Development and Evaluation of Polyherbal Tablet for PCOS

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***Abstract*—Polycystic Ovary Syndrome (PCOS) is a common endocrine disorder characterized by hormonal imbalance, Insulin Resistance, and irregular menstrual cycles. The present study aimed to formulate and evaluate a polyherbal tablet using Guduchi, Shatavari, Gokshura, Haridra, and Ashwagandha for the management of PCOS. The formulation was prepared by the wet granulation method using herbal powders and suitable excipients such as microcrystalline cellulose, HPMC, maize starch, magnesium stearate, and talc. Pre-compression studies showed good flow and compressibility of the blend. The prepared tablets were evaluated for hardness, friability, weight variation, thickness, and disintegration time, and all parameters were found within acceptable limits. Stability studies indicated no significant changes in the formulation. The polyherbal combination provides a synergistic effect targeting multiple factors of PCOS. The study concludes that the developed formulation shows promising potential for further evaluation in PCOS management.**

I. INTRODUCTION

Polycystic ovarian syndrome (PCOS) is a condition that affects women and is marked by a mix of symptoms, such as having too much testosterone, not ovulating, and being overweight. Women with PCOS also have ovaries that are larger than normal PCOS is becoming more common, and about 1–5% of women have it. Changes in lifestyle and higher levels of stress are thought to be causes of this rise. (1)

The growing demand for herbal medicines has led to the exploration of polyherbal formulations that act synergistically with minimal side effects. (2) The research focuses on investigating four prominent medicinal plants used within Indian traditional medicine which include Guduchi (Giloy), Ashwagandha (Withania Somnifera), Haridra (Curcumin 95%), Shatavari (Asparagus racemosus), Gokshura (Tribulus Terrestris). (3)

These plants are useful for scientific research because they have many pharmacological compounds that show adaptogenic properties as well as anti-inflammatory, female reproductive tonic, hormonal support, immunomodulatory functions. (5)

Symptoms: (4)

- Irregular menstrual cycles
- Acne
- Hirsutism
- Obesity
- Infertility.

Etiology:

The exact cause of Polycystic Ovary Syndrome (PCOS) is not fully understood, as it is viewed as a multifactorial disorder arising from a combination of factors in the body. (6)

1. Hormonal Imbalance: In PCOS, the body produces higher-than-normal levels of androgens (male hormones). This hormonal imbalance interferes with the normal development and release of eggs from the ovaries, leading to irregular or missed menstrual cycles. (6)
2. Insulin Resistance: Women with PCOS often experience insulin resistance, leading to increased insulin production. This can elevate androgen levels, exacerbating symptoms such as acne, weight gain, and irregular menstrual cycles. (15)
3. Genetic Factors: PCOS has a familial tendency, indicating a genetic link where having a mother or sister with the condition increases the likelihood of developing it. (6)

4. Lifestyle Factors: Modern lifestyle habits, including poor diet, inactivity, stress, and obesity, contribute to the development and exacerbation of PCOS, significantly affecting insulin resistance. (16)
5. Low-Grade Inflammation: Women with PCOS often experience chronic low-grade inflammation that increases androgen production by the ovaries, leading to further hormonal imbalance and impaired ovarian function. (15)

Organs Involved in PCOS

Polycystic Ovary Syndrome (PCOS) is a systemic hormonal and metabolic disorder, not limited to ovarian issues, involving the malfunction of multiple organs that contribute to its symptoms. (14)

- Ovaries → hormone imbalance
- Pancreas → insulin problems
- Brain (hypothalamus + pituitary) → hormone control
- Adrenal glands → extra androgens
- Liver & fat tissue → metabolism and inflammation

Need for Herbal Therapy in PCOS (9)

1. Limitations of Conventional Treatment
2. Holistic Approach of Herbal Medicine
3. Few Side Effects
4. Synergistic Effect in Polyherbal Formulation
5. Cost-Effective and Accessible
6. Scientific Support

Mechanism of Selected Herbs in PCOS (8, 12)

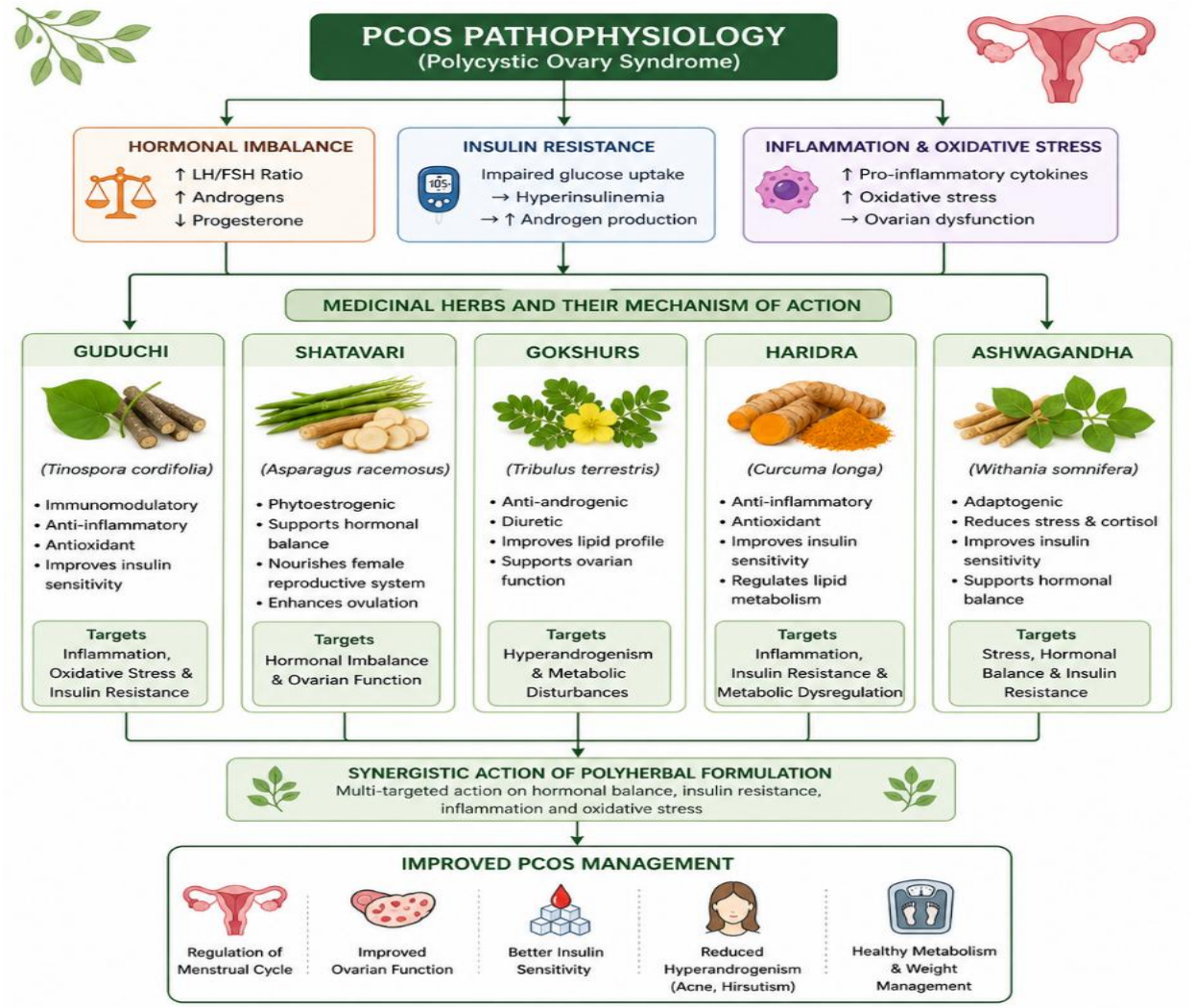

Figure 1 Pathophysiology of PCOS

Objective (10,11)

- To develop and assess a polyherbal tablet aimed at effectively managing PCOS.
- To identify appropriate medicinal plants for treating Polycystic Ovary Syndrome (PCOS) based on their therapeutic properties.
- To create a stable polyherbal tablet, appropriate excipients must be utilized.
- To evaluate the formulation's stability under normal conditions.
- To examine the synergistic effect of combined herbal components on enhancing therapeutic efficacy.

Plan of work (8, 7)

Selection of Medicinal Herbs
(Guduchi, Shatavari, Gokshura, Haridra, Ashwagandha)
↓
Collection & Authentication
↓
Preparation of Herbal Extracts
(Cleaning → Drying → Powdering → Extraction)
↓
Phytochemical Screening
(Alkaloids, Flavonoids, Tannins, Saponins)
↓
Formulation of Polyherbal Tablet
(Wet Granulation Method)
↓
Pre-compression Evaluation
(Bulk density, Angle of repose, Flow)
↓
Post-compression Evaluation
(Hardness, Friability, Weight variation, Disintegration time)
↓
Stability Studies
↓
Data Analysis & Interpretation
↓
Final Polyherbal Tablet for PCOS

II. MATERIAL AND METHOD

1. Formulation chart (Per Tablet)

Total Tablet Weight: 500mg

Ingredient	Role	Quantity (mg)
Tinospora cordifolia powder	Anti-inflammatory, immunomodulator	80 mg
Withania somnifera powder	Adaptogen, hormonal regulation	70 mg
Curcuma longa powder	Anti-inflammatory, improves insulin sensitivity	50 mg
Asparagus racemosus powder	Phytoestrogen, hormonal balance	80 mg
Tribulus terrestris powder	Supports ovulation, reproductive health	70 mg
Microcrystalline Cellulose (MCC)	Diluent, improves compressibility	90 mg
HPMC (Hydroxypropyl methylcellulose)	Binder	20 mg
Maize Starch	Disintegrant	30 mg
Magnesium Stearate	Lubricant	5 mg
Talc	Glidant	5 mg

2. Batch Formula:

For 100 Tablets,

Ingredient	Per Tablet (mg)	For 100 Tablets (g)
Tinospora cordifolia powder	80 mg	8 g
Withania somnifera powder	70 mg	7 g
Curcuma longa powder	50 mg	5 g
Asparagus racemosus powder	80 mg	8 g
Tribulus terrestris powder	70 mg	7 g
Microcrystalline Cellulose (MCC)	90 mg	9 g
HPMC (Hydroxypropyl methylcellulose)	20 mg	2 g
Maize Starch	30 mg	3 g
Magnesium Stearate	5 mg	0.5 g
Talc	5 mg	0.5 g

3. Preformulation

Preformulation studies are essential in tablet formulation, focusing on the physical and flow properties of the powder blend to ensure efficient manufacturing and high-quality tablets for Polycystic Ovary Syndrome. Parameters Evaluated:

a) Bulk Density: Mass of Powder divided by its bulk volume (g/cm^3)

Formula:

Bulk Density = Mass of powder/ Bulk volume

No. of Formulation	Result (g/cm^3)	Inference
F1	0.42	Good flow property
F2	0.44	Good flow property
F3	0.46	Acceptable Flow
F4	0.45	Acceptable flow
F5	0.47	Good flow property
F6	0.48	Good flow property

Standard Range : 0.40-0.60 g/cm^3

Figure 2 Tapped Density

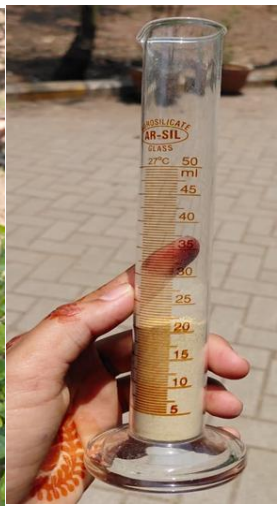

Figure 3 Bulk Density

b) Tapped Density: Density after mechanically tapping the powder (g/cm^3)

Formula:

Tapped Density = Mass of powder/ Tapped Volume

No. of Formulation	Result (g/cm^3)	Inference
F1	0.50	Acceptable compressibility
F2	0.52	Good compressibility
F3	0.55	Good compressibility
F4	0.54	Good compressibility
F5	0.56	Good compressibility
F6	0.57	Good compressibility

Standard Range: 0.50-0.75 g/cm^3

c) Angle of Repose: Maximum angle between powder pile and horizontal surface (°)

Formula: $Tan^{\theta} = h/ r$

Angle (°)	Flow Property
< 25°	Excellent
25–30°	Good
30–40°	Passable
<40°	Flowable

No. of Formulation	Result (°)	Inference
F1	24.5	Excellent flow
F2	25.8	Good flow
F3	27.2	Good flow
F4	28.4	Good fow
F5	29.1	Good flow
F6	30.0	Passable flow

Standard Range: Less than 30°

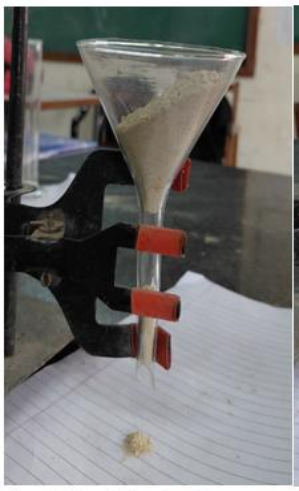

Fig. 4 Final Angle of repose

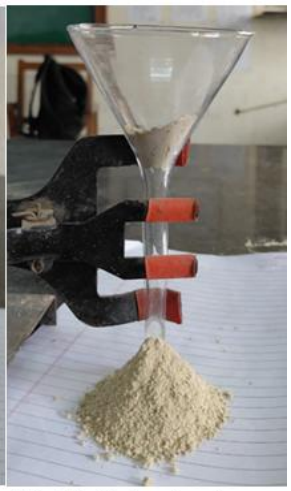

Fig. 5 Initial angle of repose

d) Carr's Index (Compressibility Index)

Formula:

Carr's Index= Tapped Density- Bulk Denity/Tapped Density X 100

% Index	Flow
5–15%	Excellent
16–20%	Good
21–25%	Fair
>25%	Poor

No. of Formulation	Result (%)	Inference
F1	16.0	Good compressibility
F2	15.3	Excellent compressibility
F3	16.4	Good compressibility
F4	16.6	Good compressibility
F5	16.0	Good compressibility
F6	15.7	Excellent compressibility

Standard Range: 5-20%

e) Hausner Ratio

Formula:

Hausner Ration = Tapped Density/ Bulk Density

Ratio	Flow
1.0–1.25	Good
>1.25	Poor

No. of Formulation	Result	Inference
F1	1.19	Good flowability
F2	1.18	Good flowability
F3	1.19	
F4	1.20	Good flowability
F5	1.19	Good flowability
F6	1.18	Good flowability

Standard range: 1.00-1.25

4. Post Compression Evaluation of Tablets

a) Hardness

Measures tablet strength

Ensure tablets don't break during handling

No. of Formulation	Result (kg/cm^2)	Inference
F1	5.2	Within acceptable limit
F2	5.4	Good hardness
F3	5.5	Good mechanical strength
F4	5.6	Acceptable hardness
F5	5.7	Good hardness
F6	5.8	Excellent mechanical strength

Standard Range: 4-8 kg/cm^2

b) Friability

Measure tablet resistance to abrasion

Loss should be less than 1%

No. of Formulation	Result (%)	Inference
F1	0.72	Pass
F2	0.68	Pass
F3	0.66	Pass
F4	0.64	Pass
F5	0.61	Pass
F6	0.59	Pass

Standard Range: Less than 1%

c) Weight Variation: Indicates uniform compression

No. of formulation	Result (mg)	Inference
F1	498 ± 3	Within limit
F2	500 ± 2	Uniform weight
F3	501 ± 3	Acceptable
F4	499 ± 2	Uniform compression
F5	502 ± 3	Acceptable
F6	500 ± 2	Uniform tablet weight

Standard Range: ±5% for 500 mg tablets

d) Thickness

Indicates uniform compression

No. of Formulation	Result (mm)	Inference
F1	4.1	Uniform thickness
F2	4.2	Acceptable
F3	4.3	Uniform compression
F4	4.2	Uniform thickness
F5	4.3	Acceptable
F6	4.4	Uniform tablet size

Standard Range: 3-5mm

e) Disintegration time

Time taken for tablet to break down in the body

Important for drug release

No. of Formulation	Result (min)	Inference
F1	14.2	Pass
F2	13.8	Pass
F3	13.5	Good disintegration
F4	13.2	Good drug release
F5	12.9	Rapid disintegration
F6	12.5	Excellence disintegration

Standard Range: Less than 15 minutes

IV. RESULT

The study concentrated on developing and accessing a polyherbal tablet derived from chosen medicinal plants, with key findings from both pre-compression and post-compression evaluations outlined.

1. Pre-Compression Results

The powder blend exhibited favourable flow and compressibility characteristics, crucial for consistent tablet formation.

Parameter	Result	Inference
Bulk Density	$0.48 g/cm^3$	Acceptable
Tapped Density	$0.57 g/cm^3$	Acceptable
Angle of Repose	30.0^o	Good flow
Carr's Index	15.7%	Good compressibility
Hausner Ratio	1.18	Good flow

2. Post-Compression Results

All parameters were found within pharmacopeial limits, indicating good mechanical strength and uniformity.

Parameter	Result	Inference
Hardness	$0.59 kg/cm^2$	Within limits
Friability	0.59%	Pass
Weight Variation	500 ± 2 mg	Within limit
Thickness	4.4mm	Uniform
Disintegration Time	12.5min	Pass

3. Stability Study Results

The formulation stayed stable even when it was stored.

Parameter	Initial	After 30 Days	Inference
Hardness	5.8	5.9	Stable
Friability	0.59%	0.68%	Stable
Disintegration	12.5 min	13.5 min	Acceptable

V. CONCLUSION

The current study effectively concentrated on the formulation and assessment of a polyherbal tablet utilizing specific medicinal herbs, including Guduchi, Shatavari, Gokshura, Haridra, and Ashwagandha. The formulation was created using the wet granulation method and tested for different pre-compression and post-compression factors. The study's findings showed that the powder blend had good flow properties and compressibility, which are both important for making tablets that are all the same size. The tablets that were made had the right hardness, low friability, consistent weight variation, and the right time to break down, all of which were within the limits set by the pharmacopeia. Stability studies showed that the formulation stayed stable in terms of both its physical and mechanical properties during the study period.

The chosen herbs are known to help with important parts of PCOS, such as hormonal imbalance, insulin resistance, and inflammation. Taking these herbs together in one dose is a synergistic and multi-target way to treat something. In general, the polyherbal tablet that was made showed good pharmaceutical properties and possible effectiveness, making it a good choice for treating PCOS.

VI. FUTURE SCOPE

1. Pharmacological Studies

Assessment employing appropriate animal models to validate therapeutic efficacy. Examination of impacts on hormonal levels and ovarian functionality

2. Clinical Studies

Do clinical trials with people to make sure the drug is safe and works. Checking for regular periods, ovulation, and metabolic markers

3. Standardization and Quality Control

Finding and measuring active phytoconstituent. Development of standard markers for quality assurance

4. Advanced Formulation Development

Modification into: Capsules, Sustained-release tablets, Herbal Syrups

5. Scale up and Commercialization

Optimization for large-scale production

Evaluation of cost-effectiveness and market potential

VII. DISCUSSION

The present study aimed to formulate and evaluate a polyherbal tablet using selected medicinal herbs. The formulation was developed successfully using the wet granulation method, and the results obtained from evaluation studies indicate that the formulation meets standard pharmaceutical requirements. The pre-compression parameters such as bulk density, tapped density, angle of repose, Carr's index, and Hausner ratio demonstrated that the powder blend possessed good flowability and compressibility, which are essential for uniform die filling and tablet formation. This ensured that the granules were suitable for further processing. Post-compression evaluation showed that the tablets had adequate hardness and low friability, indicating good mechanical strength and resistance to abrasion. The weight variation results confirmed uniformity in drug distribution, while the disintegration time was within acceptable limits, ensuring proper release of active constituents.

The stability studies revealed no significant changes in physical appearance, hardness, or disintegration time, indicating that the formulation is stable under normal storage conditions. The selected herbs Guduchi, Shatavari, Gokshura, Haridra, and Ashwagandha are known to act on multiple aspects of PCOS such as hormonal imbalance, Insulin Resistance, and inflammation. The polyherbal approach provides a synergistic effect, enhancing overall therapeutic potential. Thus, the formulation developed in this study is pharmaceutically stable, effective, and suitable for further pharmacological and clinical evaluation.

REFERENCE

[1] D. P. Prajapati, M. Patel, and A. Dharamsi, "Beneficial effect of polyherbal formulation in letrozole induced Polycystic ovarian syndrome (PCOS)," Journal of Traditional and

Complementary Medicine, vol. 12, no. 6, pp. 575–583, 2022.

[2] S. F. Witchel, S. E. Oberfield, and A. S. Pena, "Polycystic ovary syndrome: Pathophysiology, presentation, and treatment with emphasis on adolescent girls," Journal of the Endocrine Society, vol. 3, no. 8, pp. 1545–1573, 2019.

[3] D. Shi and D. F. Vine, "Animal models of polycystic ovary syndrome: A focused review of rodent models in relationship to clinical phenotypes and cardiometabolic risk," Fertility and Sterility, vol. 98, no. 1, pp. 185–193.e2, 2012.

[4] D. R. Kadam, D. K. Shinde, D. R. Kadam, D. M. Kulkarni, and D. Dimple, "Contemporary and traditional perspectives of polycystic ovarian syndrome (PCOS): A critical review," IOSR Journal of Dental and Medical Sciences, vol. 13, no. 9, pp. 89–98, 2014.

[5] P. M. G. and P. D. P., "Concept of polycystic ovarian syndrome: Perspectives of Ayurveda and modern science," International Journal of Pharmacognosy and Phytochemical Research, vol. 9, no. 10, pp. 1363–1372, 2017.

[6] M. Sakarge, V. Pandey et al., "Conceptual review on Agnimandya w.r.t. Ajeerna (Indigestion) and its Ayurveda Management," Journal of Ayurveda and Integrated Medical Sciences, vol. 5, no. 1, pp. 191–193, 2020.

[7] J. N. Lakshmi, A. N. Babu, S. M. Kiran, L. P. Nori, N. Hassan, A. Ashames, R. R. Bhandare, and A. B. Shaik, "Herbs as a source for the treatment of polycystic ovarian syndrome: A systematic review," BioTech, vol. 12, no. 1, Art. 4, 2023.

[8] Anonymous, The Ayurvedic Pharmacopoeia of India, Part-I, vol. 1, 1st ed. New Delhi, India: Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India, 2001, pp. 53–55.

[9] A. Wal, P. Wal, N. Saraswat, and S. Wadhwa, "A detailed review on herbal treatments for treatment of PCOS-polycystic ovary syndrome (PCOS)," Current Nutraceuticals, vol. 2, Art. 266597860266621080509 2103, 2021.

[10] Abdullah, A. N. Ahmad, W. Tian et al., "Recent advances in the extraction, chemical composition, therapeutic potential, and delivery of cardamom phytochemicals," Frontiers in Nutrition, vol. 9, Art. 1024820, 2022.

[11] N. Sharma, V. Kumar, U. Langeh, C. Singh, and A. Singh, "A review on the pharmacological potential of Indian spices in polycystic ovarian syndrome," Journal of Reproductive Health Medicine, vol. 4, pp. 1–5, 2023.

[12] A. H. Shankar and A. S. Prasad, "Zinc and immune function: The biological basis of an altered resistance to infection," American Journal of Clinical Nutrition, vol. 68, pp. 447S–463S, 1998.

[13] E. Diamanti-Kandarakis, H. Kandarakis, and R. S. Legro, "The role of genes and environment in the etiology of PCOS," Endocrine, vol. 30, no. 1, pp. 19–26, Aug. 2006.

[14] H. Konar and D. C. Dutta, Textbook of Gynecology Including Amenorrhea, 7th ed. New Delhi, India: Jaypee Publications, 2007, p. 378.

[15] B. Hoffman and J. Schorge, Williams Gynecology, 3rd ed. United States of America: McGraw Hill Education, 2016, p. 387.

[16] P. Vihariya et al., "Ovarian Cyst (Beejakos Granthi): An Ayurvedic Perspective - A Case Study," International Ayurvedic Medical Journal, 2017.