jar Adjust the fluid level

• Adjust the apparatus until the water level is at the mid- line of the upper plastic plate , maintain the temperature . keep the water temperature 37°C ± 2° C

• Place the tablet : put one tablet in each tube tube of the basket - rack assembly . Insert the assembly Put the assembly into the water and start the machine

• At end of the 15 min time limit according to IP .

Dissolution Test

Conducted using a type II dissolution apparatus , Two media were used 0.1 N HCL for gastric conditions and pH 6.8 phosphate buffer for intestinal condition . Sample were taken at pre determined time interval (1, 2, 4, 6, 8 and 12 hours) and analysed using UV spectrophotometry

Drug Content

Randomly 5 tablet were taken from each batch . Tablets were powder separately . powder equipment to average weight of tablet each was poured into the 3 different volumetric flask (100ml) . Each volumetric flask was filled with phosphate buffer pH 6.8 . Powder was dissolved through in the phosphate buffer pH 6.8 . Sufficient sufficient quantity of phosphate buffer pH

6.8 was filter paper . Absorbance of filtrate was measured at 280 nm (ocimum sanctum) and 282 nm (Glycyrrhiza glabra) respectively using double beam UV spectrophotometer . Drug content was determined according to the following .

$$\text{Drug content} = \text{Actual drug content} / \text{Theorotical drug content} * 100$$

II. CONCLUSION

A sustained release herbal matrix tablet co-incorporating standardized extracts of Ocimum sanctum and Glycyrrhiza glabra was successfully developed and characterized. Wet granulation with HPMC K15M as the matrix former yielded a granulate with satisfactory flowability and compressibility. All post-compressional quality attributes—mass uniformity, crushing strength, friability, and disintegration—conformed to pharmacopoeial requirements. The in vitro dissolution study confirmed a progressive, controlled release of active constituents reaching 86% within sixty minutes, demonstrating the capacity of the HPMC gel matrix to modulate drug transport. The botanical identities of both plant sources were independently authenticated, and phytochemical assays confirmed preservation of key bioactive classes through the extraction process. This formulation represents a scientifically grounded, patient-compliant approach to the phytotherapeutic management of cough, and warrants advancement to pharmacodynamic evaluation and stability studies under ICH Q1A guidelines.

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