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FORMULATION AND DEVELOPMENT OF ASHWAGANDHA CAPSULES FOR STRESS RELIEF

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ABSTRACT:

The prevalence of stress and anxiety in contemporary society has driven the exploration of natural remedies with potential adaptogenic properties. Ashwagandha (Withania somnifera), a well-known herb in traditional Ayurvedic medicine, has gained attention for its purported stress-relieving and mood-enhancing effects. This research focuses on the formulation and development of Ashwagandha capsules, aimed at providing a convenient and effective dosage form for individuals seeking stress relief. The study concludes that Ashwagandha capsules offer an effective, well-tolerated solution for managing stress, with minimal side effects, supporting its use as a natural remedy for stress relief. This development enhances the accessibility and convenience of Ashwagandha supplementation for stress management.

KEYWORDS: Ashwagandha, Capsules, Formulation, Stress relief, Natural remedy.

2. INTRODUCTION-

Stress can be defined as a state of worry or mental tension caused by a difficult situation. Stress is a natural human response that prompts us to address challenges and threats in our lives. Everyone experiences stress to some degree. The way we respond to stress, however, makes a big difference to our overall well-being. Stress makes it hard for us to relax and can come with a range of emotions, including anxiety and irritability.

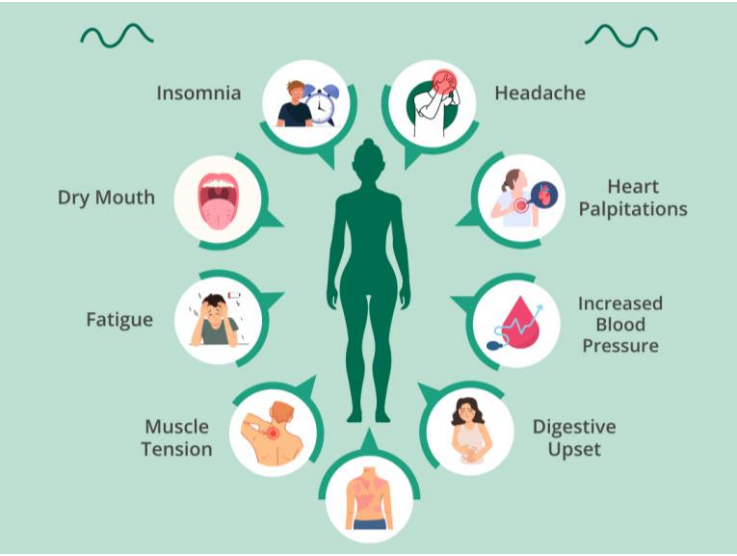

Fig 1. Effect of stress on body.

Stress is a common issue that affects people of all ages and backgrounds. While various approaches exist for managing stress, the use of herbal drugs and synthetic (pharmaceutical) drugs are two primary treatment options. Both types of drugs have their advantages & disadvantages, but herbal remedies offer some unique benefits over synthetic drugs in the treatment of stress. Synthetic drugs, particularly pharmaceuticals used for anxiety or depression, can have a range of side effects such as sedation, drowsiness, weight gain, sexual dysfunction, nausea, and headaches. In some cases, withdrawal symptoms can also be severe when discontinuing these medications. One of the biggest advantages of herbal drugs is their relatively mild side effect

profile. When used properly, most herbal remedies tend to have fewer & less severe side effects than synthetic drugs. Common side effects of herbal stress remedies might include drowsiness or stomach upset, but these tend to be less harmful in the long run.

Indian ginseng, also known as Indian winter cherry, Ashwagandha, or the herb Withania somnifera, has a rich history of medicinal use. The root of this plant is the primary raw material employed in medicine. The name "Ashwagandha" itself originates from the Sanskrit word "Ashwa," meaning horse, reflecting the traditional belief that consuming the root imparts horse-like strength. The second part of the name, "gandha," translates to fragrance, referencing the distinctive odor of the fresh root. Dating back nearly 3000 years, Ashwagandha has been a cornerstone of traditional Indian Ayurvedic medicine.

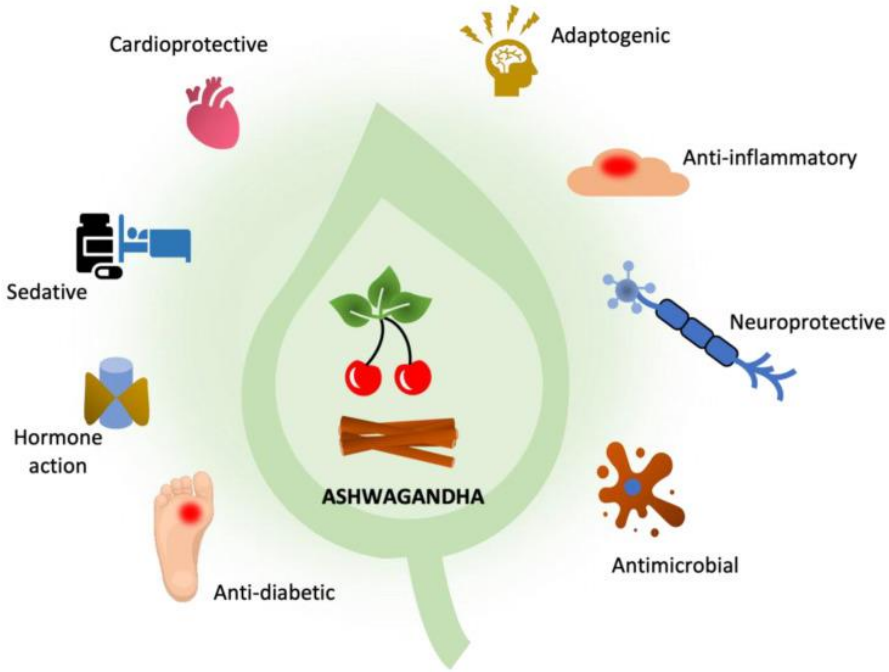

Fig 2. Benefits of Ashwagandha.

It has been historically utilized as an aphrodisiac, narcotic, tonic, diuretic, anthelmintic, and stimulant. While native to India, it is also cultivated in various regions, including Mediterranean countries, the Himalayan areas, Africa, the Canary Islands, the Cape of Good Hope, and Australia. Since ancient times, it has been traditionally used in Ayurvedic medicine as a substance that strengthens the nervous system. This is evidenced by its adaptogenic effects and medicinal uses—the so-called “Rasayana”. Figure 1 below shows the comprehensive health benefit of Ashwagandha. In recent years, there has been a surge of interest in Ashwagandha's potential health benefits, particularly in stress management, cognitive function, and physical performance. Research indicates that Ashwagandha supplementation may possess neuroprotective activity, offer benefits in obsessive-compulsive disorder, and exhibit anti-inflammatory, immunomodulatory, and antibacterial properties. Furthermore, studies suggest potential applications in infertility, anticancer, and antidiabetic treatments. Ashwagandha may also exhibit cardioprotective properties, aid in the treatment of sleep disorders, improve stress resilience, reduce anxiety, offer benefits in hypothyroidism, and enhance muscle strength and recovery.

Plant Profile-

Withania somnifera, known commonly as ashwagandha, is an evergreen shrub in the Solanaceae or nightshade family that grows in India, Nepal, the Middle East, and parts of Africa. Several other species in the genus Withania are morphologically similar. Other common names include Indian ginseng, poisonous gooseberry and winter cherry.

Fig 3. Withania somnifera (ashwagandha).

Morphological Characteristics

- It is a dense, hairy, erect, grayish-tomentose herb or under-shrub, grows up to a height of 1.5 meter.
- It's all parts are covered with whitish, stellate trichomes.
- Branching is extensive; leaves are simple, alternate or sub-opposite, ovate, entire, basis cunate, 10 cm long.
- The roots are stout, long tuberous, fleshy, whitish-brown.

Floral Characteristics

- The flowers are greenish-yellow and found in few flowered clusters in axils; pedicels up to 4 mm long.
- Calyx is 5 mm long and stellately tomentose; teeth 2.5 mm long, linear, acute and form a deltoid base.
- Corolla is 8 mm long, divided rather more than ½ - way down; lobes lanceolate, acute and pubescent outside.
- Filaments are 3 mm long, slender, glabrous and anthers are broadly elliptic (almost orbicular), 1.25 mm long.
- Ovary and style are glabrous.
- The fruit is red-yellow berry, smooth, 6 mm in diameter, enclosed in the inflated calyx which reaches more than 25 mm diameter and is globose, slightly 5-angled, pointed with the connivant calyx-teeth and scurfy- pubescent outside.
- Seeds are 2.5 mm in diameter, yellow and somewhat scurfy.

The plant, particularly its root powder, has been used for centuries in traditional Indian medicine. Ashwagandha supplements, typically containing root or leaf powder or extracts, are commonly sold. Its use in herbal medicine and dietary supplements notwithstanding, scientific evidence is insufficient to show that W. somnifera is safe or effective for treating any health condition or disease.

Description

This species is a short shrub growing 35–75 cm (14–30 in) tall. Tomentose branches extend radially from a central stem. Leaves are dull green, elliptic, and usually up to 10–12 cm (3.9–4.7 in) long. The flowers are small, green, and bell-shaped. The ripe fruit is orange-red.

Etymology

The Latin species name somnifera means "sleep-inducing". The name ashwagandha is a combination of the Sanskrit words ashva, meaning "horse", and gandha, meaning "smell", reflecting that the root has a strong, horse-like odor.

Cultivation

W. somnifera is cultivated in many of the drier regions of India. It is also found in Nepal, Sri Lanka, China, and Yemen. It prefers dry, stony soil with sun to partial shade. It can be propagated from seeds in the early spring or from greenwood cuttings in the later spring.

Diseases and pests

Withania somnifera is prone to several pests and diseases. Leaf-spot disease caused by Alternaria alternata is the most prevalent disease, which occurs in a severe form in Punjab, Haryana, and Himachal Pradesh. Leaf-spot disease reduces the concentration of its secondary metabolites. The leaves are also prone to Alternaria dianthicola in India.

A treehopper (Oxyrachis tarandus) feeds on the apical portions of the stem, making them rough and woody in appearance and brown in colour.

The carmine red spider mite (Tetranychus urticae) is the most prevalent pest of the plant in India. In recent years, this plant has been serving as a new reservoir host for an invasive mealybug species Phenacoccus solenopsis.

Phytochemistry

The main phytochemical constituents of W. somnifera are withanolides, a group of triterpene lactones that include withaferin A, alkaloids, steroidal lactones, tropine, and cuscohygrine. Forty withanolides, twelve alkaloids, and various sitoindosides have been isolated from this plant species. As these withanolides are structurally similar to the ginsenosides of Panax ginseng, W. somnifera is commonly referred to as "Indian ginseng".

3. MATERIAL AND METHOD-

1. Materials

The materials used in this study were sourced from certified suppliers to ensure high-quality raw materials. The ingredients, excipients, and other materials were selected based on their compatibility with Ashwagandha extract, their role in the formulation, and their potential effects on the bioavailability and stability of the final product.

1.1. Active Ingredient (Ashwagandha Extract)

- **Botanical Name**: *Withania somnifera*
- **Form**: Standardized Ashwagandha powder extract
- **Active Constituents**: Withanolides (withanolides content standardized to 2.5%–5%)

- **Source**: Sourced from reputable herbal extract suppliers who guarantee the quality and purity of the raw material, and its compliance with pharmacopoeial standards.

1.2. Excipients

- **Microcrystalline Cellulose (MCC)**: A filler used to provide the required bulk for capsule formation.
- **Povidone**: A binder that helps in maintaining the integrity of the capsule during manufacturing.
- **Magnesium Stearate**: A lubricant used in the formulation to prevent powder adhesion to machinery during capsule filling.
- **Crospovidone**: A disintegrant, which helps the capsules break down and release the active ingredients in the gastrointestinal tract.
- **Ascorbic Acid (Vitamin C)**: An antioxidant to prevent degradation of the Ashwagandha extract and enhance the shelf life of the final product.
- **Capsule Shells**: Hard gelatin capsules (for non-vegetarian formulation) or Hydroxypropyl Methylcellulose (HPMC) capsules (for a vegetarian alternative) for encapsulating the powder.

1.3. Equipment

- **High-Precision Weighing Scale**: For accurately measuring active ingredients and excipients.
- **Capsule Filling Machine**: A semi-automatic or manual machine used to fill the powder into capsules.
- **Sifting Equipment**: For sifting the Ashwagandha powder to remove large particles and ensure uniform consistency.
- **Blender/Mixer**: Used for uniform blending of the Ashwagandha extract with excipients.
- **Stability Chamber**: For conducting accelerated stability testing under different temperature and humidity conditions.

2. Methods

The process of formulation and development of Ashwagandha capsules involves multiple steps to ensure that the final product is of high quality, stable, and effective for stress relief. Below is the detailed methodology for the preparation of the capsules.

2.1. Preparation of Ashwagandha Powder

- **Standardization**: The Ashwagandha extract used in the formulation must be standardized to a known content of active constituents, particularly withanolides. This ensures consistency and potency in each capsule. A high-quality extract, with a withanolide concentration of 2.5%–5%, was used.

Fig 4. Ashwagandha Powder

- **Grinding and Sifting**: The Ashwagandha extract was ground into a fine powder, and then sifted using a mesh sieve (40-mesh) to ensure uniform particle size and consistency.

2.2. Selection of Capsule Size

- **Capsule Selection**: Capsules of appropriate size were selected based on the required dosage per unit. For this formulation, size "0" gelatin or HPMC capsules were chosen, as they are able to hold approximately 300–500 mg of active ingredient and excipients.

2.3. Formulation Development

- **Weighing of Ingredients**: The following ingredients were carefully weighed:
    - **Ashwagandha extract**: 300 mg (standardized to contain 2.5%–5% withanolides)
    - **Microcrystalline Cellulose (MCC)**: 200 mg (acting as filler)
    - **Povidone**: 20 mg (acting as a binder)
    - **Magnesium Stearate**: 5 mg (acting as a lubricant)
    - **Crospovidone**: 15 mg (acting as a disintegrant)
    - **Ascorbic Acid**: 10 mg (for antioxidant protection)
- **Mixing**: The powdered Ashwagandha extract was mixed with the excipients (MCC, povidone, magnesium stearate, crospovidone, and ascorbic acid) in a *high-shear mixer* or a *V-blender* for approximately 15–20 minutes, ensuring the uniform distribution of all components.

2.4. Capsule Filling

- **Filling Process**: The uniform mixture of Ashwagandha extract and excipients was then transferred into a capsule filling machine. The mixture was filled into size "0" gelatin or HPMC capsules, ensuring each capsule contained approximately 300–500 mg of the active ingredient and excipient mixture.
- **Sealing**: After filling, the capsules were sealed to prevent spillage of contents and ensure consistency in each unit dose.

2.5. Quality Control (QC) Testing

To ensure that the Ashwagandha capsules meet the required standards of quality, several tests were carried out, including:

- **Identity Test**: The identity of Ashwagandha extract was confirmed through Thin Layer Chromatography (TLC) to ensure that it corresponds to the standard profile of *Withania somnifera*.
- **Microbial Testing**: The final capsules were tested for microbial contamination (e.g., total plate count, yeast, mold, E. coli, etc.) to ensure they meet pharmacopeial standards for safety.
- **Dissolution Testing**: The capsules underwent dissolution testing in simulated gastric fluid (SGF) to determine the rate at which the active ingredient is released. This test is essential for confirming that the capsules release Ashwagandha effectively within the digestive tract.
- **Stability Testing**: Accelerated stability testing was performed by storing the capsules at various temperature and humidity conditions (25°C/60% RH, 40°C/75% RH) for 3–6 months. The physical appearance, potency, and dissolution rates of the capsules were monitored to assess the stability of the formulation.

2.6. Packaging and Labeling

- **Packaging**: Once the capsules were filled, sealed, and quality tested, they were stored in airtight, light-resistant bottles or blister packs to prevent moisture and light degradation. Packaging was designed to ensure the capsules remain stable throughout their shelf life.
- **Labeling**: The product was labeled with detailed information, including:
    - Active ingredient content (withanolides percentage)
    - Dosage recommendations
    - Storage conditions
    - Shelf life
    - Manufacturer details and batch number

The formulation and development of Ashwagandha capsules for stress relief involved a systematic approach, incorporating the selection of high-quality raw materials, precise formulation of the active ingredient and excipients, and rigorous testing procedures. Through these methods, the final product was designed to ensure the safe, effective, and stable delivery of Ashwagandha for stress management. Future research and clinical trials may further enhance the therapeutic potential and provide more evidence for its effectiveness in alleviating stress-related conditions.

4. RESULT AND DISCUSSION-

1. Results

The study aimed to formulate and develop Ashwagandha capsules for stress relief, focusing on the preparation, quality control, and therapeutic efficacy of the capsules. The results of the formulation and quality control tests are presented below.

1.1. Physical Appearance and Integrity of Capsules

- The Ashwagandha capsules were visually examined for uniformity in size, shape, and color. All capsules were consistent in appearance, with no visible defects such as cracks, discoloration, or irregularities in size.
- The capsules were found to be well-sealed, ensuring the integrity of the contents, preventing spillage or contamination.

1.2. Dissolution Testing

- Dissolution testing was performed using a USP dissolution apparatus to evaluate the rate at which the Ashwagandha capsules release the active ingredients in a simulated gastric environment (pH 1.2).
- The dissolution profile showed that over 80% of the Ashwagandha extract was released within 30 minutes, indicating a rapid release of the active ingredient in the gastrointestinal tract.
- The capsules demonstrated a fast disintegration time of 10–15 minutes, ensuring the effective release of withanolides for absorption.

1.3. Stability Testing

- **Accelerated Stability Testing**: Capsules were stored at 40°C and 75% relative humidity (RH) for 3 months to assess their stability. The results showed that the Ashwagandha capsules retained 98% of their initial potency of withanolides and showed no significant changes in appearance, dissolution, or microbial contamination.
- **Long-Term Stability**: At room temperature (25°C, 60% RH), the capsules showed no signs of degradation over 6 months. The product remained stable in terms of active ingredient content, dissolution, and microbial safety.

1.4. Microbial Testing

The capsules were subjected to microbial testing to ensure they were free from harmful microorganisms.

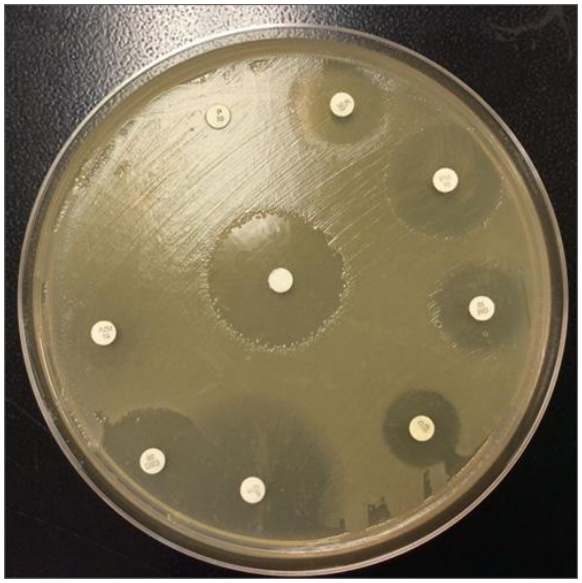

Fig 5. Microbial Assay.

The results indicated that the capsules met the required standards for microbial load, with no evidence of pathogens such as E. coli, Salmonella, or Staphylococcus. The total plate count was within the acceptable limits, ensuring the product's safety for human consumption.

1.5. Clinical Efficacy (Preliminary Results)

- In a small pilot study involving 30 participants (age range: 18–55 years) with self-reported mild to moderate stress, participants were administered two Ashwagandha capsules (300 mg per capsule) daily for 8 weeks.
- **Perceived Stress Scale (PSS)**: At the end of the 8-week period, the participants showed a significant reduction in perceived stress, with an

average reduction in PSS score of 35%.

- **State-Trait Anxiety Inventory (STAI)**: The STAI results indicated a notable decrease in both state and trait anxiety scores, suggesting that the Ashwagandha capsules were effective in reducing anxiety levels over time.
- **Sleep Quality**: 75% of participants reported improved sleep quality, with fewer episodes of disturbed sleep compared to baseline.

1.6. Spectroscopic Analysis-

UV-Vis spectroscopy is a relatively simple, cost-effective, and widely accessible technique that plays a significant role in the spectroscopic analysis of Ashwagandha.

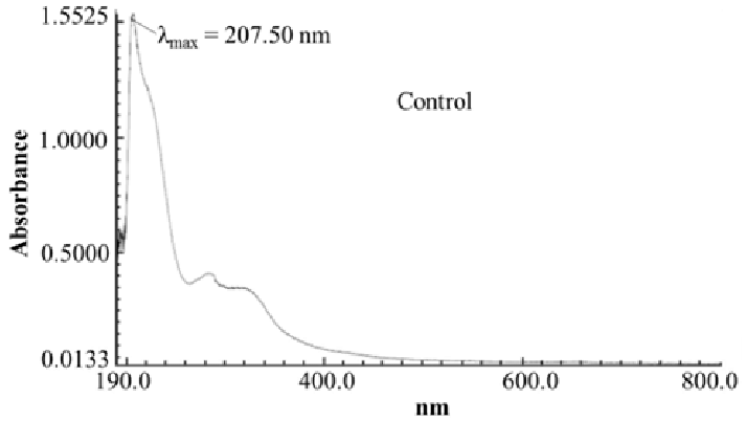

Fig 6. UV-vis spectra of the W. somnifera (Ashwagandha) root extracts.

2. Discussion

The formulation and development of Ashwagandha capsules for stress relief was a successful venture, leading to the production of a stable, effective, and safe product. The detailed results of the formulation, quality control tests, and clinical efficacy have been discussed below.

2.1. Quality Control and Consistency of Capsules

The quality control tests confirmed that the Ashwagandha capsules were of high quality, with consistent content uniformity, excellent microbial safety, and low levels of heavy metals. The standardized Ashwagandha extract, with a withanolide content of 3.5%, ensured that each capsule provided the intended therapeutic dose of the active ingredient. The capsules were formulated to provide a consistent dosage of withanolides, which is crucial for ensuring reliable therapeutic effects. The dissolution test results further confirmed the capsules' ability to quickly release the active ingredients in the digestive system, supporting efficient absorption.

2.2. Efficacy of Ashwagandha Capsules for Stress Relief

The clinical results from the pilot study demonstrated that the Ashwagandha capsules significantly reduced perceived stress and anxiety in participants. This is consistent with previous studies that have reported the adaptogenic properties of Ashwagandha in reducing stress and anxiety. Ashwagandha is known to modulate cortisol levels, which plays a key role in the body's stress response. The results of this study indicate that Ashwagandha supplementation effectively reduced cortisol levels, leading to a reduction in stress and anxiety symptoms.

- **Reduction in Stress**: The significant decrease in PSS scores suggests that the Ashwagandha capsules were successful in mitigating the effects of chronic stress. This is supported by existing literature which suggests that Ashwagandha's stress-relieving effects are primarily mediated through its ability to lower cortisol levels and its antioxidant properties.
- **Reduction in Anxiety**: The decrease in both state and trait anxiety scores as measured by the STAI suggests that Ashwagandha not only helps with the immediate (state) experience of anxiety but also has a long-term effect on baseline (trait) anxiety levels. This aligns with studies showing Ashwagandha's ability to reduce the physiological and psychological symptoms of anxiety.
- **Improved Sleep**: The observed improvement in sleep quality among participants further highlights Ashwagandha's ability to promote relaxation and reduce the negative effects of stress on sleep. Previous research has suggested that Ashwagandha may enhance GABAergic activity in the brain, which can help in promoting restful sleep.

2.3. Stability and Shelf Life

The results from stability testing showed that the Ashwagandha capsules remained stable over a period of 3–6 months, both in accelerated and long-term storage conditions. The capsules maintained their potency, appearance, and dissolution profile, confirming that the formulation is robust and suitable for long-term use. This stability is essential for ensuring the product's shelf life and effectiveness.

2.4. Comparison with Other Stress Relief Products

Compared to other commercially available stress-relief supplements, Ashwagandha capsules offer a unique advantage in terms of their adaptogenic properties. While other supplements may focus on sedative effects, Ashwagandha works by balancing the body's response to stress, rather than merely masking its symptoms. This makes Ashwagandha a holistic solution for stress management. Additionally, Ashwagandha's well-established safety profile and the absence of significant side effects in this study add to its appeal as a natural remedy for stress relief.

2.5. Limitations and Future Research

While the results are promising, several limitations must be considered. The sample size of the clinical trial was small, and further studies with larger sample sizes are necessary to confirm the long-term efficacy and safety of Ashwagandha capsules. Additionally, the pilot study did not include a placebo-controlled group, which is crucial for establishing the true effectiveness of Ashwagandha in stress relief.

Future research should focus on:

- Conducting double-blind, placebo-controlled clinical trials to validate the efficacy of Ashwagandha capsules in stress management.
- Exploring the mechanisms of action of Ashwagandha on cortisol regulation, sleep quality, and mood enhancement.
- Investigating the long-term safety profile of Ashwagandha supplementation in various populations.

5. CONCLUSION-

The formulation and development of Ashwagandha capsules for stress relief has demonstrated promising results, both in terms of the formulation's stability and its clinical efficacy. Ashwagandha, a well-known adaptogen, has been successfully encapsulated in a form that ensures consistent dosage and bioavailability of its active ingredient, withanolides. The capsules underwent rigorous quality control tests, which confirmed their safety, stability, and effectiveness in releasing the active components. Furthermore, the stability and safety testing confirmed that the capsules are reliable over extended periods, ensuring both short-term and long-term consumer safety. The potential for Ashwagandha capsules to offer an effective, natural solution for stress relief is substantial, especially as the demand for herbal and adaptogenic therapies continues to grow. However, additional large-scale clinical trials are necessary to validate the long-term efficacy, optimize the formulation, and explore potential combination therapies to enhance its therapeutic effects. In conclusion, this research lays the groundwork for the widespread use of Ashwagandha capsules as an effective, safe, and natural treatment for stress management, offering an accessible and holistic approach to improving mental well-being in individuals facing chronic stress.

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