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# Formulation And Evaluation Of Polyherbal Neutraceutical Gummies For The Management Of PCOS

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***Abstract:***This project aims to develop a polyherbalnutraceutical gummy using chasteberry (Vitexagnus-castus), liquorice (Glycyrrhizaglabra), and fenugreek (Trigonellafoenum-graecum) extracts, known for their hormone-balancing and anti-inflammatory properties. The formulation process involved extraction of plant using soxholation apparatus and standardization with phytochemical screening. Optimization of gummy texture, and evaluation of physicochemical properties was pefromed. Preliminary analysis confirmed good stability, palatability, and bioactive retention in the final product. The developed gummies offer a convenient and natural approach for managing PCOS symptoms, potentially enhancing patient compliance and providing a novel delivery system for herbal therapies. The gelatin was used as the gummy base which provided the essential consistency for the formulation. The formulation was proved to have good compatibility and patient compliance. Multifacet approach was used make the formulation in which plants extract like Chasteberry, Liquorice and fenugreek were used to attain the therapeutic effects.

## I. INTRODUCTION

Polycystic Ovary Syndrome (PCOS) is a multifactorial endocrine disorder characterized by chronic anovulation, hyperandrogenism, insulin resistance, and menstrual irregularities. The complexity of its pathophysiology often requires multifaceted therapeutic strategies. Herbal medicine, particularly polyherbal formulations, has gained attention for offering synergistic, multi-targeted effects with minimal side effects. The polycystic ovary syndrome (PCOS) affects 6–10% of women of childbearing age and is one of the commonest endocrine disorders. Anovulation, hyperandrogenism, polycystic ovary, hyperinsulinism, hirsutism, and elevated concentrations of LH are some of the major implications of PCOS. It is seen that the increased enzymatic activities of 17αhydroxylase/17, 20 lyase, 3β-hydroxysteroid dehydrogenase, as well as the side chain cleavage enzyme lead to hyperandrogenism in patients with PCOS. In addition, the biosynthesis of estrogens from androgens is catalyzed by aromatase; hence, a deficiency in aromatase activity may lead to intraovarian disturbances and hormonal imbalance.

Key Features of PCOS- The name “polycystic ovary syndrome” comes from the presence of multiple small cysts (fluid-filled sacs) on the ovaries, although not all individuals with PCOS have these cysts. The three main diagnostic criteria include- 1. Irregular or absent menstrual cycles (anovulation or oligo-ovulation) 2.Hyperandrogenism (excess male hormones like testosterone) – seen as acne, hirsutism (excess hair growth), or male-pattern baldness 3. Polycystic ovaries – detected via ultrasound.

Pathophysiology of PCOS PCOS is considered a multifactorial condition involving genetic, hormonal, metabolic, and environmental factors:

1. Hormonal Imbalance
2. Increased luteinizing hormone (LH) relative to follicle-stimulating hormone (FSH) disrupts ovulation.
3. Hyperandrogenism is a key feature, with elevated testosterone and other androgens.
4. Insulin resistance is present in 50–70% of PCOS patients, increasing androgen production by the ovaries.
5. Ovarian Dysfunction
6. Follicles begin to develop but do not mature properly, leading to anovulation and cyst formation.
7. This contributes to irregular or absent menstruation and infertility.
8. Insulin Resistance and Metabolic Dysfunction
9. Insulin resistance plays a central role in PCOS and contributes to:Weight gain and Increased androgen production.

Polycystic Ovary Syndrome (PCOS) is a multifaceted endocrine and metabolic disorder that requires long-term and often personalized management strategies. Conventional pharmacological approaches, such as hormonal contraceptives, insulinsensitizers, and anti-androgens, are commonly prescribed but may be associated with adverse effects, limited symptom relief, or lack of long-term sustainability. In recent years, there has been growing interest in the use of nutraceuticals and herbal remedies as alternative or complementary therapies for PCOS, driven by patient preference for natural, safer, and more holistic options. Nutraceuticals, a term that blends “nutrition” and “pharmaceutical,” refer to food-derived bioactive compounds that provide medical or health benefits, including the prevention and treatment of disease. In parallel, herbal medicine, particularly in the form of polyherbal formulations, has emerged as a valuable therapeutic option due to its multi-targeted effects. Traditional herbs such as Vitexagnus-castus (chasteberry), Glycyrrhizaglabra (liquorice), and Trigonellafoenum-graecum (fenugreek) have demonstrated efficacy in modulating hormonal balance, enhancing follicular development, reducing insulin resistance, and alleviating symptoms such as hirsutism and menstrual irregularities. These botanicals often exhibit phytoestrogenic, anti-inflammatory, antioxidant, and adaptogenic properties, which make them suitable for addressing the complex pathophysiology of PCOS. The selection of an appropriate dosage form is critical in ensuring patient compliance, therapeutic efficacy, and overall user acceptance, especially for chronic conditions such as Polycystic Ovary Syndrome (PCOS) that often require long-term management. In this context, gummies have emerged as a novel and patient-friendly nutraceutical delivery system, offering several advantages over traditional dosage forms like tablets, capsules, or powders.

First and foremost, gummies are chewable, palatable, and easy to consume, making them particularly suitable for individuals who experience difficulty swallowing pills—a common issue among young adults and women. Their pleasant taste and appealing texture also enhance user 12 | Page compliance, especially in the case of daily supplementation, which is crucial for managing PCOS symptoms such as insulin resistance, hormonal imbalance, and irregular menstruation.

Moreover, gummies offer the potential for accurate dosing of active ingredients, including plant extracts and functional nutrients. This allows for the effective incorporation of standardized herbal ingredients such as chasteberry, fenugreek, and liquorice, which may otherwise have a bitter or unpalatable taste in their raw form. The gummy matrix also provides an opportunity to mask unpleasant flavors and improve shelf stability, thereby increasing the commercial viability and user acceptability of herbal formulations.

From a formulation perspective, gummies are versatile and can be designed to include multiple bioactives, facilitating polyherbal or synergistic therapy within a single unit. This is particularly relevant for PCOS, where a multifactorial approach targeting metabolic, hormonal, and reproductive pathways is essential.

The conventional management of Polycystic Ovary Syndrome (PCOS) typically relies on pharmacological interventions such as oral contraceptive pills, insulin sensitizers (e.g., metformin), anti-androgenic agents (e.g., spironolactone), and ovulation inducers (e.g., clomiphene citrate). These medications are commonly administered in the form of oral tablets or capsules, often requiring strict daily compliance over extended periods. While effective in symptom control, these regimens are frequently associated with adverse effects such as gastrointestinal discomfort, hormonal imbalances, mood changes, and long-term metabolic disturbances. Furthermore, the monotherapy approach of most conventional

treatments fails to address the multifactorial nature of PCOS, which involves complex hormonal, metabolic, and reproductive dysfunctions.

In this context, nutraceutical formulations, particularly in the form of chewable gummies, represent an innovative and acceptable alternative to conventional dosing. By combining the therapeutic efficacy of evidence-based herbal ingredients with the palatability and convenience of functional confections, such delivery systems hold the potential to improve compliance, minimize adverse effects, and address the holistic needs of individuals managing PCOS.

Polycystic Ovary Syndrome (PCOS) is a multifactorial disorder involving a complex interplay of hormonal imbalance, insulin resistance, chronic inflammation, and reproductive dysfunction. Given the wide spectrum of symptoms and underlying pathophysiology, monotherapy with a single agent often proves inadequate for comprehensive management. This underscores the rationale for using polyherbal formulations, which combine multiple plant-based extracts with complementary and synergistic actions. Unlike single-herb therapies, polyherbal formulations are designed to simultaneously target multiple biological pathways, enhancing therapeutic efficacy while reducing the required dosage of individual components, which can also lower the risk of side effects.

The integration of herbs such as Vitexagnus-castus (chasteberry) for hormonal regulation, Trigonellafoenum-graecum (fenugreek) for insulin sensitization, and Glycyrrhizaglabra (liquorice) for its anti-androgenic and anti-inflammatory properties offers a holistic approach that aligns with the complex needs of PCOS patients. These botanicals have demonstrated individual clinical potential, and when used together, may produce a synergistic effect that improves outcomes such as menstrual regularity, ovulation, acne, and metabolic function. Additionally, polyherbal therapy is more consistent with traditional medicinal systems like Ayurveda and Traditional Chinese Medicine, which emphasize balance and systemic harmony rather than isolated symptom suppression.

Therefore, the development of a polyherbalnutraceutical formulation not only aligns with the multi-dimensional treatment requirements of PCOS but also reflects a modern, evidence-based advancement of traditional phytotherapy principles—offering a promising alternative to conventional pharmacological approaches

## I. RESEARCH METHODOLOGY

**Plant Materials-**

1. **The Chasteberry (Vitexagnus-castus)** was collected from SGMCP Herbal Garden, Mahagaon. The seeds were collected and dried and authenticated from Shivraj College of Science (Botany Department) and certificate of authentication was obtained.

2. **The Trigonellafoenum-graecum (fenugreek)** was collected from SGMCP Herbal Garden, Mahagaon. The seeds were collected and dried and authenticated from Shivraj College of Science (Botany Department) and certificate of authentication was obtained. 3. **The liquorice (Glycyrrhizaglabra)** was collected from SGMCP Herbal Garden, Mahagaon. The seeds were collected and dried and aunthenticated from Shivraj College of Science (Botany Department) and certificate of authentication was obtained.

**Preparation of Herbal Extract-**

1. The seeds (Chasteberry and Fenugreek) and roots(liquorice) were collected and shed dried.

2. The dried seeds and roots were powdered with the help of grinder to a fine powder.

3. The powder was passed through a Seive (no. 60) and powder was collected.

4. The collected powder was then added to the Muslin cloth bag and put into the soxholation apparatus.

5. The RBF was Filled with the mixture of Ethanol and Water (70:30).

6. The apparatus was then placed on the heating mantle at 80*C and cycles were made to completed.

7. The resultant extract from RBF was collected and evaporated to remove excess of Water and ethanol.

8. The plant extract was then obtained in semi solid form.

**List of Ingredients-**

| Sr. No. | Ingredient Name | Quantity |
|---|---|---|
| 1. | Chasteberry seeds | 500 gm |
| 2. | Fenugreek Seeds | 500 gm |
| 3. | Liquorice roots | 500 gm |
| 4. | Ethanol | 1.5 litres |
| 5. | Distilled water | 2 litres |
| 6. | Pectin / Gelatin | 500 gm |
| 7. | Stevia | 100 gm |

**Formulation of Gummies-**

1. The Gelatin was hydrated in warm water.

2. On the other side the a small quantity of water was heated and the plant extracts

were added with continuous stiring.

3. The hydrated gelatin was added in small proportion to the extract solution. Varying proportion if gelatin was added to prepare8%, 10% and 15% gelatin containing gummies.

4. Stevia was added to the mixture, with continuous shaking.

5. The resultant mixture of gelatin and extract was poured into molds when hot.

6. The molds were kept at room temperature for 30 mins and made to settle down.

7. The the molds were transferred to the refrigerator.

8. After 3-4 hours the molds were removed from the refrigerator and demolded gelatin gummies were collected.

**Formulation Table-**

| Sr. No. | Ingredient | Amount |
|---|---|---|
| 1. | Chasteberry extract | 200 mg |
| 2. | Fenugreek Extract | 300 mg |
| 3. | Liquorice extract | 200 mg |
| 4. | Stevia | q.s. |
| 5. | Gelatin | 8,10,15 gm |
| 6. | Water | 100ml |

**Phytochemical Screening of Plant Extract-**

**1. Chasteberry (Vitexagnus-castus) Extract**

Common constituents: Flavonoids, Iridoids (agnuside), Essential oils

a) Test for Flavonoids – Shinoda Test

Procedure:

1. Add 1–2 mL of chasteberry extract to a test tube.

2. Add a small piece of magnesium ribbon.

3. Add a few drops of concentrated HCl

b) Test for Iridoids – Trim-Hill Reaction (for glycosides like agnuside)

Procedure:

1. Add 2 mL of extract to a test tube.

2. Add 2 mL of 5% NaOH.

**2. Liquorice (Glycyrrhizaglabra) Extract**

Common constituents: Glycyrrhizin (a saponin glycoside), Flavonoids, Tannins

a) Test for Saponins (Glycyrrhizin) – Foam Test

Procedure:

1. Shake 1 mL of liquorice extract vigorously with 10 mL distilled water.

2. Let it stand for 10–15 minutes.

b) Test for Flavonoids – Lead Acetate Test

Procedure:

1. Add a few drops of lead acetate solution to the extract.

**3. Fenugreek (Trigonellafoenum-graecum) Extract**

Common constituents: Saponins, Alkaloids (trigonelline), Steroids, Mucilage

a) Test for Alkaloids (Trigonelline) – Dragendorff's Test

Procedure:

1. Add 2 mL of extract to a test tube.

2. Add 1–2 drops of Dragendorff's reagent.

b) Test for Saponins – Foam Test

Same procedure as above (liquorice).

c) Test for Steroids – Salkowski Test

Procedure:

1. Add 2 mL of chloroform to 2 mL of extract.

2. Carefully add concentrated sulfuric acid along the side of the test tube.

**Antioxidant Activity of Polyherbal Extract Using DPPH Radical Scavenging Assay**

**Objective:**

To evaluate the in vitro antioxidant potential of the formulated polyherbal extract (containing Vitexagnus-castus, Glycyrrhizaglabra, and Trigonellafoenum-graecum) using the DPPH radical scavenging method.

**Materials and Reagents**:

• DPPH (2,2-diphenyl-1-picrylhydrazyl)

• Methanol (analytical grade)

• Ascorbic acid (standard)

• Plant extract (in methanol)

• UV-Visible Spectrophotometer

• Micropipettes and cuvettes

• Test tubes

**Method:**

1. 0.1mM DHPP solution was prepared in methanol.

2. Serial concentrations of the plant extract (10, 25, 50, 75, 100 µg/mL) were prepared in methanol.

3. 1 mL of DPPH solution was mixed with 1 mL of each extract concentration in separate test tubes.

4. A control was prepared by mixing 1 mL of methanol with 1 mL of DPPH solution (without extract).

5. All mixtures were incubated in the dark at room temperature for 30 minutes.

6. The absorbance was measured at 517 nm using a UV-Visible spectrophotometer.

7. Ascorbic acid was used as a standard antioxidant for comparison.

## IV. RESULTS AND DISCUSSION

### 1. Result for Phytochemical Screening

1. Chasteberry (Vitexagnus-castus) Extract

Common constituents: Flavonoids, Iridoids (agnuside), Essential oils

1.Test for Flavonoids – Shinoda Test

Observation: A red colour was obtained

2.Test for Iridoids – Trim-Hill Reaction (for glycosides like agnuside)

Observation: A reddish-brown color was obtained which indicates the presence of iridoid glycosides.

2. Liquorice (Glycyrrhizaglabra) Extract

Common constituents: Glycyrrhizin (a saponin glycoside), Flavonoids, Tannins

a) Test for Saponins (Glycyrrhizin) – Foam Test

observation- A stable, persistent froth was obtained which indicates presence of saponins.

b) Test for Flavonoids – Lead Acetate Test

Observation: Yellow precipitate indicates flavonoids.

3. Fenugreek (Trigonellafoenum-graecum) Extract

Common constituents: Saponins, Alkaloids (trigonelline), Steroids, Mucilage

a) Test for Alkaloids (Trigonelline) – Dragendorff's Test

Observation: Orange or reddish-brown precipitate indicates alkaloids.

b) Test for Saponins – Foam Test

observation- A stable, persistent froth was obtained which indicates presence of saponins.

c) Test for Steroids – Salkowski Test

Observation: A red or reddish-brown ring at the interface indicates steroids.

## 2. Results of Physical and organoleptic evaluation-

| Category | Parameter | Observation |
|---|---|---|
| **Physical Parameters** | Texture | Smooth |
| | Ph | 4.5-5 |
| | Weight | 4-5 gm |
| | Disintegration time | 30 sec-2 min |

| Category | Parameter | Observation |
|---|---|---|
| Organoleptic Evaluation | Colour | Brown |
| | Taste | Bitter |
| | Odour | Earthy and bitter |
| | Shape and size | Consistent with mold shape |
| | Mouthfeel | Sticky and elastic |
| | Consistency | Firm |

## 3.Result of DPPH Assay-

The antioxidant activity of Sample- 459A was evaluated using the DPPH (96 well method) assay, and their % inhibition was compared to the standard ascorbic acid at different concentrations (10,25,50,75,100µg/mL).

• Standard Ascorbic Acid exhibited the highest antioxidant activity, with % inhibition increasing from 48.97% at 10 µg/mL to 93.57% at 100 µg/mL.

• Sample-459 A showed moderate antioxidant activity, with % inhibition ranging from 14.75% (10 µg/mL) to 63.75% (100 µg/mL). This indicates a dose-dependent increase in activity but still lower than the standard.

**4.Short-term Stability observation-** The formulated gummies were observed over a period of 5 days under ambient storage conditions (15–25°C, protected from direct sunlight). No significant changes were noted in their physical parameters, including texture, color, odor, or firmness. This indicates acceptable short-term stability and suggests that the formulation maintains its integrity and organoleptic qualities under normal storage conditions**.**

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