



FORMULATION AND EVALUATION OF SLEEP ENHANCING HERBAL JELLY

¹*Sneha Badrinarayan Ghuge*, ²*Pramod B Aghao*, ³*Manisha Virkar*

¹Gajanan Maharaj College of Pharmacy, C. Sambhaji Nagar, Maharashtra, India

²Rajarshi Shahu College of Pharmacy, Buldana, Maharashtra, India

³Gajanan Maharaj College of Pharmacy, C. Sambhaji Nagar, Maharashtra, India

ABSTRACT :

Sleep is a fundamental physiological requirement essential for maintaining cognitive function, metabolic regulation, and emotional well-being. Increasing prevalence of sleep-related disorders such as insomnia, sleep apnea, and stress-induced sleep deprivation has led to widespread reliance on synthetic medications like benzodiazepines, which pose risks of dependence, tolerance, and withdrawal symptoms. This research project explores an alternative, plant-based solution for enhancing sleep quality by developing a herbal jelly using standardized extracts of four Indian medicinal plants: *Withania somnifera* (Ashwagandha), *Bacopa monnieri* (Brahmi), *Nardostachys jatamansi* (Jatamansi), and *Ocimum sanctum* (Tulsi). These herbs have been extensively documented in Ayurvedic literature for their sedative, adaptogenic, anxiolytic, and neuroprotective effects.

The herbal extracts were obtained through aqueous decoction and concentrated before incorporation into a jelly base consisting of a natural gelling agent, sweetener, and preservatives. The formulation was evaluated for physicochemical properties (pH), organoleptic characteristics, and short-term stability. Preliminary results indicated that the jelly was physically stable, palatable, and retained its integrity over a 7-day observation period under ambient and refrigerated conditions. Given the known pharmacodynamics of the individual herbal components, the jelly has the potential to support natural sleep processes without the adverse effects commonly associated with synthetic hypnotics.

This study supports the feasibility of developing a functional, consumer-friendly herbal jelly for sleep enhancement and provides a foundation for further pharmacological and clinical evaluation.

Keywords: Sleep, Medicinal plants, Insomnia, Ayurvedic, Herbal

INTRODUCTION

Importance of Sleep and Prevalence of Sleep Disorders

Sleep plays a critical role in maintaining homeostasis, emotional regulation, memory consolidation, and immune function. Chronic sleep deficiency has been associated with a wide range of health issues, including cardiovascular diseases, diabetes, cognitive decline, depression, and reduced quality of life [1]. The modern lifestyle, characterized by irregular work schedules, excessive screen time, and high stress levels, has exacerbated the incidence of sleep disorders globally. Insomnia, one of the most common conditions, affects nearly 10–30% of the global population, with higher prevalence in urban regions and among the elderly [2].

Challenges of Current Pharmacological Treatments

Conventional treatment strategies for insomnia include sedative-hypnotic drugs such as benzodiazepines, non-benzodiazepine receptor agonists, antihistamines, and melatonin analogs. Despite their efficacy, these medications are often associated with side effects like daytime drowsiness, dizziness, tolerance, withdrawal, and cognitive impairment [3]. Moreover, long-term use can lead to dependency and diminished effectiveness. Consequently, there is growing interest in natural, plant-based alternatives that offer safer profiles and holistic benefits.

Role of Herbal Medicines in Sleep Regulation

In Ayurveda, India's traditional system of medicine, a number of botanicals are classified as *Medhya Rasayanas*—rejuvenating herbs that enhance cognitive and neurological functions while reducing stress and promoting restful sleep. Several herbs used historically have shown pharmacological activity that aligns with modern scientific understanding of sleep regulation pathways, including modulation of GABAergic activity, cortisol reduction, and antioxidant effects [4].

Herbs Used in the Study:

Ashwagandha (*Withania somnifera*): A well-known adaptogen, *Ashwagandha* roots has demonstrated anxiolytic, anti-stress, and sedative properties. It helps modulate cortisol levels and has shown efficacy in improving sleep latency and quality in various preclinical and clinical studies [5].



Figure 1: Ashwagandha Roots.

Brahmi (*Bacopa monnieri*): Brahmi leaves are revered for its nootropic and calming effects. It enhances memory and learning while reducing anxiety and mental fatigue, thereby supporting sleep indirectly by reducing cognitive hyperactivity [6].



Figure 2: Brahmi Leaves

Jatamansi (*Nardostachys jatamansi*): Rhizomes are Traditionally used for treating insomnia, Jatamansi possesses tranquilizing and neuroprotective properties. It acts on the central nervous system by increasing serotonin and GABA levels [7].



Figure 3: Jatamansi Rhizomes

Tulsi (*Ocimum sanctum*): Known as Holy Basil, Tulsi leaves exert adaptogenic, anti-inflammatory, and mild sedative effects. It helps normalize circadian rhythms disturbed by stress and supports overall well-being [8].

**Figure 4: Tulsi Leaves**

Rationale for Jelly Formulation

Jelly formulations offer several advantages over conventional dosage forms like tablets or capsules. They are easier to swallow, particularly suitable for pediatric and geriatric populations, and can mask the bitter taste of herbal extracts. Moreover, jelly allows for flexible dosing, quick onset of action due to mucosal absorption, and high patient compliance [9].

Objectives of the Study

- Extract and concentrate four sleep-supporting Indian herbs using aqueous decoction.
- Formulate a stable, palatable jelly incorporating these extracts.
- Evaluate the physical, and sensory characteristics of the herbal jelly.
- Provide a groundwork for further studies on its efficacy in sleep enhancement.

MATERIALS AND METHODS

Materials:

The herbal raw materials:

- Ashwagandha roots (*Withania somnifera*),
- Brahmi leaves (*Bacopa monnieri*),
- Jatamansi rhizomes (*Nardostachys jatamansi*), and
- Tulsi leaves (*Ocimum sanctum*)

Were procured from an authenticated Ayurvedic store.

Additional ingredients included:

- sugar,
- citric acid (pH modifier),
- sodium benzoate (preservative), and
- corn starch (gelling agent).

All chemicals and excipients used were of analytical or food grade quality

METHODS

Preparation of Herbal Extracts

- Equal weights of the herbal materials were cleaned, shade-dried, and coarsely powdered.
- The powders were mixed in the following ratio: Ashwagandha 40%, Brahmi 20%, Jatamansi 20%, and Tulsi 20%. [Fig.5,6,7,8]
- The blended herbal mixture was boiled in distilled water (1:10 w/v) for 1 hour.
- The decoction was filtered through muslin cloth and the filtrate was concentrated to one-third of its original volume using a water bath.



Figure 5: Ashwagandha



Figure 6: Brahmi



Figure 7: Jatamansi



Figure 8: Tulsi

Formulation of Herbal Jelly

- The concentrated extract was used to formulate the jelly as follows.
- The sweetener (sugar) and gelling agent (corn starch) were added to the aqueous extract with constant stirring.
- Citric acid was added once a homogeneous mixture was obtained.
- The mixture was heated at 70–80°C until a jelly-like consistency was achieved.
- Sodium benzoate was added as a preservative before transferring the formulation into sterilized containers and allowing it to cool at room temperature.

Table 1: Composition of Herbal Jelly Formulation

| Ingredient | Quantity (%) | Function |
|---------------------|--------------|--------------------------------|
| Ashwagandha extract | 40 | Sedative, adaptogen |
| Brahmi extract | 20 | Cognitive enhancer, anxiolytic |
| Jatamansi extract | 20 | Sedative, neuroprotective |
| Tulsi extract | 20 | Stress reliever, antioxidant |
| Sugar | 25 | Sweetener |
| Corn Starch | 1.5 | Gelling agent |
| Citric acid | 0.3 | Acidulant, pH modifier |
| Sodium benzoate | 0.1 | Preservative |
| Distilled water | qs | Vehicle |

Table 2: Formulations of Herbal Jelly

| Ingredient | Formulation 1 (%) | Formulation 2 (%) | Formulation 3 (%) | Formulation 4 (%) |
|---------------------|-------------------|-------------------|-------------------|-------------------|
| Ashwagandha extract | 40 | 20 | 20 | 20 |
| Brahmi extract | 20 | 40 | 20 | 20 |
| Jatamansi extract | 20 | 20 | 40 | 20 |
| Tulsi extract | 20 | 20 | 20 | 40 |

Evaluation of the Herbal Jelly

The prepared jelly was subjected to various evaluation parameters to determine its suitability as a dosage form:

- Organoleptic characteristics: The Organoleptic characteristic including Color, Odor and Taste were evaluated.
- Physicochemical properties: Consistency, Stickiness, Texture, Grittiness, pH, and Syneresis were observed.
- Consistency, Stickiness, Texture and grittiness: The formulations should be visually inspected for stickiness and grittiness by gently rubbing a jelly sample between two fingers.
- pH: At room temperature, the jellies' pH was measured using a digital pH meter. For this, 50 ml of distilled water should be mixed with 0.5 g of jelly to create a 1% solution, and the pH should be recorded. Both stability and flavor are influenced by the finished jelly's pH, in addition to both.

- Syneresis: It is when the gel contracts after being stored and the water separates from the gel. It is more noticeable in the gels if a low dose of the gelling agent is used. At room temperature (25°C 5°C) and 8°C 1°C.

Stability studies: Samples were stored at room temperature and 4°C for 7 days to evaluate consistency and physical changes



Figure 9: Tulsi

RESULTS AND DISCUSSION

Organoleptic Evaluation

The herbal jelly exhibited a uniform dark brown color with a characteristic herbal aroma. The flavor was acceptable with no bitterness detected, and the texture was smooth and gel-like.

Physicochemical Properties

The Consistency of herbal jelly was Semisolid, Non-Sticky, Smooth and Non-Gritty. The jelly had a pH of 6.8 ± 0.1 , which is within the acceptable range for oral formulations. After 7days, No Syneresis was Observed.

Stability Studies

Stability of the jelly was assessed over a 24hrs period under ambient (25°C) and refrigerated (4°C) conditions. No significant changes were observed in color, consistency. There was a negligible pH variation (± 0.2), indicating the formulation's good short-term stability.

Table 3: Composition of Herbal Jelly Formulation

| Sr. No. | Evaluation Parameter | Outcome |
|---------|----------------------|--|
| | Color | Dark Brown |
| | Odor | Herbal Aromatic |
| | Taste | No Bitterness |
| | Consistency | Semisolid |
| | Texture | Smooth |
| | Stickiness | Non-Sticky |
| | Grittiness | No-Gritty |
| | pH | 6.8 |
| | Syneresis | No Syneresis was Observed after 7 Days. |
| | Stability | No Physical Changes Observed after 7 Days. |

CONCLUSION

The formulated herbal jelly containing Ashwagandha, Brahmi, Jatamansi, and Tulsi presents a promising alternative for sleep enhancement using traditional Indian herbal medicine. The jelly was palatable, stable, and demonstrated acceptable physicochemical. This project establishes the feasibility of developing a natural, patient-friendly herbal product with potential sedative and adaptogenic benefits. Further pharmacological and clinical studies are recommended to substantiate its efficacy and safety in human subjects.

REFERENCES

1. Hirshkowitz M, Whiton K, Albert SM, Alessi C, Bruni O, DonCarlos L, et al. National Sleep Foundation's sleep time duration recommendations: methodology and results summary. *Sleep Health*. 2015;1(1):40–3.
2. Ohayon MM. Epidemiology of insomnia: what we know and what we still need to learn. *Sleep Med Rev*. 2002;6(2):97–111.
3. Holbrook AM, Crowther R, Lotter A, Cheng C, King D. Meta-analysis of benzodiazepine use in the treatment of insomnia. *CMAJ*. 2000;162(2):225–33.
4. Sharma R, Amin H, Galib R, Prajapati PK. Pharmacological perspectives of Medhya Rasayana herbs: a review. *Anc Sci Life*. 2015;34(3):134–40.
5. Langade D, Kanchi S, Salve J, Debnath K, Ambegaokar D. Clinical evaluation of the anti-stress effect of Ashwagandha root extract (*Withania somnifera*): A randomized, double-blind, placebo-controlled study. *Indian J Psychol Med*. 2019;41(6):551–5.
6. Stough C, Lloyd J, Clarke J, Downey LA, Hutchison CW, Rodgers T, et al. The chronic effects of an extract of *Bacopa monniera* (Brahmi) on cognitive function in healthy human subjects. *Psychopharmacology (Berl)*. 2001;156(4):481–4.
7. Uddin SJ, Sarker SD, Shilpi JA, Alam SM. Antidepressant properties of *Nardostachys jatamansi* DC. in behavioral models of depression in mice. *Phytother Res*. 2009;23(5):591–4.
8. Cohen MM. Tulsi - *Ocimum sanctum*: A herb for all reasons. *J Ayurveda Integr Med*. 2014;5(4):251–9.
9. Bhosale R, Hardikar SR, Desai J. Formulation and evaluation of herbal jelly containing *Trigonella foenum-graecum* extract. *Int J Pharm Pharm Sci*. 2016;8(4):128–32.
10. Singh N, Bhalla M, Jager PD, Gilca M. *Withania somnifera* (Ashwagandha): A Rejuvenating Herbal Drug. *Ayu*. 2011;32(3):408–17.
11. Sharma A, Patel V, Chaturvedi S, et al. Pharmacological properties of *Nardostachys jatamansi*: A review. *Int J Pharm Sci Res*. 2013;4(3):943–50.
12. Mondal S, Mirdha BR, Mahapatra SC. Double-blind, randomized, placebo-controlled study of the adaptogenic effects of holy basil leaves (*Ocimum sanctum*) on stress and sleep. *Evid Based Complement Alternat Med*. 2011;2011:1–7.
13. Choudhary N, Jadon RS, Jatav M. Formulation and evaluation of herbal jelly for pediatric use. *Int J Pharm Sci Rev Res*. 2019;58(2):12–7.
14. Lachmann L, Lieberman HA and Kanig JL: *Theory and Practice of Industrial Pharmacy*. 3rd Edition. Bombay: Varghese Publishing House 1991: 368.
15. Gennaro AR: *Remington: The Science and Practice of Pharmacy*, vol-II, 20th Edition, 2000; 733.
16. Kaur G: A review article on oral jellies for pediatrics, *IndoAmerican J of Pharmaceutical Sci* 2018; 05(01): 444.
17. Imai K. Alendronate Sodium Hydrate (Oral Jelly) for the Treatment of Osteoporosis: Review of a Novel, Easy to Swallow Formulation. *Clin Interv Aging*, 2013; 8: 681-8.
18. Taranum R, Mittapally S. Soft chewable drug delivery system: oral medicated jelly and soft chew, *Journal of Drug Delivery and Therapeutics*. 2018; 8(4):65-72 DOI: <http://dx.doi.org/10.22270/jddt.v8i4.1784>
19. May, C.D. (1997). Pectins. In: Imeson, A.P. (eds) *Thickening and Gelling Agents for Food*. Springer, Boston, MA. https://doi.org/10.1007/978-1-4615-2197-6_11.
20. Mohammad Nejatian, Soleiman Abbasi, Fatemeh Azarikia, Gum Tragacanth: Structure, characteristics and applications in foods, *International Journal of Biological Macromolecules*, Volume 160, 2020, Pages 846-860, ISSN 0141-8130, <https://doi.org/10.1016/j.ijbiomac.2020.05.214>.
21. Lin Lin, Joe M. Regenstein, Shun Lv, Jianfeng Lu, Shaotong Jiang, An overview of gelatin derived from aquatic animals: Properties and modification, *Trends in Food Science & Technology*, Volume 68, 2017, Pages 102-112, ISSN 0924-2244, <https://doi.org/10.1016/j.tifs.2017.08.012>.
22. Liang Li, Rui Ni, Yang Shao, Shirui Mao, Carrageenan and its applications in drug delivery, *Carbohydrate Polymers*, Volume 103, 2014, Pages 1-11, ISSN 0144-8617, <https://doi.org/10.1016/j.carbpol.2013.12.008>.
23. Debojyoti B, organoleptic agents: adaptability, acceptability, and palatability in formulations to make it lucrative. *World Journal of Pharmaceutical Research* .2015; (4):1573-1586.