FORMULATION AND EVALUATION OF HERBAL BUCCAL TABLET ALTERNATIVE TREATMENT FOR INSOMNIA

Vaishnavi B. Wable, Vaishnavi V. Waghmare, Prof. Ajit B.Tuwar, Dr. Megha T. Salve

Department of Bachelor Of Pharmacy

Shivajirao Pawar College Of Pharmacy, Pachegaon, Ahmednagar- 413725

Email ID – vaishnaviwaghmare341@gmail.com

**Corresponding Author- Vaishnavi B. Wabale, Vaishnavi V. Waghmare*

ABSTRACT

The global market for sleeping pills is becoming unsustainable due to increased population due to stress, anxiety and depression among the world's fastest growing population . 50 percent of the world's population suffers from insomnia. Hypnotics on inhaled herbicides. In Ayurveda, hazelnuts are often used to treat insomnia

Ashwagandha is a herbal remedy in ayurvedic medicines. Ashwagandha is known for its many types Of illnesses including Parkinson's, dementia, memory loss, stress induced diseases, malignant tumours and Others. Ashwagandha is used as a home remedy by Indians, and is considered the best tonic for elderly and Children and as an aphrodisiac for the young people. Preclinical studies have also shown that ashwagandha has An anti-inflammatory, anti bacterial, antioxidant , antidiabetic, anti tumour , anti-ageing and neuroprotective Properties. Insomnia is often associated with functional and social disabilities, mental and physical impairments and disorders. It represents more than 5.5 million GP employees each year. However, the number of insomnia patients treated remains low, indicating the need for further development and differentiation of effective treatments. Therefore, it becomes necessary to provide intensive treatment for medical procedures. Reveals the need for different critical thinking to evaluate sleep and different treatment options. Alternatives include both nonpharmacological treatments, particularly cognitive behavioral treatments for insomnia, and a variety of pharmacological treatments, such as orexin antagonists, "z-drugs," benzodiazepines, histamine H1 antagonists, antihistamines, melatonin receptor agonists, etc. Despite their widespread use, there is consistent evidence for the effectiveness of various sleep treatment regimens, except for individuals suffering from restless legs syndrome, depression/mood disorder, and/or insomnia due to circadian disorders. Other sedating pharmaceutical agents should be prescribed with caution in the treatment of insomnia due to the increased risk of next-day sleepiness and known side effects and toxicity. This review also aims to provide an update on various patent applications related to sleep therapy drugs.

KEYWORDS:- *Ashwagandha, Parkinson's disease, Insomina, Hypnotic Insomnia, Buccal Tablet, Lavender oil, Anxiety, Stress*

INTRODUCTION

Insomnia is technically defined as a sleep disorder. Drowsiness or persistent sleepiness that causes disability or discomfort during the day despite adequate opportunities and periods of sleep at least three times a week for at least one month. Plants have been used by all cultures throughout history.[1]The purpose of this study was to evaluate the effectiveness and safety of ashwagandha in the treatment of insomnia, anxiety, and fertility.Some extracts also showed neuroprotective, cardioprotective, immunomodulatory, antidiabetic and anti-inflammatory properties.[2]

High-risk patients with Related conditions such as anxiety, depression and chronic pain are among those most affected by daytime work. However, few studies involving hypnosis medications on the market to date examine the degree of improvement (if any) in daytime functioning or the effects of sleep disturbances. This is not surprising, because the primary group of Insomnia patients selected for clinical trials had no disease. This is in stark contrast to the 'real

world' where People with many co-morbidities may be affected, while people suffer from insomnia. . This review aims to provide an overview of Studies of hypnotic drugs (benzodiazepines, non-benzodiazepines) and complementary medicines (e.g. melatonin) in the treatment of insomnia in children (), one of the main outcomes being the quality of wakefulness.[3]

Insomnia is a health problem associated with difficulty falling asleep, waking up early, waking up during sleep, or lack of sleep. The consequences during the day are feelings of fatigue, decreased well-being, irritability and reduced ability to concentrate and learn. The main causes of insomnia are; Napping during the day, taking stimulants such as coffee, drugs and alcohol, not exercising during the day, eating junk food before going to bed, lack of rest, silence and the presence of Electronic devices in the environment. In the bedroom, while reading a book or watching television in bed. Fear is an emotion that manifests itself as a feeling of anxiety, stress, shame or anxiety, associated with the organism's perception of danger from outside or within. There is a strong relationship between stress and anxiety. Stress is the disruption of the body's homeostasis caused by physical or psychological factors.[4]

The buccal delivery system is defined as the administration of medication through the mucosal membrane of the cheek (oral mucosa). Oral administration of drugs was developed by Orabase in 1947. In recent years, the delivery of therapeutic drugs through various transdermal routes has attracted great attention.[5]Buccal drug administration offers an attractive alternative to oral drug administration, particularly in eliminating inefficiencies associated with the final mode of administration.[6]

Drug detail

Ashwagandha

Biological name :- It consists of the dried roots and steam bases of Withania Somifera Dunal , belonging to family solanaceace

Ashwagandha, also technically known as Withania somnifera, is an herb with deep roots in Ayurvedic medicine. Ashwagandha, also known as "Indian Ginseng" and "Cherry Cherry," has been used for centuries to improve overall health and combat stress-related illnesses. Over the years, its benefits for improving sleep quality have attracted a lot of attention.[7]

Ashwagandha Health Benefits

1.Improved memory and focus

2.Reduced stress levels

3.Increased energy levels

4.Increased muscle strength

5.Reduced arthritis pain

Lavender oil

Biological name :-It is extracted from lavendula angustifolia (also known as tavendulan officinalis, spica and vera) Family -Labiatae

Lavender oil has an anti-inflammatory effect due to its high content of linalool and linalyl acetate, which inhibit inflammatory cytokines. Lavender oil, obtained from the lavender plant (Lavandula angustifolia), is known for its aromatic and therapeutic properties, including anti-inflammatory effects. Lavender oil has anti-inflammatory effects in several ways:[8]

Many primary studies have focused on the anti-inflammatory effects of lavender oil and its components These studies have shown efficient results in reducing inflammation by suppressing symptoms such as carrageenan-induced paw edema in various animal models. Clinical Studies of anti-inflammatory lavender oil inflammation have some limitations compared to previous studies. But some studies have shown its potential [9]

OBJECTIVE

1.Promotes Relaxation:

Ashwagandha is known for its adaptogenic properties that help the body cope with stress and promote relaxation; Lavender oil increases this calming effect.

2. Reduces Anxiety:

Both Ashwagandha and lavender oil have been shown to reduce anxiety levels, which may contribute to better sleep.

3.Improve sleep quality:

Combining the relaxing and stress-relieving effects of ashwagandha and lavender oil, the herb aims to improve overall sleep quality, helping people fall asleep faster and sleep longer.

4. Improves Stress Management:

The adaptogenic nature of Ashwagandha may also help control mood levels, which may contribute to better sleep patterns over time.

5. Reduces sleep disorders:

The scent of lavender oil can reduce sleep disorders such as slow waking up at night

6. .Supporting overall well-being:

Addressing both the physical and mental issues of insomnia, herbal supplements aim to support overall well-being and provide a better sleep experience.

2. MATERIALS AND METHOD

Material procurement

Ashwagandha powered and lavender oil (helps to reduce insomnia) are collected from the local market. Magnesium stearate ,gum tragacanth (as mucoadhesive) ,starch (as binder) ,and lactose (as lubricant) these all ingredient was collected from college laboratory.

Method

Preparation: Determine the amount of each ingredient based on the desired dosage and tablet size.

Mixing: Combine powdered ingredients (ashwagandha, starch, and lactose) in a blender or food processor until well blended.

Excipients: While mixing, gradually add magnesium stearate to act as a lubricant and help break down the tablet.

Binder: Add lavender oil to the mixture to act as a binder, helping shape the pills and possibly giving them additional healing properties.

Granulation (optional): Mix with a little water or alcohol if necessary to improve consistency and shrinkage.

Compression: Use a tablet press to cut the granules to the desired size and shape.

Drying (optional): Once granulation is complete, place on a tablet to remove excess moisture.

Sr.No	Ingredient used	Category	Quantity F1	Quantity F2	Quantity F3	Quantity F4
1	Ashwagandha	API	100mg	100mg	100mg	100mg

2	Lavender oil	API	40mg	40mg	40mg	40mg
3	Magnesium stearate	Lubricant	1mg	1mg	1mg	1m
4	Mucoadhesive (Tragacanth gum)	Binder	0.5mg	1mg	1.5mg	2m
5	Starch	Binder	1mg	1mg	1mg	1mg
6	Lactose	Diluent	q.s	q.s	q.s	q.s

Evaluation of pre-compressional blend :-

It is important to know the basic physical and chemical properties of the drug molecule and other properties of the drug powder before making the basic dosage.

Preformulation is the process of characterizing the physicochemical properties of pharmaceutical ingredients using biopharmaceutical concepts to determine the best possible drug delivery method. A preformulation scientist should keep the following points in mind before beginning the formulation process:

- The quantity of medication that is accessible.

- The drugs physicochemical characteristics are well understood.

- The compounds expected dose and therapeutic category.

- The type of knowledge that a formulation needs to or desires to have.

Determination of granules parameter :-

- Angle of Repose
- Bulk density
- Tapped bulk density
- Compressibility index.

Angle of Repose :-

- Angle of repose is an important parameter to study the Flow property analysis of any powdered formulation with respect to their frictional forces. Using the funnel method, the position of repose was determined by placing a carefully weighed blend with in a funnel. The “head of blend” or “apex of the heap” was the point at which the funnel tip barely touches due to the arrangement of the funnel height. It was possible for “the drug excipient blend” to freely flow to the surface through the funnel. The link between Powder Flow and Angle of Repose is displayed in Table 2. The following formula was used to get the angle of repose and the diameter of the powder cone:

$$\mathbf{Tan\ \Theta = h/r,}$$

$$\mathbf{\Theta = tan\text{-}1\ (h/r)}$$

Where, Θ – the angle of repose,

H- the height in cm and

R- radius in cm.

Angle of repose	Type of flow
25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Table 2- Relationship between angle of repose (0) and Powder flow

Bulk density:-

The bulk density is defined as the ratio of bulk mass of the granule to the bulk volume. And it is denoted by ρb. The Bulk density is used to find out homogenecity of the given sample to be found. (Nagaich U, 2014)

Bulk density (ρb) = M/Vb

Where, M is given as the mass of the sample,

Vb as the bulk volume.

Tapped bulk density :-

The following formula was used to determine tapped density.

Tapped density (Dt) = mass of powder (M) / tapped volume (Vt)

Tapped density was determined by tapping the graduated 10ml. measuring cylinder 100 times from

A height of about 1.5 inch.

Compressibility index :-

The Compressibility index of the blends was determined by Carr's compressibility index. Table 3 shows grading of powders for their flow properties.

Carr's index = Tapped density-Bulk density × 100/ Tapped Density.

Consolidation flow index (Carr's index)	Flow
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-35	Poor
33-38	Very poor
<40	Very -very poor

Table 3- Grading of powder for their flow properties

Evaluation parameters of tablets :-

Tablets were subjected to following evaluation parameters.

Organoleptic properties:-

Odour , shape, color, taste was determined.

Tablet Hardness:-

The hardness was being evaluated by using Monsanto hardness tester.

Weight Variation Test:

For variation 20 tablets average weight was determined. Individually each tablet weight was Examined. In each case deviation from the average weight was calculated and expressed as Percentage. Not more than two of the tablets from the sample size deviate from the average Weight by a greater percentage and none of the tablets deviate by more than double that Percentage.

Friability test :-

Friability test is carried out, using Friability apparatus. The weighted tablets are being placed in the apparatus And which is been rotated at 25 rpm for 5 minutes. After an interval tablets are taken out from apparatus and Once again they are weight. The friability is calculated by given formula.

Friability = Initial weight (Wi) – Final weight (Wf)/Initial weight (Wi) × 100

Disintegration test :-

6 tablets were taken for the estimation of the disintegration time. The tablets were placed in the disintegration Apparatus and then the time was observed uptill the tablet were totally disintegrated. The temperature for the Apparatus was maintained at 37º C.

RESULT AND DISCUSSION :-

Formulation of herbal buccal tablet for Insomnia:-

Formulation prepare by wet granulation method were tested for the preformulation studies for potential evaluation to tablet compression. All the evaluated preformulation parameters are shown in table 4. Based on the preformulation studies powder flow properties are good. Then the process is continued with compression of tablet by wet granulation method, after compression tablets were evaluated by post compression parameters observed were displayed on below table 5.

Weight Variation: The weight of tablet is measured to ensure that a tablet contain the proper amount of drug. Randomly selected twenty tablets form each batch were subjected to weight variation test as per Indian Pharmacopoeia 2007. Not more than two individual weight deviates from the average weight by more than 5% percentage deviation.

Formulation code	Bulk Density (gm/cm^3)	Tapped Density (g/cm^3)	Hausner's Ratio	Compressibility Index	Angle of Repose
FI	0.33±0.01	0.37±0.00	1.16±0.06	18.16±0.58	27.58±0.84

FII	0.32±0.00	0.33±0.00	1.05±0.05	9.85±0.89	24.60±1.37
FIII	0.30±0.00	0.32±0.00	1.11±0.02	11.88±0.78	24.82±1.45
FIV	0.28±0.00	0.31±0.00	1±0.00	8.2±0.85	25.51±0.8

Evaluation Post Compression Parameter

Formulation No	Weight variation (mg)	Hardness (Kg/cm)	Thickness (mm)	% Friability	% Drug Content
F1	Passes	7.2±0.21	4.2±0.16	0.99±0.00	89.01±0.47
F2	Passes	7.9±0.23	4.3±0.2	0.94±0.00	90.30±0.33
F3	Passes	7.7±0.21	4.5±0.12	0.86±0.00	92.04±0.45
F4	Passes	6.8±0.52	4.1±0.11	0.96±0.00	91.43±0.34

Surface pH Study:-

Formulation code	Surface pH
F1	6.7±0.04
F2	6.8±0.01
F3	6.8±0.05
F4	6.9±0.00

CONCLUSION:-

The present research was carried out to develop mucoadhesive herbal buccal tablets of Nutmeg and lavender oil to overcome the problem of insomnia. The preparation process was simple, reliable and inexpensive. All the prepared tablet formulations were found to be good without capping and chipping. The mucoadhesive herbal buccal tablets of Nutmeg and lavender oil by using direct compression method. All the prepared tablets were in acceptable range of weight variation, hardness, thickness, friability and drug content as per

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