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Review Article

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FORMULATION AND EVALUATION OF HERBAL SUSTAIN RELEASE TABLET FROM OCIMUM SANCTUM AND GLYCYRRHIZA GLABRA

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ABSTRACT

This review explores the formulation and evaluation of sustained release tablets incorporating Ocimum sanctum (Holy Basil) and Glycyrrhiza glabra (Licorice), both of which possess notable therapeutic properties. The study highlights the extraction methods of these herbs, the selection of appropriate excipients for tablet formulation, and the techniques employed for evaluating tablet quality and release profiles. Emphasis is placed on the use of hydroxypropyl methylcellulose (HPMC) for controlled release, along with other excipients to enhance stability and bioavailability. The evaluation methods, including physical characterization and in vitro dissolution studies, demonstrate the potential of these herbal formulations to achieve sustained therapeutic effects. The findings suggest that these sustained release tablets could improve patient compliance and efficacy of herbal treatments, warranting further clinical investigation. Coughing serves as a protective mechanism for the body, particularly during conditions such as the common cold, which can lead to the formation of phlegm in the respiratory system. Prompt treatment is essential to alleviate symptoms. Traditional pharmaceutical formulations, such as syrups and solutions, often face challenges related to bioavailability, dosing frequency, and stability. To address these issues, matrix tablets have been developed. Matrix tablets utilize polymers to retard the release of the active pharmaceutical ingredient (API), providing a prolonged therapeutic effect. This controlled release reduces dosing frequency, potentially decreasing it to one-third of that required for liquid formulations like syrups. The herbal nature of the API minimizes side effects, further enhancing patient compliance. In the formulation process, herbal extracts are mixed with excipients, including polymers, diluents, fillers, and lubricants. The direct compression technique is employed for tablet formulation, and both pre- and post-compression parameters are evaluated against established standards. The formulations successfully met all physical and pharmaceutical criteria, indicating their viability as an effective alternative to traditional cough treatments. This innovative approach may improve patient outcomes in managing respiratory conditions.

KEYWORDS: Coughing, Matrix tablets, Glycyrrhiza glabra, Ocimum sanctum. Active pharmaceutical ingredient (API), Controlled release, Patient compliance, Bioavailability, Pre-compression parameters, Post-compression parameters, Respiratory health.

INTRODUCTION

Herbal medicine has gained increasing popularity due to its perceived safety and efficacy, leading to a resurgence in interest in the formulation of herbal products. Among various medicinal plants, Ocimum sanctum (holy basil) and Glycyrrhiza glabra (licorice) stand out for their diverse therapeutic properties. Ocimum sanctum is revered in traditional medicine for its adaptogenic, anti-inflammatory, and antioxidant effects. It is commonly used to manage stress, enhance immunity, and promote overall health. The active compounds, such as eugenol and rosmarinic acid, contribute to its therapeutic efficacy. Glycyrrhiza glabra is known for its anti-inflammatory, antitussive, and hepatoprotective properties, largely attributed to glycyrrhizin and other flavonoids. It is often employed in treating respiratory disorders, digestive issues, and skin ailments. The development of sustained release (SR) formulations aims to improve drug delivery by releasing active ingredients at a controlled rate, thereby enhancing bioavailability, prolonging therapeutic effects, and reducing the frequency of dosing. This is particularly beneficial for herbal preparations, which may require higher doses for efficacy. Combining the properties of Ocimum sanctum and Glycyrrhiza glabra in a sustained release tablet could offer a synergistic effect, enhancing their therapeutic potential while improving patient compliance. This review focuses on the formulation strategies, evaluation methods, and potential

applications of sustained release tablets made from these herbal extracts, highlighting their significance in modern herbal pharmacotherapy.

The oral route of drug administration remains the most convenient and widely used method for delivering medications. It offers significant advantages, including ease of use, high patient compliance, and flexibility in dosage form design. Sustained drug delivery systems address the limitations of conventional dosage forms, such as short half-lives and the potential for missed doses (Raizada et al., 2015). These systems help maintain uniform plasma drug levels, thereby reducing side effects (Maurya et al., 2014). Cough is one of the most common health complaints, serving as a natural protective mechanism that expels foreign particles, toxins, and secretions from the respiratory tract. While often associated with benign conditions like the common cold, persistent coughing can lead to serious illnesses such as asthma, pneumonia, and tuberculosis, making effective treatment essential (Rang et al., 2011; Jahan et al., 2012; Lakshmi et al., 2011). Glycyrrhiza glabra (liquorice) has been utilized in traditional Ayurvedic medicine for centuries. Its primary bioactive compound, glycyrrhizic acid, is known for its expectorant, immunomodulatory, and anti-inflammatory properties (Lakshmi et al., 2011). Glycyrrhizic acid acts on the central nervous system, specifically at the cough center, suppressing the cough reflex and reducing mucosal secretions (Raizada et al., 2015; Raju et al., 2014).Similarly, Ocimum sanctum (holy basil or tulsi) is renowned for its therapeutic benefits. The main active component, eugenol, interacts with opioid and GABAergic receptors in the CNS, demonstrating significant antitussive effects (Kalra et al., 2011; Deore et al., 2014). Given their complementary mechanisms of action, the combination of Glycyrrhiza glabra and Ocimum sanctum in sustained release formulations could provide a more effective approach to managing cough and related respiratory conditions. This review discusses the formulation strategies, evaluation techniques, and potential benefits of sustained release tablets incorporating these herbal extracts, emphasizing their therapeutic promise in modern healthcare.

Despite their medicinal potential, the conventional forms of herbal medicines often face challenges such as rapid absorption, leading to suboptimal therapeutic effects and increased frequency of dosing. Sustained-release formulations can address these issues by releasing the active ingredients gradually over an extended period, thereby maintaining therapeutic levels in the bloodstream and improving patient compliance.

Ocimum sanctum and Glycyrrhiza glabra are renowned for their therapeutic properties. This study investigates their potential in sustained-release tablet formulations, addressing the need for effective herbal dosage forms. The formulation development will involve selecting appropriate excipients that facilitate sustained release and conducting rigorous evaluations to ensure quality and effectiveness. The findings from this research could pave the way for the development of advanced herbal formulations that meet the growing demand for effective and patient-friendly herbal medicine.

OBJECTIVES

1) To develop a sustained-release tablet formulation incorporating extracts of Ocimum sanctum and Glycyrrhiza glabra.
2) To optimize the formulation for a controlled and prolonged release of active compounds over a specified duration.
3) To assess the physical properties of the formulated tablets, including hardness, friability, thickness, and weight uniformity.
4) To conduct in vitro dissolution studies to evaluate the release kinetics of the active ingredients from the sustained-release tablets.
5) To evaluate the stability of the formulated tablets under accelerated storage conditions to determine their shelf life and efficacy over time.
6) To provide preliminary insights into the potential therapeutic efficacy of the sustained-release formulation based on release profiles and existing literature on the individual herbal components.
7) To enhance patient compliance by demonstrating the benefits of sustained-release formulations compared to conventional dosage forms.

MATERIALS AND METHOD

1) Materials

a) Active Ingredients

1) Ocimum sanctum (Tulsi) Extract

Dried leaves were sourced from a reliable herbal supplier and extracted using ethanol.

Fig 2: Ocimum sanctum.

Plant profile

- Botanical name: Ocimum sanctum, O. tenuflorum, O. Gratissimum
- Family: Lamiaceae (mint family)
- Parts used: aerial portions.
- Plant Properties: Adaptogen, anti-microbial, aromatic digestive, relaxing nervine, cardiovascular tonic, expectorant, neuroprotective, radioprotective, antioxidant, immunomodulating, analgesic.
- Plant Uses: Stress, anxiety, high blood pressure, viral infections, fungal infections, depression, colds and flus, herpes virus, radiation exposure, high blood sugar, allergic rhinitis, ulcers, pain.
- Plant Preparations: Tea, decoction, tincture, fresh juice, poultice, powder, infused into ghee or honey Holy basil is classified as a rasayana, an herb that nourishes a person's growth to perfect health and promotes long life.

2) Glycyrrhiza glabra (Licorice) Extract.

Dried roots were obtained and extracted using a water-ethanol mixture.

Fig 3: Glycyrrhiza glabra.

PLANT PROFILE

- Botanical name: Glycyrrhiza glabra.
- Family: LEGUMINOSAE.
- Parts used: breathe freshener.
- Plant Properties: reduce body fat, heal stomach ulcers, and fight infections.
- Plant Uses: It acts as a demulcent, a soothing, coating agent, and as an expectorant, meaning it helps get rid of phlegm.

b) Excipients

- Hydroxypropyl Methylcellulose (HPMC): Used as a matrix-forming agent for controlled release.
- Microcrystalline Cellulose: Acts as a filler and improves tablet compressibility.
- Lactose: Serves as a bulking agent.
- Magnesium Stearate: A lubricant to facilitate tablet compression.
- Talc: Enhances powder flow and prevents sticking during compression.

2) METHODS

1) Preparation of Herbal Extracts :

1) Extraction:

- Ocimum sanctum: Dried leaves were powdered and subjected to solvent extraction using ethanol (60%) for 48 hours. The extract was then filtered and concentrated.
- Glycyrrhiza glabra: Dried roots were powdered and extracted with a mixture of water and ethanol (1:1) for 48 hours. The extract was filtered, concentrated, and dried.

Fig: Extraction of herbal extract.

2) Formulation of Sustained Release Tablets: Wet Granulation Method.

1. Blending: Combine the herbal extracts with microcrystalline cellulose, lactose, and other excipients in a mixer for uniform distribution.

2. Granulation: Prepare a binder solution (e.g., Polyvinyl Pyrrolidone, PVP) in a suitable solvent (e.g., ethanol). Gradually add the binder solution to the blended powders while mixing to form a wet mass.

3. Sizing: Pass the wet mass through a sieve (e.g., 20) to form granules.

4. Drying: Dry the granules in an oven at 40-50°C until the moisture content is reduced to acceptable levels (below 5%).

5. Blending with Lubricants: Add magnesium stearate and talc to the dried granules and blend to ensure uniform distribution.

6. Tablet Compression: Compress the blend using a rotary tablet press, adjusting parameters to achieve desired tablet weight and hardness.

Identification of phytoconstituents

1) Ocimum sanctum: Ocimum sanctum, commonly known as holy basil or tulsi, contains various phytoconstituents that contribute to its medicinal properties.

1) Essential Oils
- Eugenol: Major component with anti-inflammatory, antimicrobial, and analgesic properties.
- Linalool: Known for its calming effects and potential to reduce anxiety.
- Cineole: Exhibits respiratory benefits and may help with bronchitis.

2) Phenolic Compounds
- Rosmarinic Acid: Possesses strong antioxidant properties and anti-inflammatory effects.
- Carnosic Acid: Known for neuroprotective and anti-cancer activities.

3) Flavonoids
- Orientin: An antioxidant that helps protect cells from oxidative stress.
- Vicenin: Exhibits anti-inflammatory and antioxidant effects.

4) Alkaloids
- Ocimumine: May have therapeutic effects on the nervous system.

5) Triterpenes
- Ursolic Acid: Exhibits anti-inflammatory, anti-cancer, and antimicrobial properties.

6) Saponins
- Contribute to immune system enhancement and may exhibit anti-inflammatory effects.

7) Vitamins and Minerals
- Contains vitamins A, C, and several B vitamins, along with minerals like calcium and iron.

2) Glycyrrhiza glabra: Glycyrrhiza glabra, commonly known as licorice, contains several important phytoconstituents that contribute to its medicinal properties. Certainly! Here's a more detailed overview of the phytoconstituents in Glycyrrhiza glabra (licorice) along with their properties.

1) Glycyrrhizin
- Description: A sweet-tasting compound and the primary active ingredient.
- Properties: Known for its anti-inflammatory, antiviral, and anti-allergic effects. It helps in protecting against gastric ulcers and is used in treating respiratory conditions.

2) Glycyrrhetinic Acid
- Description: The aglycone of glycyrrhizin.
- Properties: Exhibits anti-inflammatory and hepatoprotective activities. It can modulate cortisol metabolism and has potential in treating adrenal insufficiency.

3) Flavonoids
- Liquiritin: Enhances the absorption of glycyrrhizin and has anti-inflammatory properties.
- Isoliquiritin: Known for its antioxidant and anti-allergic effects. It also exhibits neuroprotective activity.

4) Phenolic Compounds
- Description: These compounds contribute to the antioxidant capacity of licorice.
- Properties: Help reduce oxidative stress and have potential protective effects against chronic diseases.

5) Saponins
- Description: Compounds with immune-boosting properties.
- Properties: May reduce inflammation and enhance the immune response, aiding in the treatment of infections.

6) Coumarins
- Description: Compounds that can have anticoagulant effects.
- Properties: May support cardiovascular health by improving circulation.

7) Starch and Sugars
- Description: Present in the root.
- Properties: Provide energy and may have a soothing effect on the gastrointestinal tract.

3) Evaluation of Tablets

1) Physical Characteristics

A) Weight Variation

- Weight variation test was done by weighing 20 tablets individually.
- From this total weight and average weight of 20 tablets are calculated.

B) Hardness

- Monsanto hardness tester. Here, tablet is put between moving jaw and fixed jaw. Moving jaw is moved and pressure is applied on tablet by means of screw knob. The point where tablet get break down, it is recorded by means of scale. The hardness is measured in Kg/cm².

C) Friability

- The tablets should be carefully dedusted prior to testing.
- Accurately weigh the tablet sample, and place the tablets in the drum.
- Rotate the drum 100 times, with a speed of 25 rpm and remove the tablets.
- Remove any loose dust from the tablets as before, and accurately weigh.

D) Thickness and Diameter

- Measured using a caliper for uniformity.

2) In-Vitro Release Studies

A) Dissolution Testing: Conducted using a USP type II dissolution apparatus, Two media were used: 0.1 N HCl for gastric conditions and pH 6.8 phosphate buffer for intestinal conditions. Samples were taken at predetermined time intervals (1, 2, 4, 6, 8, and 12 hours) and analyzed using UV spectrophotometry.

B) Disintegration Testing

Depending on the formulation and regulatory requirements, Tablets should disintegrate within a specified time frame (e.g. within 15 minutes)

➢ The procedure for an uncoated tablet disintegration test involves the following steps

- Assemble the apparatus Add water: Add 2.5 liters 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 at 37°C ± 2°C.
- Place the tablets: Put one tablet in each 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 acc to IP

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