



FORMULATION AND EVALUATION OF A POLYHERBAL TABLET FOR THE MANAGEMENT OF POLYCYSTIC OVARY SYNDROMES.

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ABSTRACT

Background: Polycystic ovary syndrome (PCOS) is a heterogeneous endocrine-metabolic disorder in which reproductive; metabolic and psychological features may coexist. Herbal products are widely investigated as complementary approaches; however, pharmaceutical quality must be established before biological efficacy can be meaningfully assessed. **Objective:** To formulate and compare polyherbal tablets containing equal quantities of *Withania somnifera*, *Cinnamomum verum*, *Trigonella foenum-graecum*, *Zingiber officinale* and *Mentha piperita* using HPMC, PVP, gellan gum (GG), or GG:PVP combinations. **Methods:** Twelve 750-mg formulations (F1-F12) were prepared and evaluated for powder-flow indices and tablet physical properties. **Results:** Carr's index ranged from 7.84% to 12.00%, Hausner ratio from 1.07 to 1.15, and angle of repose from 22.4° to 25.8°, indicating generally favorable flow. Average tablet weights were 0.750-0.761 g. Marked formulation-dependent differences were observed in hardness (2.96-9.26 kg/cm²), friability (0.01-29.24%) and disintegration (6.48-36.49 min). F11, containing GG:PVP at 75:25 mg, provided the most balanced measured profile: average weight 0.759 g, hardness 5.86 kg/cm², friability 0.58%, and disintegration time 12.35 min. **Conclusion:** Within the limits of the measured pharmaceutical tests, F11 was the most suitable formulation for further development. The findings demonstrate the pharmaceutical feasibility of the optimized polyherbal tablet formulation, with F11 showing the most satisfactory overall physical characteristics among the formulations studied.

1. INTRODUCTION

Polycystic ovary syndrome (PCOS) is a common, heterogeneous endocrine disorder characterized by combinations of hyperandrogenism, ovulatory dysfunction and polycystic ovarian morphology, with important metabolic and psychological comorbidities. The 2023 International Evidence-based Guideline emphasizes individualized assessment and management across reproductive, metabolic and psychological domains [1].

Insulin resistance and compensatory hyperinsulinaemia are frequent metabolic features

of PCOS and can interact with ovarian androgen production and reduced hepatic sex hormone-binding globulin. Obesity and adverse cardiometabolic risk factors may further aggravate the clinical phenotype. Current management can include lifestyle intervention, combined oral contraceptive pills, metformin, anti-androgen therapy and fertility-directed treatment according to individual indications and goals [1].

Medicinal plants have attracted interest as complementary sources of bioactive compounds. Cinnamon has been investigated in women with PCOS, including a randomized trial reporting

improved menstrual cyclicality [2], while a later randomized clinical trial reported changes in insulin resistance and testosterone with cinnamon and hormonal changes with ginger [3]. Fenugreek seed extract has also been evaluated clinically in women with PCOS [4]. These studies concern specific preparations and do not establish efficacy of a new polyherbal combination; nevertheless, they provide a rationale for investigating a standardized dosage form.

The five herbs selected for the present formulation were *Mentha piperita* (peppermint), *Zingiber officinale* (ginger), *Cinnamomum verum* (cinnamon), *Trigonella foenum-graecum* (fenugreek) and *Withania somnifera* (ashwagandha). Peppermint contains phenolic and volatile constituents with reported antioxidant and related bioactivities [5]. Ginger is rich in gingerols and shogaols and has documented antioxidant and anti-inflammatory properties [6,7]. Cinnamon has been extensively reviewed for metabolic and other pharmacological activities [8]. Fenugreek contains fiber, saponins and other constituents and has evidence for effects on glycaemic outcomes in broader populations [9]. Ashwagandha contains withanolides and other steroidal lactones with diverse pharmacological activities [10,11].

For a multi-component herbal product, reproducible pharmaceutical quality is a prerequisite for subsequent biological evaluation. Powder flow, compressibility, tablet mechanical strength, friability and disintegration are particularly relevant during formulation development [12-15]. Accordingly, the objective of this study was to prepare twelve polyherbal tablet formulations using different polymer systems and to identify the formulation with the most balanced measured pre-compression and post-compression characteristics.

2. MATERIALS AND METHODS

2.1 HERBAL MATERIALS AND AUTHENTICATION

The herbal materials comprised *W. somnifera* root, *C. verum* bark, *T. foenum-graecum* seed, *Z. officinale* rhizome and *M. piperita* leaf. The plant materials were collected from locations within approximately 50 km of Tiruvannamalai, Tamil Nadu, and authenticated by Dr. J. Suresh Kumar. The authenticated materials were dried, pulverized,

passed through a 60-mesh sieve and stored in clean, dry, airtight containers until further use.

2.2 EXCIPIENTS

Microcrystalline cellulose (MCC), lactose, talc and magnesium stearate were used as diluent/filler, filler, glidant and lubricant, respectively. Hydroxypropyl methylcellulose (HPMC), polyvinylpyrrolidone (PVP) and gellan gum (GG) were evaluated as polymeric binders/matrix-forming materials. All excipients were of pharmaceutical grade.

2.3 EVALUATION OF INDIVIDUAL HERBAL POWDERS

The individual herbal powders were evaluated for organoleptic characteristics, moisture content, pH of a 1% dispersion, total ash, acid-insoluble ash, water-soluble ash, water-soluble extractive and alcohol-soluble extractive using standard pharmacognostic approaches [13,14]. Visual physical stability was also recorded after 90 days. These measurements were used as preliminary raw-material quality indicators; they should not be interpreted as complete botanical standardization.

2.4 FORMULATION OF POLYHERBAL TABLETS

Each tablet contained a total of 500 mg herbal powder, comprising 100 mg of each of the five herbs. Formulations F1-F3 contained HPMC at 50, 75 and 100 mg; F4-F6 contained PVP at 50, 75 and 100 mg; F7-F9 contained GG at 50, 75 and 100 mg. F10-F12 contained 100 mg total GG:PVP at ratios of 50:50, 75:25 and 25:75 mg, respectively. MCC was adjusted to maintain a nominal tablet weight of 750 mg; lactose (50 mg), talc (5 mg) and magnesium stearate (5 mg) were constant.

The polyherbal tablets were prepared by the wet granulation method. The required quantities of *W. somnifera*, *C. verum*, *T. foenum-graecum*, *Z. officinale* and *M. piperita* powders were accurately weighed and mixed uniformly by geometric dilution. The required quantity of microcrystalline cellulose and lactose was added and blended thoroughly. A polymer paste containing the respective binder system—HPMC, PVP, gellan gum (GG), or GG:PVP combination according to the formulation design—was gradually added to the herbal powder blend with continuous mixing to obtain a coherent wet mass. The wet mass was passed through a suitable sieve to prepare granules.

The granules were dried and subsequently resieved to obtain uniformly sized granules. Talc and magnesium stearate were then added as glidant and lubricant, respectively, and mixed gently. The lubricated granules were compressed into tablets of 750 mg using a tablet compression machine.

2.5 PRE-COMPRESSION EVALUATION

Bulk density and tapped density were measured for each formulation blend. Carr's compressibility index and Hausner ratio were calculated from the density values, and angle of repose was determined as an index of flow behavior [12,15].

2.6 POST-COMPRESSION EVALUATION

The prepared tablets were evaluated for average tablet weight, hardness, friability and disintegration

time using standard tablet-quality procedures [12,15,16]. Average tablet weight was determined for each formulation, while hardness was measured in kg/cm². Friability was expressed as percentage weight loss after testing in a friabilator. Disintegration time was determined using a standard disintegration test apparatus and expressed in minutes.

3. RESULTS

3.1 RAW-MATERIAL CHARACTERISTICS

The five herbal powders showed characteristic organoleptic profiles. Moisture content ranged from 4.82% (cinnamon) to 5.51% (peppermint) while the pH of 1% dispersions ranged from 5.91,

Parameter	Peppermint	Ginger	Cinnamon	Fenugreek	Ashwagandha
Colour	Dark green	Pale yellow	Brown	Yellowish-brown	Light cream
Odour	Strong aromatic	Characteristic spicy	Sweet aromatic	Characteristic aromatic	Characteristic earthy
Taste	Cooling	Pungent	Sweet-spicy	Slightly bitter	Bitter-astringent
Moisture Content (%)	5.51	5.12	4.82	5.36	5.21
pH (1% dispersion)	6.38	6.24	5.91	6.18	6.54
Total Ash (%)	9.18	5.74	4.41	3.82	4.87
Acid Insoluble Ash (%)	0.61	0.49	0.36	0.41	0.38
Water Soluble Ash (%)	4.19	2.71	2.17	1.92	2.36
Water Soluble Extractive (%)	24.38	18.03	15.88	22.46	19.84
Alcohol Soluble Extractive (%)	17.24	15.28	18.08	12.84	15.92
Visual observation after 90 days	No visible change / fungal growth / pest attack	No visible change	No visible change	No visible change	No visible change

Table 1. Preliminary characteristics of the individual herbal powders.

Parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Bulk Density (g/mL)	0.45	0.46	0.47	0.44	0.48	0.45	0.46	0.47	0.44	0.48	0.46	0.47
Tapped Density (g/mL)	0.5	0.51	0.52	0.5	0.53	0.5	0.51	0.52	0.5	0.53	0.5	0.51
Carr's Index (%)	10	9.8	7.84	12	9.43	10	9.8	9.62	12	9.43	8	7.84
Hausner Ratio	1.12	1.11	1.08	1.14	1.1	1.13	1.1	1.15	1.14	1.1	1.07	1.09

Angle of Repose (°)	24.2	23.9	22.4	25.8	23.6	24.5	23.95	23.2	25.4	23.75	22.8	22.5
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Table 2. Pre-compression properties of formulation blends F1-F12.

3.3 FORMULATION COMPOSITION

Ingredient (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Polyherbal powder	500	500	500	500	500	500	500	500	500	500	500	500
-Polymer system	HPMC	50	75	100	-	-	-	-	-	-	-	-
	PVP	-	-	-	50	75	100	-	-	-	-	-
	Gellan gum	-	-	-	-	-	-	50	75	100	-	-
	GG:PVP	-	-	-	-	-	-	-	-	-	50:50	75:25
MCC	140	115	90	140	115	90	140	115	90	90	90	90
Lactose	50	50	50	50	50	50	50	50	50	50	50	50
Talc	5	5	5	5	5	5	5	5	5	5	5	5
Magnesium stearate	5	5	5	5	5	5	5	5	5	5	5	5
Total	750	750	750	750	750	750	750	750	750	750	750	750

Table 3. Composition of polyherbal tablet formulations. The 500 mg polyherbal powder contained 100 mg of each herb. GG, gellan gum; PVP, polyvinylpyrrolidone; HPMC, hydroxypropyl methylcellulose; MCC, microcrystalline cellulose.

Formulation	Average tablet weight (g)	Hardness (kg/cm ²)	Friability (%)	Disintegration Time (min)
F1	0.751	2.96	29.24	30.09
F2	0.761	3.21	25.74	32.55
F3	0.758	3.48	13.94	35.05
F4	0.759	3.84	0.04	30.45
F5	0.755	5.87	0.08	34.33
F6	0.753	9.26	0.05	36.49
F7	0.75	3.91	0.08	30.09
F8	0.756	3.67	0.11	33.45
F9	0.758	3.34	0.01	33.5
F10	0.756	3.42	1.36	6.48
F11	0.759	5.86	0.58	12.35
F12	0.760	6.92	0.24	17

Table 4. Post-compression properties of polyherbal tablets.

to 6.54. Total ash values ranged from 3.82% to 9.18%. No visible colour change, fungal growth or pest attack was recorded after 90 days under the conditions used in the study. The complete raw-material observations are summarized in Table 1.

3.2 PRE-COMPRESSION PROPERTIES

The formulation blends showed bulk densities of 0.44-0.48 g/mL and tapped densities of 0.50-0.53 g/mL. Carr's index was 7.84-12.00%, Hausner ratio 1.07-1.15, and angle of repose 22.4-25.8°. Taken together, these values indicate generally favorable

flow and packing behavior for all twelve blends. F11 showed Carr's index of 8.0%, Hausner ratio of 1.07 and angle of repose of 22.8°, supporting adequate flow prior to compression.

3.4 POST-COMPRESSION PROPERTIES

Average tablet weights varied narrowly from 0.750 to 0.761 g. In contrast, mechanical and disintegration properties were strongly formulation dependent. Hardness ranged from 2.96 to 9.26 kg/cm². F1-F3 had very high friability (13.94-29.24%), while F10 also exceeded the commonly applied 1% friability criterion at 1.36% [15,16]. F4-F9, F11 and F12 were below 1% friability. Disintegration ranged from 6.48 to 36.49 min. Using the conventional 15-min criterion for uncoated tablets as a development benchmark, F10 (6.48 min) and F11 (12.35 min) met this time criterion, whereas F12 (17.0 min) and F1-F9 did not. Because F10 had unacceptable friability, F11 provided the best overall balance among. The measured attributes.

4. DISCUSSION

This formulation study demonstrates that polymer type and composition substantially influenced the physical performance of the 750-mg polyherbal tablets. The pre-compression data were relatively consistent across F1-F12, with low Carr's index values, Hausner ratios close to unity and angles of repose below approximately 26°. These findings suggest that poor powder flow was unlikely to be the principal cause of the large differences subsequently observed in friability and disintegration. Rather, the post-compression results point to differences in interparticulate bonding and matrix behavior associated with the polymer system and its level.

The HPMC series (F1-F3) showed a progressive increase in hardness from 2.96 to 3.48 kg/cm² as polymer level increased, but friability remained extremely high (29.24% to 13.94%) and disintegration was prolonged (30.09-35.05 min). These data indicate that, under the processing conditions used, HPMC did not provide sufficient mechanical integrity even at the highest tested level. The magnitude of friability in F1-F3 is not a minor deviation but a clear formulation failure relative to the usual compendial expectation of not more than about 1% weight loss for conventional tablets [15,16].

The PVP formulations (F4-F6) behaved differently. Friability was very low (0.04-0.08%), indicating strong particle bonding, while hardness increased markedly with polymer concentration from 3.84 kg/cm² in F4 to 9.26 kg/cm² in F6. The accompanying increase in disintegration time from 30.45 to 36.49 min is consistent with a stronger, more slowly penetrated compact. Thus, although PVP produced mechanically robust tablets, the tested single-polymer formulations disintegrated too slowly for an immediate-release conventional tablet development target.

The GG formulations (F7-F9) also showed low friability (0.01-0.11%) but prolonged disintegration (30.09-33.50 min). The combined GG:PVP systems produced a more useful range of behavior. F10 disintegrated fastest (6.48 min), but its hardness was only 3.42 kg/cm² and friability reached 1.36%, indicating inadequate resistance to abrasion. F12 showed good mechanical integrity (6.92 kg/cm² hardness; 0.24% friability) but required 17.0 min to disintegrate. F11, containing GG:PVP 75:25 mg, occupied the most favorable middle ground: hardness 5.86 kg/cm², friability 0.58%, and disintegration 12.35 min. This formulation-level comparison is the main experimental finding of the study.

The herbal composition was selected on the basis of complementary reported bioactivities, but those literature findings must be distinguished from the results of the present experiment. Cinnamon has clinical evidence suggesting effects on menstrual cyclicity in PCOS [2], and an eight-week randomized trial comparing cinnamon, ginger, metformin and placebo reported reductions in HOMA-IR and testosterone with cinnamon and changes in gonadotropins with ginger [3]. A fenugreek seed extract has also been studied in women with PCOS [4]. However, these studies used defined interventions that differ from the present five-herb powder tablet. Consequently, they support biological plausibility for future testing but cannot be used as evidence that F11 treats PCOS.

Similarly, the broader literature describes antioxidant, anti-inflammatory or metabolic actions for peppermint, ginger, cinnamon, fenugreek and ashwagandha [5-11]. Combining herbs may produce additive, synergistic or antagonistic interactions, and polyherbal concepts have been discussed in

phytomedicine [17,18]. Such interactions cannot be assumed from composition alone. The present work measured pharmaceutical quality attributes only; it did not measure marker compounds, dissolution/release of phytoconstituents, antioxidant activity, glucose metabolism, reproductive hormones, ovarian morphology, safety or clinical outcomes.

The average tablet weights of F1-F12 were close to the target tablet weight of 750 mg, ranging from 0.750 to 0.761 g. The small variation among the formulation averages indicates consistent filling and compression of the wet-granulated blends. Friability and disintegration results were compared with standard pharmaceutical quality criteria [15,16].

Overall, the formulation study demonstrated clear differences in tablet characteristics depending on the polymer system and concentration. The wet granulation process produced granules with satisfactory flow characteristics, while optimization of the binder composition was important for achieving adequate mechanical strength and acceptable disintegration. Among the tested formulations, F11 showed the most suitable balance of these pharmaceutical properties.

5. CONCLUSION

Twelve polyherbal tablet formulations containing equal quantities of five medicinal plant powders were compared using HPMC, PVP, gellan gum and gellan gum:PVP polymer systems. All formulation blends showed generally favorable pre-compression flow indices, whereas post-compression behavior varied substantially. F11 (GG:PVP 75:25 mg) showed the most balanced measured profile, with an average tablet weight of 0.759 g, hardness of 5.86 kg/cm², friability of 0.58% and disintegration time of 12.35 min. F11 is therefore the preferred formulation for subsequent development on the basis of the available physical-quality data. Before therapeutic relevance to PCOS can be claimed, the formulation should undergo botanical and phytochemical standardization, assay/content-uniformity testing, dissolution or release studies, formal stability testing, safety assessment and appropriately designed pharmacological and clinical studies.

DECLARATIONS

Conflict of Interest: The authors declare no conflict of interest.

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