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Formulation & Evaluation of Herbal Tea Bags For Treatment Of PCOS A Ovarian Disorder

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ABSTRACT: Polycystic ovarian syndrome (PCOS) is most prevalent endocrine disorder in women & can leads the serious complications among females. One in every 5-6 females facing serious complications regarding infertility & irregularities in their menstruation cycle. This can be occurred due to hormonal imbalance, stress, obesity etc. It can be identifies by the presence of hypervascularized androgen-secreting stroma & enlarged ovaries with numerous tiny cyst. The present work is based on formulation and evaluation of herbal tea bags for treatment of PCOS a ovarian disorder. This includes herbal drugs such as Turmeric, Linseed, Fenugreek seeds, Cinnamon, Fennel, Ginger, and Stevia. The preparation made by preparation of granules by weight granulation method and that will packed within tea bags. This herbal formulation evaluated by various parameters.

KEY WORDS: PCOS, Tea Bags, Linseed, Turmeric, Evaluation

INTRODUCTION:

The most prevalent endocrine condition in women is polycystic ovary syndrome (PCOS). It can be identified by the presence of hypervascularized androgen-secreting stroma and enlarged ovaries with numerous tiny cysts. Menstrual irregularities, polycystic ovary, obesity, infertility, hairy, acne, and hyperandrogenism are among the clinical signs [1] .The presence of two or more of the following characteristics is required for the clinical diagnosis of polycystic ovarian syndrome, including persistent oligo- or anovulation, androgen excess, and polycystic ovaries [2] According to the World Health Organization (WHO), PCOS affected 116 million women (3.4%) in the world in 2012 [3] .A complex condition with an uncertain cause, polycystic ovarian syndrome (PCOS) affects 5% to 10% of women of reproductive age [4] Estimates of PCOS prevalence vary widely around the globe, from 2.2% to as high as 26%. According to specialists, 10% of women in India have PCOS [5]. In addition to PCOS, metabolic disorders including

dyslipidemia and insulin resistance can lead to diseases like diabetes, obesity, cancer, and infertility as well as coronary heart disease [6] . In a healthy person, reactive oxygen species and antioxidants are in balance, but when this balance is upset, oxidative stress results [8] .This could result in various illnesses. In women with PCOS [9], increased oxidative stress raises the risk of cardiovascular disease.

In the case of PCOS, the ovaries create abnormally high levels of androgens, the male sex hormones that are typically present in women in trace amounts. The many little cysts (fluid-filled sacs) that develop in the ovaries are known as polycystic ovarian syndrome. While some women without the disease do develop cysts, some people with this disorder do not.

OBJECTIVES:

1) It is more affordable than other medicines on the market.

2) It is simple to utilise at any time or place.

3) It does not have any adverse effects.

4) Its efficacy has been demonstrated.

5) Better patient compliance.

MATERIAL AND MATHODS:

FORMULA

Table1: Formulation of tea bags

Sr. No.	Ingredients	Quantity (gms)
1	Turmeric (gm)	1.00
2	Linseed (gm)	1.00
3	Fenugreek Seeds (gm)	1.00
4	Cinnamon (gm)	0.75
5	Fennel (gm)	1.25
6	Ginger (gm)	1.00
7	Stevia (gm)	0.10
Total (gms)		6.10

Procedure:

Formulation of Granules

a. Granules were prepared using wet granulation technique. All the herbs were grinded to fine powder using mixer. And sieved using through using sieve number 85.
b. All the fine powder transferred to mortar and damp mass was prepared by adding sufficient quantity of water.
c. The damp mass was passed through sieve number 16 to form granules. Wet granules were shed dried for 24 hours at room temperature.
d. 6.1 gms of granules were packed in each teabag and used for analysis.

Fig 1 : Tea Bag

Evaluation of Herbal Tea Bag:

a. Phytoconstituent Analysis:

i. Test for Curcuminoids:

Weigh accurately 0.1 g of the sample into a small beaker and transfer into a 100 ml volumetric flask with 95% ethyl alcohol. Dilute to mark with the alcohol and pipette 10 ml of this solution into another 100 ml volumetric flask. Dilute to volume with the 95% ethyl alcohol. Scan the sample from 400 to 800 nm in 1 cm cells against an 95% ethyl alcohol as blank. The sample should show maximum absorbance at 425 nm. [10]

Test for Flavonoids: Take 1 ml sample of aqueous extract of tea powder. To each 10ml of analyzed solution, 2ml of water and 5ml of AlCl3 reagent was added (133mg crystalline aluminum chloride and 400mg crystalline sodium acetate were dissolved in 100ml of extracting solvent) and absorbance recorded at 430nm against the blank (10ml of analyzed solution + 5ml of water). The amt of flavonoids was calculated as a quercetin equivalent from the calibration curve of quercetin standard solution and expressed an mg quercetin/ 100gm of extract. [11]

ii. Test for Long Chain unsaturated fatty acids:

The Long chain fatty acid i.e. Linolenic acid was identified by Gas chromatography.

iii. Test for Phenols:

The total phenolic content in the aqueous and methanolic seed extract of ajwain and fennel was determined spectrophotometrically with Folin-Ciocalteau reagent. An aliquot of the extract (0.5 ml)

was mixed with 2.5 ml of 10% Folin-Ciocalteu reagent and 2 ml of Na2CO3 (75% w/v). The resulting mixture was vortexed for 15 s and incubated at 40°C for 30 min for colour development. The absorbance of the samples was measured at 765 nm using UV/visible spectrophotometer. Total phenolic content was expressed as mg/g tannic acid equivalent from the calibration curve using the equation:

Y = 0.1216x, R2 = 0.936512

Where; x was the absorbance and Y was the tannic acid equivalent (mg/g). [12]

iv. Test for Vitamins and Gingerols:

The vitamins as tocopherols and gingerols were identified by using HPLC.

v. The secondary metabolites present in the herbal tea blend were evaluated by phytochemical analysis using standard procedures.

b. Micromeritics of Granules: [13]

i. **Angle of repose:** The static angle of repose was measured according to the fixed funnel and free-standing cone method (Well 2003). A 50 g quantity of powder was transferred into a funnel of 1 cm orifice. The funnel was clamped 10 cm from the base (such that the funnel neck tip was 10 cm from the flat surface). The tip of the funnel neck was closed with a finger until all the granules have been transferred. The granules were then allowed to flow through to the surface. When all the granules had completely drained, the height (H) and the diameter (D) of the granule mound on the surface was measured and recorded. This was repeated three times. The angle of repose was calculated using Equation 4:

Tan Θo = 2H/D

Where: Θo = angle of repose, H= height and D= diameter.

ii. **Bulk and tapped densities:** The volume occupied by 50 g of the granules was determined using a 200-mL graduated measuring cylinder. The tapped volume which corresponds to the final volume of consolidation after tapping with an automated tapping machine (Stampfvolumeter, STAV 2003JEF, Germany) was determined. The bulk (Vo) and tapped (VT) volumes were evaluated (Well 2003). The bulk and tapped densities were calculated as the ratio of weight to volume (Vo and VT, respectively) as presented by Equation 5: Mass (g)/Volume (Vo or VT)

iii. **Compressibility index:** The Compressibility index (CI %) was extrapolated from the bulk and tapped densities using Equation : $Compressibility\ index$ (%) = $PT{-}PoPTX$ 100

c. Organoleptic Evaluation:

i. **Colour:** Colour of the brew was observed against white background.

ii. **Odour**: Odour of the brew was evaluated physically.

iii. **Taste:** Taste of the brew was tested physically.

d. pH:

Aqueous solution of the tea bag was prepared by dipping the tea bag into 100 hot water and upon cooling the solution to the room temperature, the pH of the batches were measured by dipping the electrode in to the solution and directly measuring the pH on display of the pH meter.

e. Ash Value:

Five tea bags were randomly selected from each formulation and the content emptied in a large Petri dish. A 2 g quantity of the herbal tea was weighed and transferred into a crucible which has initially been heated to 105℃ for 5 min and placed in a desiccator until use. The crucible containing the herbal material was then incinerated. The heating temperature was 525 ± 25℃. The crucible was allowed to cool before the weight was determined. Then it was again heated for 30 min and reweighed. This was repeated twice until a constant weight was obtained. The percentage of ash value was determined using Equation

% Ash Value = (W3-W1 / W2-W1) x 100

Where, W1 = weight of ash & crucible,

W2 = Weight of granules and crucible,

W3 = weight of crucible.

f. Water Soluble Extract:

A tea bag corresponding to 6.10 g of the herbal tea was brewed using 250 mL of boiling potable water (100 ± 2℃). The water containing the tea bag was allowed to stand for 24 h with intermittent stirring. A 20 mL quantity of the brew was filtered into a pre-weighed porcelain dish and the water evaporated on a water bath set at 100℃. The porcelain dish was then transferred into a hot air oven set at 50℃ and allowed to stay for 1 h. The percentage of the water soluble extractive matter was calculated with reference to the dry weight of the sample without the empty bag.

g. LOD:

Five tea bags were randomly selected from each formulation and the content emptied into a large Petri dish. A 3 g quantity of the herbal material was weighed and transferred into an evaporating dish crucible which has initially been heated to 105℃ for 5 min and placed in a desiccator until use. The evaporating dish containing the granules was placed into an oven maintained at 105℃, removed every 30 min and weighed until no change in weight was obtained over two consecutive readings. This was repeated three times. The percentage LOD was determined using Equation

$$\%\, \boldsymbol{LOD} = \frac{\boldsymbol{C2 - C3}}{\boldsymbol{C2 - C1}} \times \mathbf{100}$$

Where,

C1= Weight of empty evaporating dish

C2= Weight of dish + Sample before heating

C3= Weight of dish + Sample after heating

Dissolution studies: The tea bags were subjected to dissolution studies using USP paddle type II Apparatus. The dissolution medium used was 0.1 N HCL (pH 1.2) temperature 37°C ± 0.5°C and paddles rotated at 50 rpm.

Samples of 6 gm. of pure drug, were filled inside Muslin cloth pouches and dropped inside 900 ml of dissolution Medium. A volume of 10 ml of samples were withdrawn every 10 min, filtered through a membrane filter (pore size 0.45 µm) and analyzed at 304 nm. Dissolution studies were done in triplicate (N = 3) and calculated mean values of cumulative Drug release were used while plotting the drug release curves. Based on the above studies, the formulation was selected for further studies.

8.8 Preparation of standard calibration curve:

The standard stock solution was prepared by dissolving 6 gm of anti-PCOS drug in tea bag in 30 ml methanol by sonication for 10 minutes and volume was made up to the 50 ml mark using methanol. From the standard stock solution (1000ug/ml), different aliquots were diluted with distilled water separately to prepare a series of concentrations from range 10-50 ug/ml. The standard solution (10ug/ml) was scanned in the range of 400-200 NM against distilled water as a blank. The max of this solution was found to be 287nm.Absorbance of all solutions was measured at 287 nm against distilled water as a blank. The calibration curve was prepared by plotting absorbance versus concentration.

Result:

PHASE I

Table 2: Phytochemical Analysis

Sr. No.	Constituent	Result
1	Curcuminoids	Present
2	Fatty Acids	Present
3	Flavonoids	Present
4	Phenolic compounds	Present
5	Vitamins	Present
6	Ginger resins	Present

PHASE II

Table 3: Results of evaluation parameter

Sr.no.	Parameters	Results
1	Angle of Repose	23.49
2	Bulk Density	0.7839
3	Tapped Density	0.7547
4	Carr's index	15.22
5	Taste	Sweet

6	Odour	Agreeable
7	Colour	Brown
8	Appearance	Slightly Turbid
9	pH	4.34
10	Ash Value	3.18 %
11	Water Soluble Extract	14.56 %
12	LOD	9.43 %

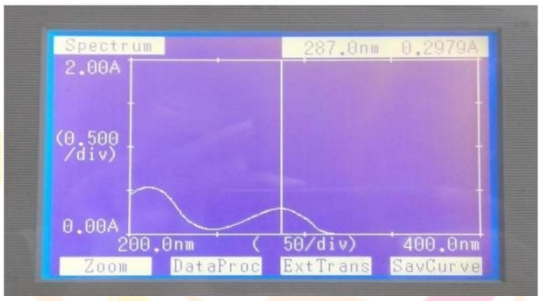

FIG 2 Calibration Curve

Conclusion:

The present work is based on herbal formulation for treatment of PCOS including various drugs as formulated in above table 1.The herbal preparation was prepared and evaluated and finally packed in tea bags.

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