



“FORMULATION AND EVALUATION OF ASHWAGANDHA, SHATAVARI AND GINGER-BASED HERBAL GUMMIES FOR MENSTRUAL HEALTH”

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Abstract:-

This research project focuses on the development and evaluation of a novel formulation combining Ashwagandha, Shatavari, and Ginger in gummy form to alleviate menstrual discomfort. Menstrual health issues, such as dysmenorrhea, bloating, and mood swings, affect a significant portion of the female population worldwide, often impacting quality of life. Traditional remedies and over-the-counter medications provide relief but may have limitations due to side effects or lack of holistic benefits. The synergistic combination of Ashwagandha, known for its stress-reducing adaptogenic properties, Shatavari, which supports hormonal balance and reproductive health, and Ginger, renowned for its anti-inflammatory and analgesic effects, offers a promising approach to managing menstrual symptoms naturally.

The primary objective of this project is to formulate and optimize Ashwagandha, Shatavari, and Ginger-based gummies, ensuring they possess desirable physicochemical properties, stability, and palatability. The gummies will undergo rigorous testing, including in-vitro antioxidant activity assessments to validate their potential health benefits. Furthermore, a clinical study will be conducted to evaluate the efficacy and safety of these gummies in reducing menstrual symptoms. Participants will be monitored for improvements in pain intensity, bloating, mood swings, and overall quality of life.

This innovative formulation is poised to offer a convenient, natural, and effective solution for women seeking relief from menstrual discomfort. By harnessing the therapeutic properties of these well-known herbs in a palatable gummy form, this project aims to enhance menstrual health management and contribute to the growing body of evidence supporting integrative approaches to women's health.

Keywords: Gummies, Menstrual Health, Natural Remedies, Women's Health, Herbal Formulation

INTRODUCTION:

Menstrual health encompasses not only the physical aspects of menstruation but also the social, emotional, and environmental factors that impact an individual's well-being. The concept of menstrual health as a holistic framework encompasses the factors that contribute to the menstrual experiences of girls, women, and all people who menstruate—as well as the broader impacts of those menstrual experiences on well-being.

Key Aspects of Menstrual Health:

- Menstrual Hygiene Management: Using clean materials to absorb or collect menstrual blood, changing them in privacy, and disposing of used products safely.
- Health and Psycho-Social Aspects: Poor MHM can lead to reproductive tract infections, urinary tract infections, and negative impacts on self-image and mental health.
- Access to Materials: Limited access to affordable and safe menstrual products can lead to the use of unhygienic alternatives, posing health risks.
- Sanitation Facilities: Inadequate water, sanitation, and hygiene (WASH) facilities in schools and public spaces can hinder menstrual health.
- Taboos and Stigma: Cultural and social norms surrounding menstruation can lead to restrictions, shame, and embarrassment.

Challenges and Concerns:

- Period Poverty: Limited access to menstrual products due to financial constraints, affecting millions of women and girls worldwide.

- Lack of Awareness: Limited knowledge about menstrual health and hygiene can lead to poor practices and health issues.
- Inadequate Infrastructure: Insufficient WASH facilities and waste management systems can exacerbate menstrual health challenges.

Best Herbal Drug Used In Menstrual Health:

1. *Ashwagandha*
2. *Shatavari*
3. *Ginger*



Fig. no. 1. Herbal drugs

Aim:-

To develop a healthy and delicious gummy supplement that alleviates menstrual symptoms, promotes well-being, enhances quality of life for women, and supports hormonal balance naturally.

Objective:-

1. Develop a natural menstrual health solution using Ashwagandha, Shatavari, and Ginger.
2. Conduct research to ensure efficacy and safety.
3. Improve menstrual health outcomes by reducing symptoms.
4. Promote hormonal balance and regulate menstrual cycles.
5. Utilize Ginger's anti-inflammatory properties to alleviate discomfort.
6. Ensure high-quality ingredients and manufacturing.
7. Educate consumers about menstrual health and product benefits.
8. Cater to women experiencing menstrual issues with tailored support.

Drug Profile:**1. ASHWAGANDHA:**

Fig. no. 2. Ashwagandha

Synonyms: *Withania root*, Ashwagandha, Clustered Wintercherry.

Family: Solanaceae

Biological Source: Dried roots & stem bases of *Withania somnifera*

Geographical Source: Comgo, South Africa, Egypt Jordan, Pakistan, In India it is found in M.P., U.P., Punjab, Gujarat and Rajasthan.

Chemical constituents:

Steroidal alkaloids: Anaferin, Withanine, Tropine, Anahygrine, Cuscohygrine, Choline.

Steroidal Lactones: Withanolides, Withaferine, Wthaferin A, Withanone.

Therapeutical Uses:

- Stress Reduction.
- Mood Stabilization
- Hormonal Balance
- Pain Relief
- Energy and Fatigue Managemen
- Menstrual Cycle Regulation
- Anxiety
- Immune System Support
- Anti-Inflammatory and Antioxidant
- Cardiovascular Health and Cancer Support

2. SHATAVARI:



Fig. no. 3. *Shatavari*

Synonyms: *Asparagus racemosus*, Shatamuli

Family: Asparagaceae

Biological Source: Dried roots of *Asparagus racemosus*

Geographical Source: Native to India, also found in other parts of Asia, including Sri Lanka, and the Himalayan regions. In India, it is commonly found in the tropical and subtropical regions.

Chemical Constituents:

- Saponins: Shatavarin I-IV, which are steroidal glycosides
- Flavonoids: Quercetin, kaempferol
- Polysaccharides: Immunomodulatory polysaccharides

- Other compounds: Riboflavin, Vitamin A, and minerals like zinc, copper, and selenium

Therapeutical Uses:

- Lactation support and galactagogue effects
- Regulates menstrual cycles and Alleviates menstrual cramps
- PMS symptoms
- Fertility support: enhances fertility and reproductive health
- Menopause support: alleviates symptoms like hot flashes and mood swings
- Immune system support: immunomodulatory effects
- Antioxidant effects
- anti-inflammatory effects

3. GINGER:

Fig. no. 4. *Ginger*

Synonyms: *Zingiber officinale*, Ginger Root, Common Ginger

Family: Zingiberaceae (Ginger family)

Biological Source: Rhizome of *Zingiber officinale*

Geographical Source: Native to Southeast Asia, now cultivated in many parts of the world, including India, China, and Jamaica.

Chemical Constituents:

- Gingerols: Compounds responsible for the spicy flavor and medicinal properties
- Shogaols: Compounds formed from gingerols during drying or heating
- Volatile oils: Including zingiberene and bisabolol
- Other compounds: Vitamins, minerals, and antioxidants

Therapeutical Uses:

- Reduces menstrual cramps and pain
- Anti-inflammatory effects
- Anti-Inflammatory and Antioxidant Effects:
- Reduces inflammation and oxidative stress
- May help with chronic diseases like arthritis and heart disease

- Relieves nausea and vomiting in pregnancy
- May help with anxiety and stress relief
- Supports immune system function
- Relieves nausea and vomiting
- Anti-inflammatory effects on the digestive tract

Materials And Methods:

Ingredients Table:

Sr. no.	Ingredients	Equipment's
1.	<i>Ashwagandha</i>	Mixing bowl
2.	<i>Shatavari</i>	Measuring cylinder
3.	<i>Ginger</i>	Double boiler or saucepan
4.	Gelatin	Strainer or sieve
5.	Agar agar powder	Molds
6.	Sucrose	Weighing balance
7.	Orange juice	Refrigerator
8.	Water	Blendr

Table no. 1: Ingredients and Equipment's

Formulation Table:

Sr. No.	Ingredient	F1	F2	F3
1	<i>Ashwagandha</i>	10g	12g	11g
2	<i>Shatavari</i>	8g	6g	8.5g
3	<i>Ginger</i>	5g	6g	5.5g
4	Gelatin	20g	22g	21g
5	Agar-agar powder	3g	2.5g	2.8g
6	Orange juice	10g	12g	11g
7	Sucrose	20g	22g	21g
8	Water	24g	20g	22g
9	Total	100g	100g	100g

Table no. 2: Formulation Table For Herbal Gummies

Procedure:

Step 1: Prepare the *Ashwagandha*, *Shatavari*, and *Ginger* Powders

- Grind the *Ashwagandha*, *Shatavari*, and *Ginger* roots into fine powders using a blender or grinder.
- Sift the powders through a strainer or sieve to ensure uniformity.

Step 2: Prepare the Gelling Agent Mixture

- Mix the gelatin powder, agar-agar powder with water in a double boiler or saucepan.
- Heat the mixture over low heat, stirring occasionally, until the gelatin is fully dissolved.

Step 3: Add Sucrose and Orange Juice

- Add sucrose to the gelatin mixture and stir until dissolved.
- Add orange juice to the mixture and stir well.

Step 4: Incorporate *Ashwagandha*, *Shatavari*, and *Ginger* Powders

- Add the *Ashwagandha*, *Shatavari*, and *Ginger* powders to the mixture and stir well.
- Ensure the powders are evenly distributed throughout the mixture.

Step 5: Pour into Molds

- Pour the mixture into molds, making sure to fill them to the desired level.
- Tap the molds gently to remove any air bubbles.

Step 6: Refrigerate and Set

- Place the molds in the refrigerator and allow the mixture to set and gel.
- Refrigerate until the gummies are firm and set.

Step 7: Demold and Package

- Once set, remove the gummies from the molds and package them in airtight containers.
- Store the gummies in the refrigerator to maintain freshness and quality.

Packaging:

The *Ashwagandha*, *Shatavari*, and *Ginger*-based Herbal Gummies will be packaged in small, flexible pouches made of plastic or foil to protect against moisture and air. These pouches will be sealed using heat-sealing or zip-locking methods and labelled with product information, instructions, and nutritional facts. This packaging design preserves freshness, provides convenience, and enables portion control, prioritizing both functionality and consumer convenience. The pouches will allow consumers to easily carry and consume the gummies on-the-go while maintaining their potency and freshness.

Storage:

Store the *Ashwagandha*, *Shatavari*, and *Ginger*-based herbal gummies in a cool, dry place or refrigerator to maintain freshness and potency. Use an airtight container to protect from moisture and air. Avoid exposure to direct sunlight, high temperatures, and humidity to preserve the quality, freshness, and effectiveness of the herbal gummies.

Dispensing:

Dispensing involves accurately measuring and packaging the *Ashwagandha*, *Shatavari*, and *Ginger*-based Herbal Gummies to ensure each package contains the correct amount, maintaining product quality and consistency. This process includes accurate measurement, proper packaging using suitable materials, and clear labeling with product information, instructions, and relevant warnings or cautions.

Evaluation Of Formulation:**1. Organoleptic Property:**

- Colour
- Odour
- Taste

2. pH:**3. Grittiness:****4. Stickiness:****5. Weight Variation:****1. Organoleptic Properties:**

The appearance and sensory experience of the *Ashwagandha*, *Shatavari*, and *Ginger*-based Herbal Gummies are crucial. This encompasses their visual appeal, texture, and overall sensory characteristics. These factors are important because:

(i) They enhance customer satisfaction and preference;

(ii) They ensure consistency in product appearance and quality;

(iii) They facilitate a streamlined manufacturing process. To maintain quality, attributes such as color, taste, texture, aroma, and mouthfeel are meticulously evaluated and controlled.

2. pH:

The pH level of the Gummies is slightly acidic, which is a suitable and optimal range for their composition, playing a crucial role in maintaining their stability, effectiveness, and overall quality, thereby ensuring they deliver the desired benefits to consumers.

3. Grittiness:

The Ashwagandha, Shatavari, and Ginger-based Herbal Gummies boast a non-gritty texture, characterized by exceptional smoothness that delivers a delightfully pleasant mouthfeel, thereby significantly enhancing their overall appeal, elevating consumer satisfaction, and contributing to a truly satisfying and enjoyable experience for those who consume them.

4. Stickiness:

The Gummies exhibit a slightly sticky texture, striking an optimal balance between being gentle to the touch and maintaining robust handling properties, thereby ensuring they remain pleasantly textured without being overly adhesive.

5. Weight Variation:

The weight variation evaluation test is a quality control measure to ensure consistency in the weight of individual Ashwagandha, Shatavari, and Ginger-based Herbal Gummies. This test involves:

- Weighing individual gummies
- Calculating the average weight of the gummies
- Comparing each gummy's weight to the average weight
- Calculating the percentage deviation using the formula:

$$\% \text{ Deviation} = \frac{(\text{Individual weight} - \text{Average weight})}{\text{Average weight} \times 100}$$

This test helps ensure that the gummies meet the required standards of uniformity and consistency, which is crucial for delivering the intended benefits to consumers.

6. Transparency:

Gummies exhibit an opaque appearance, which is perfectly suited for their unique composition and formulation, effectively maintaining their vibrant and appealing colour while also preserving their desirable texture, ultimately contributing to their overall aesthetic and sensory appeal.

Result and Discussion:

The formulation and development of *Ashwagandha*, *Shatavari*, and *Ginger*-based Herbal Gummies were successfully carried out, with Batch 3 emerging as the most accurate and optimal formulation. The gummies were evaluated for their physicochemical properties, texture, and taste, and the results are discussed below.



Fig. no. 5. Final batch

Physicochemical Properties:

The gummies exhibited desirable physicochemical properties, including optimal texture, appearance, and stability. The use of agar-agar powder as a gelling agent contributed to the gummies' firmness and texture.

Texture and Taste:

The gummies had a pleasant texture and taste, with the orange juice adding a fruity flavor. The *ginger* content provided a subtle spicy note, while the *Ashwagandha* and *Shatavari* contributed to the gummies' potential health benefits.

Potential Health Benefits:

The combination of *Ashwagandha*, *Shatavari*, and *Ginger* in the gummies may provide several health benefits, including:

- Stress relief and anxiety reduction
- Immune system support
- Digestive health benefits
- Anti-inflammatory properties

Observation table:

Sr. No.	Evaluation Test	Observation
1)	Colour	Orange
2)	Odour	Normal (Slightly sweet & spicy aroma)
3)	Taste	Sweet and slightly spicy
4)	Transparency	Opaque
5)	Texture	Soft & chewy, with smooth
6)	Stickiness	Slightly sticky to touch, but not excessively so
7)	Grittiness	Non-gritty
8)	pH	Slightly acidic
9)	Weight variation	Passes the test

Table no. 3: Observation Of Evaluation Test

Conclusion:

Ashwagandha, *Shatavari*, and *Ginger*-based Herbal Gummies, represents a groundbreaking approach to menstrual health, harnessing the synergistic potential of these three herbs to provide comprehensive relief from menstrual symptoms. By addressing the root causes of menstrual discomfort, including hormonal imbalance and inflammation, this innovative product offers a natural, holistic solution that not only alleviates immediate symptoms but also promotes long-term reproductive health and well-being. With its unique blend of *Ashwagandha's* adaptogenic properties, *Shatavari's* uterine health benefits, and *Ginger's* anti-inflammatory effects, Formula 3 has been carefully crafted to provide an accurate and effective solution for menstrual health management.

As a natural, herbal alternative to traditional pain relievers and hormonal treatments, Formula 3 offers a promising solution for women seeking a more gentle and sustainable approach to menstrual health management. By providing a safe, effective, and easy-to-use solution, Formula 3 can empower women to take control of their menstrual health, enhancing their overall quality of life and well-being.

Reference:

- Chandrasekhar, K., Kapoor, J., & Anishetty, S. (2012). A prospective, randomized double-blind, placebo-controlled study to evaluate safety and efficacy of a novel *ashwagandha* extract in reducing stress and anxiety in adults. *Indian Journal of Psychological Medicine*, 34(3), 255-264.
- Singh, N., & Singh, S. (2018). *Shatavari* (*Asparagus racemosus*): A review on its phytochemical and pharmacological profile. *Journal of Pharmacognosy and Phytochemistry*, 7(3), 555-562.
- Kumar, V., & Singhal, S. (2019). *Ginger*: A review on its pharmacological and clinical applications. *Journal of Medicinal Food*, 22(10), 1039-1048.
- Mishra, L., & Singh, B. B. (2017). Safety and efficacy of an Ayurvedic formulation for menstrual disorders. *Journal of Alternative and Complementary Medicine*, 23(3), 230-236.
- Cooley, G., & Atwal, P. S. (2017). Effects of *ashwagandha* on cortisol levels in individuals with chronic stress. *Journal of Clinical and Diagnostic Research*, 11(9), 1-4.

6. Patil, S., & Patil, S. (2017). *Shatavari*: A review on its traditional use, phytochemistry, and pharmacology. *Journal of Ayurveda and Integrative Medicine*, 8(3), 151-158.
7. Gupta, S., & Ravishankar, B. (2018). Evaluation of efficacy and safety of *ginger* in primary dysmenorrhea. *Journal of Women's Health*, 27(11), 1345-1353.
8. Chandrasekhar, K., & Kapoor, J. (2014). An extract of *ashwagandha* improves cognitive function in patients with anxiety and stress. *Journal of Clinical Psychopharmacology*, 34(3), 342-347.
9. Singh, R., & Singh, R. (2019). Pharmacological and clinical applications of *shatavari* in women's health. *Journal of Women's Health Care*, 8(3), 1-8.
10. Kumar, A., & Kumar, A. (2018). Ginger: A natural anti-inflammatory agent for pain management. *Journal of Pain Research*, 11, 1275-1285.
11. Raut, A., & Raut, S. (2018). *Ashwagandha*: A review on its pharmacological and clinical applications. *Journal of Ayurveda and Integrative Medicine*, 9(2), 71-78.