

## FORMULATION AND EVALUATION OF POLYHERBAL ORAL THIN FILM FOR SLEEP INDUCTION

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### ABSTRACT

Sleep disorders such as insomnia and poor sleep quality are increasingly common due to stress, anxiety, and unhealthy lifestyles, significantly affecting overall health and well-being. Herbal medicines have gained attention as safer alternatives to synthetic sedatives because of their reduced side effects and better patient acceptability. The present study focuses on the **formulation and evaluation of a polyherbal oral thin film (OTF) for sleep induction** using **Ashwagandha (Withania somnifera)** and **Tagara (Valeriana wallichii)** as active herbal ingredients. Ashwagandha is known for its adaptogenic, anti-stress, and anxiolytic properties, while Tagara possesses natural sedative and calming effects that promote sleep. The oral thin film was prepared by the **solvent casting method**. The prepared films were evaluated for various physicochemical and mechanical parameters including **physical appearance, thickness, weight variation, folding endurance, surface pH,**

**and in-vitro disintegration time**. The formulated polyherbal oral thin film demonstrated satisfactory film characteristics, rapid disintegration, and acceptable flexibility, indicating its potential as an effective and convenient drug delivery system for sleep induction. This novel herbal dosage form may offer a promising alternative to conventional oral medications by

providing rapid onset of action, ease of administration, and improved therapeutic efficacy for individuals suffering from sleep disturbances.

**KEYWORDS:** Polyherbal formulation, Oral thin film, Sleep induction, Ashwagandha, Tagara, Herbal drug delivery, Solvent casting method, Insomnia management, Rapid disintegration, Herbal sedative, Patient compliance, sleep disorder.

## INTRODUCTION

Sleep is an essential physiological process necessary for maintaining physical health, mental well-being, and overall quality of life. Adequate sleep plays a crucial role in restoring body functions, enhancing memory consolidation, regulating metabolism, and supporting immune function. However, due to increasing stress, anxiety, irregular lifestyles, and excessive screen exposure, sleep-related disorders such as insomnia and poor sleep quality have become increasingly prevalent worldwide. Chronic sleep disturbances can lead to various health complications, including fatigue, reduced cognitive performance, mood disorders, weakened immunity, and an increased risk of cardiovascular diseases.

Conventional pharmacological treatments for sleep induction, such as benzodiazepines and other sedative-hypnotic drugs, are often associated with adverse effects including dependency, tolerance, daytime drowsiness, and cognitive impairment. Therefore, there is growing interest in the use of herbal medicines as safer and more effective alternatives for the management of sleep disorders. Herbal remedies have been traditionally used for centuries due to their natural origin, better safety profile, and reduced side effects.

Among various medicinal plants, Ashwagandha (*Withania somnifera*) and Tagara (*Valeriana wallichii*) are well-known herbs recognized for their calming, anxiolytic, and sleep-promoting properties. Ashwagandha acts as an adaptogen, helping to reduce stress and anxiety while improving overall sleep quality. Tagara possesses natural sedative and tranquilizing effects that help in inducing and maintaining sleep. The combination of these herbs in a polyherbal formulation may provide a synergistic therapeutic effect for effective sleep induction.

Oral thin films (OTFs) are an innovative and patient-friendly drug delivery system designed to rapidly disintegrate or dissolve in the oral cavity without the need for water. OTFs offer several advantages such as rapid onset of action, improved bioavailability, ease of administration, enhanced patient compliance, and convenience, particularly for pediatric,

geriatric, and dysphagic patients. Incorporating herbal extracts into oral thin films represents a promising approach to deliver natural therapeutic agents efficiently.

The present study aims to formulate and evaluate a polyherbal oral thin film for sleep induction using Ashwagandha and Tagara as active herbal ingredients. The formulation is prepared by the solvent casting method using suitable polymers and excipients, and evaluated for various physicochemical and performance parameters including physical appearance, thickness, weight variation, folding endurance, surface pH, and disintegration time. This novel herbal oral thin film may serve as an effective, convenient, and safe alternative for individuals experiencing sleep disturbances and insomnia.

### **Oral Thin Films (OTF) as Drug Delivery System**

#### **Overview**

OTFs are ultra-thin, flexible films that dissolve rapidly in the oral cavity without water.

#### **Advantages in Sleep Induction**

- Rapid onset of action
- Improved bioavailability
- Bypasses first-pass metabolism
- Easy administration (ideal for elderly & pediatric patients)
- No choking risk

#### **Mechanism of Action**

1. Film placed on tongue
2. Rapid hydration by saliva
3. Disintegration within seconds
4. Drug absorption through oral mucosa
5. Direct entry into systemic circulation

#### **Plant Profile**

##### **1. Ashwagandha**



**Fig. no. 1: Ashwagandha.**

**Scientific Name:** *Withania somnifera*.

**Family:** Solanaceae.

**Common Name:** Ashwagandha, Indian Ginseng, Winter Cherry.

### Biological Source

Ashwagandha consists of the dried roots and leaves of *Withania somnifera*.

### Geographical Source

Widely cultivated in India, especially in dry regions such as Madhya Pradesh, Rajasthan, Gujarat, and Maharashtra. Also found in parts of the Middle East and Africa.

### Parts Used

Roots, leaves, berries, and seeds.

### Major Chemical Constituents

Withanolides, Withaferin A, Alkaloids (Somniferine, Anaferine), Saponins, Flavonoids, Steroidal lactones.

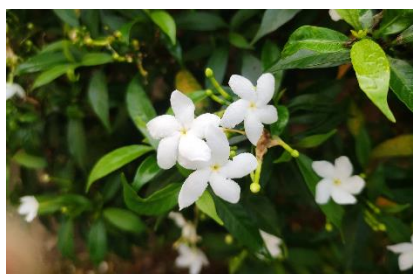
### Pharmacological Activities

Adaptogenic, anti-stress, anxiolytic, sedative, antioxidant, anti-inflammatory, immunomodulatory, neuroprotective.

### Uses

Used for reducing stress and anxiety, improving sleep quality, enhancing memory and cognitive function, boosting immunity, and promoting overall health and vitality.

## 2. Tagara



**Fig. no. 2: Tagara.**

**Scientific Name:** *Valeriana wallichii*.

**Family:** Caprifoliaceae (formerly Valerianaceae).

**Common Name:** Tagara, Indian Valerian.

**Biological Source:** Tagara consists of the dried rhizomes and roots of *Valeriana wallichii*.

**Geographical Source:** Found mainly in the **Himalayan regions of India**, Nepal, and Bhutan, at high altitudes.

**Parts Used:** Roots and rhizomes.

**Major Chemical Constituents:** Valepotriates, Valerenic acid, Alkaloids, Essential oils, Sesquiterpenes, Flavonoids, Tannins.

**Pharmacological Activities:** Sedative, hypnotic, anxiolytic, tranquilizing, anticonvulsant, antioxidant, anti-inflammatory.

### Uses

Used for sleep induction, treatment of insomnia, relief from anxiety and nervousness, calming the nervous system, and improving mental relaxation.

### Extraction Procedure of Ashwagandha and Tagara

#### Method: Maceration Extraction

#### Materials Required

- Dried Ashwagandha root powder
- Dried Tagara root/rhizome powder
- Ethanol: Water (70:30) or distilled water
- Conical flask / beaker
- Magnetic stirrer (optional)
- Whatman filter paper
- Water bath
- Glass container for storage

### Procedure

#### 1. Powder Preparation

- Take dried Ashwagandha roots and Tagara roots/rhizomes.
- Clean and dry properly.
- Grind separately into coarse powder using grinder.
- Sieve through suitable mesh to obtain uniform powder.



Fig. no. 3: Extract powder of ashwagandha and tagara.

## 2. Weighing

- Weigh 5 g of Ashwagandha powder.
- Weigh 5 g of Tagara powder.

(You can extract separately or together; **separately is preferred** for better control.)



Fig. no. 4: Weighing extract powder.

## 3. Maceration

- Transfer each powder into separate conical flasks.
- Add 250 mL hydroalcoholic solvent (Ethanol: Water = 70:30) to each flask (drug: solvent ratio = 1:10).
- Cover flask with aluminum foil or stopper.
- Keep for 24–48 hours at room temperature.
- Shake occasionally or stir every few hours for better extraction.

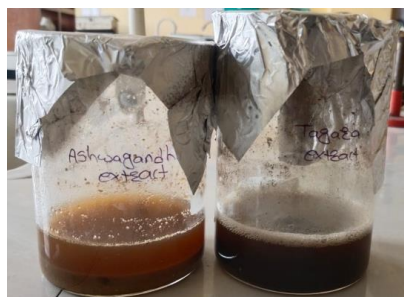


Fig. no. 5: Ashwagandha and tagara extract kept for maceration.

#### 4. Filtration

- After maceration, filter each extract through **muslin cloth** first.
- Then filter using **Whatman filter paper** to obtain clear filtrate.



Fig. no. 6: Filtration.

#### 5. Concentration of Extract

- Transfer filtrate to a **water bath**.
- Heat at **40–50°C** until solvent evaporates and extract becomes concentrated.

##### For liquid extract (your case)

- Do not dry completely.
- Concentrate until thick liquid consistency is obtained.



Fig. no. 7: Concentration of extract.

## 6. Storage

- Store concentrated extracts in **airtight amber-colored containers**.
- Keep refrigerated until formulation.

## Phytochemical Screening of Ashwagandha and Tagara.

**Table no. 1: Phytochemical screening of ashwagandha and tagara.**

Sr. No.	Phytochemical Test	Ashwagandha Extract	Tagara Extract
1	Alkaloids	Present (+)	Present (+)
2	Flavonoids	Present (+)	Present (+)
3	Tannins	Present (+)	Present (+)
4	Saponins	Present (+)	Absent (-)
5	Glycosides	Present (+)	Present (+)
6	Terpenoids	Present (+)	Present (+)
7	Phenols	Present (+)	Present (+)

## METHODOLOGY

### Materials Used

#### Active Ingredients

- Ashwagandha liquid extract
- Tagara liquid extract

#### Herbal/Natural Excipients

- Sodium alginate – Natural film-forming polymer
- Guar gum – Natural thickener and film enhancer
- Gum acacia – Natural binder and film former
- Liquorice powder – Natural sweetener and flavor enhancer
- Xanthan gum – Natural stabilizer and viscosity enhancer
- Citric acid – Saliva stimulating agent
- Peppermint oil – Flavoring agent
- Distilled water – Solvent

**Table no. 2 Formulation table.**

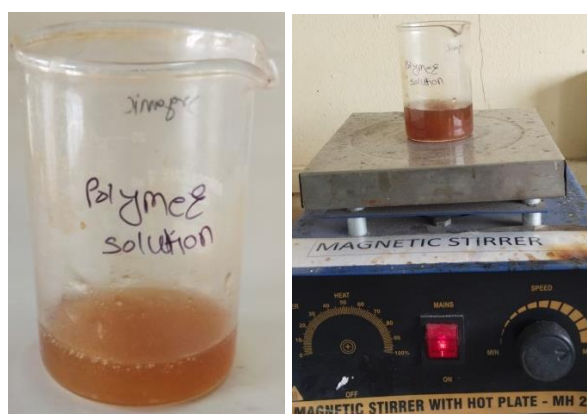
Sr. No.	Ingredients	Quantity (for one batch)	Role
1	Ashwagandha liquid extract	1 mL	Sleep inducer, anti-stress
2	Tagara liquid extract	1 mL	Sedative, sleep promoter
3	Sodium alginate	300 mg	Primary film-forming polymer
4	Guar gum	100 mg	Film strengthening agent
5	Gum acacia	100 mg	Natural binder
6	Xanthan gum	50 mg	Stabilizer, viscosity enhancer

7	Liquorice powder	100 mg	Natural sweetener
8	Citric acid	10 mg	Saliva stimulant
9	Peppermint oil	2–3 drops	Flavoring agent
10	Distilled water	10–15 mL q.s.	Solvent

### Formulation Procedure (Solvent Casting Method)

#### Step 1: Preparation of Polymer Solution

1. Take **10 mL distilled water** in a clean beaker.
2. Add **sodium alginate (300 mg)** slowly with continuous stirring.
3. Stir for **20–30 minutes** until completely dissolved.
4. Add **guar gum (100 mg)** slowly and continue stirring.
5. Add **gum acacia (100 mg)** and mix thoroughly.
6. Add **xanthan gum (50 mg)** slowly to avoid lump formation.
7. Continue stirring until a smooth, homogeneous viscous solution is formed.



**Fig no. 8: Preparation of polymer solution.**

#### Step 2: Preparation of Herbal Extract Mixture

1. Take another clean beaker.
2. Add.
  - **Ashwagandha liquid extract (1 mL)**
  - **Tagara liquid extract (1 mL)**
3. Mix both extracts properly.

#### Step 3: Addition of Herbal Sweetener and Other Excipients

1. Add **liquorice powder (100 mg)** to the herbal extract mixture.
2. Add **citric acid (10 mg)**.
3. Add **2–3 drops peppermint oil**.

4. Stir well until all components are uniformly mixed.



**Fig. no. 9: Excipient mixture.**

#### **Step 4: Mixing of Herbal Extract with Polymer Base**

1. Slowly add the herbal extract mixture into the prepared polymer solution.
2. Stir continuously for **20–30 minutes**.
3. Ensure uniform distribution of all ingredients.



**Fig. no. 10: mixing both solution.**

#### **Step 5: Removal of Air Bubbles (Degassing)**

1. Keep the final solution undisturbed for **30–45 minutes**.
2. Allow entrapped air bubbles to escape.

#### **Step 6: Casting of Film**

1. Pour the prepared solution carefully into a clean **glass petri plate or casting mould**.
2. Spread uniformly to obtain even thickness.



**Fig. no. 11: Casting of film.**

### **Step 7: Drying**

1. Keep the cast film for drying at **room temperature for 24–36 hours.**

#### **If not completely dry:**

- Dry further in **hot air oven at 40–45°C for 2–4 hours.**



**Fig. no. 12 Drying.**

### **Step 8: Film Removal and Cutting**

1. Carefully peel the dried film from the casting surface.
2. Cut into suitable size strips.



**Fig. no. 13: Oral thin film.**

**Step 9: Packaging and Storage**

1. Wrap each strip in **butter paper or aluminum foil**.
2. Store in an **airtight container** away from moisture and light.

**Evaluation of Polyherbal Oral Thin Film****Table no. 3: evaluation of polyherbal oral thin film.**

Sr. No.	Evaluation Parameter	Procedure (Brief)	Result Obtained
1	Physical Appearance	Film visually observed for color, transparency, smoothness, flexibility, and absence of cracks/air bubbles.	Light brown, smooth, flexible, uniform, no cracks or air bubbles
2	Thickness	Measured at 3 different points using Vernier caliper and average calculated.	$0.24 \pm 0.02$ mm
3	Weight Variation	Three strips of equal size weighed individually using digital balance.	$98 \pm 4$ mg
4	Folding Endurance	Film folded repeatedly at same point until breakage.	$115 \pm 5$ folds
5	Surface pH	Film moistened with distilled water and pH measured using pH meter/pH paper.	$6.6 \pm 0.1$
6	Disintegration Time	Film placed in petri dish containing 10 mL distilled water/phosphate buffer and time recorded for complete disintegration.	$42 \pm 3$ sec

**RESULT**

The polyherbal oral thin film containing **Ashwagandha and Tagara extracts** was successfully formulated by the **solvent casting method** using natural herbal excipients such as sodium alginate, guar gum, gum acacia, xanthan gum, and liquorice powder. The prepared films were evaluated for various physicochemical parameters including physical appearance, thickness, weight variation, folding endurance, surface pH, and disintegration time.

The formulated film showed a **smooth surface, uniform appearance, good flexibility, and no visible cracks or air bubbles**. The average thickness and weight variation were found to be within acceptable limits, indicating uniform distribution of ingredients throughout the film. The folding endurance value demonstrated good mechanical strength and flexibility of the film. The surface pH was found to be near neutral, suggesting that the film would be non-irritating to the oral mucosa. The disintegration time was rapid, confirming suitability of the formulation for quick dissolution and faster onset of action. Overall, the developed oral thin film exhibited satisfactory characteristics suitable for oral administration.

## DISCUSSION

The present study focused on the development of a **polyherbal oral thin film for sleep induction** as an alternative to conventional dosage forms. Oral thin films are advantageous due to their rapid disintegration, ease of administration, and improved patient compliance. The combination of **Ashwagandha** and **Tagara** was selected because of their well-known adaptogenic, anxiolytic, sedative, and sleep-promoting activities.

Natural excipients were selected to maintain the herbal nature of the formulation and enhance patient safety. **Sodium alginate** acted as the primary film-forming agent, while **guar gum, gum acacia, and xanthan gum** improved viscosity, flexibility, and film strength. **Liquorice powder** provided natural sweetness and improved palatability. The solvent casting method proved effective in producing uniform and stable films.

Evaluation results indicated that the formulated films possessed acceptable mechanical and physicochemical properties. Rapid disintegration suggests the possibility of faster release and absorption of active constituents in the oral cavity, which may help achieve quicker therapeutic action for sleep induction. The near-neutral pH further supports the safety and comfort of the formulation during administration.

The findings indicate that polyherbal oral thin films can serve as an innovative and effective herbal drug delivery system for managing sleep disturbances and improving patient compliance.

## CONCLUSION

The present study successfully formulated and evaluated a **polyherbal oral thin film for sleep induction** containing **Ashwagandha and Tagara extracts** using natural herbal excipients. The prepared films showed satisfactory physical appearance, good flexibility, uniform thickness and weight, appropriate surface pH, and rapid disintegration time.

The developed oral thin film offers several advantages such as convenience of administration, improved patient acceptability, rapid onset of action, and the therapeutic benefits of herbal medicine with minimal side effects. This formulation may serve as a promising alternative to conventional synthetic sleep-inducing medications for the management of insomnia and sleep-related disorders.

Further studies such as **drug release studies, stability studies, and clinical evaluation** are recommended to confirm its efficacy and long-term safety.

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