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Formulation and Evaluation of herbal cream of *Ipomea cairica* Linn. Root extract for the treatment of Vaginal Candidiasis

Sumeet Dwivedi

University Institute of Pharmacy, Oriental University, Indore, (M.P.)

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Abstract

The present work aims to investigate the anti-*candidal* herbal cream of aqueous and ethanolic extract of *Ipomea cairica* Linn. (Roots) ICR. The extracts were used to formulate herbal cream and both were compared with standard anti-fungal drug. Results indicate that prepared herbal cream showed optimum and significant anti-candidal activity. Further studies need to be establish to deepen knowledge on this area, namely, focused on clinical trials to provide safer and more effective anti-fungal than the current ones extensively used for the treatment of vaginal candidiasis.

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

Introduction

Ipomea cairica Linn root is most widely used for the treatment of gynecological disorders due to various active constituents such as lignans, arctigenin, matairesinol, trachelogenin and indole alkaloids. The plant belongs to family Convolvulaceae and ccommonly known as railway creeper or nili bel.[1]

The present study was designed to formulate and evaluate the herbal cream containing aqueous and ethanolic root extract of *Ipomea cairica* Linn. (roots) ICR widely used to treat the gynecological disorders as mentioned in traditional system of medicine.

***Corresponding Author**
E.mail: herbal0914@rediffmail.com

Material and Method

Preparation of Extract

250 gm of the air dried coarsely powdered roots of *Ipomea cairica* Linn. (ICR) was placed in soxhlet apparatus and was extracted with aqueous and ethanolic until the extraction was completed. After extraction, the filtrate was evaporated to get the extract.[2]

Plant extracts

The aqueous and ethanolic 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:[3-5]

Preparation of oil phase

Stearic acid, cetyl alcohol, almond oil in desired quantity were taken in porclean dish and was melted at 70^0C.

Preparation of aqueous phase

Aqueous and ethanolic extracts of dried plant material of *Ipomea cairica* Linn. (roots) ICR

glycerol, methyl paraben, triethanolamine and water were taken in another porclean dish and were heated at 70^0C.

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: Formulation of herbal cream containing extract of *Ipomea cairica* Linn. (roots) ICR

Ingredients	Formulation Code (HAEASR)							
	HC1/9	**HC2/10**	**HC3/11**	**HC4/12**	**HC5/13**	**HC6/14**	**HC7/15**	**HC816**
AEICR/EEICR	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

Evaluation parameters of herbal cream

The prepared formulations were evaluated for the following parameters: [3-5]

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 ^{o}C and 37^{o}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 Spreadibility

The spreadibility 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 make up to mark with methanol. The solution was shaked and filtered though whatman filter paper. The 0.1ml of the filterate 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 ten 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 predetermine interval and the fresh equal volume was replaced simultaneously. The samples were withdraw till one week and were diluted and analyzed by UV Visible spectrophotometer at suitable λmax. The experiment was repeated trice and the cumulative amount of drug release was calculated from the reading.

Anti-candidal Activity of herbal cream

The formulated herbal cream were screened for anti-candidal activity using standard procedure.[6]

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 aqueous and ethanolic 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 HC13 i.e., 98.49 than HC5 98.32 (Table 3). The results of drug release profile indicates that the formulation HC13 has 96.26% release and HC5 has 91.28 % release (Table 4, Graph 2)

Table 2: Evaluation parameters of herbal cream containing root extract of *Ipomea cairica* Linn.

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

Formulation Code	Parameters								
	Appearance	pH	Viscosity	Homogeneity	Spreadibility	Wetness	Type of smear	Emolliency	Type of Emulsion
HC1	Pale white & Clear	6.8	27015	H	65.29	++	NG	NRL	o/w
HC2	Pale white & Clear	6.9	27009	H	62.18	++	NG	NRL	o/w
HC3	Pale white & Clear	6.8	27015	H	59.23	++	NG	NRL	o/w
HC4	Pale white & Clear	6.9	27022	H	64.82	+	NG	NRL	o/w
HC5	Pale white & Clear	7.0	27019	H	60.38	+++	NG	NRL	o/w
HC6	Pale white & Clear	6.9	27018	H	63.29	++	NG	NRL	o/w
HC7	Pale white & Clear	6.9	27025	H	62.15	++	NG	NRL	o/w
HC8	Pale white & Clear	6.8	27019	H	61.72	++	NG	NRL	o/w
HC9	Pale white & Clear	6.9	27022	H	66.32	++	NG	NRL	o/w
HC10	Pale white & Clear	7.1	27032	H	64.44	++	NG	NRL	o/w
HC11	Pale white & Clear	7.1	27035	H	60.39	+	NG	NRL	o/w
HC12	Pale white & Clear	6.9	27038	H	59.22	+	NG	NRL	o/w
HC13	Pale white & Clear	7.0	27030	H	60.12	+++	NG	NRL	o/w
HC14	Pale white & Clear	6.9	27028	H	61.23	++	NG	NRL	o/w
HC15	Pale white & Clear	7.1	27024	H	62.22	++	NG	NRL	o/w
HC16	Pale white & Clear	7.1	27030	H	62.28	++	NG	NRL	o/w

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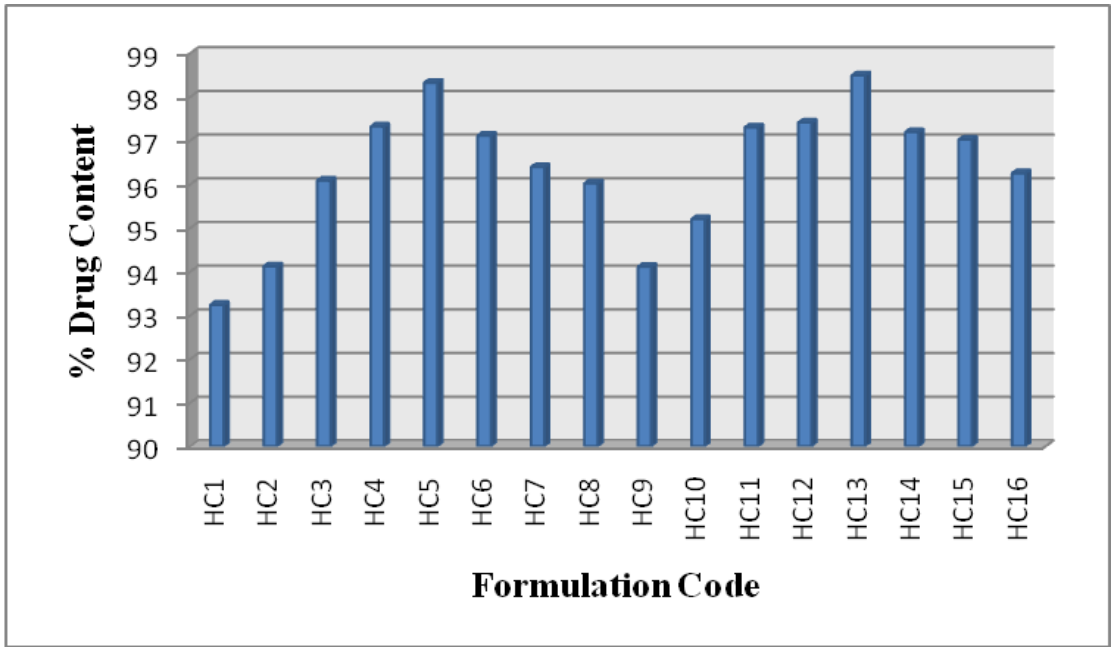
Table 3: Drug content of herbal cream containing root extract of *Ipomea cairica* Linn.

Formulation Code	HAEASR
HC1	93.24
HC2	94.12
HC3	96.08
HC4	97.32
HC5	98.32
HC6	97.11
HC7	96.39
HC8	96.02
HC9	94.11
HC10	95.20
HC11	97.30
HC12	97.41
HC13	98.49
HC14	97.19
HC15	97.02
HC16	96.25



Graph 1: Drug content of herbal cream containing root extract of *Ipomea cairica* Linn.

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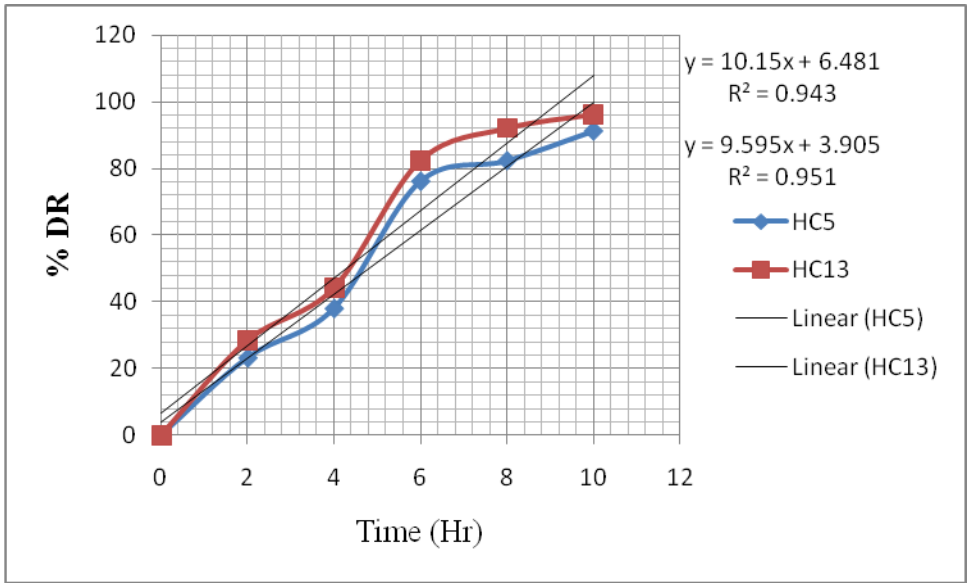
Table 4: % Drug release of herbal cream containing root extract of *Ipomea cairica* Linn.

Time (Hrs)	% Drug Release	
	HC5	HC13
0	0	0
2	23.32	28.43
4	38.11	44.21
6	76.21	82.39
8	82.39	92.11
10	91.28	96.26



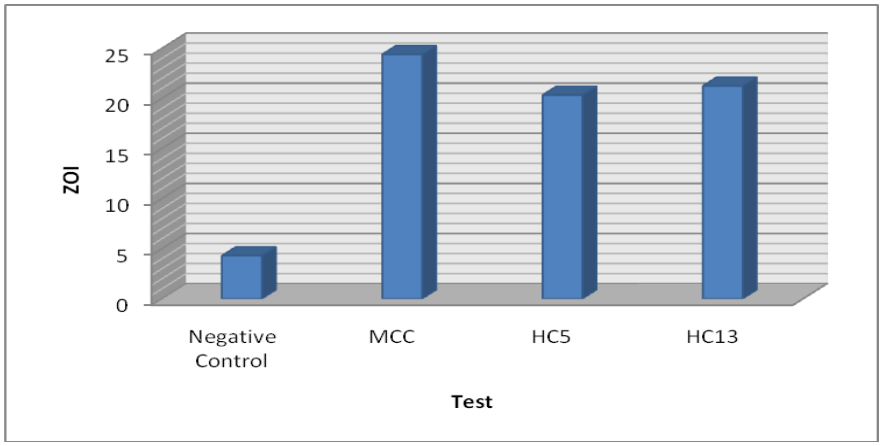
Graph 2: % Drug release of optimized herbal cream

The optimized herbal cream HC5 and HC13 were 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 HC13 were more potent when compared with HC5 (Table 5).

Table 5: Anti-*Candidal* Activity of herbal cream HC5 & HC 13

S/No.	Test	Zone of Inhibition (mm)
1.	Negative Control	4.30±0.11
2.	MCC	24.39±0.11**
3.	HC5	20.33±0.04*
4.	HC13	21.24±0.19**

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.



Graph 3: Anti-*Candida* Activity of herbal cream HC5 & HC 13

Conclusion

The formulation code HC13 has promising and effective drug content and release. Also, anti-candidal activity of herbal cream containing ethanolic extract (HC13) were found more than aqueous extract (HC5) of ICR. Hence, it was concluded from the present investigation that the selected herbal formulation i.e., herbal cream (HC13) 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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