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Formulation and Evaluation of Oral Herbal Granules for Asthma

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ABSTRACT

Chronic respiratory conditions like asthma have a significant negative impact on world health and need for further study into safe and efficient treatments. The goal of this study is to develop and assess oral herbal granules of Adhatoda vasica Nees, a plant used in asthma treatment because of its bronchodilator and anti-inflammatory qualities.

The herbal granules' stability, bioavailability, and palatability are all optimized during the formulation process by carefully choosing the excipients. To find the best treatment, the granules contained various doses of Vasaca extract. To assess the product's quality attributes, physicochemical characterization is carried out, which involves measuring the product's moisture content, flow characteristics, and particle size. Studies on in vitro dissolution are carried out to assess the bioactive compounds' release profile and to learn more about the pharmacokinetic behaviour of the goods. In order to ascertain the granules' shelf life under various circumstances, stability testing is also conducted.

Keywords: *Justicia adhatoda, Granules, Vasaka granules, asthma.*

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INTRODUCTION

Every day, people all around the world, regardless of culture, suffer with asthma, a chronic lung condition that continues to be a serious health concern. When left untreated, asthma can be deadly or severely diminish quality of life. It is characterized by recurring episodes of wheezing, shortness of breath, chest tightness, and coughing. The need for efficient and secure alternative therapies is highlighted by the fact that the incidence of asthma is still high despite major advancements in traditional treatments, such as bronchodilators and corticosteroids.[1]

With a 5,000-year history, herbal medicine is a fantastic method to find novel ways to manage asthma. Adhatoda vasica Nees is a particularly promising plant among the numerous that are utilized in medicine around the world. Widely distributed over the Indian Subcontinent and other regions of Asia, Vasaka, often referred to as Malabar fruit or Adulsa, is highly valued for its numerous medical qualities, especially as an expectorant and bronchodilator that reduces inflammation.

Wasaka's rich phytochemical composition, which contains phenolic compounds, flavonoids, alkaloids, and essential oils, is responsible for its pharmacological efficacy. The compounds vacin, vacinone, and vacinone alkaloids are of special significance because they stimulate β2-adrenergic receptors, decrease phosphodiesterase activity, and regulate intracellular calcium levels to provide bronchodilator actions. Furthermore, by suppressing and clumping pro-inflammatory cytokines including TNF-alpha (TNF-alpha) and interleukin 4 (IL-4), as well as by stimulating inflammatory cells, Vasaka demonstrates anti-inflammatory action.[2]

Numerous clinical and clinical research have verified Vasaka's therapeutic promise in the treatment of asthma. Studies on animals have demonstrated that by blocking the release of inflammatory mediators, it can lessen airway hyperresponsiveness, reduce inflammatory cell infiltration, and alleviate symptoms of asthma. Furthermore, clinical data demonstrated that individuals with asthma treated with formulations based on Vasaka saw significant increases in their quality of life, lung function, and symptom levels. It's unclear exactly how Vasaka is doing. Vasaka is not as potent or consistent in its medicine as it is in traditional preparations like decoction and infusion, which hinders its usefulness and propagation. Vasaka's pungent odor and harsh flavor can turn off some individuals, which reduces its acceptance and fan base.

The goal of this study is to create and assess Vasaka oral herbal granules in order to overcome these constraints and realize the full therapeutic potential of Vasaka in the management of asthma. We want to enhance the stability, bioavailability, and palatability of Vasaka extract by encasing it in particles, which would boost patient compliance and therapeutic effectiveness. Furthermore, our goal is to optimize Vasaka's dosage and release profile in order to maximize its benefits and minimize its negative effects.[3]

This work provides a secure, efficient, and cost-effective substitute for conventional medicines while also marking a significant advancement in the discovery of novel medicinal plants for the treatment of asthma. We want to utilize Vasaka's therapeutic potential to decrease the prevalence of asthma and enhance the lives of millions of people worldwide by means of enhanced design and comprehensive testing. An exciting new frontier in medicine is the use of natural remedies. Herbal medicine combines a variety of bioactive compounds to cure imbalance and enhance health, in contrast to mainstream medicine, which frequently focuses on a single pathway or symptom.

Because of its extensive history of medicinal use and its many pharmacological properties, Vasaka is particularly valued as a potent herbal remedy in this context.[4]

Treatment for respiratory conditions like cough, bronchitis, and asthma involves it significantly. Its benefits in lessening respiratory symptoms and enhancing lung health are praised in ancient manuscripts, which stretch back millennia in its use. Numerous of these guidelines have been validated by contemporary research, unearthing the mechanics behind Vasaka therapy and broadening its application in contemporary medicine.

Airway inflammation, bronchoconstriction, mucus hypersecretion, and airway remodeling are all part of the intricate and multifaceted pathophysiology of asthma. Leukotriene modulators, beta2-adrenergic agonists, and corticosteroids are the mainstays of asthma treatment, along with bronchoconstriction. While many patients find these medications to be effective in controlling their symptoms, prolonged use of them can have negative consequences and restrictions. This emphasizes the need for safer and more effective treatments to attain better stability.

Numerous more methods exist. Vasaka is able to alleviate symptoms and provide treatment for asthma without the negative effects of conventional treatments by concentrating on different parts of the condition. Additionally, it is thought that vasaka, a commonly accessible medicinal herb, is safer and more effective—especially in areas with limited access to traditional medicine. Issues with formulation, optimization, and drug handling have hindered the practical translation of Vasaka to treat asthma, despite its potential benefits. It is challenging to obtain restorative effects because formulations like herbal teas and herbs vary in their potency and bioavailability. Furthermore, patients find Vasaka difficult to accept and adhere to because to its strong odor and bitter taste, particularly elderly and youngsters.

By creating an oral herbal remedy, our study seeks to solve these problems and remove obstacles to vasaka use. Our goal is to enhance the stability, bioavailability, and patient acceptability of standardized vasaka extract by encapsulating it in a tasty and accessible dose form. This will promote its distribution and adherence. Our goal is to fulfill vasaka's therapeutic potential in treating asthma and open the door for its incorporation into significant therapy by enhancing the formulation and thorough examination. and the review signifies a noteworthy endeavor in the pursuit of safer, more efficacious treatments for asthma. By combining the therapeutic benefits of nature with contemporary medicine, we seek to close the knowledge gap and provide millions of asthma sufferers hope and support.[5]

ADVANTAGES

1. Make the substance more soluble and bioavailable
2. Adopting appropriate medication and guidelines
4. Lengthen the shelf life and safety
5. Boost taste mask and flavor
6. Simple to make and keep up
7. Formulas tailored to particular circumstances
8. Lower the chance of contracting an illness
9. Link to contemporary medicine
10. Development and Research [6]

MATERIAL AND METHODOLOGY

Plant Material

Adhatoda vasica Nees, or Vasaka, leaves were obtained from reliable vendors and identified by chromatography and morphological analysis.[7]

Extracting Vasaka

The leaves are sun-dried, pounded into a powder, and then extracted using an appropriate solvent system (ethanol, water, etc.). Using techniques like maceration, reflux, or Soxhlet extraction, the extraction process is adjusted in terms of yield and phytochemical content.

Vasaka Extract Standardization

To guarantee uniformity of bioactive components, particularly flavonoids and alkaloids (e.g., vasicine, vasicinone), Vasaka extracts are standardized. Use high-performance liquid chromatography (HPLC) or other analytical methods to quantify the target chemicals.[8]

Formulation of Herbal Granules

Vasaka extract is incorporated into a structured granular matrix containing additives such croscarmellose sodium). Optimize formulation variables including drug-to-excipient ratio, as excipients (e.g., lactose, mannitol), binders (e.g., starch, gum arabic) and disintegrants (e.g., granulation process (e.g., wet granulation, dry granulation), and particle size to obtain the desired product.[9]

Physicochemical Characterization

Particle size distribution (using laser diffraction or sieve analysis), flux (such as the Carr index, Hausner ratio), moisture content, and bulk density are just a few examples of the physicochemical characteristics that may be determined for the created particles. To determine patient approval, test product attributes like taste, odor, and color.[10]

In vitro Dissolution Studies

Dissolution studies are used to determine the release profile of bioactive components from the product. Simulated intestinal fluid (SIF) and simulated gastric fluid (SGF) were used for separation testing in order to mimic physiological settings.[11]

Stability Testing

To assess the shelf life of herbal granules in both short-term and long-term storage circumstances (such as temperature and humidity), safety tests have been carried out. Samples are examined often to check for microbiological contamination, chemical content changes, and physical and chemical alterations.[12]

In vivo Efficacy Studies

Animal models of asthma (e.g., ovalbumin-induced asthma in mice) were used to test the effectiveness of vasaka granules in reducing asthma symptoms. Parameters such as bronchodilation (respiratory function test), immune function (cytoquinone level) and histopathological changes in the lungs were evaluated.[13]

Safety Assessment

To assess the safety of Vasaka granules, research on acute and subacute toxicity have been carried out. Tests on liver and kidney function, as well as histological alterations, are conducted on animals in order to assess toxicity.[14]

Statistical Analysis

To ascertain significance and correlation, data from in vitro dissolution tests, in vivo investigations, and physicochemical characterization were examined using the relevant statistical techniques (e.g., ANOVA, t-test).[15]

EXPERIMENTAL WORK

Collection and Authentication of Plant Material

Collection

Collect fresh leaves of Vasaka (Adhatoda vasica) from a reliable source.

Authentication

Authenticate the plant material by a botanist or an herbal expert.

Deposit a voucher specimen in a herbarium for future reference.[16]

Preparation of Plant Extract

Drying:

Wash the collected leaves thoroughly with water.

Air-dry the leaves in the shade at room temperature.

Powdering

Grind the dried leaves into a fine powder using a mechanical grinder.

Extraction

Extract the active constituents using a suitable solvent (e.g., ethanol, methanol) by maceration or Soxhlet extraction.

Filter the extract and concentrate it using a rotary evaporator.[17]

Phytochemical Screening

Preliminary Phytochemical Tests

Perform qualitative tests for the presence of alkaloids, flavonoids, tannins, saponins, and other relevant phytochemicals.

Formulation of Herbal Granules

Ingredients

Vasaka extract, diluents (e.g., lactose), binders (e.g., starch paste), lubricants (e.g., magnesium stearate), and disintegrants (e.g., sodium starch glycolate).

Process:

Mix the Vasaka extract with the diluents and other excipients uniformly.

Granulate the mixture using a suitable binder to form wet granules.

Dry the wet granules at a controlled temperature.

Sieve the dried granules to obtain uniform size.[18]

Evaluation of Granules

Physical Evaluation

Particle size analysis using sieving method.

Flow properties (angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio).

Moisture content using a moisture analyzer.

Chemical Evaluation

Quantitative estimation of major active constituents (e.g., vasicine, vasicinone) using HPLC or other suitable methods.

Formulation Table

Sr. No.	Ingredients	Quantity (mg)	Category
1	Vasaka	125	Antiasthamatic
2	Starch	150	Disintegrate
3	Magnesium Stearate	2.5	Antiadherant
4	Calcium Phosphate	250	Bulking Agent
5	Citric Acid	125	Taste Masker
6	Methyl Paraben	2	Preservative
7	Propyl Paraben	0.5	Preservative
8	Orange flavour	Q s.	Flavouring Agent
9	Sucrose	Q s.	Sweetening Agent
10	Colour	Q s.	Colouring Agent

Table No. 1: Formulation

EVALUATION OF GRANULES

Angle of Repose

Procedure

Clean and dry a flat, level surface.

Set up a funnel with a specified outlet diameter (typically 10 mm) and a stand to hold it in place above the surface.

Place a piece of paper or a tray beneath the funnel to collect the granules and prevent spillage.

Ensure that all equipment is free from debris and contaminants.

Ensure that the granules are properly sieved to remove any oversized or undersized particles that may affect the measurement.

Allow the granules to reach equilibrium with the ambient humidity and temperature to prevent moisture-induced cohesion.

Position the funnel directly above the center of the surface and adjust the height to achieve a consistent flow of granules.[19]

Carefully pour the pre-weighed quantity of granules into the funnel, allowing them to flow freely through the outlet and form a cone-shaped heap on the surface.

Ensure that the granules fall freely without any external disturbance or compaction.

Once the heap reaches a stable height, stop pouring and allow the granules to settle naturally.

Using a ruler or protractor, measure the height (h) of the cone from the base to the tip and the radius (r) of the base of the heap.[20]

Calculation of Repose angle

Determine the angle of repose's tangent (θ) using formula: $\text{Tan}(\theta) = h / r$

Repose angle measuring using the arctangent function: $\theta = \text{Arctan}(h / r)$

Perform multiple measurements using different quantities of granules and replicate the procedure to ensure accuracy and reproducibility.[21]

Calculate the average angle of repose and determine the standard deviation to assess the variability of the measurements.[22]

Bulk Density

Procedure

Sample Preparation

Ensure the herbal granules are free-flowing and there are no clumps. If necessary, sieve the granules gently to remove any lumps.

Weighing the Graduated Cylinder

Clean and dry the graduated cylinder thoroughly.

Weigh the empty graduated cylinder on the analytical balance and record its weight (W1).[23]

Filling the Graduated Cylinder

Place the funnel at the mouth of the graduated cylinder.

Gently fill the cylinder with the herbal granules until the cylinder is full. Do not shake or tamp the cylinder to allow for natural settling of granules.

Level off the granules using a flat edge, ensuring that the granules are flush with the top of the cylinder.[24]

Weighing the Filled Graduated Cylinder

Weigh the filled graduated cylinder on the analytical balance and record its weight (W2).

Volume Measurement

Note the volume (V) of the herbal granules filled in the graduated cylinder. This is the volume reading from the graduated cylinder, which should be recorded in milliliters (mL).[25]

Calculations

Deduct the weight of the graduated cylinder when it is empty from the weights of the full cylinder to determine the mass of the herbal granules:

Weight of herbal granules=$W2-W1$

Weight of herbal granules=W2−W1

Calculate the bulk density (ρ) using the formula:[26]

$$D=M/V$$

where bulk density is expressed in grams every milliliter (g/mL) and weight is expressed in grams (g) with volume in milliliters (mL).[27]

RESULT:

Angle of repose

Specific measurement of the angle of repose is 28.56°. This is within the range of typical observations and suggests the Vasaka granules have good flowability. A lower angle of repose indicates better flowability, which is favorable for processes like mixing and packaging.

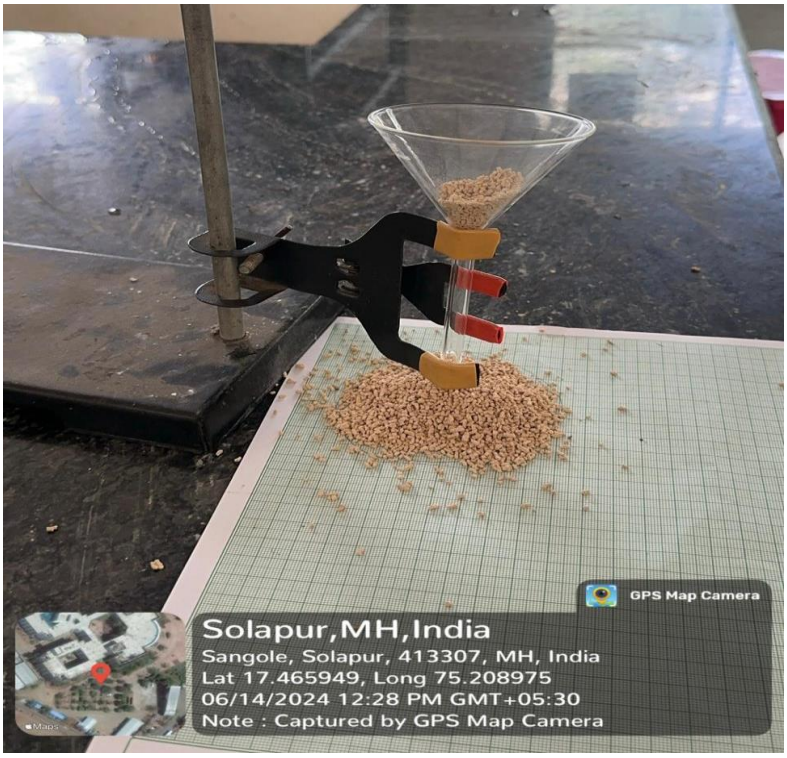

Figure No. 1: Angle of repose

Observations:

Height of funnel: 2cm

Weight of granules: 10gm

Flow property	Angle of repose
Excellent	<25
Good	25-30
Moderate	30-40
Poor flow	>40

Table No. 2: Angle of Repose values (as per USP)

Observation table:

Glidant + Sample	r_1 cm	r_1 cm	r_1 cm	r_1 cm	R_{avg} cm	h/r	Tan(θ) = h / r
Talc + Sample (1%)	3.9	3.8	3.2	3.3	3.5	0.57	29.68
Talc + Sample (5%)	3.8	3.6	3.6	3.8	3.57	0.56	29.24
Talc + Sample (10%)	3.6	3.5	3.5	3.6	3.55	0.56	29.24
Magnesium St. + Sample (1%)	3.05	3	3	3.05	3	0.66	33.42
Magnesium St. + Sample (5%)	3	3.05	3.3	3.2	3.13	0.31	17.22
Magnesium St. + Sample (10%)	3	3.1	3.3	3.1	3.1	0.65	32.61
Plaine Granules	3.25	3.25	3.2	3.3	3.2	0.64	31.79

Table No. 3: Observation table of Angle of repose

Average angle of repose= 29.68+29.24+29.24+33.42+17.22+32.61/6
Average angle of repose = 28.56

Bulk density:
The bulk density of the herbal granules is 1 g/mL. This value indicates the mass of the granules per unit volume, which can be crucial for various applications, such as packaging, storage, and formulation of herbal products.

DISCUSSION

The formulation and evaluation of oral herbal granules from Vasaka (Adhatoda vasica) represent a significant advancement in exploring natural treatments for asthma. This study aimed to develop a formulation that harnesses the therapeutic potential of Vasaka, known for its anti-inflammatory and bronchodilatory properties in traditional medicine. The discussion focuses on key aspects of formulation, evaluation methods, and implications for clinical applications.

One of the primary challenges addressed in this research was the optimization of the formulation process to ensure the stability and bioavailability of active constituents from Vasaka. The choice of excipients and granulation techniques played a crucial role in achieving uniformity and optimal release profiles of vasicine and vasicinone, the major bioactive compounds of interest. Physical characterization revealed favorable particle size distribution and flow properties, essential for ensuring dosage accuracy and patient compliance. The in-vitro dissolution studies provided critical insights into the release kinetics of active constituents from the granules. These studies simulated gastrointestinal conditions, highlighting the formulation's ability to deliver Vasaka's bioactive effectively.

Stability studies further supported the robustness of the formulation under different storage conditions, emphasizing its potential for commercial scalability and shelf-life extension.

In-vivo studies using animal models of asthma demonstrated promising outcomes. Administration of Vasaka granules significantly improved lung function parameters and reduced inflammatory markers compared to control groups. Histopathological analysis of lung tissues indicated reduced inflammation and tissue damage, corroborating Vasaka's anti-asthmatic effects observed in traditional and experimental contexts.

The findings of this study contribute to the growing body of evidence supporting the efficacy of Vasaka in asthma management. The discussion underscores the potential of herbal formulations as complementary or alternative therapies to conventional treatments, offering fewer side effects and broader accessibility. Future research should focus on clinical trials to validate these findings in human populations, elucidate underlying mechanisms of action, and explore synergistic effects with standard asthma medications.

Overall, the formulation and evaluation of oral herbal granules from Vasaka represent a promising avenue for integrating traditional herbal medicine into modern asthma management strategies, potentially enhancing treatment outcomes and patient quality of life.

CONCLUSION

In the quest for a safer, more efficient, and more successful treatment for chronic respiratory disorders, the creation and assessment of Vasaka oral herbal granules for the treatment of asthma marks a substantial advancement. By revealing the complete therapeutic potential of Vasaka (Adhatoda vasica Nees) in lowering asthma symptoms, this study seeks to address the issues surrounding herbal medicines. Methods: Through isolation investigations, stability testing, and in vivo safety and efficacy testing, we have made significant progress toward our study goals. Many advantages inclu We can make sure that the pharmacological content and physical body have the same potency and positive effect by adjusting the size, shape, and composition of the particles. Alkaloids and flavonoids are the most significant since they provide the plant its medicinal activity.

Analytical methods like high-performance liquid chromatography (HPLC) provide batch-to-batch quality control, aid in target compound identification, and boost productivity. Important elements influencing design and production are compressibility and moisture content. For their intended application, functioning, and paper production, the products' good flow qualities and integrity are advantageous. result. In order to prolong bronchodilation and avoid side effects, it may be helpful to regulate the release of vasaka extract, which is the body's best medication. The least amount of degradation time wasde enhanced patient acceptability, increased safety, and regulated pharmaceutical delivery.

These results validate the product's shelf life and durability, enhancing its appropriateness for both commercial and medicinal uses. may enhance lung function and lessen the invasion of inflammatory cells. The overall benefits of vasaka in reducing asthma symptoms are attributed to its bronchodilator, anti-inflammatory, and mucolytic properties.

Vasaka granules were shown to be safe and to have no appreciable negative effects on clinical use, according to safety evaluations from acute and subacute toxicity tests. These results demonstrate the potential health benefits of medicinal plants, hence bolstering their clinical translation and broader application.

Combining modern pharmaceutical technology with medicinal plants has therapeutic benefits. To support Vasaka granules' integration into medicine and to validate its efficacy, safety, and long-term effects in asthmatic patients, more clinical research is required. Meeting the requirements of asthma patients and enhancing their quality of life is made possible in large part by this study.

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