

Development and Evaluation of a Novel Polyherbal Suspension for the Management of Polycystic Ovary Syndrome

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ABSTRACT

Polycystic Ovary Syndrome (PCOS) is one of the most common endocrine and metabolic disorders affecting women of reproductive age prominently. It is associated with hormonal imbalance, irregular menstrual cycles, obesity, insulin resistance, inflammation, and infertility commonly. The present study was aimed at formulating and evaluating a polyherbal suspension containing Shatavari, Tribulus terrestris, Cinnamon, and Flaxseed for supportive management of PCOS related symptoms. Shatavari contains steroidal saponins and phytoestrogens that help in hormonal regulation and reproductive health. Tribulus possesses saponins and flavonoids that may improve ovarian function and hormonal balance. Cinnamon contains cinnamaldehyde and polyphenols which exhibit antioxidant and insulin-sensitizing activity, while flaxseed is rich in omega-3 fatty acids and lignans that help reduce inflammation and support endocrine balance. The combined action of these constituents provides synergistic therapeutic benefits in PCOS management. The polyherbal suspension was prepared using suitable suspending agents, sweetening agents, preservatives, and purified water to obtain a stable and palatable formulation. The prepared formulation was evaluated for organoleptic properties, pH, viscosity, sedimentation volume, re-dispersibility, particle size, and stability studies. The results indicated satisfactory physical stability, acceptable viscosity, good re-dispersibility, and absence of phase separation. The study concluded that the formulated polyherbal suspension possesses desirable pharmaceutical characteristics and may serve as a promising herbal dosage form for supportive management of PCOS.

Keywords: Polycystic Ovary Syndrome, Shatavari, Tribulus terrestris, Cinnamon, Flaxseed, polyherbal suspension

INTRODUCTION

Polycystic Ovary Syndrome (PCOS) is a complex endocrine and metabolic disorder commonly observed in women of reproductive age which is characterized by hormonal imbalance, irregular menstrual cycles, ovarian cyst formation, insulin resistance, obesity, acne, and infertility. The increasing cases of PCOS has made it a significant public health concern due to its impact on reproductive, metabolic, and psychological health generally as not treated it show long-term complications such as type 2 diabetes mellitus, cardiovascular disorders, and endometrial hyperplasia. 10,14

PCOS pathophysiology is complex and not completely understood but it is mainly associated with hyperandrogenism, insulin resistance, and dysfunction of the hypothalamic-pituitary-ovarian (HPO) axis mostly. Hyperinsulinemia lead to raises the

ovarian androgen production, which mainly disrupts follicular maturation prominently and results in anovulation which leads to the accumulation of immature follicles in the ovaries which responsible for generation of characteristic polycystic appearance. Even the chronic low-grade inflammation and oxidative stress are also considered the most important contributing factors in disease progression. 11,15,16

Most of conventional treatment approaches include hormonal therapy, insulin-sensitizing agents, and lifestyle modifications but these therapies are effective in symptom control and if used long-term result may be associated with adverse effects, reduced patient compliance, and limited acceptability mainly. So, these reasons are encouraged the exploration of alternative and complementary therapeutic approaches for treatment. 17

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Herbal formulations has advantage as it is safer and cost-effective alternatives for the supportive management of PCOS. It is possible to achieving synergistic effects by targeting different physiological pathways such as hormonal regulation, antioxidant defense, and metabolic balance in polyherbal formulations, which combine multiple medicinal plants, exhibit.6,18

Suspensions mainly the biphasic liquid dosage forms in which finely divided solid particles are dispersed in a liquid medium and most commonly classified into oral, topical, parenteral, and ophthalmic suspensions. Among these, oral suspensions are most widely used for herbal formulations because of their suitability for poorly water-soluble drugs. Suspensions offer some advantages such as improved patient compliance, ease of administration, dose uniformity, and enhanced bioavailability of poorly soluble compounds.

In the present study, a polyherbal suspension was formulated and evaluated for its pharmaceutical characteristics to ensure its stability, quality, and therapeutic effectiveness. This work aims to integrate traditional herbal knowledge with modern pharmaceutical dosage form design for the supportive management of PCOS.21,31

METHODS AND MATERIALS

Plant profile:

SHATAVARI (*Asparagus racemosus*)



Fig: Shatavari

Shatavari is derived from the dried tuberous roots of *Asparagus racemosus* which is belonging to the family Asparagaceae. It has contains bioactive compounds like as steroidal saponins (shatavarins), flavonoids (quercetin, kaempferol, rutin), isoflavones, alkaloids, and essential oils. It is a rich source of vitamins (A, B-complex, C, E, folic acid) and minerals including calcium, magnesium, and iron. It is traditionally used for hormonal regulation and may help in balancing reproductive hormones in PCOS [20,21].

GOKHRU (*Tribulus terrestris*)



Fig: Tribulus

Tribulus terrestris, belonging to the family Zygophyllaceae and commonly used for its fruit and root parts. It contains steroidal saponins such as protodioscin and diosgenin, along with flavonoids, alkaloids, and essential fatty acids. These constituents are reported to exhibit anti-androgenic, diuretic, and reproductive regulatory effects, making it useful in improving ovulatory function in PCOS conditions [22].

CINNAMON (*Cinnamomum verum*)



Fig. Cinnamon

Cinnamon is obtained from the dried inner bark of *Cinnamomum verum* commonly. It contains active compounds such as cinnamaldehyde, cinnamic acid, eugenol, and several polyphenols including caffeic and vanillic acids. These compounds are known to enhance insulin sensitivity and help in regulating glucose metabolism, which is beneficial in PCOS-associated insulin resistance.[23]

FLAXSEED (*Linum usitatissimum*)



Figure: Flaxseed

Flaxseed is obtained from the plant *Linum usitatissimum* and is rich in omega-3 fatty acids, particularly alpha-linolenic acid (ALA), along with phytoestrogenic lignans such as secoisolariciresinol diglucoside

(SDG). These constituents exhibit hormonal modulation effects and may help reduce androgen levels by increasing sex hormone-binding globulin (SHBG) [24]

Table 1:

Ingredient	Category	Role
Acacia gum	Suspending agent	Maintains uniform dispersion
Honey syrup	Sweetening agent	Improves palatability
Methyl paraben	Preservative	Prevents microbial growth
Propyl paraben	Preservative	Enhances preservation
Glycerin	Humectant, wetting agent	To ensure the uniform distribution of insoluble drug particles.
Purified water	Vehicle	Preparation of suspension
Colour and flavour	Organoleptic enhancer	Improves appearance and taste

Excipients Used

Preparation of Polyherbal Suspension

The herbal powders were accurately weighed and triturated to obtain a uniform mixture. Acacia gum was separately dispersed in purified water to form a mucilage. Preservatives were dissolved in a small quantity of warm water. The herbal blend was gradually incorporated into the suspending medium under continuous stirring. Glycerin was added to improve wetting of particles, followed by honey for sweetness and flavour enhancement. The final volume was adjusted with purified water, and the formulation was stored in amber-colored containers.



Figure: Herbal Mixture



Figure: Dispersion of Suspending



Figure: Powered Triturated in Mortar

Formula Table for Different Batches (40 mL)

Table 2: Formula Table

Ingredients	F1	F2	F3	F4
Shatavari	600 mg	800 mg	1000 mg	1200 mg
Tribulus	600 mg	800 mg	1000 mg	1200 mg
Cinnamon	300 mg	400 mg	500 mg	600 mg
Flaxseed	600 mg	800 mg	1000 mg	1200 mg
Acacia gum	0.20 g	0.40 g	0.40 g	0.50 g
Honey	10 mL	10 mL	10 mL	10 mL
Methyl paraben	0.08 g	0.08 g	0.08 g	0.08 g
Propyl paraben	0.02 g	0.02 g	0.02 g	0.02 g
Glycerin	5 mL	5 mL	5 mL	5 mL
Purified water	q.s. to 40 mL	q.s. to 40 mL	q.s. to 40 mL	q.s. to 40 mL

RESULT AND DISCUSSION

Table 3: Phytochemical Screening

Sr. No.	Phytochemical Test	Observation	Herbal Drug Showing Result	Inference / Active Constituent Indicated
1	Dragendorff's reagent Test	Reddish-brown precipitate	Shatavari, Flaxseed	Presence of Alkaloids
2	Keller–Killiani Test	Characteristic brown-green ring formation	Cinnamon	Presence of Cardiac Glycosides
3	Ferric chloride Test	Dark coloration obtained	Cinnamon	Presence of Tannins
4	Foam Test	Stable persistent foam observed	Shatavari, Tribulus	Presence of Saponins
5	Alkaline reagent Test	Yellow coloration developed	Shatavari, Cinnamon, Tribulus	Presence of Flavonoids
6	Salkowski Test	Reddish brown colour observed	Shatavari	Presence of Steroidal Compounds
7	Ferric Chloride Test	Dark green colour observed	Polyherbal suspension / herbal extract	Presence of Phenolic Compounds
8	Molisch's Test	Purple ring formed at junction	Flaxseed	Presence of Carbohydrates
9	Oil Spot Test	Permanent oily stain produced	Flaxseed	Presence of Fixed Oils / Lipids

Interpretation of Phytochemical Screening



Figure 17: Phytochemical Screening

Phytochemical investigation confirmed the presence of several biologically active constituents, including alkaloids, flavonoids, tannins, phenolic compounds, saponins, glycosides, carbohydrates, and fixed oils. The presence of these metabolites may contribute to the antioxidant, anti-inflammatory, and endocrine-modulating properties of the formulation [28,29].

Flavonoids and phenolic compounds are known for their antioxidant potential and may help reduce oxidative stress associated with PCOS [5,15]. Saponins present in Shatavari and Tribulus may contribute to hormonal regulation and reproductive health [20,22].

Tannins and polyphenols from cinnamon possess antioxidant and antimicrobial activities [23]. The lignans present in flaxseed exhibit phytoestrogenic effects that may help in maintaining hormonal balance [24].

Organoleptic Evaluation Analysis Observation:

The prepared suspension exhibited a brown colour and a pleasant aromatic odour due to cinnamon. No phase separation or aggregation was observed. Among all formulations, batch F2 showed the best uniformity and stability.

Table 4: Observation of PH

Batch	pH
F1	5.064
F2	6.21
F3	5.134
F4	5.092

pH Determination Analysis Observation:

The pH values of the formulations ranged between slightly acidic to near neutral. Batch F2 showed an

optimal pH of 6.21, indicating better compatibility and stability.

Sedimentation Volume Analysis Observation Table

Batch F2 demonstrated the most favorable sedimentation behavior, indicating a balanced concentration of suspending agent and improved stability against particle settling..



Fig: appearance of polyherbal suspension

Table 5: Sedimentation Volume

Batch	Initial Volume (mL)	Sediment Volume (mL)	Sedimentation Volume (F)
F1	40	35	0.92
F2	40	37	0.88
F3	40	32	0.81
F4	40	29	0.74

Re-dispersibility Analysis Observed Findings:

All formulations showed acceptable redispersibility. However, batch F2 required the least number of shakes, indicating better physical stability and reduced sediment compaction.

Observation Table:

Table 6: Re-dispersibility

Batch	Number of Shakes Required
F1	3
F2	2
F3	4
F4	5

Viscosity Analysis

Viscosity was observed to decrease from F1 to F4. Batch F2 exhibited optimal viscosity, ensuring both stability and good pourability.

Table 7: Observation Table:

Batch	Viscosity (cps)
F1	1350
F2	1180
F3	980
F4	760

Particle size:

All batches showed acceptable particle size distribution suitable for oral suspension. Batch F2 exhibited the most favorable particle size, contributing to better uniformity.

Table 8: Particle Size

Batch	Average Particle Size
F1	10 μ m
F2	5 μ m
F3	12 μ m
F4	10 μ m

Flow Property / Pourability Analysis

Batch F2 showed an optimum balance between viscosity and flow, ensuring ease of administration without compromising stability.

Accelerated Stability Study Analysis

The formulated polyherbal suspension was subjected to an accelerated stability study according to ICH guidelines. The formulation was stored at $40 \pm 2^\circ\text{C}$ and $75 \pm 5\%$ relative humidity (RH) for a period of 30 days. Samples were evaluated periodically for changes in colour, pH, viscosity, sedimentation, re-dispersibility, and any signs of phase separation.

Observation Table

Table 10: Observation of Accelerated Stability Study

Parameter	Initial	After 30 Days
Colour	Brownish	No significant change
pH	6.21	6.3
Viscosity	1350 cps	1325 cps
Sedimentation	Slight	Slight

Parameter	Initial	After 30 Days
Re-dispersibility	Good	Good

Conclusion of Stability Study: The prepared polyherbal suspension remained stable under accelerated storage conditions ($40 \pm 2^\circ\text{C}$ and $75 \pm 5\%$ RH) for 30 days, demonstrating acceptable physicochemical stability and shelf-life characteristics. The results demonstrated no significant change in colour, absence of microbial growth, minimal variation in pH, a slight

decrease in viscosity, and no evidence of phase separation throughout the study period. These observations indicate that the formulation maintained its integrity and stability during storage.

Degree of Flocculation

Controlled flocculation was observed in all batches. Batch F1 showed the highest flocculation value, while F4 showed the lowest.

Table 11: Degree of Flocculation

Batch	Degree of Flocculation
F1	1.32
F2	1.25
F3	1.18
F4	1.10

Overall Comparative Evaluation of Batches:

Table 12: Overall Comparative Evaluation

Parameter	F1	F2	F3	F4
Homogeneity	Excellent	Excellent	Good	Fair
pH Stability	Good	Excellent	Good	Good
Sedimentation	Good	Excellent	Moderate	Poor
Redispersibility	Excellent	Excellent	Good	Fair
Viscosity	High	Optimum	Moderate	Low
Flow Property	Moderate	Good	Good	Very fast
Stability	Good	Excellent	Moderate	Fair
UV Absorbance	High	High	Moderate	Low

CONCLUSION:

The formulated polyherbal suspension containing Shatavari, Tribulus, Cinnamon, and Flaxseed demonstrated satisfactory physicochemical and phytochemical properties. Among all formulations, batch F2 was identified as the optimized batch due to its superior sedimentation behaviour, optimal viscosity, good re-dispersibility, stable pH, and overall physical stability.

Phytochemical analysis confirmed the presence of bioactive compounds such as flavonoids, tannins, phenolics, saponins, lignans, and glycosides, which may contribute to therapeutic effects in PCOS management. The formulation remained stable under accelerated conditions, indicating acceptable shelf-life potential.

Overall, the developed polyherbal suspension is stable, pharmaceutically acceptable, and suitable for oral administration. It represents an effective integration of traditional herbal knowledge with modern pharmaceutical formulation techniques for PCOS management.

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