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Formulation & Evaluation of Herbal Nutraceutical Tablet for the Prevention of Insomnia from Ashwagandha & Shilajit

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ABSTRACT
Herbal tablets are solid dosage forms of powdered herbs, herbal extracts or their ingredients prepared by compression. They vary greatly in shape, size, and weight which depend on the amount of drug used and mode of administration. Pharmaceutical oral solid dosage forms have been used extensively form long time, substantially due to their ease of administration and suitability for systemic medicine delivery. Withania somnifera member of Solanaceae family generally known as Ashwagandha, Indian Ginseng, or winter cherry has been used in Ayurveda, Indian system of traditional medicine. Ashwagandha root is among the most well known herbal medicine used in Ayurveda, a comprehensive system of medicine that originated in India. Ashwagandha is referred to as the "Prince of Herbs" in Ayurveda because it has an impressively wide range of remedial effects. The treatment of numerous terrible diseases in the modern day has benefited greatly from the traditional. Ashwagandha powder, an ayurvedic medicament made from the herb withania somnifera is used to treat a variety of conditions including osteoarthritis, type 2 diabetes, anxiety-related issues, and tumour mending capabilities. It's an unique Indian herb, has significant stress-relieving properties analogous to those of powerful medicines used to treat depression and anxiety.
In this research study, we had tried to formulate and evaluate the herbal sustained release tablet for the prevention of insomnia from ashwagandha & shilajit and evaluated the granules properties such as bulk, tapped density, angle of repose, etc.

Keyword - *Withania somnifera, insomnia, Conventional treatments, Shilajit , Lavendula angustifolia,*

1. INTRODUCTION

Sleep is a crucial aspect of human health that plays a vital role in cognitive function, emotional regulation, physical health, and quality of life. However, sleep disorders, particularly insomnia, have become increasingly prevalent in modern society. About 50–70 million adults in the United States experience sleep disorders, with insomnia being the most common. Insomnia is characterized by difficulty falling asleep, maintaining sleep, or obtaining restful sleep, which causes daytime impairments such as fatigue, mood disturbances, and decreased performance. Conventional treatments for insomnia often involve pharmacological treatment, such as benzodiazepines and non-benzodiazepine hypnotics. Although these medications can be effective in the short term, they are associated with various side effects, such as dependence, tolerance, and adverse reactions. Moreover, long-term use of these hypnotics can lead to rebound insomnia and withdrawal symptoms upon discontinuation. Given the limitations and potential risks associated with pharmacological treatments, there has been growing interest in alternative and complementary approaches for managing sleep disorders. Herbal and natural supplements have gained popularity as potential sleep aids because of their perceived safety, lower risk of dependence, and fewer side effects than conventional medications. These supplements often contain compounds with sedative, anxiolytic, or sleep-

promoting properties, such as flavonoids, terpenes, and amino acids. The use of herbal and natural supplements for sleep has been documented in various traditional medicine systems [1].

Insomnia is defined as a situation in which a patient is too sleepy in terms of which continues to exacerbate daily functioning. Unlike, insomnia is not just a disease that causes shorter nighttime sleep is because the problem is much more complicated and involves many complications.

Insomnia is thought to be difficult to sleep, difficulty maintaining sleep, or can wake up too much with. All of these symptoms can also occur with good sleep hygiene. The occurrence of these disorders adversely affects adequate presence, problem concentration, affective disorders, cognitive disorders, and lack of motivation to affect both professional and social life of. Researchers around the world agree that insomnia affects 4,444 women more frequently than men. Age is also a factor in insomnia. Unfortunately, has a significant increase in the proportion of people taking sleeping pills, indicating the magnitude of insomnia. Nevertheless, it is assumed that a condition has been diagnosed. Epidemiological data differs from countries, and this could be the reason for various ways to diagnose this disorder. It is also worth noting that sleep is about 30% of human life. Therefore, the conclusion greatly disrupts the homeostasis of the organism. Because many current sleeping pills have side effects, it is assumed that Herbal Agent can provide alternative therapy for insomnia. This study significantly improved the distribution of ashwagandha root extracts (300 mg of extract was administered twice daily) in patients, resulting in a faster and faster. Researchers believe this could be a treatment for people suffering from insomnia and anxiety. However, is required. Research has also been conducted in elderly people aged 65 to 80 to assess the security, effectiveness and tolerability of Ashwagandha root Extract [2].

Depending on its focus, nutraceuticals typically contain the necessary amounts of fats, protein, carbs, vitamins, minerals, and other nutrients. There are both traditional and non-traditional foods in the market for nutraceuticals. The nutrients in supplement tablets must be absorbed and digested by the body after consumption. items such as dietary supplements, herbal items, processed meals, and separated nutrients can all be classified as nutraceuticals. In 1994, the "Dietary Supplements Health and Education Act" (DSHEA) was created in the United States due to the increasing opposition of patients over synthetic therapeutic medicines and their toxicological profile. By increasing the supply of natural building blocks, nutraceutical dosage forms are thought to give functional benefits [3].

2. Drug Profile

2.1. Ashwagandha- The plant Withania somnifera (L.) Dunal, which belongs to the Solanaceae family, is commonly referred to as "ashwagandha" in Sanskrit because of its usage in Indian traditional medicine. As a Rasayana herb—one that may revitalize the body and support the health of all the tissues—Withania somnifera (WS) has a strong reputation in Ayurvedic treatment. WS is consequently also categorized as an adaptogen, which is a substance that supports homeostasis throughout the body through more than 100 formulations in Ayurvedic, Unani, and Siddha medicine, in addition to one particular pharmacological mechanism. complex answers as well. As well as offering resistance against infections and illnesses, WS is said to have the capacity to enhance mood, memory, and focus. illness. [4]. Found in the less humid parts of tropical and subtropical zones, such as the Canary Islands, the Mediterranean, Africa, China, South Asian nations as India and Sri Lanka, and the Middle East, the WS plant is a woody shrub that grows to a height of 0.5-2 meters. Due to its adaptogenic properties, it is often referred to as "Indian Ginseng," Indian Winter Cherry, or Poison Gooseberry in English, Ashwagandha in Sanskrit, and Asgand in Urdu. More than 100 formulas of Ayurvedic, Unani, and Siddha medicine use WS, which is frequently grown for therapeutic purposes in India. feature the capacity to improve your mood, memory, and memory in in addition to offering immunity against infections and sickness. Illness [4]

- **Molecular Formula-** $C_{28}H_{38}O_6$
- **Molecular Weight-** 470.6 g/mol

- **Family-** Solanaceae
- **Uses-** Antistress, Depression, Joint pain.
- **Solubility -**Soluble in water
- **Appearance -**Whitish cream fine powder

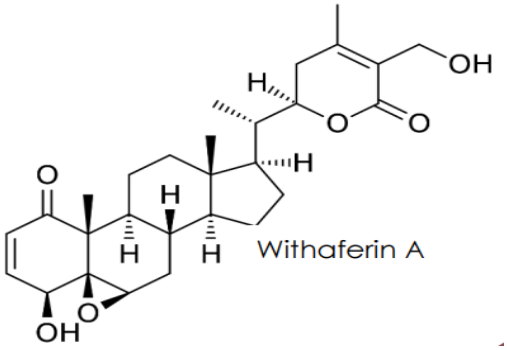

Fig.1 Chemical Struture of Ashwagandha

2.2 Shilajit- Shilajit is a blackish-brown powder or exudate from high mountain rocks, particularly in the Himalayans between India and Nepal. It is also known in the north of India as salajit, shilajatu, mimie, or mummiyo. It has also been found in Russia, Tibet, Afghanistan, and, more recently, the north of Chile, where it is known as Andean Shilajit. Shilajit has been utilized as an antiaging and rejuvenating ingredient in Ayurvedic therapy for millennia. In traditional Indian Ayurvedic medicine, a rasayana substance has two key properties: it supports human health and builds physical power [5].
Shilajit is an organic mineral which includes a variety of chemical components, such as dibenzo-alpha-pyrones, fulvic acids, humic acids, and organic plant matter. Depending on where the ingredient originates from, shilajit's chemical makeup can change.

2.3 Lavender Oil-
Its biological name is **Lavendula angustifolia**, which may also be referred to as tavendulan officinalis, spica, and vera.
-Labiatae Family
Because lavender oil contains a lot of linalool and linalyl acetate, which block inflammatory cytokines, it has an anti-inflammatory effect. Lavender oil, which is extracted from the lavender plant (Lavandula angustifolia), is well-known for its anti-inflammatory and fragrant qualities. There are multiple methods in which lavender oil reduces inflammation: The anti-inflammatory properties of lavender oil and its constituents have been the subject of numerous primary investigations. In a variety of animal models, these investigations have demonstrated effective outcomes in lowering inflammation by inhibiting symptoms such paw edema brought on by carrageenan. Compared to earlier research, clinical trials on the anti-inflammatory effects of lavender oil have certain limitations. However, some research has indicated its potential [6].

3. **Material & Method**
Material used

- Ashwagandha & Shilajit (API help in prevention of insomnia) collected from local market, Magnesium stearate (as lubricant), Tragacanth & Starch (as binder), Crospovidone (as disintegrant), Talc (as glidant), Lactose (diluent). All ingredient are obtained from the college. All ingredient where weighed as per requirement.

Procedure for the formulation of herbal tablet of ashwagandha and shilajit

- A tablet of was prepared by wet granulation method.
- The API was mixed with lactose, crospovidone, starch.
- This powder blend was kneaded in the mortar and pestle for 15-20 min.
- The blend was granulated using tragacanth gum as a binder in water.
- The wet mass was formed; resulting wet mass was passed through sieve # 22. Granules were dried in an oven at 50 °C for 2 h.
- Dried granules were lubricated with magnesium Stearate and talc.
- Lubricated blend was evaluated for powder characteristics and flow properties like bulk density, tapped density, Carr index, Angle of repose and Hausner's ratio.
- Then desired amount of blend was compressed into the tablet using tablet punch machine equipped with 8 mm punch, weight of the tablet was kept to 280 mg.

Ingredients (mg)	F1	F2	F3	F4	F5
Ashwagandha	20	20	20	20	20
Shilajit	10	10	10	10	10
Lactose	105	105	105	115	115
Tragacanth	90	85	95	----	----
Starch	---	---	---	75	80
Crospovidone	45	50	40	55	50
Magnesium stearate	2	5	5	2	2
Talc	3	5	5	3	3
Total	280	280	280	280	280

Table-1. Formulation Table of herbal tablet

4. Evaluation and Characterization of Herbal tablet of Ashwagandha & Shilajit-

4.1 Organoleptic Properties

- **Ashwagandha-**
  - **Taste-** Bitter & Astringent
  - **Odor-** Pungent

- **Color-** Off White

4.2 Solubility Profile - The solubility of a solid substance is defined as the concentration at which the solution phase is in equilibrium with a given solid phase at a stated temperature and pressure [7].

Descriptive term	Parts of solvent required for 1 part of solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 30 to 100
Very slightly soluble	From 1,000 to 10,000
Practically insoluble or insoluble	10,000 and over

Table-2. Solubility Profile of drug

4.3 Evaluation of Granules

- **Angle of Repose-** A simple practical technique for measuring resistance to particle movement is a quantity called the angle of repose of a powder. This is the angle, θ as defined by the equation[7].
  tan θ = h/r
- **Bulk Density-** The abbreviation "Db" were used to denote the Bulk density. The powder sample were transferred into measuring cylinder and its initial value were noted and weight of the sample was measured. The bulk volume is this preliminary volume [8] .

Bulk density = weight of the powder/ bulk volume of the powder

- **Tapped Density-** The tapped density is expressed as the rate of total weight of the powder sample and the tapped quantity of the powder sample. The powder sample was transferred in the measuring cylinder and the measuring cylinder were tapped for 20 times and after that the final volume were noted and the weight of the sample were measured.

Tapped density = weight of the sample / tapped volume of the sample

- **Carre's Index -** The following formula is used for the calculation of Carre's index [9].

Therefore,

Carre's Index = (Dt - Db / Db) × 100

Where, Dt = the tapped density

Db = bulk density.

- **Hausner's Ratio-** Hausner"s ratio is defined as the rate of tapped and bulk density [10]
  Hausner's Ratio = Tapped Density/ Bulk Density

Flow Property	Angle of Repose	Compressibility Index
Excellent Flow Property	If, Ɵ= 25-30	<10 %
Good Flow Property	If, Ɵ= 31-35	11-15 %
Fair Flow Property	If, Ɵ= 36-40	16-20 %
Passable Flow Property	If, Ɵ= 41-45	21-25 %

Poor Flow Property	If, Θ= 46-55	26-31 %
Very poor Flow Property	If, Θ= 56-65	32-37 %
Very Very Poor Flow Property	If, Θ is >65	>38 %

Table-3. Minimum and Maximum Ranges of Flow Properties

4.4 Evaluation of Ashwagandha and Shilajit Tablets-

- **Thickness of Ashwagandha and Shilajit Tablets-**
  A digital vernier caliper was utilized to measure the depth consistency. The tablet's average thickness was determined
- **Weight Variation of Ashwagandha and Shilajit Tablets-**
  20 tablets were weighed individually, and the average weight of all the tablets was determined. The typical weight was linked to the individual weights. The appropriate limitations (±7.5%) must be met by the percentage change in the weight difference.

- **Hardness of Ashwagandha and Shilajit Tablets-**
  A Monsanto hardness tester was used to measure the tablets' rigidity. This tablet was tightened from one end and placed between the plungers. The pressure required to break the tablet completely was measured.
- **Friability of Ashwagandha & Shilajit Tablets-**
  Twenty tablets were taken into consideration and placed in a Roche Friability Test apparatus for this test. The pills were separated, cleaned, and weighed once more following 100 revolutions. The % decrease in tablet weight was used to calculate the friability.

$$\% \text{ Friability} \frac{\text{Initial weight of tablet} - \text{Final weight of tablets}}{\text{Final weight of tablet}} \text{ x } 100$$

- **In-vitro Drug Release-**

  To in vitro dissolution investigations employing type-II equipment at 50 rpm in 900 mm of phosphate buffered saline 7.4 pH as a dissolution medium, kept at 37+5.

5. Result & Discussion

5.1 Result-

5.1.1 Solubility of Ashwagandha Powder-

Solvent	**Observation**
Water	Freely Soluble
Ethanol	More Soluble

Phosphate buffer Ph 7.8	Partially Soluble

Table-4 Solubility of Ashwagandha in different Solvent.

5.1.2 Solubility of Shilajit Powder-

Solvent	Observation
Water	Soluble
Ethanol	Insoluble
Phosphate buffer Ph 7.8	Partially Soluble

Table-5 Solubility of Shilajit in different Solvent.

5.1.3 Evaluation Result of Granules of Ashwagandha & Shilajit

Formulation Code	Angle of Repose	Carr's Index	Hausner's Ratio	Tapped Density	Bulk Density
F1	**26.62±0.43**	**12.30±0.19**	**1.10±0.02**	**0.3102±0.013**	**0.2589±0.003**
F2	**25.88±0.73**	**14.04±0.93**	**1.18±0.01**	**0.3115±0.003**	**0.2593±0.013**
F3	**25.12±0.35**	**13.89±0.42**	**1.06±0.03**	**0.3280±0.002**	**0.2415±0.002**
F4	**25.71±0.05**	**13.68±0.58**	**1.19±0.02**	**0.3116±0.014**	**0.2421±0.003**

Table-6 Evaluation Result of Granules

5.1.4 Evaluation Result of Tablets of Ashwagandha & Shilajit

Formulation Code	Weight Variation (mg)	Hardness (kg/cm^3)	Friability (%)	Thickness (mm)
F1	275±0.3964	3.53±0.1725	0.50±0.006	3.50±0.1280
F2	271±0.1842	2.65±0.1519	0.14±0.02	3.65±0.0902
F3	279.4±0.3211	3.70±0.1420	0.22±0.09	3.78±0.0773
F4	275.7±0.2515	3.95±0.0945	0.48±0.015	3.54±0.2153

Table-7 Evaluation Result of Tablets of Ashwagandha & Shilajit

Formulations	% drug content
F1	95.40± 0.4064
F2	97.03±0.2510
F3	99.25 ± 0.1355
F4	97.20±0.1296

Table-9 Drug content uniformity

5.5. Discussion-

The organoleptic properties of Ashwagandha and Shilajit were evaluated, After that, total four types of formulations of Ashwagandha & Shilajit tablet were formed by using wet granulation method and post-evaluation of Ashwagandha & Shilajit tablet were performed such as drug, hardness, thickness, friability, weight variation test drug content uniformity test, of tablets and the results were shown in the above mentioned tables.

6. CONCLUSION-

The results of experimental studies of Ashwagandha & Shilajit tablets proved that the granules of Ashwagandha & Shilajit showed good flow properties, tablet evaluation tests are within the acceptable limits, stability studies revealed that all formulations were found to be stable after storing at temperature

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8. REFERENCES-

[1]. Yeom Ji Won and Cho Hyun- Chul; Herbal and Natural Supplements for Improving Sleep: A Literature Review; eISSN 1976-3026 OPEN ACCESS.
[2]. Mikulska, P.; Malinowska, M.; Ignacyk, M.; Szustowski, P.; Nowak, J.; Pesta, K.; Szel ˛ag, M.; Szklanny, D.; Judasz, E.; Kaczmarek, G.; et al. Ashwagandha (Withania somnifera)—Current Research on the Health-Promoting Activities: A Narrative Review. Pharmaceutics 2023, 15, 1057
[3]. Pal et al; RESEARCH ARTICLE FORMULATION AND EVALUATION OF NUTRACEUTICAL TABLET USING HERBAL DRUGS BY DIRECT COMPRESSION METHOD
[4]. Speers B. Alex ,Cabey .A Kadine ; REVIEW ARTICLE ;Effects of Withania somnifera (Ashwagandha) on Stress and the Stress Related Neuropsychiatric Disorders Anxiety, Depression, and Insomnia.
[5]. Carlos Carrasco-Gallardo, Leonardo Guzman, and Ricardo B. Maccioni; Review Article Shilajit: A Natural Phytocomplex with Potential Procognitive Activity.
[6] Vaishnavi B. Wable; A research on formulation and evaluation of herbal buccal tablet alternative treatment for insomnia; Vol-10 Issue-3 2024 IJARIIE-ISSN(O)-2395-4396

[7]. Rosendorff C, Lowe RD, Lavery H, Crausron WI. C..ardiovascular effects of angiorensin mediated by the cemral nervous sysrem of the rabbit. *Cardiovasc Res* 1970; 4: 36-43.
[8]. Sahoo, C.K.; Rao, S.R.; Sudhakar, M. Evaluation Of Controlled Porosity Osmotic Pump Tablets: A Review. Res. J. Pharm. Technol.**2015**, 8, 1340. [Crossref]