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Formulation and Evaluation of herbal tablet containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots) used for the treatment of vaginal infection

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Abstract

Now-a-days gynecological disorders are very common among Indian women's among which vaginal infection is more frequent which include irritation, itching and swelling. A major fungus causing infection is *Candida* species. Several herbs and their products are used to cure women disorders, though their proper documentation and validation need to be screened out. It has increasingly deserved a special attention among the medical community. In spite of the presence of *Candida* species as a human commensal, alarming rates of local and systemic infections have been observed, varying from moderate to severe impact. The present investigation aims to formulate and evaluate herbal tablet containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots). Eight batches F1 to F8 were prepared using different ratio of ingredients and were evaluated as per IP. The data obtained indicate that F7 have excellent results when compared with other formulation codes.

Keywords: Vaginal infection, *Clitoria ternatea* Linn., Roots, Formulation

Introduction

According to NICHD i.e., National institute of Child Health and Human development there are five types of major gynecological disorders associated with females, these include vulvodynia, vaginitis, pelvic floor disorders, pelvic pain and menstrual disorders. In India approximately every woman suffers from gynecological disorders such as vaginal infection, menstrual troubles or any other associated disease. The percentage is more in rural women than urban women and the reason behind this is the life style, food habit and un-hygienic conditions in rural areas¹⁻².

During past few years plant derived extracts and their isolated phytochemicals are gaining importance and are also a new emerging area of research. Vaginal infection also referred as vaginitis include irritation, itching and swelling are very frequent and common among women due to various un-hygienic issues including a major fungus causing infection is *Candida* species. *Candida*, a fungus is very often associated with the vaginal infections.

In fact, *Candida* species have been implicated in an onset of mild and severe clinical conditions, although it was considered a commensal microorganism of healthy individuals.³⁻⁵

Clitoria ternatea Linn. commonly known as aprajita belongs to family Fabaceae is traditional herbal drug used in the treatment of women disorders from ancient. Part of selected is used for the treatment of inflammation, bacterial infection, fungal infection etc. especially concerned to women disorders.⁶ Keeping this concept in mind the present study was designed to formulate and evaluate herbal tablet containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots).

Material and Methods

Selection of plant material

The herb viz., *Clitoria ternatea* Linn. (Roots) CTR, used in the treatment of gynecological disorders were selected based on the traditional claims as mentioned in folk-lore. The above mentioned herbs are widely used in traditional medicine for the treatment of gynecological disorders.

Collection and authentication of plant/plant material

The plant material selected for the present investigation viz., *Clitoria ternatea* Linn. (Roots)

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CTR, was collected in the months of Dec' 2016 to Jan, 2017 from various sites of Malwa region of Madhya Pradesh and identified & authenticated by Dr. S.N. Dwivedi, Professor and Head, Department of Botany, Janata PG College, A.P.S. University, Rewa, (M.P.) and was deposited in our Laboratory, Voucher specimen No. P/CT-R/1813

Extraction of Plant material

250 gm of the air dried coarsely powdered roots of *Clitoria ternatea* Linn. (Roots) CTR was placed in soxhlet apparatus and was extracted with ethanolic and hydro-alcohol (water:ethanol:70:30) until the extraction was completed. After extraction, the filtrate was evaporated to get the extract.⁷

Plant extracts

The hydroalcoholic extracts of dried plant material of *Clitoria ternatea* Linn. (Roots) were taken for formulation of herbal tablets.

FTIR compatibility studies

The FTIR studies were carried out to ascertain any type of chemical interaction between drug and the excipients used for the investigation. FTIR affinity-1 spectrophotometer (DRS-8000) SHIMADZU, Japan was used for the same. A small quantity of sample of hydroalcoholic extracts of dried plant material of *Clitoria ternatea* Linn. (Roots) CTR was taken and scan for the FTIR spectra.

Pre formulation studies (Pre compression studies) blended⁹⁻¹²

Standard protocols and procedures were adopted for determination of Bulk density, Tapped density, Compressibility index (Carr's index), Hausner ratio and Angle of repose.

Bulk density

25 gm of blend sample was taken in 100 ml of graduated measuring cylinder using a glass funnel to determine the bulk density. The volume occupied by the blend were recorded and bulk density was calculated using the formula:

$$\text{Bulk density (g/ml)} = \frac{\text{weight of sample in gm}}{\text{volume occupied by the sample Tapped density}}$$

Tapped density

25 gm of blend sample was taken in 100 ml of graduated measuring cylinder using a glass funnel to determine the tapped density. The measuring cylinder was tapped from the height of 2 inch till a constant volume was obtained. The volume occupied after tapping were recorded and tapped density was calculated using the formula:

$$\text{Tapped density (g/ml)} = \frac{\text{weight of the sample in gm}}{\text{volume occupied by the sample after tapping}}$$

Compressibility index (Carr's index)

Compressibility index is very simple method to evaluate flow property of powders comparing the bulk and tapped density. This index will be useful in determining the flow of the powders. It is calculated using the formula:

$$\text{Carr's index} = \frac{\text{TD}-\text{BD}}{\text{TD}} \times 100$$

Hausner ratio

Hausner ratio provides the indication of the degree of densification and is calculated using the formula:

$$\text{Hausner ratio} = \frac{\text{TD}}{\text{BD}}$$

Lower HR indicates better flow ability and higher HR indicates poor flow ability of the powders.

Angle of repose

Angle of repose was determined to reveal the flow ability of the powders. It was determined using a funnel and was calculated using the formula:

$$\tan \theta = \frac{h}{r}$$

Where, θ is angle of repose, h is height of the pile and r is average radius of the powder area.

Table 1: Grading of powders for their flow properties

Carr's index	Flow
5-15	Excellent
15-16	Good
18-21	Fair to Passable
23-25	Poor
33-38	Very Poor
<40	Very very poor

Table 2: Relation between angle of repose and powder flow

Carr's index	Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Preparation of herbal tablet

The herbal tablets were prepared by direct compression technique using hydroalcoholic extracts of dried plant material of *Clitoria ternatea* Linn. (Roots) CTR and different proportion of excipients. The compositions of various formulations were mentioned in table 3. All the ingredients used in the present investigation to formulate herbal tablet were passed through mesh no 100. The flow properties were determined for all the mixtures; the powder mixtures possess good flow properties and good packing ability. The mixture were directly compressed each of 300 mg in weight using a 10-station Mini Press-I rotary tablet compression machine which was fitted with 6-mm flat shaped

punches. After punching the tablets were observed for tablet defects like capping, lamination &

chipping, no any tablet defects were observed.¹³

Table 3: Formulation of herbal tablet containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots) CTR

Ingredients	Formulation Code (HAECTR)							
	F1	F2	F3	F4	F5	F6	F7	F8
HAECTR	150	150	150	150	150	150	150	150
Spray dried lactose	126	123	120	117	126	123	120	117
Acacia	10	10	10	10	10	10	10	10
Talc	3	3	3	3	3	3	3	3
Potato starch	-	-	-	-	6	9	12	15
Sodium starch glycolate	6	9	12	15	-	-	-	-
Mg sterate	5	5	5	5	5	5	5	5
Total weight	300	300	300	300	300	300	300	300

Note: All values are taken in mg

Results and Discussion

The investigation of the efficiency of plant extract and their formulations in induced systemic and local infection model is of quite interesting. There are several mimics that the real conditions of infected organism and at the same time the achievements of the direct effects of the extract. Several scholars have evaluated the effects of plant extracts along with their formulations in systemic infections and in induced vaginal infection. It was also noted that now-a-days there are several herbal formulations are in the market used for the vaginal infection and they having very less or no adverse/side effects. The present work was undertaken to formulate and evaluate herbal

tablet containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots) CTR. The selected hydroalcoholic extract viz., HAECTR along with various excipients selected were mixed according to the formula mentioned and various pre-formulation parameters were evaluated. In this study bulk density, tapped density, carr's index, hausner's ratio and angle of repose were recorded. The data were presented in table 4. It was revealed from the present study that all the studied parameters were within limit as per IP. The FTIR study was carried out and it was concluded that no any drug-excipients incompatibility has been observed.

Table 4: Pre-formulation studies of formulation containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots) CTR

Formulation Code	Parameters				
	Bulk density	Tapped density	Hausner's ratio	Carr's index	Angle of repose
F1	0.465	0.522	1.12	10.91	20.18
F2	0.456	0.512	1.12	10.93	24.16
F3	0.499	0.588	1.17	15.13	22.83
F4	0.428	0.502	1.17	14.74	22.67
F5	0.42222	0.5	1.18	15.55	22.10
F6	0.426	0.5	1.173	14.80	21.04
F7	0.472	0.5226	1.107	9.68	24.21
F8	0.469	0.54	1.15	13.14	20.58

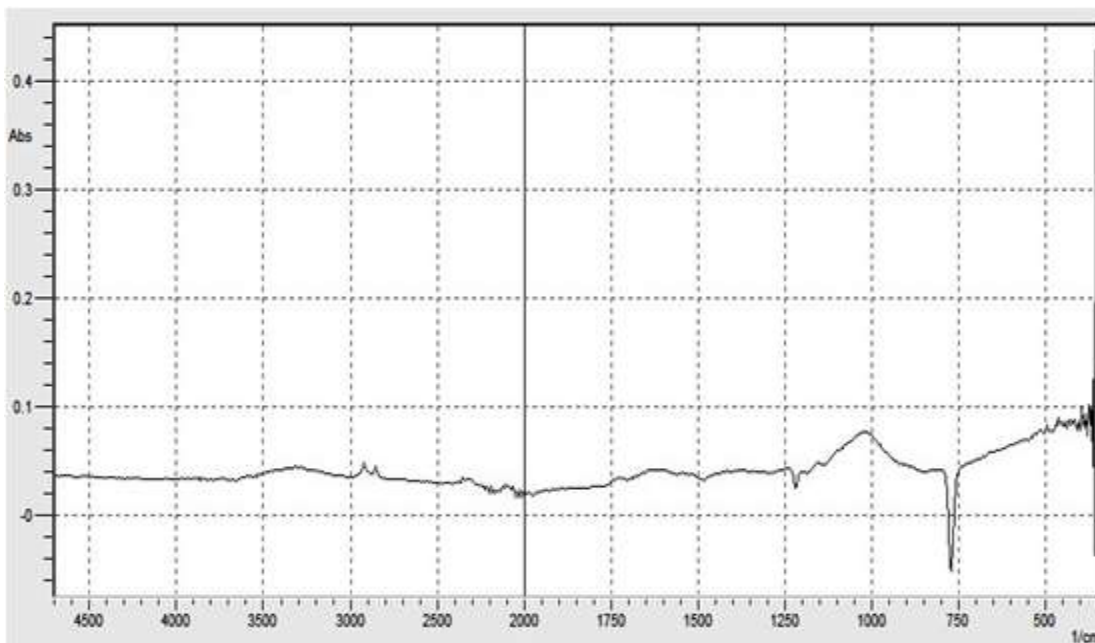


Fig. 1: FTIR curve of *Clitoria ternatea* Linn. (Roots) CTR

The formulated herbal tablets containing hydroalcoholic extracts of dried plant material of *Clitoria ternatea* Linn. (Roots) CTR were evaluated as per IP. In all the batches no any tablet defects were recorded. The organoleptic properties such as color, odor, taste for all the five different types of formulation and their batches were recorded and were presented in table 5. The hardness, friability & weight variation for all the batches was recorded

and result indicated that for all the batches it was within the limit (Table 6.). The disintegration times for all the batches were recorded and it was found that the range of DT was from 12.19 to 19.44 mts. (Table 7). The drug content was found maximum in F7 i.e., 99.91% and minimum 95.10 % (Table 7). The results of drug release profile indicates that the formulation F7 has maximum release of 98.15 % at 30 mts. (Table 8, Fig. 2)

Table 5: Organoleptic properties of formulation containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots) CTR

Formulation Code	Parameters		
	Color	Odor	Taste
HAEASR			
F1	Light brown	Pleasant	Acceptable
F2	Light brown	Pleasant	Acceptable
F3	Light brown	Pleasant	Acceptable
F4	Light brown	Pleasant	Acceptable
F5	Light brown	Pleasant	Acceptable
F6	Light brown	Pleasant	Acceptable
F7	Light brown	Pleasant	Acceptable
F8	Light brown	Pleasant	Acceptable

Table 6: Evaluation parameters of formulation containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots) CTR

Formulation Code	Parameters		
	Hardness (kg/cm ²)	Friability (%)	Weight variations
HAECTR			
F1	4.50±0.28	0.66±0.02	±3.91
F2	4.51±0.31	0.71±0.01	±3.98
F3	4.23±0.61	0.91±0.03	±3.12
F4	4.98±0.22	0.48±0.18	±3.88
F5	4.89±0.09	0.60±0.19	±3.81
F6	4.77±0.22	0.71±0.01	±3.77
F7	4.21±0.21	0.77±0.06	±3.67
F8	4.40±0.02	0.82±0.11	±3.72

Table 7: Disintegration time and drug content of formulation containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots) CTR

Formulation Code	Parameters	
	Disintegration time (mts)	Drug content (%)
HAEASR		
F1	12.54±0.91	95.33
F2	13.22±0.39	96.29
F3	19.44±0.15	95.10
F4	15.23±0.67	96.11
F5	18.31±0.31	97.89
F6	16.22±0.11	97.67
F7	12.19±0.09	99.91
F8	14.20±0.61	98.15

Table 8: *In-vitro* drug release of formulation containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots) CTR

S/No.	Time (Mts)	% Drug Release							
		F1	F2	F3	F4	F5	F6	F7	F8
1	0	0	0	0	0	0	0	0	0
2	10	18.92	20.11	23.84	23.10	25.81	28.19	30.82	30.17
3	20	44.19	60.39	60.18	59.22	62.39	67.82	67.20	64.11
4	30	85.82	89.32	90.30	90.62	91.25	94.92	98.10	97.29

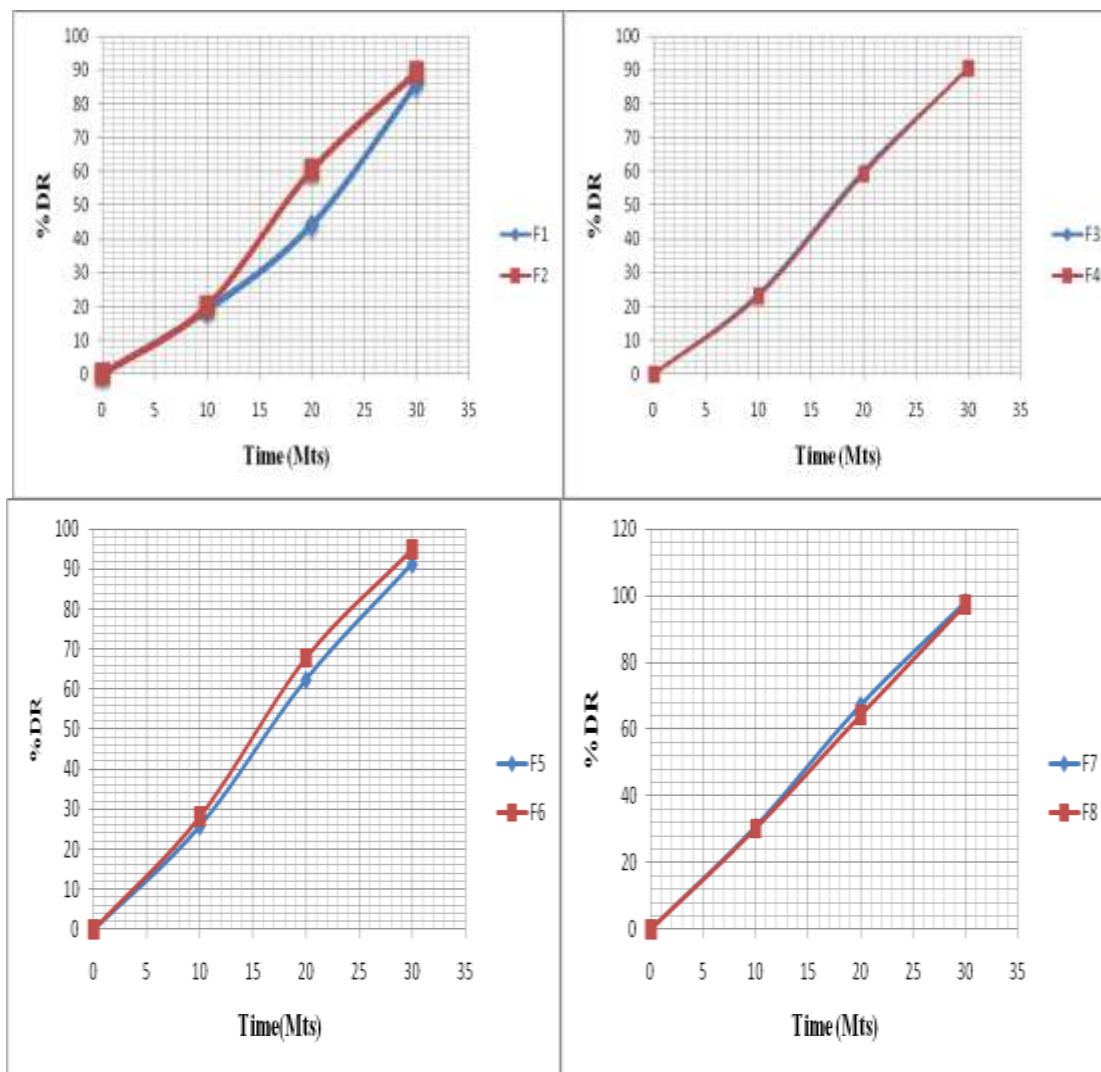


Fig. 2: Drug release of formulation containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots) CTR

Conclusion

It was found that the hydro-alcoholic extract of selected herbs *Clitoria ternatea* Linn. (Roots) CTR have effective results when formulated in the form of tablet. The formulation code F7 has promising and effective drug content and release. Thus, from the present investigation it was concluded that the herbs selected will have a prominent effect in the treatment of vaginal infection, though the pharmacological screening and clinical approaches need to establish for the formulation of safe and effective herbal drugs.

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