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Formulation And Evaluation Process of Polyherbal Mouth Dissolving Tablet for The Treatment of Insomnia Disorder

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Abstract- ***Insomnia is one of the most prevalent sleep disorders characterized by difficulty in initiating or maintaining sleep, leading to impaired daytime functioning and reduced quality of life. Conventional hypnotic drugs such as benzodiazepines and non-benzodiazepines are associated with adverse effects including dependency, tolerance, cognitive impairment, and withdrawal symptoms. Herbal medicines have emerged as safer alternatives because of their natural origin, fewer side effects, and synergistic therapeutic activity. Polyherbal formulations combine multiple medicinal plants to achieve enhanced pharmacological efficacy through synergism. Mouth dissolving tablets (MDTs) are innovative oral dosage forms that disintegrate rapidly in saliva without the need for water, thereby improving patient compliance and rapid onset of action. The present review discusses insomnia disorder, herbal therapies used in its management, principles of polyherbal formulation, preparation methods of mouth dissolving tablets, excipients used, evaluation parameters, advantages, limitations, and future prospects. Herbal ingredients such as Ashwagandha, Tagara, Brahmi, Jatamansi, and Shankhpushpi possess sedative, anxiolytic, and neuroprotective activities that make them suitable candidates for formulation into polyherbal MDTs. The review highlights the importance of natural therapies and advanced drug delivery systems for effective insomnia management.***

Keywords: Mouth Dissolving Tablets (MDTs), Fast Dissolving Tablets, Herbal Medicine, Sleep Disorder, Insomnia

I. INTRODUCTION

Sleep is an essential physiological process necessary for maintaining mental, emotional, and physical health. Insomnia disorder is characterized by dissatisfaction with sleep quantity or quality associated with difficulty in sleep initiation, sleep maintenance, or early morning awakening. Chronic insomnia negatively affects cognition, mood, cardiovascular health, immunity, and overall quality of life. Approximately one-third of adults experience symptoms of insomnia globally.

Modern pharmacological therapies include benzodiazepines, melatonin agonists, antihistamines, and antidepressants. Although effective, these medications are associated with tolerance, dependence, sedation, dizziness, and memory disturbances. Therefore, there is growing interest in herbal medicine and traditional systems such as Ayurveda and Traditional Chinese Medicine for insomnia management.

Polyherbal formulations offer synergistic therapeutic effects and improved efficacy compared to single herb therapy. Mouth dissolving tablets provide rapid drug release, ease of administration, better patient compliance, and improved bioavailability. The combination of herbal medicines with MDT technology can provide a promising alternative for insomnia treatment.

II. INSOMNIA DISORDER

2.1 Definition

Insomnia is a sleep disorder characterized by difficulty in falling asleep, maintaining sleep, or experiencing non-restorative sleep despite adequate opportunity for sleep.

2.2 Types of Insomnia

1. Acute insomnia
2. Chronic insomnia
3. Sleep onset insomnia
4. Sleep maintenance insomnia
5. Comorbid insomnia

2.3 Causes of Insomnia

- Stress and anxiety
- Depression
- Lifestyle disturbances
- Excessive caffeine intake
- Chronic pain
- Neurological disorders
- Hormonal imbalance
- Drug abuse

2.4 Symptoms

- Difficulty falling asleep
- Frequent nighttime awakening
- Daytime fatigue
- Irritability
- Poor concentration
- Headache
- Mood disturbances

2.5 Pathophysiology

Insomnia is associated with hyperarousal of the central nervous system, dysregulation of neurotransmitters such as GABA, serotonin, dopamine, melatonin, and elevated cortisol levels. Herbal medicines exert sedative action mainly through modulation of GABAergic pathways.

III. HERBAL MEDICINES USED FOR INSOMNIA

3.1 Ashwagandha

Ashwagandha
Scientific name: *Withania somnifera*

Pharmacological Actions

- Adaptogenic
- Anti-stress
- Sedative
- Anxiolytic

Active Constituents

- Withanolides
- Alkaloids
- Saponins

Mechanism

Ashwagandha reduces cortisol levels and improves sleep quality through anxiolytic effects.

3.2 Brahmi

Brahmi
Scientific name: *Bacopa monnieri*

Uses

- Memory enhancer
- Sedative
- Neuroprotective

Active Constituents

- Bacosides
- Alkaloids

3.3 Jatamansi

Jatamansi
Scientific name: *Nardostachys jatamansi*

Actions

- CNS depressant
- Antidepressant
- Sleep inducer

3.4 Tagara

Tagara
Scientific name: *Valeriana wallichii*

Actions

- Sedative
- Tranquilizer
- Hypnotic

Tagara contains valepotriates responsible for sedative activity.

3.5 Shankhpushpi

Shankhpushpi

Pharmacological Uses

- Brain tonic
- Anti-anxiety
- Improves sleep quality

IV. POLYHERBAL CONCEPT

Polyherbal formulation refers to the combination of multiple medicinal herbs in a fixed ratio to achieve synergistic therapeutic effects.

Advantages

- Enhanced efficacy
- Reduced dose requirement
- Reduced toxicity
- Multiple therapeutic targets
- Better patient acceptability

Principle of Polyherbalism

The concept is based on synergism where herbs complement each other pharmacologically.

V. MOUTH DISSOLVING TABLETS (MDTS)

5.1 Definition

Mouth dissolving tablets are solid dosage forms that disintegrate rapidly in saliva without water, usually within 60 seconds.

5.2 Advantages

- Ease of administration
- Better patient compliance
- Rapid onset of action
- No need for water
- Improved bioavailability
- Suitable for geriatric and pediatric patients

5.3 Limitations

- Hygroscopicity
- Fragility
- Taste masking challenges

VI. IDEAL CHARACTERISTICS OF MDTS

- Rapid disintegration
- Pleasant mouthfeel
- Adequate mechanical strength
- Good stability
- Uniform drug content
- Acceptable taste

VII. SELECTION OF HERBAL INGREDIENTS

The herbs selected for insomnia MDTs should possess:

- Sedative activity
- CNS depressant activity
- Anxiolytic effect
- Neuroprotective action
- Safety for long-term use

VIII. EXCIPIENTS USED IN POLYHERBAL MDTS

8.1 Superdisintegrants

- Crospovidone
- Sodium starch glycolate
- Croscarmellose sodium

8.2 Binders

- PVP K30

- Starch paste

8.3 Sweeteners

- Mannitol
- Aspartame

8.4 Lubricants

- Magnesium stearate
- Talc

8.5 Flavoring Agents

- Peppermint oil
- Orange flavor

IX. METHODS OF PREPARATION

9.1 Direct Compression

Direct compression is one of the simplest and most economical techniques used in tablet manufacturing. In this method, the powder blend containing the active pharmaceutical ingredient (API) and excipients is directly compressed into tablets without undergoing any granulation step. This technique requires powders with excellent flowability and compressibility. Suitable excipients such as superdisintegrants, fillers, and lubricants are carefully selected to ensure uniform mixing and proper tablet formation. Due to fewer processing steps, this method reduces production time, minimizes moisture exposure, and is highly preferred for moisture- and heat-sensitive drugs.

9.2 Dry Granulation

Dry granulation is a method used to convert fine powders into granules without the addition of any liquid binder. In this process, powder particles are compacted under high pressure to form larger aggregates, which are then milled into granules of desired size. This technique is particularly useful for drugs that are sensitive to heat and moisture. Two common approaches used in dry granulation are slugging (using a tablet press) and roller compaction. The granules produced show improved flow properties and compressibility, making them suitable for tablet formation while avoiding stability issues associated with wet processes.

9.3 Wet Granulation

Wet granulation is a widely employed method in which powder particles are bound together using a liquid binder to form granules. The process involves mixing the drug with excipients, followed by the addition of a granulating fluid to form a wet mass. This mass is then passed through a sieve to produce granules, which are subsequently dried and lubricated before compression. Wet granulation enhances flow characteristics, improves compressibility, and ensures uniform drug distribution. It is especially useful when the formulation contains poorly compressible drugs.

X. PREFORMULATION STUDIES

10.1 Angle of Repose

The angle of repose is defined as the steepest angle formed between the surface of a pile of powder and the horizontal plane. It is an important parameter used to evaluate the flowability of powders. A lower angle indicates better flow properties, while a higher angle suggests poor flow.

10.2 Bulk Density

Bulk density refers to the ratio of the mass of powder to the total volume it occupies, including the spaces between particles. It provides insight into the packing behavior of the powder.

10.3 Tapped Density

Tapped density is determined by measuring the volume of powder after it has been mechanically tapped for a fixed time or number of taps. It indicates how particles rearrange under external forces.

10.4 Carr’s Index (Compressibility Index)

Carr’s index is a measure of the compressibility and flowability of a powder. Lower values represent good flow, while higher values indicate poor flow characteristics.

10.5 Hausner Ratio

Hausner ratio is another parameter used to evaluate flow properties of powders. It is calculated as the ratio of tapped density to bulk density.

XI. POST-COMPRESSION EVALUATION PARAMETERS OF TABLETS

11.1 Thickness

Tablet thickness is measured to ensure uniformity in size and shape, which is essential for packaging and patient acceptability. It is commonly determined using a Vernier caliper or a digital micrometer.

11.2 Hardness

Hardness indicates the mechanical strength of a tablet and its ability to withstand handling, packaging, and transportation. It is measured as the force required to break a tablet using instruments such as Monsanto or Pfizer hardness testers.

11.3 Friability

Friability evaluates the tendency of tablets to crumble or break during handling. It is expressed as the percentage weight loss after subjecting tablets to mechanical stress in a friabilator.

Roche friabilator is commonly used for this test.

11.4 Weight Variation

The weight variation test ensures uniformity of tablet weight, which indirectly reflects uniform drug distribution. Tablets are individually weighed using a digital balance and compared with the average weight.

11.5 Wetting Time

Wetting time measures how quickly a tablet absorbs liquid and becomes wet. It is an important parameter for mouth dissolving tablets. The test is usually performed using a Petri dish lined with tissue paper, and a stopwatch is used to record the time.

11.6 Drug Content

Drug content analysis determines whether the amount of active ingredient present in the tablet meets the required specifications.

This is typically measured using analytical techniques such as UV-visible spectrophotometry or High-Performance Liquid Chromatography (HPLC).

11.7 Disintegration Time

Disintegration time is the duration required for a tablet to break down into smaller particles under specified conditions. It is a crucial factor for fast dissolving tablets.

The test is performed using a USP/IP disintegration apparatus.

11.8 In-vitro Dissolution Study

In-vitro dissolution testing is performed to evaluate the rate and extent of drug release from tablets in a specific dissolution medium. It helps predict the drug's behavior in the body.

The study is carried out using USP dissolution apparatus such as:

- Type I (Basket method)
- Type II (Paddle method)

XII. PHARMACOLOGICAL MECHANISM OF HERBAL SEDATIVES

Herbal sedatives mainly act through:

- GABA receptor modulation
- Serotonin regulation
- Melatonin enhancement
- Reduction of cortisol levels

XIII. SYNERGISTIC ACTIVITY OF POLYHERBAL FORMULATION

Combination of multiple herbs:

- Enhances therapeutic efficacy
- Minimizes side effects
- Provides multi-target action
- Improves patient outcomes

XIV. CHALLENGES IN POLYHERBAL MDT DEVELOPMENT

- Standardization of herbal extracts
- Taste masking
- Stability issues
- Batch-to-batch variation

XV. FUTURE PROSPECTS

- Nanoherbal MDTs
- Personalized herbal medicine
- Improved taste masking technologies
- Clinical validation of herbal combinations
- AI-assisted herbal formulation development

XVI. CONCLUSION

Polyherbal mouth dissolving tablets represent a promising approach for insomnia management by combining the therapeutic benefits of herbal medicines with patient-friendly drug delivery technology. Herbal ingredients such as Ashwagandha, Brahmi, Jatamansi, Tagara, and Shankhpushpi possess sedative and anxiolytic activities useful for improving sleep quality. MDTs provide rapid onset of action, improved compliance, and better bioavailability. Although challenges such as standardization and stability remain, advancements in formulation science may improve the effectiveness of herbal MDTs. Polyherbal MDTs can serve as safer alternatives to conventional hypnotic drugs with reduced side effects and enhanced therapeutic outcomes.

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