

Formulation Of Herbal Gummies for Pcos

Rohit R. Rathod¹, Nilesh B. Chougule²

¹*Student Ashokrao Mane Institute of Pharmacy, Ambap.*

²*Principal, Ashokrao Mane Institute of Pharmacy, Ambap*

Abstract— Polycystic Ovary Syndrome (PCOS) is a complex endocrine disorder affecting millions of women worldwide, characterized by hormonal imbalances, irregular menstrual cycles, insulin resistance, and other associated symptoms. Conventional treatments often involve pharmacological interventions, but there is growing interest in natural remedies due to concerns about side effects and long-term safety. In this context, the formulation of herbal gummies for the treatment of PCOS emerges as a novel and promising approach. This abstract outlines the rationale, methodology, and potential benefits of developing herbal gummies tailored specifically for PCOS management. By leveraging the therapeutic properties of herbs known to address the underlying hormonal dysregulation and symptomatology of PCOS, such as chasteberry, cinnamon, and spearmint, these gummies offer a convenient, palatable, and potentially effective alternative to traditional treatments.

Index Terms— considerations in the formulation process include the selection of herbs with evidence-based efficacy, optimization of dosages for maximum therapeutic benefit, and formulation of gummies free from common allergens and artificial additives to ensure safety and tolerability. Furthermore, the development of herbal gummies allows for enhanced compliance and adherence to treatment regimens, particularly among individuals who may find traditional medications challenging to tolerate or administer.

I. INTRODUCTION

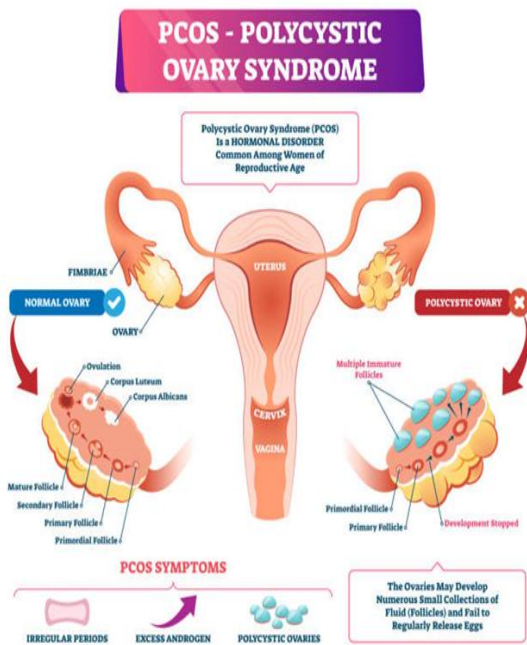
Polycystic Ovary Syndrome (PCOS) is a common hormonal disorder affecting women of reproductive age. It is characterized by the presence of multiple small cysts on the ovaries and the hormonal imbalances that occur as a result. The exact cause of PCOS is not fully understood, but it is believed to be a combination of genetic and environmental factors that contribute to the condition. Insulin resistance, which is when the body is unable to use insulin effectively, is

also a common feature of PCOS. Symptoms of PCOS can vary, but often include irregular menstrual periods, excessive hair growth, acne, and weight gain. PCOS can also cause fertility issues, as the hormonal imbalances can prevent ovulation from occurring regularly. PCOS is a chronic condition that requires ongoing management, but there are treatments available to help manage the symptoms and reduce the risk of long-term health complications

PCOS (Polycystic Ovary Syndrome) is a hormonal disorder that affects many women of reproductive age. It can cause a range of symptoms, including irregular periods, excessive hair growth, acne, weight gain, and infertility. While there is no cure for PCOS, there are various ways to manage its symptoms. One such method is through the use of PCOS gummies supplements. These supplements contain a combination of herbs that are believed to help improve the symptoms of PCOS.

Reasons why using PCOS gummies supplements

- ✓ Regulation of menstrual cycles
- ✓ Management of insulin resistance
- ✓ Support for fertility
- ✓ Reduction of androgen levels
- ✓ Improve Insulin Sensitivity
- ✓ Regulate Hormone Levels
- ✓ Support Ovarian Health
- ✓ Reduce Inflammation
- ✓ Support Weight Management
- ✓ Convenience: Gummies can be a convenient way to take supplements.
- ✓ Hormonal Imbalances



II. AIM

Formulation of Auyurvedic gummies for PCOS (Supplement).

Objective for pcos gummies

PCOS (Polycystic Ovary Syndrome) gummies can have several objectives, such as:

- 1) **Improve Insulin Sensitivity:** Insulin resistance is a common issue for women with PCOS. PCOS gummies can contain ingredients like chromium and cinnamon that can help improve insulin sensitivity.
- 2) **Regulate Hormone Levels:** PCOS is caused by hormonal imbalances, particularly high levels of androgens. PCOS gummies can contain ingredients like myo-inositol and d- chiro-inositol, which have been shown to help regulate hormone levels in women with PCOS.
- 3) **Support Ovarian Health:** Women with PCOS often have cysts on their ovaries, which can affect fertility. PCOS gummies can contain nutrients like vitamin D and antioxidants that can support ovarian health.
- 4) **Reduce Inflammation:** Inflammation is a common issue in women with PCOS. PCOS gummies can contain ingredients like omega-3

fatty acids and turmeric that have anti-inflammatory properties.

- 5) **Support Weight Management:** Many women with PCOS struggle with weight management due to insulin resistance and other hormonal imbalances. PCOS gummies can contain ingredients like fiber and chromium that can help support healthy weight management.
- 6) **Convenience:** Gummies can be a convenient way to take supplements, especially for those who struggle with swallowing pills or dislike the taste of liquid supplements.
- 7) **Nutrient Deficiencies:** Women with PCOS may have certain nutrient deficiencies that can be addressed with supplements. For example, vitamin D deficiency is common in women with PCOS, and PCOS gummies can contain vitamin D to support bone health and other functions.
- 8) **Hormonal Imbalances:** PCOS gummies can contain ingredients like myoinositol and d- chiro-inositol, which have been shown to help regulate hormone levels in women with PCOS.
- 9) **Weight Management:** PCOS gummies can contain ingredients like fiber and chromium that can help support healthy weight management, which is often a struggle for women with PCOS.
- 10) **Overall, Health:** PCOS gummies can contain antioxidants, omega-3 fatty acids, and other nutrients that can support overall health and well-being, which is especially important for women with PCOS who may be at increased risk for certain health conditions.

III. DRUG PROFILE

1) Aswagandha



Scientific name: *Whithania Somnifera*

Biological source: Dried roots and stem bases of *Whithania Somnifera*.

Family: Solanaceae

Chemical constituents: It consist alkaloids and whitanolides(steroidal lactones).

Uses:

1. It may help stabilize and adjust menstrual cycles.
2. It stimulates blood flow.
3. It fights against the infection.

2) Ashoka



Scientific name: *Saraca asoca*

Biological source: Dried stem bark of plant *Saraca Indica* Linn.

Family: Fabaceae

Chemical constituents: It contains tannins (0.57%-7.85%), Ash (2.43%-6.69%),

Flavonoids, Alkanes.

Uses:

1. It is useful to manage female disorders like dysmenorrhea and menorrhagia due to its vata balancing property.
2. It helps in alleviating pain.

3) Dashamoola



Scientific name: *Aegle marmelo*

Biological source: Dried stem bark of plant *Aegle marmelo*.

Family: Fabaceae

Chemical constituents: It contains tannins, Flavonoids, alkaloids, glycosides, terpenoids

Uses:

1. Treating various types of fever.
2. It reduces pain.
3. It improves impaired digestion.

4) Lodhara:



Scientific name: *Symplocos racemose* Roxb.

Biological source: Dried stem bark of plant *Symplocos racemose* Roxb.

Family: Symplocaceae

Chemical constituents: It contains flavonoids, cardiac glycosides, saponins, tannins, triterpenes and Phytosterols. Flavonoids exhibited the highest antimicrobial potential whereas tannins, triterpenes and phytosterols were completely inactive.

Uses:

1. It helps to cure acne, blemishes.
2. It also helps in gynaecological or female disorders.

5) Guduchi



Scientific name: *Tinospora cordifolia*

Biological source: Dried stem of plant *Tinospora cordifolia*.

Family: Menispermaceae

Chemical constituents: It contains Diterpene compounds, polyphenols, polysaccharides including arabinogalactinan polysaccharide.

Uses:

1. It boosts the body defense mechanism(immunity).
2. Helps regularizes and normalizes menstrual cycle.

Chemical constituents: chemical constituents in Aloe vera are Anthraquinones, saccharides, prostaglandins, and fatty acids.

Uses:

- Analgesic
- Antibacterial
- Antiviral
- Antifungal
- Anti-oxidant immune modulator
- Antiseptic
- Anti-inflammatory

6) Kakamachi:



Scientific name: *Solanum Nigrum* Linn.

Family: Solanaceae

Chemical constituents: It consist of alkaloid, steroid, carbohydrate, tannin, saponins

Uses:

1. It effective in heart disease.
2. It relives pain.

7) Aloe Vera



Scientific name: *Aloe barbadensis*

Biological source: Aloe is the dried juice collected by incision, from the bases of the leaves of various species of Aloe. Aloe vera Linn or Aloe barbadensis

Family: Liliaceae

8) Punarnava



Scientific name: *Boerhavia diffusa*

Family: Nyctaginaceae

Chemical constituents: It contains sterols, beta sitosterol and alkaloid.

Uses:

1. It uses as diuretic
2. It helps to manage symptoms of spleen enlargement.
3. Useful to control obesity.

9) Shatavari



Scientific name: *Asparagus racemosus*

Biological source: It is a dried root and leaves of plant *Asparagus racemosus*.

Family: Liliaceae

Chemical constituents: It contains steroids, alkaloids, mucilage. Saponine also present.

Uses:

1. It treats conditions related to hormone imbalance such as polycystic ovarian syndrome and infertility.

IV. EXCIPIENT PROFILE

1) Sweetening agent

Sucrose is also used as an excipient to provide solution-state stabilization, biological products (e.g therapeutic proteins). Sucrose is generally considered suitable and works with most products unless limited by specific formulation constraints.

2) Flavouring agent

Strawberry flavor is a natural or artificial flavor used in medicine to mask or impart taste to medications. A flavor, as used in the pharmaceutical industry for inactive ingredients, refers to natural or artificial tastes, which may include fragrances and colors of the flavoring. Flavors are used for orally consumed products such as syrups, chewable tablets, suspensions, or gums that impart beneficial therapeutic effect, as well.

3) Colouring agent

Chemical used to produce a distinctive appearance that may serve to differentiate a particular formulation from others. Most of these substances are subdivided into dyes, inorganic pigments and natural colorants.

V. MATERIALS AND METHOD

Materials

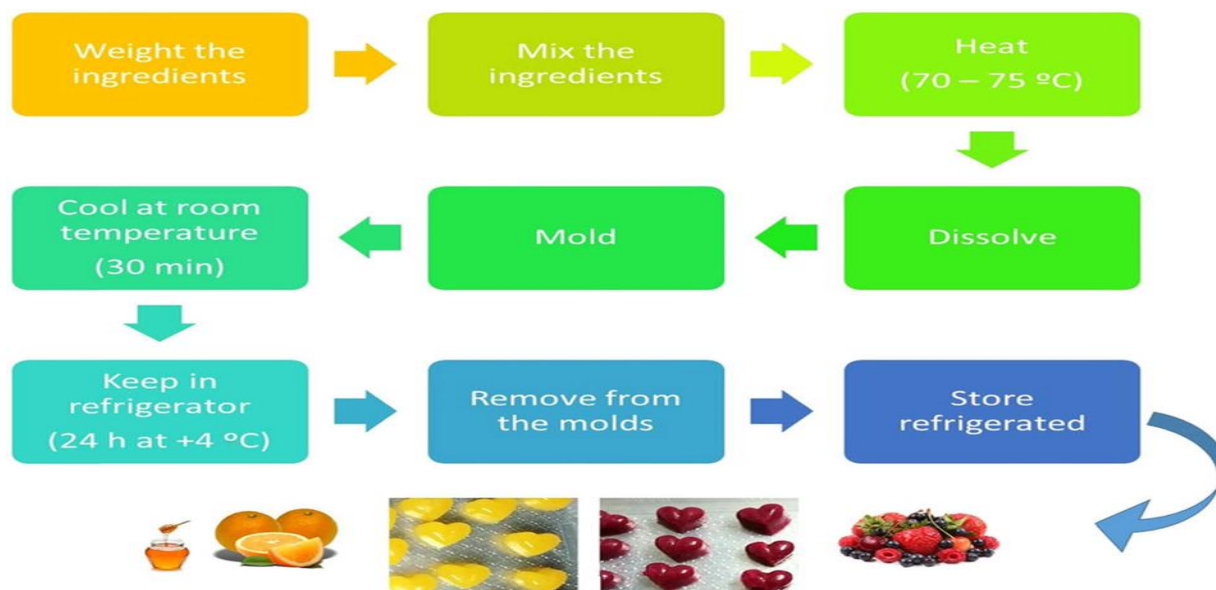
Each gummies contains

Sr.no	Ingredients	Quantity
1	Ashwagandha	19.8mg
2	Ashoka	30mg
3	Dashamoola	19.8mg
4	Lodhra	19.8mg
5	Guduchi	19.8mg
6	Kakamachi	19.8mg
7	Aloevera	15mg
8	Punarnava	19.2mg
9	Shatavari	19.2mg

Excipients

Ingredients	Role	Quantity
Gelatine	Binding Agent	5gm
Carmosine	Colouring agent	2-3drops
Strawberry Extract	Flavouring agent	4-6 drops
Sucrose	Sweetning agent	10 gm
Water	Vehicle	50 ml
Herbal Extract		4.56 ml

VI. METHOD



- Appropriate amount of agar should be dissolve in 50 ml of hot water on moderate agitation.
- Extract of all herbs added into above solution.
- Add 10 mg of Sucrose as sweetening agent .
- Add colouring and Flavouring agent with continuous stirring.
- Then cool above solution at room temperature and transfer it into any shape of
- silicon mould .
- After 2 days remove gummies from mould.
- Store in air tight container.



Evaluation Parameters:

1. Sensory evaluation: Colour, Odour, Taste, Hardness, Chewing
2. Moisture Content: Take Weight of 1 gummie then put it in hot air oven for 2 hours for drying .After 2 hours again take weight of that gummie and calculate moisture content
- 3.Osmosis: Take Weight of 1 gummie then deep it in water for 2 hours for osmosis .After 2 hours again take

weight of that gummie and calculate weight of gummie after osmosis.

4. pH of gummies: Blending a gummies into invariant paste. Calibrating the pH cadence and conforming the sample temperature to room temperature before measuring the pH. Irrigating the pH electrode with distilled water.Immersing the electrode to the gummy paste and measuring the p.

5. Friability Testing: Constantly dropping a sample of gummies over a fixed time, using arotating barrel with a baffle. The result is examining for broken tablets, and the chance of tablet mass lost through dicing.

VII. RESULT AND DISCUSSION

1.Sensory Evaluation: Observation is done by sensory organs.

Sr no	Sesnsory evaluation	Result
1	Colour	Reddish Brown
2	Odour	Pleasant
3	Taste	Sweet
4	Texture	Smooth Gelatinous

2. Moisture Content:

Take Weight of 1 gummie then put it in hot air oven for 2 hours for drying .After 2 hours again take weight of that gummie and calculate moisture content and it was found to be ,0.84gm.



(Before moisture removing)



(After moisture removing content)

3. Osmosis:

Take Weight of 1 gummie then deep it in water for 2 hours for osmosis. After 2 hours again take weight of that gummie and calculate weight of gummie after osmosis and it was found to be ,0.67gm.



(Before osmosis)



(After osmosis)

4. pH of Gummie:pH of Gummie should be 4.5-5.0 pH.

5. Concentration of solution:

To calculate the concentration of the solution of gummies, we need to determine the total mass of the ingredients and the volume of the solution.

First, let's calculate the total mass of the ingredients:

Total Mass = Ashwagandha + Ashoka + Dashamoola + Lodhra + Guduchi +

Kakamachi + Shatavari + Purnarnava + Aloe vera + Agar

Total Mass = 19.8 mg + 30 mg + 19.8 mg + 19.8 mg + 19.8 mg + 19.8 mg + 19.2 mg + 19.2 mg + 15 mg + 5 mg

Total Mass = 188.6 mg

Next, we need to convert the volume of water from milliliters to liters:

Volume = 50 ml = 50/1000 L = 0.05 L

Finally, we can calculate the concentration of the solution using the formula:

Concentration = (Total Mass of Ingredients) / (Volume of Solution)

Concentration = 188.6 mg / 0.05 L

Concentration = 3772 mg/L

Therefore, the concentration of the solution of gummies is 3772 mg/L

VIII. CONCLUSION

the formulation of herbal gummies for the treatment of Polycystic Ovary Syndrome (PCOS) holds significant promise in providing a natural and convenient approach to managing this complex hormonal disorder. By harnessing the therapeutic properties of herbs known to regulate hormonal balance, reduce insulin resistance, and alleviate symptoms associated with PCOS, such as irregular menstrual cycles and hirsutism, these gummies offer a holistic alternative to traditional pharmaceutical interventions.

The synergistic combination of carefully selected herbs, such as Ashoka, Cinnamon, and Shatavari, in a palatable gummy format not only enhances compliance but also ensures optimal absorption and bioavailability of the active compounds. Moreover, the absence of common allergens and artificial additives makes these herbal gummies suitable for a wide range of individuals seeking natural remedies for PCOS management.

However, it is essential to underscore the importance of further research and clinical trials to validate the efficacy, safety, and long-term effects of herbal gummies in the management of PCOS. Additionally, healthcare professionals should play a pivotal role in guiding patients on the appropriate use and integration of herbal supplements into their treatment regimens, considering individual health profiles and potential interactions with other medications.

Overall, the formulation of herbal gummies represents a promising avenue in the holistic management of PCOS, offering patients a convenient, natural, and potentially effective approach to addressing the multifaceted aspects of this common endocrine disorder.

REFERENCE

- [1] Azziz R. PCOS: a diagnostic challenge. Reproductive biomedicine online. 2004 Jan 1;8(6):644-8.
- [2] Rosenfield RL, Ehrmann DA. The pathogenesis of polycystic ovary syndrome (PCOS): the hypothesis of PCOS as functional ovarian hyperandrogenism revisited. Endocrine reviews. 2016 Oct 1;37(5):467-520.
- [3] Mukerjee N. Polycystic Ovary Syndrome (PCOS) symptoms, causes & treatments-a review. International Journal of Science and Research. 2020 Aug;9(7):1949-57.
- [4] Moini Jazani A, Nasimi Doost Azgomi H, Nasimi Doost Azgomi A, Nasimi Doost Azgomi R. A comprehensive review of clinical studies with herbal medicine on polycystic ovary syndrome (PCOS). DARU Journal of Pharmaceutical Sciences. 2019 Dec; 27:863-77.
- [5] Jazani AM, Azgomi HN, Azgomi AN, Azgomi RN. A comprehensive review of clinical studies with herbal medicine on polycystic ovary syndrome (PCOS). DARU Journal of Pharmaceutical Sciences. 2019 Dec;27(2):863.
- [6] Pursell JJ. The Woman's Herbal Apothecary: 200 Natural Remedies for Healing, Hormone Balance, Beauty and Longevity, and Creating Calm. Fair Winds Press; 2018 Jul 17.
- [7] Wal A, Wal P, Saraswat N, Wadhwa S. A detailed review on herbal treatments for treatment of PCOS-polycystic ovary syndrome (PCOS). Current Nutraceuticals. 2021;2(2174):2665978602666210805092103.
- [8] Pachiappan S, Matheswaran S, Saravanan PP, Muthusamy G. Medicinal plants for polycystic ovary syndrome: A review of phytomedicine research. Int J Herb Med. 2017;5(2):78-80.
- [9] Rotterdam ES. Revised 2003 consensus on diagnostic criteria and long-term health risks related to polycystic ovary syndrome. Fertil Steril. 2004;81(1):19-25.
- [10] Kalidoss G, Velraja S, Narayanan P. Development and formulation of phytoestrogen-rich supplement for women with polycystic ovary syndrome. International Journal of Infertility & Fetal Medicine. 2021 Jul 29;12(2):31-6.
- [11] Mishra LC, Singh BB, Dagenais S. Scientific basis for the therapeutic use of Withania somnifera (ashwagandha): a review. Alternative medicine review. 2000 Aug 1;5(4):334-46.
- [12] Pradhan P, Joseph L, Gupta V, Chulet R, Arya H, Verma R, Bajpai A. Saraca asoca (Ashoka): a review. Journal of chemical and pharmaceutical research. 2009;1(1):62-71.
- [13] Khanage SG, Subhash TY, Bhaiyyasaheb IR. Herbal drugs for the treatment of polycystic ovary syndrome (PCOS) and its complications. Pharm. Res. 2019;2(1):5-13.
- [14] Goswami PK, Khale A, Ogale S. Natural remedies for polycystic ovarian syndrome (PCOS): a review. Int J Pharm Phytopharmacol Res. 2012;1(6):396-402.
- [15] Aulia G, Sayyidah S, Fadhilah H, Ismaya NA, Indah FP. Formulation and Evaluation of Gummy Candy from the Extract of Jathropa Leaf (Jatropha curcas L.). Jurnal Kefarmasian Indonesia. 2023 Aug 31:103-14.
- [16] Vojvodić Cebin A, Bunić M, Mandura Jarić A, Šeremet D, Komes D. Physicochemical and sensory stability evaluation of gummy candies fortified with mountain germander extract and prebiotics. Polymers. 2024 Jan 17;16(2):259.
- [17] Knochenhauer ES, Key TJ, Kahsar-Miller M, Waggoner W, Boots LR, Azziz R. Prevalence of the polycystic ovary syndrome in unselected black and white women of the southeastern United States: a prospective study. The Journal of Clinical Endocrinology & Metabolism. 1998 Sep 1;83(9):3078-82.
- [18] Günelan E, Yaba A, Yılmaz B. The effect of nutrient supplementation in the management of polycystic ovary syndrome-associated metabolic dysfunctions: A critical review. Journal of the Turkish German Gynecological Association. 2018 Dec;19(4):220.
- [19] Romo-Zamarrón KF, Pérez-Cabrera LE, Tecante A. Physicochemical and sensory properties of gummy candies enriched with pineapple and papaya peel powders. Food and Nutrition Sciences. 2019 Nov 14;10(11):1300.
- [20] La-Ong Saleepoung CS. Formula Optimization of Chewing Gum from Medicinal Herbal Extract. Journal of Hunan University Natural Sciences. 2023;50(8).

- [21] Niam ML, Amin RS, Utami N, Wahyuni AS. Formulation of Dietary Supplement Chewable Gummy with Bastard Cedar Leaves (*Guazuma Ulmifolia*), Senna Leaves (*Cassia Angustifolia*) and Lime Extracts Using a Simplex Lattice Design. In Proceedings of the International Conference on Sustainable Innovation on Health Sciences and Nursing ICOSI-HSN 2022 Dec 26 (pp. 122-135). Amsterdam, The Netherlands: Atlantis Press.