

Development and Evaluation of Herbal Cream Containing Hydro-Alcoholic Extract of *Clitoria Ternatea* Linn. (Roots) Used For the Treatment of Vaginal Infection

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Abstract

Women's are suffering from various gynecological diseases among which vaginal infection is most common which include irritation, itching and swelling and are very frequent and common. According to ancient literature several herbs are used to cure women disorders. *Clitoria ternatea* Linn. Commonly known as aprajita is widely used in the treatment of fungal infection including vaginitis as mentioned in folk-lore. The present investigation aims to development of herbal cream containing hydro-alcoholic extract of *Clitoria ternatea* Linn. (Roots). Different batches viz., HC₁ to HC₈ were prepared using different ratio of ingredients and were evaluated. The results of evaluation parameters revealed that HC₅ have best results when compared with other formulation codes.

Keywords: Vaginal infection; *Clitoria ternatea* linn; Herbal cream

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Introduction

National institute of Child Health and Human development indicates that there are five types of major gynecological disorders associated with females, these include vulvodynia, vaginitis, pelvic floor disorders, pelvic pain and menstrual disorders. In developing countries like India approximately every women 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 areas [1,2]. *Clitoria ternatea* Linn. Commonly known as aprajita belongs to family fabaceae is traditional herbal drugs used in the treatment of women disorders from ancient. Major phytoconstituents of the plant are pentacyclic triterpenoids viz., taraxerol & taraxerone, kaempferol, quercetin, myriceti. The various part of plant is used for the treatment of inflammation, bacterial infection, fungal infection etc. especially concerned to women disorders [3]. Keeping this concept in mind the present study was designed to formulate and evaluate herbal cream containing hydro-alcoholic extract of *Clitoria ternatea* Linn (Roots).

Material and Methods

Selection of plants/plant material

The herb viz., *Clitoria ternatea* Linn. (Roots) ASR, 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) ASR, 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, JanataPG 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. (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 [4].

Plant extracts

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

Formulation of herbal cream

The various steps involved in formulation of herbal cream were mentioned as described below [5,6].

Preparation of oil phase

Stearic acid, cetyl alcohol, almond oil in desired quantity were taken in porcelain dish and was melted at 70°C.

Preparation of aqueous phase

Hydroalcoholic extracts of dried plant material of Clitoria ternatea Linn. (Roots) CTR, glycerol, methyl paraben, triethanolamine and water were taken in another porcelain dish and were heated at 70°C.

Addition of aqueous phase to oil phase

The aqueous phase was added to the oil phase with continuous stirring at room temperature. Perfume was added at last and the formulation was transferred in a suitable container (Table 1).

Note: All values are taken in gm

Evaluation parameters of herbal cream

The prepared formulations were evaluated for the following parameters:

Physical evaluation

The physical evaluation of the herbal cream was done by evaluating clarity and transparency which was determined visually. The samples were observed in light at white background.

Determination of pH

The pH meter was calibrated first and zero reading was recorded. The samples were taken in the beaker and the readings were taken from calibrated electrode. The procedure was repeated and three average reading was recorded.

Determination of Viscosity

The viscosity of the herbal cream was determined by Brookfield viscometer using spindle no 01 at 20 rpm at temperature 4 °C and 37°C. About 15ml of the was taken in beaker and spindle was immersed in the formulation. The reading was recorded at initial and after rotation at different temperature. The reading was recorded thrice.

Determination of Homogeneity

All the prepared herbal cream was tested for homogeneity by visual inspection and was evaluated for presence of any aggregates present in the formulation [7].

Determination of Spreadability

The spreadability was determined for all the prepared herbal cream. The formulations were placed on the glass slide and the empty glass slide was placed on the top of gel containing slide. The formulation was placed in such a way that it was placed between two slides. The occupied distance of the slides was observed to be of 7.5 cm. The herbal cream was placed between slide and pressed form thin uniform layer. The weight kept on the herbal cream was removed. The excess herbal cream observed in the slides was removed. The two slides were fixed and on the upper glass slide the 20 ±0.5 g of the weight was tied. Due to weight the both the slides were separated which was recorded as time to complete the separation distance of 7.5 cm. The three readings were recorded and mean time was taken. The spreadability was calculated as

$$S = m \times l/t$$

l is the length of slide (7.5 cm), m is the weight which is tied to

slides and t is the time taken in second.

Determination of Wetness

The prepared herbal cream was determined for wetness by applying on skin surface.

Determination of type of smear

The prepared herbal cream was applied on the skin surface and after the application the type of film or smear formed on the skin was recorded.

Determination of Emolliency

The prepared herbal cream was checked for emolliency, slipperiness and amount of residue left after the application of cream.

Determination of type of Emulsion

Dilution test

The prepared herbal cream was diluted with oil or water depending upon the type of emulsion whether o/w or w/o the results obtained were noted down.

Dye solubility test

The prepared herbal cream was mixed with a water soluble dye i.e., amaranth and was observed under the microscope. The results obtained were interpreted.

Determination of Drug content

The content of the herbal cream was estimated using UV-Visible spectrophotometer. Near about 1g of the formulation was taken in 50 ml of volumetric flask. The solution was made up to mark with methanol. The solution was shaken and filtered through Whatman filter paper. The 0.1ml of the filtrate was further diluted to 10ml with solvent and estimated at suitable wavelength.

In vitro drug release

The semi permeable dialysis membrane bag (7cm long) was prepared and the herbal cream was placed in the membrane. The dialysis bag was then suspended in 50ml of ethanol: water (1:1) at temperature 37°C ± 0.5 °C in water bath. About 1ml of sample was withdrawn from the membrane at predetermined interval and the fresh equal volume was replaced simultaneously. The samples were withdrawn till one week and were diluted and analyzed by UV Visible spectrophotometer at suitable λ_{max} . The experiment was repeated thrice and the cumulative amount of drug release was calculated from the reading.

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. Several researchers have evaluated the effects of plant extracts along with their formulations in systemic infections and in induced vaginal infection. It was also noted that nowadays there are several herbal formulations in the market used for the vaginal infection and they having very less or no adverse/side effects. The present work was undertaken to develop

and evaluate herbal cream containing hydro-alcoholic extract of Clitoria ternatea Linn. (Roots) [8,9].

Table 1: Formulation of herbal cream containing hydro-alcoholic extract of Clitoria ternatea Linn. (Roots) CTR.

Ingredients	Formulation Code (HAECTR)							
	HC1	HC2	HC3	HC4	HC5	HC6	HC7	HC8
HAECTR	0.5	0.75	1.0	1.5	0.5	0.75	1.0	1.5
Stearic acid	5	5	5	5	10	10	10	10
Cetyl alcohol	10	10	10	10	5	5	5	5
Almond oil	5	5	5	5	5	5	5	5
Glycerol	3	3	3	3	3	3	3	3
Methyl paraben	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Triethanolamine	qs	qs	qs	qs	qs	qs	qs	qs
Water (100 ml)	qs	qs	qs	qs	qs	qs	qs	qs
Total weight	100	100	100	100	100	100	100	100

Table 2: Evaluation parameters of herbal cream containing hydro-alcoholic extract of A Clitoria ternatea Linn. (Roots) CTR.

FC	Appearance	pH	Viscosity	Homogeneity	Spreadibility	Wetness	Smear	Emolliency	Emulsion
HC1	Pale brown & Clear	6.9	27018	H	65.23	+++	NG	NRL	o/w
HC2	Pale brown & Clear	6.8	27012	H	62.1	+++	NG	NRL	o/w
HC3	Pale brown & Clear	7	27018	H	59.24	+++	NG	NRL	o/w
HC4	Pale brown & Clear	6.9	27024	H	64.78	+++	NG	NRL	o/w
HC5	Pale brown & Clear	7	27021	H	60.29	+++	NG	NRL	o/w
HC6	Pale brown & Clear	7	27012	H	63.19	+++	NG	NRL	o/w
HC7	Pale brown & Clear	6.9	27026	H	62.14	+++	NG	NRL	o/w
HC8	Pale brown & Clear	6.9	27011	H	61.7	+++	NG	NRL	o/w

Table 3: Drug content & % Drug release of herbal cream containing hydro-alcoholic extract of Clitoria ternatea Linn. (Roots) CTR.

FC	Drug content	Time (Hr)	% Drug Release
HC1	94.22	0	0
HC2	95.18	2	41.22
HC3	97.20	4	52.81
HC4	96.16	6	82.31
HC5	99.42	8	96.28
HC6	96.16		
HC7	95.22		
HC8	95.29		

The selected hydroalcoholic extract viz., HAECTR *Clitoria ternatea* Linn. (Roots) along with various excipients selected were mixed according to the formula mentioned and various evaluation parameters were carried out to validate the efficacy of the prepared formulation. The formulated herbal cream containing hydroalcoholic extracts of dried plant material of *Clitoria ternatea* Linn. (Roots) were evaluated as per standard protocols. The detail results are mentioned in (Tables 2 and 3). The drug content was found maximum in F5 i.e., 99.42% (Table 3). The results of drug release profile indicates that the formulation F5 has maximum release of 96.28 % at 8 hr (Table 3).

Note: H=Homogeneous, NH=Non homogeneous, +=Good, ++=Better, +++=Best, G=Greasy, NG= Non-greasy, NRL=No residue left, LR=Residue left

Conclusion

From the results obtained it was concluded that the hydro-alcoholic extract of selected herbs *Clitoria ternatea* Linn. (Roots) have effective results when formulated in the form of cream. The formulation code F5 has promising and effective drug content and release. Hence, it was concluded from the present investigation that the selected herbs 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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