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DEVELOPMENT AND EVALUATION OF POLYHERBAL TABLETS BY WET GRANULATION: A THERAPEUTIC APPROACH FOR PCOS/PMS ASSOCIATED HORMONAL IMBALANCE AND WELLNESS

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ABSTRACT- Polyherbal products are preferred over single herbal drugs and synthetic drugs in the health care system in respect of hormonal imbalance. The herbal drug products provide added benefits like synergism of various active principles, fewer side effects, consistent therapeutic efficacy and novel market access through easy patent-free life to the formulators. The present work involves the formulation and optimisation of a polyherbal drug product formulation for the treatment of Polycystic Ovary Syndrome/Premenstrual Syndrome, general health and augmenting immunity. The proposed herbal drug product was formulated using an herbal ingredient in powder form; the strength of the proposed herbal drug product was 300 mg. In this formulation, the proposed eight herbal drugs, namely Shatavari, fenugreek, fennel seeds, coriander, Tulsi, amla, spearmint and deglycyrrhizinated Liquorice (DGL), along with diluents, namely starch, microcrystalline cellulose (MCC) and talc, were mixed with lubricant, namely magnesium stearate. Various batches of tablets were prepared and were reformulated to optimise the tablet formulation. The post-compression parameters and phytochemical study reveal the presence of bioactive principles such as saponins, alkaloids, flavonoids, tannins and volatile oils from the herbs in the herbal drug. The general appearance, weight variation, hardness, friability, thickness, disintegration time and loss on drying of the tablets of the final optimised batch of tablets were found to be within the limit as per pharmacopeial standards. Drug content of approximately 98.8% of the labelled amount was found uniform throughout the dose using UV spectrophotometry from the marker of Shatavari. The hardness of tablets was significantly increased with an increase in binder concentration. In view of the above, the optimised formulation contains eight herbs in the matric form. It contains all the eight herbal drugs in a balanced formulation having adequate mechanical strength and exhibiting the required therapeutic efficacy.

KEYWORDS: Polyherbal tablet, PCOS/PMS, Wet granulation, Herbal formulation, Shatavari, Pharmaceutical evaluation, Immunity

1. INTRODUCTION

Polycystic Ovary Syndrome (PCOS) and Premenstrual Syndrome (PMS) are among the most prevalent endocrine and reproductive disorders affecting women of reproductive age across the globe [3,4,5]. PCOS is a multifactorial metabolic and hormonal disorder characterized by chronic anovulation, hyperandrogenism, insulin resistance, obesity, and polycystic ovarian morphology [3,4]. It is considered one of the leading causes of infertility in women and is often associated with long-term metabolic complications such as type 2 diabetes mellitus, cardiovascular disorders, and endometrial hyperplasia [3,4]. PMS, on the other hand, is a cyclic disorder that occurs during the luteal phase of the menstrual cycle and is characterized by physical, emotional, and behavioural symptoms such as irritability, anxiety, depression, breast tenderness, bloating, fatigue, and mood swings [5]. Although PMS is not life-threatening, it significantly affects daily productivity, emotional stability, and quality of life [5].

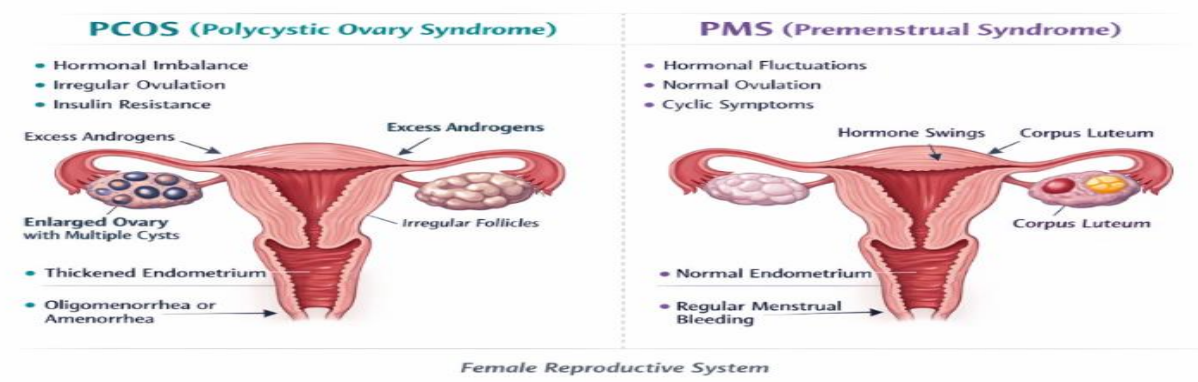

Figure 1: Comparative illustration of female reproductive system showing key structural and hormonal differences in Polycystic Ovary Syndrome (PCOS) and Premenstrual Syndrome (PMS).

The pathophysiology of Polycystic Ovary Syndrome is associated with disruption of the hypothalamic–pituitary–ovarian (HPO) axis, resulting in elevated luteinizing hormone (LH), reduced follicle-stimulating hormone (FSH), and increased androgen secretion from ovarian theca cells [4]. Insulin resistance is a major contributing factor in disease progression, as it enhances ovarian androgen production and decreases sex hormone-binding globulin (SHBG), leading to increased levels of free testosterone [3,4]. In Premenstrual Syndrome, variations in estrogen and progesterone levels throughout the menstrual cycle affect neurotransmitter function, especially serotonin, which plays a key role in regulating mood and emotional behaviour [5]. These hormonal and neurochemical disturbances collectively contribute to the manifestation of symptoms. Thus, both conditions involve the interaction of multiple physiological systems, including endocrine, metabolic, and neuropsychological pathways [3-5].

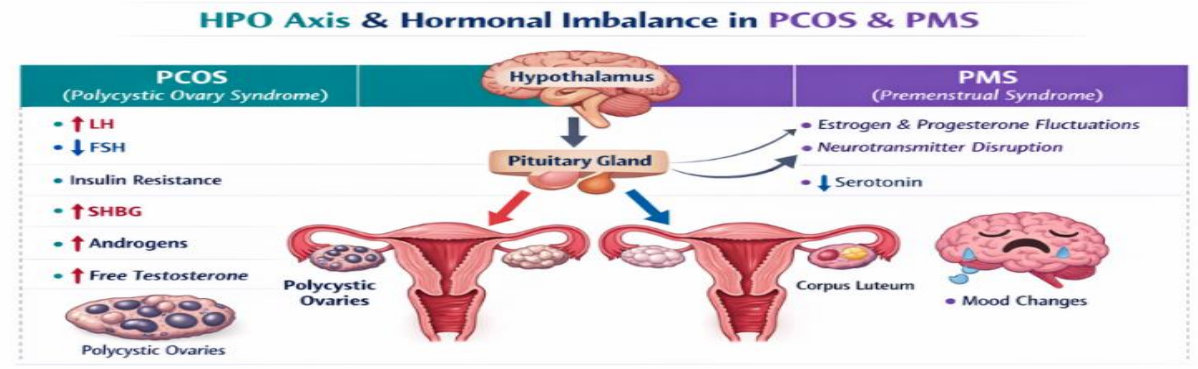

Figure 2: Schematic of HPO axis dysfunction in PCOS and hormonal fluctuations in PMS. Interpretation: PCOS involves chronic LH–FSH imbalance and androgen excess, whereas PMS arises from transient estrogen–progesterone variations affecting serotonin.

In recent years, the prevalence of Polycystic Ovary Syndrome and Premenstrual Syndrome has risen considerably, largely attributed to modern lifestyle changes. Key contributing factors include sedentary habits, poor dietary patterns, increased consumption of processed foods, chronic psychological stress, disrupted sleep cycles, and reduced physical activity [3,8]. Additionally, exposure to endocrine-disrupting chemicals found in plastics, cosmetics, and environmental pollutants can further impair hormonal homeostasis. Activation of the hypothalamic–pituitary–adrenal (HPA) axis in response to stress results in increased cortisol levels, which indirectly disrupt reproductive hormone balance and may exacerbate symptoms [10].

Conventional management of Polycystic Ovary Syndrome and Premenstrual Syndrome typically involves hormonal therapies such as oral contraceptives, anti-androgens, progesterone supplementation, analgesics, and antidepressants, depending on the severity of symptoms [4,5]. Although these therapies offer symptomatic relief, they are frequently linked with adverse effects such as weight gain, nausea, headaches, mood disturbances, and potential long-term hormonal dependence [4]. Moreover, these treatments primarily focus on symptom management rather than correcting the underlying hormonal imbalance, thereby emphasizing the need for safer and more holistic therapeutic approaches.

Herbal medicine has traditionally been employed in systems such as Ayurveda, Unani, and Traditional Chinese Medicine for the management of reproductive and endocrine disorders [6,11]. Herbal drugs are generally regarded as safer owing to their natural origin and are associated with comparatively fewer side effects than synthetic medications [6]. Polyherbal formulations (PHFs), which comprise combinations of multiple medicinal plants, exert synergistic therapeutic effects by acting on multiple biological pathways simultaneously [32,36]. This multi-targeted approach is especially beneficial in complex conditions such as Polycystic Ovary Syndrome and Premenstrual Syndrome, which are associated with hormonal, metabolic, inflammatory, and psychological components [32].

Several medicinal plants are recognized for their potential role in regulating hormones and supporting reproductive health. Shatavari (Asparagus racemosus) is known to possess phytoestrogenic and adaptogenic properties that help support female hormonal balance [10,12]. Fenugreek (Trigonella foenum-graecum) is reported to enhance insulin sensitivity and help reduce androgen levels [13,14]. Spearmint (Mentha spicata) exhibits anti-androgenic activity and may help in reducing hirsutism [23,24,25]. Amla (Emblica officinalis) and Tulsi (Ocimum sanctum) are known for their potent antioxidant and immunomodulatory properties [15,26,27]. Fennel (Foeniculum vulgare) and Coriander (Coriandrum sativum) help support metabolic and digestive balance [17,20,22]. Deglycyrrhizinated Liquorice (DGL) demonstrates anti-inflammatory properties and may help in modulating endocrine function [28,29]. The combined action of these herbs provides a comprehensive therapeutic approach for managing hormonal imbalance and promoting overall wellness.

From a pharmaceutical standpoint, tablet dosage forms are preferred because they offer precise dosing, ease of administration, enhanced stability, and improved patient compliance [1,34]. Tablets also provide a longer shelf life when compared to liquid dosage forms. Among different manufacturing techniques, wet granulation is commonly employed for herbal tablet formulation as it enhances powder flow, compressibility, and content uniformity while minimizing segregation [1,35]. It also improves the mechanical strength of tablets and reduces their friability [35].

Despite extensive research on individual herbal drugs, there remains a lack of standardized polyherbal tablet formulations specifically developed for the combined management of Polycystic Ovary Syndrome and Premenstrual Syndrome [6,7,11]. Most existing studies focus on individual herbs or single-disease models, with limited attention given to multi-herb synergistic formulations and key pharmaceutical optimization parameters such as binder selection and tablet performance evaluation [32,33]. Therefore, the present study aims to develop and evaluate a standardized polyherbal tablet formulation prepared by the wet granulation technique for the management of Polycystic Ovary Syndrome and Premenstrual Syndrome, along with additional benefits including improved immunity, antioxidant potential, and overall health promotion.

2. LITERATURE REVIEW

Polyherbal formulations (PHFs) have gained significant attention in modern pharmaceutical research owing to their ability to exert multi-targeted therapeutic actions while minimizing adverse effects [32,36]. These formulations are developed by combining two or more medicinal plants into a single dosage form to achieve synergistic, additive, or potentiating pharmacological effects [32]. Traditional systems of medicine, including Ayurveda and Traditional Chinese Medicine, have long employed such combinations for the management of complex diseases [36]. In recent years, there has been a growing scientific interest in validating polyherbal formulations through detailed phytochemical characterization, investigation of pharmacological mechanisms, and advancements in formulation development [31,36].

2.1. Overview of Polyherbal Formulations

Polyherbal formulations are based on the principle that multiple bioactive compounds derived from different plants can simultaneously act on various biological targets [32]. This multi-targeted approach is particularly valuable in chronic and multifactorial diseases, including endocrine disorders, metabolic syndrome, and inflammatory conditions [3,8,32]. Polyherbal formulations (PHFs) offer several advantages, including improved therapeutic efficacy, reduced toxicity, enhanced bioavailability, and better patient compliance when compared to single-herb preparations [32,36]. The pharmacological efficacy of polyherbal formulations (PHFs) is primarily due to synergistic interactions among various phytoconstituents, including flavonoids, alkaloids, tannins, glycosides, and saponins [31,32]. These phytochemical

constituents collectively influence multiple biochemical pathways, thereby contributing to enhanced therapeutic outcomes. Recent scientific evidence suggests that herbal combinations may demonstrate greater efficacy in disease management than single-compound approaches, primarily due to their wider and more diverse mechanisms of action [31,32].

2.2. Global Research Advances in Polyherbal Formulations

Globally, research on polyherbal formulations has grown rapidly over the past decade [36]. India continues to be a major contributor in this field, largely due to its rich traditional medicinal systems such as Ayurveda, Siddha, and Unani [36]. In addition, countries such as China, Nigeria, Pakistan, and Bangladesh are also actively contributing to research in herbal drug development. A global review shows that most research on polyherbal formulations is concentrated on metabolic disorders, diabetes, inflammatory conditions, and reproductive health disorders [32,36]. Modern research has increasingly focused on the standardization of herbal formulations, quality assurance, and mechanism-oriented investigations [33,36]. Advanced analytical techniques, including HPLC, GC-MS, and LC-MS, are now widely employed to identify active phytoconstituents and maintain batch-to-batch consistency [33]. Such scientific validation is crucial for the integration of herbal formulations into evidence-based medical practice.

2.3. PCOS and PMS: Herbal Therapeutic Perspective

Polycystic Ovary Syndrome and Premenstrual Syndrome are among the most prevalent endocrine disorders affecting women of reproductive age [3,4,5]. Polycystic Ovary Syndrome is characterized by features such as hyperandrogenism, chronic anovulation, insulin resistance, obesity, and polycystic ovarian morphology [3,4]. Premenstrual Syndrome is a cyclical condition characterized by physical, emotional, and behavioural symptoms that occur during the luteal phase of the menstrual cycle [5]. Studies indicate that Polycystic Ovary Syndrome is strongly linked with metabolic dysfunction, oxidative stress, and hormonal imbalance [3,8]. Premenstrual Syndrome is associated with fluctuations in estrogen and progesterone levels, which influence neurotransmitters such as serotonin and gamma-aminobutyric acid (GABA) [5]. These conditions can significantly impact fertility, psychological well-being, and overall quality of life [3-5]. Herbal medicines have demonstrated promising potential in managing both conditions by helping regulate hormonal balance, improving insulin sensitivity, reducing oxidative stress, and supporting mood stabilization [6,7,11].

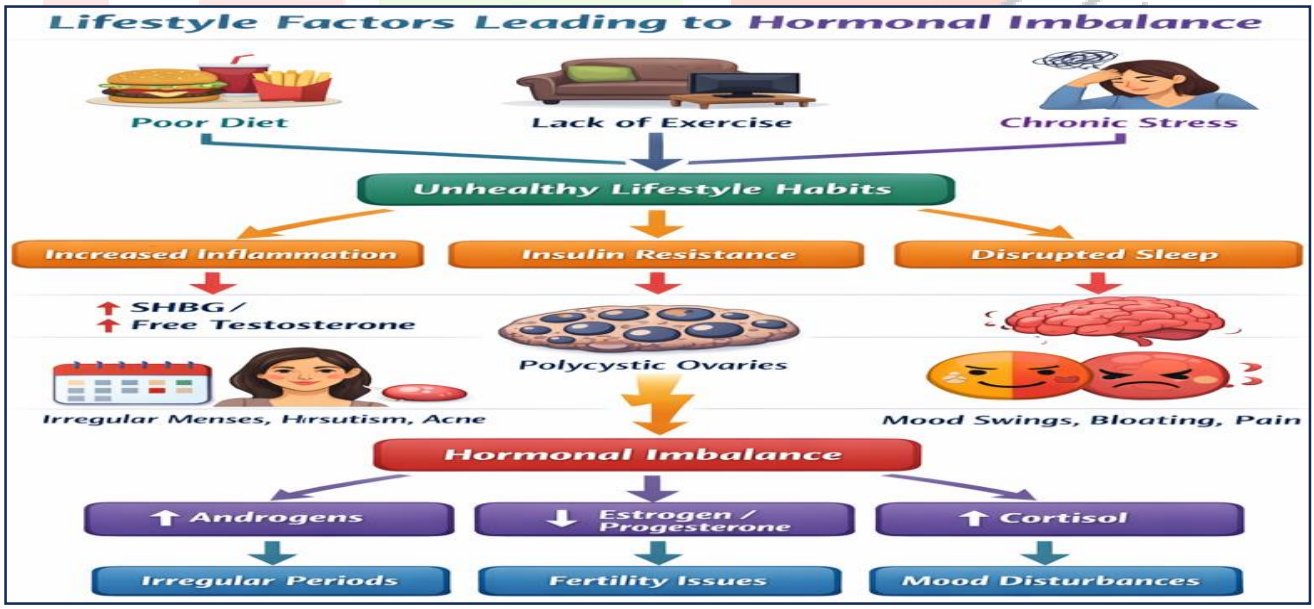

Figure 3: Flowchart showing how poor diet, inactivity, and stress lead to insulin resistance and inflammation, resulting in hormonal imbalance and associated reproductive and emotional disturbances.
Poor diet, stress, and inactivity trigger insulin resistance and inflammation, leading to endocrine disruption and PCOS/PMS symptoms.

2.4. Limitations of Conventional Therapy

Conventional management of Polycystic Ovary Syndrome and Premenstrual Syndrome mainly involves hormonal therapies, including oral contraceptives, anti-androgens, progesterone supplementation, analgesics, and antidepressants [4,5]. Although these treatments are effective in alleviating symptoms, they do not target the underlying pathophysiology responsible for hormonal imbalance [4]. Prolonged use of hormonal medications may be associated with adverse effects such as weight gain, mood changes, nausea, headache, and fluid retention [4,5]. In addition, long-term hormonal therapy may lead to dependence and may not be appropriate for all patients, particularly those requiring sustainable long-term management options. Moreover, conventional treatments primarily offer symptomatic relief rather than addressing the condition in a holistic manner that considers metabolic, endocrine, and psychological factors. These limitations have driven growing interest in safer and more holistic alternatives, particularly herbal and polyherbal formulations [6,11].

Table 1: Comparative analysis of conventional and polyherbal therapy in hormonal disorders such as PCOS and PMS.

FEATURES	CONVENTIONAL THERAPY	POLYHERBAL THERAPY
Target mechanism	Single biological pathway	Multi-target approach (hormonal, metabolic, antioxidant)
Therapeutic action	Mainly symptomatic relief	Holistic disease management
Side effects	Relatively high (nausea, weight gain, hormonal imbalance)	Minimal / lower incidence
Long-term use	Often limited due to adverse effects	More suitable for long-term use
Safety profile	Moderate risk of hormonal dependency	Generally safer with natural origin
Disease approach	Symptom suppression	Root cause modulation
Patient compliance	Moderate	High due to fewer side effects

2.5. Synergistic Mechanism of Polyherbal Formulations

The therapeutic efficacy of polyherbal formulations is largely attributed to synergistic interactions among various plant-derived constituents [31,32]. Synergism may be pharmacodynamic, where compounds act on similar receptors or biological pathways, or pharmacokinetic, where they influence the absorption, metabolism, or elimination of active compounds [31]. These interactions enhance the overall therapeutic efficacy while also helping to reduce the likelihood of adverse effects. In Polycystic Ovary Syndrome and Premenstrual Syndrome, several physiological systems are involved, including endocrine, metabolic, inflammatory, and neurological pathways [3,4]. Therefore, a single-drug approach is often inadequate for effective management. Polyherbal combinations offer a holistic therapeutic approach by acting on multiple mechanisms simultaneously [32]. For example, agents with insulin-sensitizing, anti-androgenic, antioxidant, and adaptogenic properties can act synergistically to improve overall reproductive health [10,13,23].

2.6. Review of Selected Herbal Ingredients

Shatavari (Asparagus racemosus): It is commonly used in Ayurveda as a tonic for supporting female reproductive health. It possesses phytoestrogenic, adaptogenic, and immunomodulatory activities [10,12]. It aids in regulating menstrual cycles, supporting fertility, and reducing stress-induced hormonal imbalance. It also supports ovarian function and helps maintain reproductive hormonal balance.

Fenugreek (Trigonella foenum-graecum): They are recognized for their insulin-lowering and anti-androgenic effects. They help improve insulin sensitivity, lower testosterone levels, and support normal ovarian function. Clinical studies indicate its potential beneficial role in the management of Polycystic Ovary Syndrome symptoms [13,14].

Spearmint (Mentha spicata): It exhibits anti-androgenic activity and may help reduce hirsutism and hormonal imbalance. Regular intake has been reported to reduce free testosterone levels in females with Polycystic Ovary Syndrome [23-25].

Tulsi (Ocimum sanctum): It exhibits strong antioxidant, anti-inflammatory, and adaptogenic properties [15]. It helps reduce oxidative stress and supports endocrine balance. It also helps improve the stress response by regulating cortisol levels.

Amla (Emblica officinalis): It is a rich source of vitamin C and polyphenolic compounds. It helps reduce oxidative stress, enhance metabolic function, and support immune health. It also supports reproductive health by promoting hormonal stability [26,27].

Fennel (Foeniculum vulgare): It shows estrogen-like activity and is beneficial in regulating the menstrual cycle [17,18]. It helps alleviate Premenstrual Syndrome symptoms and supports hormonal balance in women.

Coriander (Coriandrum sativum): It helps improve glucose metabolism and demonstrates insulin-like activity. It is beneficial in managing metabolic syndrome associated with Polycystic Ovary Syndrome [20,22].

Deglycyrrhizinated Liquorice (DGL): It exhibits anti-inflammatory, anti-stress, and endocrine-modulating properties. It supports hormonal regulation and helps improve adrenal function [28,29].

2.7. Role of Natural Binders in Tablet Formulation

Natural binders, including starch, cellulose derivatives, gums, and mucilage, play a crucial role in tablet formulation. They enhance tablet hardness, compressibility, and overall structural integrity [35,38]. They are preferred over synthetic binders because of their biodegradability, safety profile, and cost-effectiveness [35]. Natural polymers also improve drug release behaviour and enhance the stability of herbal formulations [35].

2.8. Summary of Literature and Research Gap

An extensive review of the literature indicates that polyherbal formulations have significant potential in the management of Polycystic Ovary Syndrome and Premenstrual Syndrome due to their multi-targeted mechanisms of action [6,7,11,32]. However, most existing studies are limited to individual herbs or remain restricted to preclinical investigations [7,11]. There is a lack of standardized polyherbal tablet formulations supported by comprehensive pharmaceutical evaluation [33,34]. Furthermore, limited research has focused on formulation optimization strategies such as wet granulation, appropriate binder selection, and systematic evaluation of tablet quality parameters [33,35]. Therefore, there is a need to develop a scientifically standardized polyherbal tablet formulation to bridge the gap between traditional medicinal knowledge and modern pharmaceutical validation.

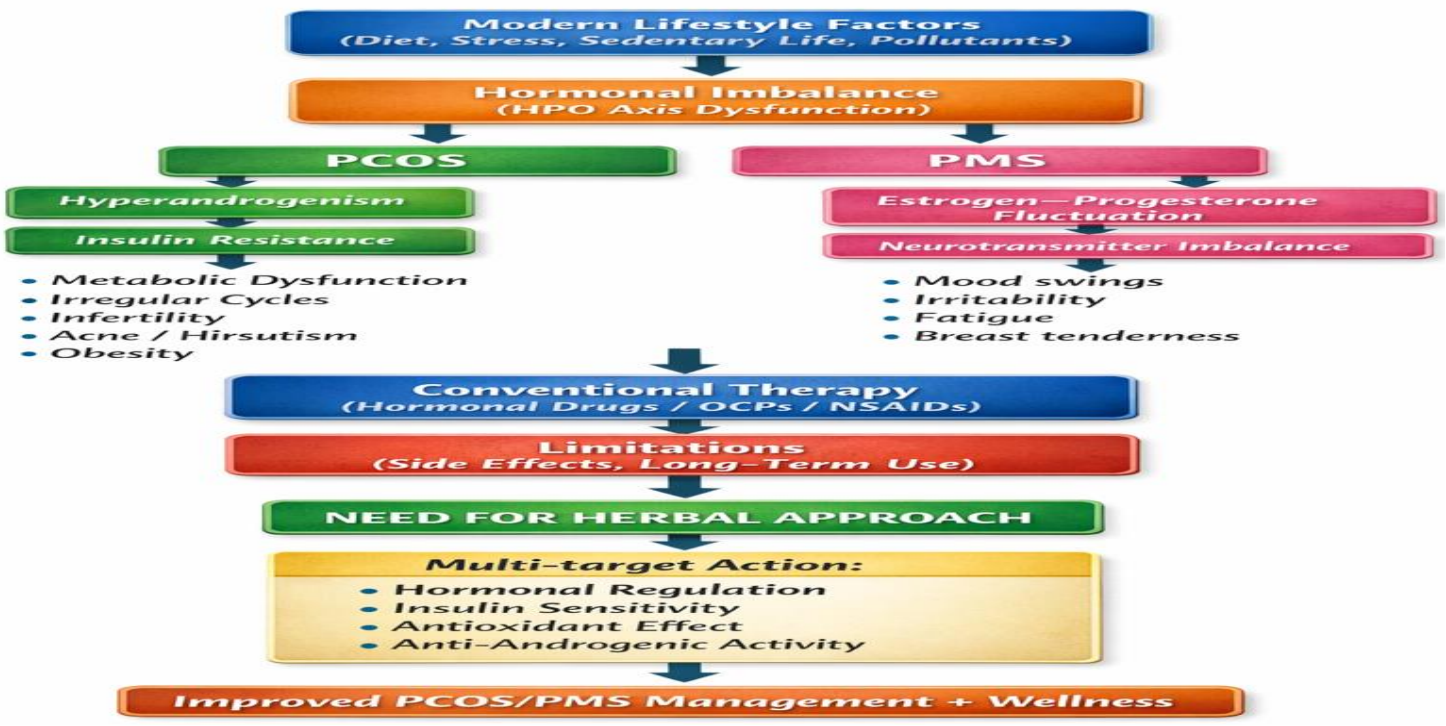

Figure 4: Pathophysiology and Therapeutic Approach of PCOS/PMS and Role of Polyherbal Formulation

3. MATERIALS & METHODOLOGY

3.1. Materials

The herbal ingredients incorporated in the formulation include Shatavari (root powder), Fenugreek (seed powder), Tulsi (shade-dried leaf powder), Spearmint (leaf powder), Coriander (seed powder), Fennel (seed powder), Deglycyrrhizinated Liquorice (DGL extract), and Amla (fruit powder). All crude drugs were either shade-dried and powdered under laboratory conditions or procured from authenticated commercial sources. Excipients including Microcrystalline Cellulose (MCC) as a diluent, starch as a binder, talc as a glidant, and magnesium stearate as a lubricant were procured from the college laboratory and were of pharmaceutical grade quality [1,35,38]. All instruments utilized in the study included a digital weighing balance, sieve set (mesh no. 60–80), mortar and pestle, tray dryer, tablet compression machine, hardness tester, friabilator, disintegration test apparatus, and UV–Visible spectrophotometer [1,34]. All instruments were calibrated before use to ensure accuracy and reliability of the results.

Table 2: List of Ingredients and Their Roles

Ingredient	Part Used	Role
Shatavari	Root	Hormonal balance, adaptogen
Fenugreek	Seeds	Insulin sensitizer
Tulsi	Leaves	Antioxidant, anti-stress
Spearmint	Leaves	Anti-androgenic
Coriander	Seeds	Metabolic regulation
Fennel	Seeds	Estrogenic support
DGL	Root extract	Anti-inflammatory
Amla	Fruit powder	Antioxidant
MCC	—	Diluent
Starch	—	Binder
Talc	—	Glidant
Mg Stearate	—	Lubricant

3.2. Selection of Herbal Ingredients

The selection of herbal ingredients was based on their pharmacological activities relevant to the management of Polycystic Ovary Syndrome and Premenstrual Syndrome [6,7,11]. Shatavari was selected for its phytoestrogenic and hormone-balancing properties [10,12], whereas Fenugreek was included due to its insulin-sensitizing and anti-androgenic activities [13,14]. Tulsi and Amla were selected because of their antioxidant and adaptogenic properties [15,26,27]. Spearmint was included for its anti-androgenic potential [23-25], while Fennel contributes mild estrogenic activity and helps support menstrual regulation [17,18]. Coriander supports metabolic balance [20,22], while Deglycyrrhizinated Liquorice (DGL) provides endocrine-modulating and anti-inflammatory effects [31,32]. Thus, the formulation was designed to offer a multi-targeted approach encompassing hormonal regulation, metabolic control, antioxidant activity, and stress reduction. Thus, the combination was designed to produce a synergistic and holistic therapeutic effect [31,32].

3.3. Formulation Design

Five experimental batches of polyherbal tablets were prepared by varying the binder concentration, diluent ratio, and herbal composition to optimize both pharmaceutical and therapeutic performance [1,33]. The batches were designed as follows:

- Batch I: Standard formulation
- Batch II: Increased binder concentration
- Batch III: Increased diluent concentration
- Batch IV: Increased Fenugreek content (metabolic focus)
- Batch V: Increased Shatavari content (hormonal focus)

The detailed composition of each batch is presented in the formulation table. An optimized batch was selected based on evaluation parameters [1,34].

Table 3: Formulation Design of Batches (mg/tablet)

Ingredient	Batch I	Batch II	Batch III	Batch IV	Batch V
Shatavari	40	40	40	30	55
Fenugreek	30	30	30	45	20
DGL	25	25	25	25	25
Fennel	25	25	25	25	25
Coriander	20	20	20	20	20
Spearmint	20	20	20	20	20
Tulsi	20	20	20	20	20
Amla	30	30	30	30	30
MCC	60	50	80	55	55
Starch	20	35	10	20	20
Talc	5	5	5	5	5
Mg Stearate	5	5	5	5	5
Total	300mg	300mg	300mg	300mg	300mg

3.4. METHOD OF PREPARATIONS

Polyherbal tablets were formulated using the wet granulation technique [1,35]. All herbal powders were sieved through mesh size no. 60 to ensure uniform particle size distribution. The required quantities of each ingredient were accurately weighed and thoroughly blended to obtain a uniform and homogeneous mixture [1]. A 5% starch paste binder solution was prepared separately and added gradually to the powder blend with continuous mixing until a damp mass of suitable consistency was formed [35]. The wet mass was then passed through sieve no. 10–16 to obtain granules, which were subsequently dried in a tray dryer at 40–50°C until the desired level of dryness was achieved [1,35]. The dried granules were then resized by passing them through sieve no. 20–30 to achieve uniform granule size distribution. Lubricants, including magnesium stearate and talc, were added to the dried granules and gently blended to ensure uniform distribution [35,38]. The final blended mass was compressed into tablets using a tablet compression machine [1,34].

Figure 5: Wet granulation process illustrating sequential steps from powder blending to tablet formation.

3.5. PREFORMULATION STUDIES

The prepared granules were evaluated for flow properties and compressibility prior to compression using standard pharmacopeial methods [1,35].

Angle of Repose

Angle of repose was determined by the funnel method, where granules were allowed to flow through a funnel to form a conical pile [1].

$$\tan\theta = h/r$$

Where:
h = height of pile
r = radius of pile
This parameter indicates the flowability of the granules [1,35].

Bulk Density

Bulk density was determined by pouring a known mass of granules into a graduated cylinder and measuring the volume [35].

$$Bulk\ Density = M/Vb$$

Where:
M = mass of granules
V_b = bulk volume

Tapped Density
Tapped density was determined by mechanically tapping the cylinder until a constant volume was obtained [35].

$$Tapped\ Density = M/Vt$$

Where:
V_t = tapped volume

Carr's Index
Carr's compressibility index was calculated to assess powder flow characteristics [35].

$$Carr's\ Index = (\rho t - \rho b)/\rho t \times 100$$

Where:
ρ_t = tapped density
ρ_b = bulk density

Hausner Ratio
Hausner ratio was determined as the ratio of tapped density to bulk density [35].

$$Hausner\ Ratio = \rho t/\rho b$$

These parameters were used to evaluate the flowability and compressibility characteristics of granules prior to compression [1,35].

3.6. EVALUATION STUDIES

The compressed tablets were evaluated for different quality control parameters in accordance with pharmacopoeial standards [1,34].

General Appearance
The tablets were visually examined for colour, shape, size, and surface characteristics. This parameter indicates the uniformity of tablet surface, colour, and shape, ensuring patient acceptability and consistency [1].

Weight Variation
Twenty tablets were individually weighed, and the average weight was calculated. The results were then compared with the acceptable pharmacopoeial limits [1,34]. This test assesses dose uniformity and ensures that each tablet contains the appropriate amount of formulation.

Hardness Test
Tablet hardness was determined using a hardness tester and expressed in kg/cm² to evaluate the mechanical strength of the tablets [34]. This parameter reflects the mechanical strength of the tablets and their ability to withstand handling during packaging and transportation.

Friability Test
Friability was evaluated using a friabilator operated at 25 rpm for 4 minutes [1].

$$\%\ Friability = (W1 - W2)/W1 \times 100$$

Where:
W_1 = initial weight
W_2 = final weight
This test indicates the durability of tablets and their resistance to abrasion or breakage during handling [1,34].

Disintegration Test
Disintegration time was determined using a disintegration test apparatus at 37 ± 2°C with distilled water as the medium, in accordance with standard pharmacopoeial procedures [1,34]. This parameter reflects the ability of tablets to disintegrate in the gastrointestinal tract, which is essential for effective drug release and subsequent absorption.

Thickness and Diameter
Tablet thickness and diameter were measured using vernier callipers to ensure dimensional uniformity [34].

Loss on Drying (LOD)
LOD was determined to evaluate the moisture content of tablets [35]. A known weight of tablets was dried in an oven at 105 °C until constant weight was achieved.

$$\%LOD = (W1 - W2)/W1 \times 100$$

Where:
- W_1= initial weight of sample
- W_2= final weight after drying

This parameter indicates the residual moisture content and ensures adequate drying for tablet stability [35].

Content Uniformity

Content uniformity was determined using UV–Visible spectrophotometry by estimating the Shatavari marker at λmax 254 nm. A calibration curve was constructed, and the drug concentration was determined using Beer–Lambert's law [1]. This test reflects the uniform distribution of the drug within the tablets, ensuring accurate and consistent therapeutic dosing.

Stability Studies

Stability studies were not conducted experimentally; however, according to literature, herbal tablets are typically assessed under accelerated conditions of 40°C ± 2°C and 75% RH ± 5% for 1–3 months to evaluate changes in physical appearance, hardness, and drug content [33,36].

4. RESULTS

4.1. PREFORMULATION RESULTS

Granules of all formulation batches were evaluated for flow and compressibility parameters prior to compression.

Table 4: Pre-compression Parameters of Granules

Parameter	Batch I	Batch II	Batch III	Batch IV	Batch V	Optimized
Angle of Repose (°)	28.5	29.2	27.8	28.9	29.0	28.7
Bulk Density (g/ml)	0.42	0.40	0.45	0.41	0.43	0.44
Tapped Density (g/ml)	0.50	0.48	0.52	0.49	0.51	0.50
Carr's Index (%)	16.0	16.6	13.5	16.3	15.7	12.0
Hausner Ratio	1.19	1.20	1.15	1.19	1.18	1.14

All batches exhibited good flow properties with angle of repose values below 30°. Carr's Index ranged between 12–16%, indicating fair to good compressibility. Hausner ratio values (1.14–1.20) were within acceptable limits (<1.25), confirming suitability for tablet compression. The optimized batch showed comparatively better flow properties with lowest Carr's Index and Hausner ratio.

4.2. EVALUATION RESULTS

The prepared tablets were evaluated for standard quality control parameters.

Table 5: Post-compression Parameters of Tablet

Parameter	Batch I	Batch II	Batch III	Batch IV	Batch V	Optimized	Limit
General Appearance	Round, smooth	Round, smooth	Slightly rough	Round, smooth	Round, smooth	Round, smooth	Uniform
Weight Variation (mg)	298–302	297–303	298–301	299–302	298–301	299–301	±5%
Hardness (kg/cm²)	4.5	5.5	4.2	4.6	4.8	5.6	4–8
Friability (%)	0.65	0.40	0.75	0.60	0.55	0.35	<1%
Disintegration Time (min)	10.0	11.0	9.5	10.5	10.8	10.2	<15
Thickness (cm)	0.35	0.36	0.34	0.35	0.36	0.37	Uniform
Diameter (cm)	0.9	0.9	0.9	0.9	0.9	0.9	Uniform
Loss of Drying	4.2	3.8	4.5	4.0	3.9	3.7	<5%

All formulation batches complied with the specified pharmacopoeial limits. Tablet hardness was found to range between 4.2 and 5.6 kg/cm², indicating adequate mechanical strength. Friability values were found to be below 1%, confirming good tablet durability. Disintegration time for all batches was found to be within acceptable limits (<15 minutes). Loss on drying (LOD) values ranged from 3.7% to 4.5%, which were within the pharmacopoeial limit (<5%), indicating adequate drying and good formulation stability. The optimized batch exhibited the best overall performance, with higher hardness (5.6 kg/cm²), lowest friability (0.35%), and acceptable disintegration time (~10.2 minutes).

Comparative evaluation of all formulation batches demonstrated that variations in formulation parameters significantly affected tablet characteristics, as illustrated in Figure 1 [1,33].Batch II (with increased binder concentration) showed higher hardness and reduced friability, but a slightly longer disintegration time. In contrast, Batch III (with increased diluent) exhibited faster disintegration, but lower hardness and higher friability [35,38].Batches IV and V were modified to improve therapeutic efficacy, with Batch IV emphasizing fenugreek for metabolic regulation and Batch V focusing on Shatavari for hormonal balance [10,13].The optimized batch exhibited a well-balanced profile with adequate hardness, low friability, and acceptable disintegration time, making it the most suitable formulation among all batches [1,34].

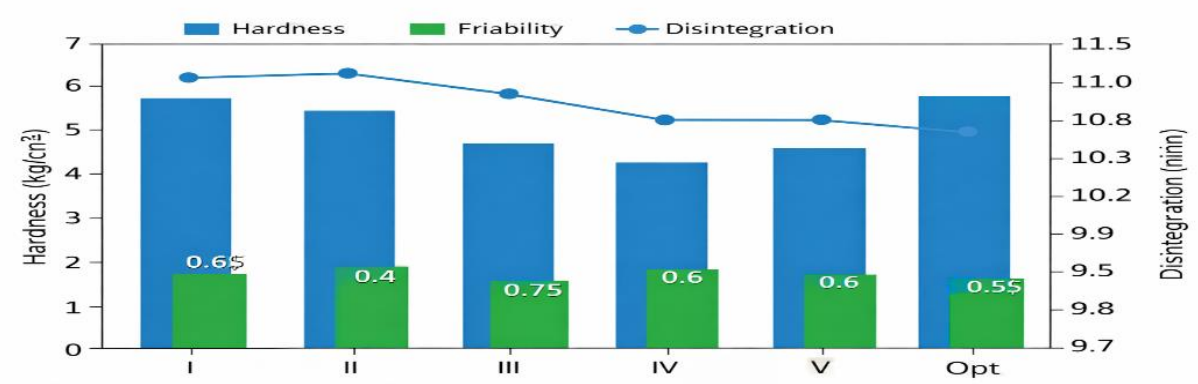

Figure 6: Comparative evaluation of hardness, friability, and disintegration time across formulation batches (I–V and optimized). The graph illustrates that the optimized batch exhibited the highest hardness (5.6 kg/cm²), lowest friability (0.35%), and acceptable disintegration time (~10 min), confirming balanced mechanical strength and rapid disintegration.

The graphical representation of tablet evaluation parameters clearly illustrates the effect of formulation variables on tablet characteristics.

The hardness graph shows that Batch II and the optimized batch exhibited the highest hardness values (5.5 and 5.6 kg/cm², respectively), indicating that increased binder concentration significantly enhances mechanical strength [35]. In contrast, Batch III exhibited the lowest hardness (4.2 kg/cm²), likely due to higher diluent content, which reduced binding efficiency [38]. The friability graph further supports this trend, with Batch II and the optimized batch showing the lowest friability values (0.40% and 0.35%, respectively), indicating improved resistance to mechanical stress [1,34]. Batch III exhibited the highest friability (0.75%), indicating reduced tablet integrity due to insufficient binding.

The disintegration graph reveals that Batch III exhibited the fastest disintegration time (9.5 minutes), attributed to higher diluent concentration and reduced binder effect. The disintegration graph reveals that Batch III exhibited the fastest disintegration time (9.5 minutes), attributed to higher diluent concentration and reduced binder effect. The optimized batch demonstrated a balanced disintegration time (10.2 minutes), which remained well within pharmacopoeial limits [1,34].

Overall, the graphical analysis confirms that increasing binder concentration enhances tablet strength but may delay disintegration, whereas higher diluent concentration improves disintegration but may compromise mechanical stability [35,38]. The optimized batch successfully achieved a balance among these parameters, making it the most suitable formulation.

4.3. PHYTOCHEMICAL SCREENING

Table 6: Phytochemical Screening Results

Ingredient	Test	Observation	Result
Shatavari	Foam test	Persistent froth	+
DGL	Glycyrrhizin test	Froth + sweet taste	+
Fennel	Anethole test	Aroma	+
Coriander	Volatile oil test	Odor	+
Spearmint	Menthol test	Cooling	+
Tulsi	Shinoda test	Pink/red	+

Amla	Ferric chloride test	Dark green	+
Fenugreek	Dragendroff's test	Orange ppt	+

These compounds are responsible for antioxidant, hormonal, metabolic, and anti-inflammatory activities, confirming the therapeutic potential of the formulation. These phytoconstituents are responsible for antioxidant, hormonal, metabolic, and anti-inflammatory activities [31,32], thereby supporting the therapeutic potential of the formulation.

Content Uniformity

Table 7: Calibration Curve Data (λmax = 254 nm)

Concentration (µg/ml)	Absorbance
10	0.18
20	0.36
30	0.54
40	0.72
50	0.90

Regression equation:

$y = 0.018x + 0.002$ ($R^2 = 0.998$)

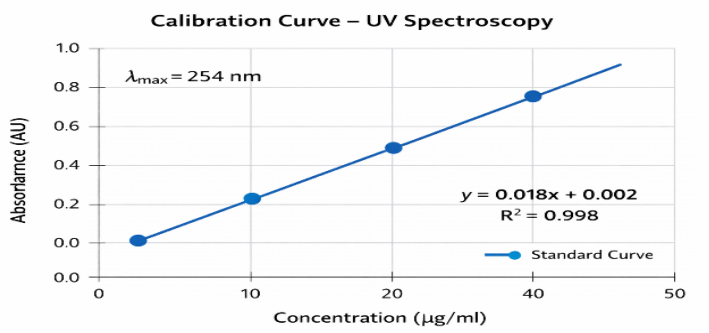

Figure 7: Calibration curve showing UV spectroscopic linear regression fit with equation y = 0.018x + 0.002 (R^2 = 0.998) at λmax 254 nm, demonstrating excellent linearity between concentration and absorbance.

Table 8: Content Uniformity of Optimized Batch

Tablet No.	Absorbance	Content (mg)	% Label Claim
1	0.88	48.9	97.8%
2	0.91	50.5	101.0%
3	0.89	49.4	98.8%
4	0.90	50.0	100.0%
5	0.87	48.3	96.6%
Mean	0.89	49.4	98.8%

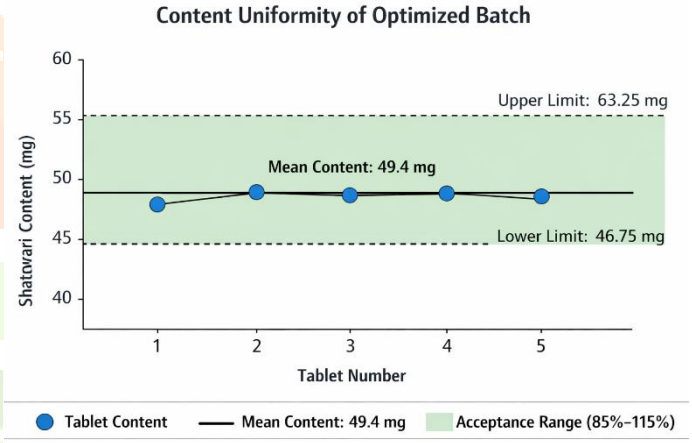

Figure 8: Content uniformity of optimized batch showing % label claim values within pharmacopeial range (85–115%), with mean drug content 98.8%, indicating uniform distribution of active constituents.

The calibration curve exhibited excellent linearity at λmax 254 nm, indicating accurate spectrometric analysis [1]. Content uniformity results showed a mean drug content of 98.8%, which falls within pharmacopoeial limits (85–115%), confirming uniform distribution of active constituents [1,34].

Figure 6: Optimized polyherbal tablet (300 mg) — final formulation appearance.

Interpretation: Uniform, smooth-surfaced tablets with balanced mechanical strength and acceptable disintegration time, confirming successful optimization of binder and herbal ratio.

The study demonstrated that all formulation batches exhibited satisfactory pharmaceutical properties. The optimized batch demonstrated superior flow characteristics, balanced mechanical strength, low friability, acceptable disintegration time, and uniform drug content [1,35]. These findings indicate the successful development of a stable and effective polyherbal tablet formulation [32,33].

5. DISCUSSION

5.1. Correlation with Literature Findings

The results of the present study are consistent with previously reported literature on polyherbal formulations [32,36]. The results of the present study are consistent with previously reported literature on polyherbal formulations. In agreement with the literature, increased binder concentration in the present study improved tablet hardness and reduced friability, as observed in Batch II and the optimized formulation [35,38]. Similarly, higher diluent levels accelerated disintegration but reduced mechanical strength, a trend reported in earlier studies and also observed in Batch III [35]. Phytochemical screening confirmed the presence of saponins, flavonoids, alkaloids, and tannins, which are well documented for their antioxidant, anti-inflammatory, and endocrine-modulating properties [31,32]. Thus, the formulation outcomes are in close agreement with established scientific evidence.

5.2. Therapeutic Potential in PCOS/PMS Management

The developed polyherbal tablet demonstrates multi-targeted therapeutic potential in the management of Polycystic Ovary Syndrome and Premenstrual Syndrome [6,7,11]. Shatavari contributes phytoestrogenic activity that supports hormonal balance [10,12], Fenugreek enhances insulin sensitivity [113,14], and Spearmint exhibits anti-androgenic effects that are beneficial in reducing symptoms of Polycystic Ovary Syndrome [23-25]. Tulsi and Amla provide antioxidant and adaptogenic support [15,26,27], while Fennel, Coriander, and DGL contribute to endocrine regulation, stress modulation, and digestive health [17,20,28]. Collectively, these herbs help address hormonal imbalance, oxidative stress, and metabolic dysfunction, offering a holistic approach that goes beyond symptomatic relief [32].

Beyond disease management, the formulation also supports overall health and general well-being. The immunomodulatory and antioxidant properties of Tulsi and Amla help strengthen the body's natural defence mechanisms [15,27], while the digestive support provided by Fennel and Coriander enhances nutrient absorption [17,20]. The adaptogenic effects of Shatavari and Tulsi contribute to stress reduction and overall well-being. These findings indicate that the optimized polyherbal tablet is not only effective in the management of Polycystic Ovary Syndrome and Premenstrual Syndrome but also beneficial for improving immunity, supporting metabolic health, and promoting long-term wellness.

6. CONCLUSION

In this study, a polyherbal tablet formulation was successfully prepared and evaluated for the management of PCOS and PMS employing the wet granulation technique [1,35]. The integration of diverse herbal constituents with complementary pharmacological activities facilitated a multitargeted approach toward hormonal regulation, metabolic support, and overall health improvement [32,36]. Pre-compression evaluation revealed favourable flow characteristics and compressibility of the powder blends, while post-compression assessment demonstrated conformity with pharmacopeial specifications for hardness, friability, weight variation, and disintegration [1,34]. The optimized formulation achieved an ideal compromise between mechanical integrity and disintegration characteristics, thereby ensuring stability and therapeutic effectiveness [35]. Content uniformity evaluation further demonstrated homogeneous drug distribution, complying with acceptable pharmacopeial limits [1,34].

Phytochemical evaluation revealed the presence of key constituents such as flavonoids, alkaloids, tannins, and saponins, thereby substantiating the formulation's therapeutic potential [31,32]. Relative to conventional therapy, the developed polyherbal formulation demonstrates a holistic therapeutic approach, with the potential for reduced adverse effects and improved patient compliance [6,11]. However, the scope of the study was limited to in vitro evaluation only. Future research should encompass in vivo and clinical studies to establish efficacy and safety, alongside long-term stability assessments and advanced analytical standardization to ensure batch-to-batch consistency [33,36]. Collectively, the findings suggest that polyherbal tablets represent a promising and efficacious approach for the management of PCOS, PMS, and associated conditions, while also enhancing overall health, immune function, and well-being.

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