FORMULATION AND EVALUATION OF HERBAL SLEEP SUPPORT GUMMIES

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Abstract: The present study was aimed at the formulation and evaluation of herbal sleep support gummies using natural herbal ingredients such as ashwagandha, Tulsi, chamomile, and tart cherry extract, which are traditionally known for the calming, antioxidant, adaptogenic, and sleep enhancing properties. The herbal extract was prepared by maceration using a hydroalcoholic solvent system and incorporated into gelatin-based gummy formulation along with sweeteners, citric acid. The formulated gummies are evaluated for various physicochemical parameters including appearance, color, odor, texture, PH, weight variation, hardness, friability, moisture content, and content uniformity. Preliminary phytochemical screening confirmed the presence of bioactive constituents such as flavonoids, alkaloids, phenolic compound and withanolides. The developed gummies show satisfactory organoleptic properties acceptable stability, and remained physically stable with no significant change in color, texture. The study concluded that herbal sleep support gummies can serve as a convenient and patient-compliance nutraceutical formulation for promoting relaxation and improving sleep quality.

Keywords: Herbal gummies, Melatonin, Nutraceuticals, Sleep quality, Adaptogenic herbs, Natural sleep aid.

Introduction:

Sleep is a fundamental physiological process essential for good health. It helps the body rest, repair itself and keep the mind working properly. Melatonin is a natural hormone produced by pineal gland in brain. It plays key role in regulating sleep – wake cycle. However, many people today suffer sleep problems due to stress, a busy lifestyle, excessive screen time and unhealthy habits a most common is insomnia. Insomnia is a sleep disorder characterized by difficulty falling asleep, staying asleep or waking up too early and being unable to return sleep. People with insomnia feel tired, stressed, and unable to concentrate during day.

Mainly medicines are commonly used to treat sleep problem, they are effective but cause side effects and also cause dependence when used for long time. Because of this problem many people prefer safer and more natural way to improve sleep. In sleep support one of the herbal remedies is gummies, mainly known for herbal sleep support gummies. Herbal sleep support gummies are consumer – friendly form of sleep supplement. These gummies commonly contain the herbal ingredient such as ashwagandha, chamomile, Tulsi leaves, and tart cherries as a main source of melatonin.

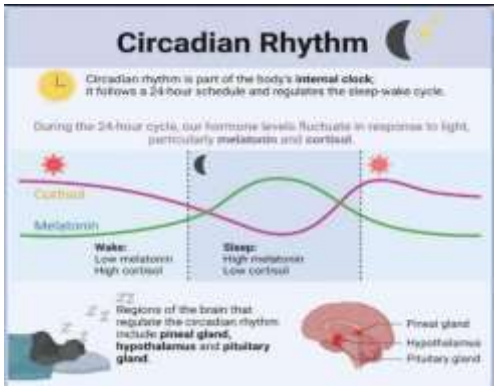

Fig. Regulation of sleep cycle

In modern lifestyles, sleep disturbances have become increasingly common, necessitating the development of safe and effective interventions. Cortisol is a stress hormone released during anxiety. In anxiety patients, prolonged high cortisol levels and sleep affects the quality, timing or duration of sleep, leading to difficulty in functioning during the day. In sleep disorder person has trouble falling asleep, cannot stay asleep, experience abnormal behaviors during sleep and common disorder like insomnia, which cause due to stress, anxiety or staying asleep. Insomnia is trouble falling or staying a sleep, or poor-quality sleep, despite having the chance to rest, leading to daytime problems. Causes include medications and health issues.

Gummies offer the potential advantages of enhanced adherence, particularly among individuals who have difficulty in swallowing pills. Gummies are especially beneficial for populations such as paediatric, geriatric, and dysphagic patients who may have experience difficulty swallowing solid oral dosage forms. Its chewable nature eliminates the need for water and reduces risk of choking, and making them more convenient for routine use.

Tart cherry:

Tart cherry extract was selected due to its natural source of melatonin and presence of polyphenols, and anthocyanins that support sleep regulation. It can be use as standardized extract or in powder form. Polyphenols and anthocyanins present in tart cherries exhibit antioxidant and anti – inflammatory effects that may support relaxation and improve sleep efficiency. Tart cherry supports sleep by providing natural melatonin, which help regulate circadian cycle.

Fig: Tart Cherry

Chamomile:

Chamomile was selected due to its traditional use as a natural sleep – promoting and calming agent. Selection based on its reported sedative, anxiolytic and relaxation properties. It used in the form of dried flower extract or powder. Chamomile contains bioactive compounds such as apigenin, flavonoids and terpenoids that bind to benzodiazepine receptors in the brain promoting relaxation and sleep. It helps to reduce anxiety calm the nervous system and improve sleep quality.

Fig : Chamomile

Ashwagandha:

Ashwagandha is selected in sleep support gummies due to its adaptogenic and anxiolytic properties due to its adaptogenic and anxiolytic properties. It helps reduce cortisol levels, thereby lowering stress and improving sleep quality. It promotes natural sleep without causing dependency.

Fig: Ashwagandha

Tulsi:

Tulsi is selected in sleep support gummies due to its adaptogenic and calming properties. It helps in reducing stress and cortisol levels, promotes relaxation, and eases anxiety, which indirectly improves sleep quality. Its active compound like eugenol provides mild sedative effects.

Fig: Tulsi

Stevia:

Stevia is used in sleep support gummies as a natural, zero – calorie sweetening agent that improves taste and masks the bitterness of herbal extracts. It is 200 – 400 times sweeter than sucrose, so it is required in very small amounts and helps in developing a sugar – free, low – calorie formulation suitable for diabetic and calorie – conscious individual. Stevia does not raise blood glucose levels and is non – cariogenic, making it ideal for chewable dosage forms like gummies.

Fig: Stevia

Gummies:

Herbal gummies are chewable formulations containing plant-based extracts or nutraceutical ingredients embedded in a gel system, used to provide health benefits such as sleep support, immunity, or stress relief.

They are semi-solid preparation that combine active ingredients, gelling agent, sweeteners, to form an attractive, easy to consume dosage form.

Types of gummies:

- Medicated gummies: contain API
- Nutraceutical gummies: contain vitamins, minerals, herbal supplements

- **Active Ingredients:** Gummies can contain a wide range of active ingredients such as herbal extracts (Ashwagandha, Chamomile, Tulsi, Tart cherry), vitamins, minerals, and nutraceuticals. These ingredients provide therapeutic effects like sleep support, stress reduction, and relaxation.
- **Excipients:** Gummies contain various excipients including gelling agents (agar), sweeteners (stevia), acidulants (citric acid), flavoring agents (orange oil), and stabilizers. Gelling agents provide structure and texture. Sweeteners improve taste and palatability. Acidulants enhance flavor and maintain Ph. Flavoring agents mask unpleasant taste of actives
- **Base Material:** Gummies are prepared using base materials such as agar, with water and sweeteners. These materials form a gel-like matrix that gives gummies their characteristic chewable consistency.

- **How Gummies acts:**

Herbal sleep support gummies help regulate the distributed sleep cycle by promoting relaxation and supporting the natural circadian rhythm. Ingredients help to reduce stress and anxiety, increase serotonin and melatonin production, calm the nervous system, and improves sleep quality, resulting in better initiation and maintenance of sleep.

- **Uses:**

- Used for delivering herbal and nutraceutical ingredients (e.g., sleep support, immunity).

- Improves patient compliance, especially in pediatric and geriatric patients.
- Used for taste masking of bitter or unpleasant drugs

- **Types:**

- **Medicated gummies** – Contain active pharmaceutical ingredients for therapeutic effect
- **Nutraceutical/Herbal gummies** – Contain vitamins, minerals, and herbal extracts
- **Sugar-based and sugar-free gummies** – Based on type of sweetener used

❖ **Advantages:**

- Easy to chew and swallow (no need for water).
- Pleasant taste and high patient acceptability.

❖ **Disadvantages:**

- Sensitive to temperature and humidity (may melt or stick)
- Limited drug loading capacity compared to tablets/capsules.

Objective:

1. To promote natural and restful sleep using herbal sleep support gummies.
2. To improve overall sleep quality and sleep duration.
3. Sleep onset latency (reduce the time required to fall asleep).
4. To provide safe and non – habit forming alternative to synthetic sleep medication.
5. To minimize nighttime awakenings and improve sleep continuity.

Plan of Work:

Selection of Herb

Formulation of Gummies

Evaluation study

1. **Selection of herb:**
suitable herbal ingredients such as ashwagandha, Tulsi, chamomile was selected based on their sleep-enhancing and calming properties.
2. **Selection of Material**:
Required excipients, sweeteners, gelling agents, flavors and preservative were selected for the preparation of stable and palatable gummies.
3. **Selection of Method:**
Required excipients, sweeteners, gelling agents were selected for preparation of stable gummies**.**
4. **Formulation of gummies:**
Herbal gummies prepared by mixing herbal extracts with the gummy base followed by molding and demolding.
5. **Evaluation study:**
The prepared gummies were evaluated for parameters such as weight variation, PH, appearance, texture, and stability.

Materials and Methods:

1. **Materials:**

Materials	Source
Ashwagandha	Botanical garden, TC college, Baramati
Tulsi	Botanical garden, TC college, Baramati
Chamomile	Botanical garden, TC college, Baramati
Tart cherry	Commercial store
Agar	College Laboratory
Stevia	Commercial store
Citric acid	College Laboratory

Orange oil	College Laboratory

2. Instruments:

Sr No.	Instrument/Equipment	Purpose
1	Heating Mantle	For heating of gummy mixture
2	Digital Weighing Balance	To accurate weighing of ingredients
3	Thermometer	To monitor temperature during preparation
4	PH Meter	To check PH of gummies

Methods:

Extraction Method:

Maceration method was selected as the extraction method for Tulsi, ashwagandha, and chamomile due to its simplicity, minimal equipment requirement, and effectiveness in extracting bioactive compounds without degradation of heat-sensitive constituents. This method also allows better preservation of volatile components present in herbal materials.

In simple, maceration is a simple extraction technique where powdered plant materials are soaked in a suitable solvent to extract active constituents

1. Accurately weighed quantity of coarsely powdered plant materials was taken in clean and dry container.
2. A suitable solvent i.e. ethanol was added in drug solvent ration 2:20
3. The mixture was kept in closed container for 48 hours at room temperature.
4. The content was shaken intermittently to enhance extraction.
5. After maceration, the mixture was filtered by filter paper.
6. The extract was stored in an airtight container under refrigeration until further use.

Fig: Process of Maceration

1) TULSI (*Ocimum Sanctum*)
- Fresh leaves were collected washed with water and shade dried for 3 days.
- Dried leaves were pulverized using a mechanical grinder.
- Powder drug was taken in a closed container.
- Ethanol was added.
- The mixture was kept for 48 hours with intermittent shaking.
- The extract was filtered by filter paper.
- Final extract was store in an airtight container.

2) ASHWAGANDHA (*Withania somnifera*)
- Accurately weight powder drug was taken in clean and dry container.
- Ethanol was added.
- Maceration was carried out for 48 hours.
- Mixture was shaken intermittently to enhance extraction.
- Filtration done using filter paper.
- Extraction was stored in airtight container.

3) CHAMOMILE (*Matricaria chamomilla* L)
- Flowers was shade dried to preserve volatile oil.
- Dried flowers were powdered.
- Maceration was carried out for 48 hours with intermittent shaking.
- Filtrate using filter paper.
- Stored in airtight container.

Phytochemical Test:

1. Sodium hydroxide (NaOH) Test:(For Eugenol)

Procedure: To 1ml herbal extract, a few 10% sodium hydroxide solution were added. The mixture was observed for colour change.

Fig: presence of eugenol

Observation:

Formation of yellow coloration which disappeared on addition of dilute HCL.

Inference:

The test indicates the presence of eugenol.

2. Shinoda Test:(For Flavonoids)

Procedure: To 1ml of extract a small quantity of magnesium was added followed by few drops of

concentrated hydrochloric acid.

Fig: presence of flavonoids

Observation:

Development of pink colour.

Inference:

Presence of flavonoids.

3. Salkowski Test:(For Withanolides) Procedure:

To 1ml of extract, 2ml chloroform was added followed by addition of concentrated sulfuric acid.

Fig: presence of withanolides

Observation:

Appearance of reddish-brown coloration>

Inference:

Presence of withanolides.

4. Picric Acid Test:(For Alkaloids) Procedure:

To 1ml extract few drops of picric acid solution were added.

Fig: presence of alkaloids

Observation:

Formation of yellow crystalline precipitate.

Inference:

Presence of alkaloids was indicated.

Formulation table for 30 Gummies:

SR NO.	INGREDIENTS	QUANTITY	ROLE
1	Tulsi extract	4 ML	Anti – anxiety, relaxation
2	Ashwagandha extract	4 ML	Stress relief
3	Chamomile extract	4 ML	Calming, sedative effect
4	Tart cherry	1 GM	Source of melatonin
5	Agar	6 GM	Gelling agent
6	Stevia	3 GM	Sweetener
7	Orange oil	0.5 ML	Flavouring agent
8	Orange colour	0.3 MG	Colouring agent
9	Citric acid	1 GM	preservative
10	water	100 ML	Solvent

For Preparation of Gummies:

The formulation of herbal sleep support gummies begins with the accurate weighing of all ingredients using a calibrated balance. The required quantity of purified water is taken in a suitable beaker, and the selected gelling agent such as agar, is slowly added with continuous stirring to avoid lump formation. The mixture is then heated to an appropriate temperature typically around 90°C until a clear and homogeneous solution is obtained.

Once the gelling agent is completely dissolved, sweeteners such as stevia added to the mixture. The solution is continuously stirred and maintained at a temperature of about 75°C to form a uniform viscous mass. The heating is continued further to concentrate the mixture and achieve the desired consistency, generally at a temperature of 90°C, ensuring that the temperature does not exceed 110°C to prevent caramelization or degradation.

After achieving the required consistency, the mixture is removed from heat and allowed to cool to about 50°C. This cooling step is critical to protect heat-sensitive herbal constituents. At this stage, herbal extracts such as Ashwagandha, Chamomile, Tulsi, extract, and tart cherry powder are added and mixed thoroughly to ensure uniform distribution throughout the mass.

Following this, excipients including citric acid as a preservative, orange oil as flavouring agent, are incorporated into the mixture at a temperature of around 40°C. The mass is stirred gently to avoid the incorporation of air bubbles. The prepared gummy mixture is then poured into pre-lubricated silicone Molds while maintaining a temperature of approximately 45°C to ensure proper flow and uniform filling.

The filled Moulds are allowed to stand at room temperature, for complete setting and gel formation, which may take around 12 hours. After proper setting, the gummies are removed from the mould by gently pressing the bottom of the mould edges. The finished product is stored under room temperature and low humidity to maintain stability and shelf life.

Fig. Preparation and moulding of gummies

Fig. Casting of Herbal Gummies in Silicone Molds

Fig: Demoulding

Evaluation Parameter:

1. Organoleptic Parameters:

Parameters	Observation
Color	Yellowish- Orange
Odor	Pleasant
Texture	Smooth, Soft
Appearance	Uniform, glossy

2. Weight Variation:

The weight variation test showed that all gummies had uniform weight with only minor variations, indicating good consistency and accuracy during formulation and molding process

SR NO.	WEIGHT
1	3 gm
2	3 gm
3	2.8 gm
4	3 gm
5	3 gm
6	2.8 gm
7	2.8 gm
8	3 gm
9	3 gm
10	3 gm
11	2.8 gm
12	2.8 gm
13	2.8 gm
14	2.8 gm
15	2.8 gm

SR NO.	WEIGHT
16	3 gm
17	2.9 gm
18	3 gm
19	2.8 gm
20	2.8 gm
21	3 gm
22	2.8 gm
23	2.8 gm
24	3 gm
25	3 gm
26	2.8 gm
27	3 gm
28	3 gm
29	3 gm
30	2.8 gm

Total weight of 30 gummies: 86.1

Average weight of gummies: Total weight of gummies

No. of gummies

= 86.1

30

= 2.87 gm

3. Stability testing:

The formulated herbal gummies remained stable at elevated temperature conditions (40°C) without significant changes in color, texture, odor.
The gummies showed good physical and chemical stability at higher temperature during accelerated stability studies.
Stability Testing in Hot Air Oven: stable up to 50°C Stability Testing in Incubator: Melts at above 55°C
Stability Testing in AC Room: Becomes hard below 25°C

4. PH Determination:

Gummies crushed and weighed as 2 gm and dissolve in water. The solution is stirred until the gummy was completely dispersed. The PH of formulated gummies was measured using the calibrated digital PH meter by immersing the electrode in the sample solution, and reading is 4.

Fig: PH of Gummies

Result:

1. Maceration is carried out with 2gm powder is added to 20 ml of ethanol and put at room temperature for 48 hours and 12 ml of filtrate extract was obtained after filtration.
2. The prepared herbal gummies were soft, uniform and has good stability with pleasant odor.
3. Phytochemical test:

Test name	Result
NaOH Test	+
Shinoda Test	+
Salkowski Test	+
Picric acid Test	+

4. From the above study total 30 gummies were formulated. Out of 30 average weights of gummies were found to be 86 gm. Each gummy weighs about 2.8 gm.

5. Evaluation test:

Parameters	Result
Color	Yellowish-orange
Odor	Pleasant
Texture	Smooth, soft

Appearance	Uniform, glossy
Weight variation	2.87 gm
PH	4
Stability	Stable at room temperature (25°C-40°C)

Discussion:

The present study was carried out to formulate and evaluate herbal sleep support gummies containing herbal extract of ashwagandha, Tulsi, chamomile, and tart cherry powder. The formulation was developed with the objective of preparing a palatable, stable, and patient-friendly herbal gummy dosage form for sleep support and stress relief.

The herbal extract was prepared by maceration method using suitable solvent system. The extraction process showed satisfactory yield and to obtain extracts possessed characteristic color and odor of respective herbs. Preliminary phytochemical screening confirmed the presence of important phytoconstituents such as flavonoids, alkaloids, phenolic compounds and withanolides.

The prepared gummies were evaluated for various parameters including appearance, color, texture, weight variation, pH, moisture content, and stability. The gummies showed uniform shape, smooth texture, acceptable taste, and pleasant odor, indicating good organoleptic properties. The weight variation test demonstrated uniformity in formulation, suggesting proper mixing and molding process.

The pH of the formulation was found to be within acceptable range, indicating suitability for oral administration. Moisture content was maintained within limit, which may help in preventing microbial growth and improving stability of gummies. No significant syneresis or cracking was observed during storage, indicating good gel consistency and stability of the formulation.

The gummies exhibited satisfactory texture and chewability due to proper concentration of gelling agent. Stability studies indicated that the formulation remained stable without significant changes in color, odor, texture, or appearance during the study period.

The herbal ingredients used in the formulation are traditionally known for their calming and sleep supportive activity. Ashwagandha possesses adaptogenic and stress-relieving properties, Chamomile exhibits mild sedative effect, Tulsi helps in stress management, while Tart Cherry is a natural source of melatonin which may help in sleep regulation. The combination of these herbal ingredients may provide synergistic activity in promoting relaxation and sleep support.

Thus, the prepared herbal gummies were found to possess satisfactory physicochemical properties and may serve as a promising herbal nutraceutical formulation for sleep support. Further studies including in-vivo studies and clinical evaluation may be carried out to confirm therapeutic efficacy and safety of the formulation.

Conclusion:

The study concluded that patient friendly approach for sleep support and relaxation by combining natural herbal extracts of ashwagandha, Tulsi, chamomile in a easily consumable form. The formulation showed satisfactory physicochemical characteristics including acceptable PH, stability. Bioactive constituents such as withanolides, flavonoids, and eugenol present in herbs may exert calming and sleep promoting activity by interacting with the central nervous system and enhancing GABA- mediated neurotransmission which helps reduce stress and induce relaxation. Due to their lipophilic nature, these phytoconstituents may also support absorption and possible penetration across the blood-brain barrier, enhancing therapeutic action. The use of

stevia provided sweetness without adding sugar, making the formulation suitable for health-conscious individuals. Overall, the study highlights the potential of herbal gummies as a modern, safe, effective, and convenient nutraceutical alternative for sleep and anxiety management.

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