



Formulation and Evaluation of Herbal cream for the treatment of Vaginal Candidiasis

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Abstract

Gynecological disorders are very common in women and are due to many factors which may include weak immune system, imbalance in body hormones, high sugar intake in food, regular or frequent use of antibiotics, improper hygiene, physical/mental stress, some microbial infections. , bacteria and yeasts cause fungal or other major infections of the delicate female genitalia. According to Ayurvedic literature, many herbs are used to treat female disorders, although proper documentation and validation needs to be established. One of the main fungi that cause vaginal candidiasis infections is *Candida* species. It deserves more and more special attention in the medical community. Despite the presence of *Candida* species as human communicators, alarming rates of local and systemic infections have been observed, varying from moderate to severe effects. The present work aimed to formulate and evaluate herbal cream containing hydro-alcoholic extract of *Ipomea cairica* Linn. The extracts of the root of selected plant was used to make herbal cream and was compared with a standard anti-fungal drug formulation. The results showed that the prepared herbal cream showed superior and significant antifungal activity. More studies need to be established to deepen the knowledge on this field focusing on clinical trials to provide safer and more effective anti-fungal than the current studies widely used to treat vaginal candidiasis.

Keywords: Vaginal candidiasis, *Ipomea cairica* Linn., Herbal cream

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Introduction

Vaginal candidiasis is the second most common vaginal infection and it is so frequent that after using allopathic herb female tends to use herbal medication. It accounts for a quarter and about 85-95% are due to fungus *Candida albicans*. It has been noticed and recorded that about 75% of females pursue with vaginal candidiasis once in her life time, and about 50% twice and 5% women's 4 times in a year. [1-3] Several researcher have studied the potential of synthetic drugs in the treatment of diseases. [4-6]. Also, there is great interest in Plant-derived extracts and their

isolated phytochemicals as they gained increasing importance in the past few years and are also an emerging field of research. Anti-Candida effects have been of great interest in a range of antimicrobials over the past two decades. Candida, a fungus often associated with gynecological infections. In fact, Candida species have been associated with the onset of mild and severe clinical conditions, although it was considered a normal microorganism of healthy individuals.[7-9]

Ipomea cairica Linn is a perennial twiner herb with tuberous root commonly known as railway creeper or blue bell belonging to the Convolvulaceae family. The major chemical constituents of the plant include lignans, arctigenin, metarecinol, trachelogenin and indole alkaloids. Various parts of the plant are used medicinally to treat microbial infections, inflammation, pain, liver disorders and malaria. [10] The present work was undertaken to formulate and evaluate the herbal cream containing hydroalcoholic extract of *Ipomea cairica* Linn. (roots).

Material and Method

Selection of plant material

The roots of *Ipomea cairica* Linn. 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 but till date no any systematic investigation has been carried out to study the toxicity profile of these medicinal plants, therefore an attempt was made to study the acute toxicity profile.

Collection and authentication of plant/plant material

The plant material selected for the present investigation *Ipomea cairica* Linn. (roots) ICR was collected in the months of July 2022 from various sites of Malwa region of Madhya Pradesh and identified & authenticated by Dr. S.N. Dwivedi, Retd. 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/IC-R/11.

Extraction of Plant material

250 gm of the air dried coarsely powdered roots of *Ipomea cairica* Linn. (ICR) was placed in soxhlet apparatus and was extracted with ethanol:water (90:1) until the extraction was completed. After extraction, the filtrate was evaporated to get the extract.⁶

Plant extracts

The hydro-alcoholic extracts of dried plant material of *Ipomea cairica* Linn. (ICR) were taken for formulation of herbal cream.

Formulation of herbal cream

The various steps involved in formulation of herbal cream were mentioned as described below: [11]

Preparation of oil phase

Stearic acid, cetyl alcohol, almond oil in desired quantity were taken in porcelain dish and was melted at 70⁰C.

Preparation of aqueous phase

Hydro-alcoholic extracts (HAEICR) of dried plant material of *Ipomea cairica* Linn. (roots) ICR glycerol, methyl paraben, triethanolamine and water were taken in another porcelain dish and were heated at 70⁰C.

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.

Evaluation parameters of herbal cream

The prepared formulations were evaluated for the following parameters: [12]

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.

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 place on the top of gel containing slide. The formulation was placed in such as 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 $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ 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.

Anti-candidal Activity

The anti-candidal activity was determined as per method described by Shriwas et al., [12]

Table 1: Composition of herbal cream

Ingredients	Formulation Code							
	HC1	HC2	HC3	HC4	HC5	HC6	HC7	HC8
HAEICR	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

Note: All values are taken in gm

Result and Discussion

Several researchers have evaluated the effects of plant extracts and their formulations in systemic infections for the treatment of fungal infection including vaginal candidiasis. It was also revealed that presently there are some herbal formulations available in the market used for the vaginal infection and they having very promising as having less or no adverse/side effects. The present work was undertaken to formulate and evaluate herbal cream containing hydro-alcoholic extract of *Ipomea cairica* Linn. (roots) ICR. The formulated herbal cream was evaluated as per standard

protocols. The results are mentioned in table 2. The drug content was found maximum in HC5 i.e., 97.21 (Table 3). The results of drug release profile indicates that the formulation HC5 has 96.19 % release (Table 4)

Table 2: Evaluation parameters of herbal cream

FC	Parameters								
	Appearance	pH	Viscosity	Homogeneity	Spreadibility	Wetness	Type of smear	Emolliency	Type of Emulsion
HC1	Pale white & Clear	7.0	26830	H	64.29	++	NG	NRL	o/w
HC2	Pale white & Clear	7.0	26846	H	66.32	++	NG	NRL	o/w
HC3	Pale white & Clear	6.8	26850	H	60.42	++	NG	NRL	o/w
HC4	Pale white & Clear	7.0	26854	H	66.38	+	NG	NRL	o/w
HC5	Pale white & Clear	7.0	26890	H	62.22	+++	NG	NRL	o/w
HC6	Pale white & Clear	7.0	26886	H	55.20	++	NG	NRL	o/w
HC7	Pale white & Clear	7.0	26880	H	50.30	++	NG	NRL	o/w
HC8	Pale white & Clear	6.9	268860	H	60.30	++	NG	NRL	o/w

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

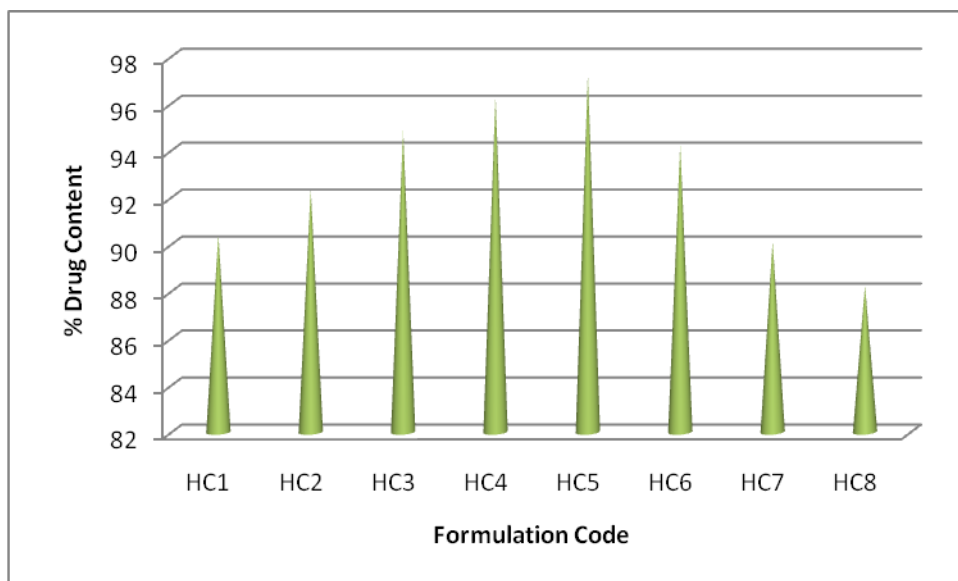
Table 3: Drug content of herbal cream

Formulation Code	% DC
HC1	90.39
HC2	92.33
HC3	94.84
HC4	96.29
HC5	97.21
HC6	94.22
HC7	90.12
HC8	88.23

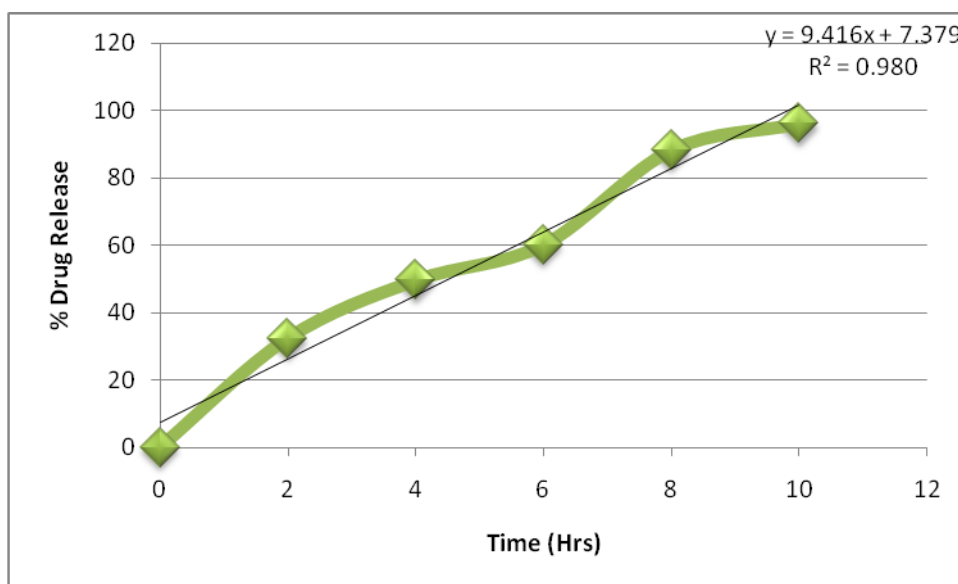
Table 4: % Drug release of herbal cream

Time (Hrs)	% Drug Release
	HC5
0	0
2	32.43
4	49.64

6	60.20
8	88.32
10	96.19



Graph 2: Drug content of herbal cream



Graph 3: % Drug release of optimized herbal cream

The optimized herbal cream HC5 was tested against fungal strain to proof the efficacy of herbal formulation. The results obtained were compared with standard marketed preparation and it was found that HC5 have significant value. (Table 5).

Table 5: Anti-Candidal Activity of herbal cream

S/No.	Test	Zone of Inhibition (mm)
1.	Negative Control	5.11±0.02
2.	MCC	23.21±0.007**
3.	HC5	19.82±0.004*

Note: All values are expressed as Mean (X) ±SEM, (n=3). One way ANOVA followed by student test, values are statistically significance *P<0.01, **P<0.001 when compared with control and standard.

Conclusion

From the results obtained it was concluded that the herbal cream containing hydro-alcoholic extract of roots of *Ipomea cairica* Linn. have optimum anti-candida activity and may be used for the treatment of gynecological disorders. Moreover detailed pharmacological screening and clinical approaches need to establish for the formulation of safe and effective drugs. The formulation code HC5 has promising and effective drug content and release. Hence, it was concluded from the present investigation that the selected herbal formulation i.e., herbal cream (HC5) have a prominent effect in the treatment of vaginal candidiasis, though the detailed clinical approaches need to establish for the formulated cream in order to establish its of safety and effectiveness.

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