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Research Article

FORMULATION, DEVELOMENT AND EVALUATION OF POLYHERBAL GEL OF PLANTS USED IN ALOPECIA

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Abstract

In the present study, an attempt was made to prepare, characterize and evaluate of topical therapeutic system for management of alopecia from seed extract of *Trigonella foenum greacum*, flower extract of *Hibiscus rosa sinensis Linn*, leave extract of *Eclipta alba (L.)* and bulb of *Allium cepa L* herbal plant. Various formulations such as hydrogel and hydroalcohalic gel were designed and optimized. Recently, the number of men and women who suffered from hair loss and/or hair thinning is increasing. Hair loss is a dermatological disorder, and the surge for discovering natural products with hair growth promoting potential is continuous. Hair loss or alopecia is a common patient complaint and a source of significant psychological and physical distress. Androgens are considered to be one of the most important causes for alopecia apart from a variety of other factors. Minoxidil, a drug of scientific origin was scientifically proved for the treatment of alopecia. Though the side effect associated with this drug has limited its pharmacological benefits hence the drug of plant origin is necessary to replace the synthetic one. A number of herbal products have been acclaimed with hair growth promoting activity. The traditional system of medicine in India acclaims a number of herbal drugs for hair growth promotion but lack of sound scientific backing and information limits their use.

Keywords: Alopecia, gel, viscosity, Ph, drug content

Introduction :

Medicinal plants contain inherent active ingredients to cure disease or relieve pain. The use of traditional medicines and medicinal plant in most developing countries as therapeutic agent for the maintenance of good health has been widely observed. The world health organization estimated that 80% of the population of developing countries relies on traditional medicines, mostly herbal plant drugs for their primary health care. The medicinal property of plant could be based on the anti-oxidant, antimicrobial, antipyretic effect of the phytochemicals present. Traditionally, herbs have been considered to be non-toxic and have been used for treating various problems by the general public and/or traditional medicine doctors worldwide. Although, the literature has documented several toxicity resulted from the use of herbs on many occasions, still the potential toxicity of herbs has not been recognized by the general public or by professional groups of traditional medicine. The use of medicinal plants as raw materials in the production of drug is gaining popularity.

India perhaps the largest producer of medicinal herbs and is called Botanical Garden of the World. Medicinal herbs have been in use for thousands of years, in one form or another, under the indigenous systems of medicine like Ayurveda, Sidha and Unani. On earth, around 3.6 lakh species of medicinal plants are present, among these 1.4 lakh species are in India. A latest survey indicates that about 70000 plants are used in traditional systems of medicines.[3] All over the world, plants were used as main source of medicines by ancestors. The rise of modern western medicine was initially accompanied by a decline in the practice of herbalism in all cultures and it was believed that synthetic chemicals were best medicines to treat illness and cure disease. The quest for a healthier lifestyle has made people to once again recognize the healing power of herbs. The disadvantages of modern medicine have led the researchers to look for alternative systems especially the ancient and traditional medicine..[1-5]

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Materials and Methods[6-13]

Collection of plant material: The seeds of Trigonella foenum greacum and Allium cepa L were obtained from local market while Hibiscus rosa sinensis, Linn and Eclipta alba (L.) were collected from natural habitat

Method of Preparation of extracts: About 250-250 gm of dried powder of Trigonella foenum greacum seed, flower ofHibiscus rosa sinensis Linn and leave of Eclipta alba (L.) were subjected to soxhlation separately.

Preparation of Polyherbal Gel Formulations Containing Plants extract

(a) Hydrogel: Different proportions of Carbopol 934 and Sodium CMC 3:0, 3:1, 2:1, 1:1, 0:3, 1:3 and 1:2 were dispersed in 50 ml of distilled water with continuous stirring. 5 ml of distilled water was taken and required quantity of methyl paraben and propyl paraben were dissolved by heating on water bath and cooled. Propylene glycol 5 % w/v was added and then mixed with first solution. Selected combinations of plant extracts were

dissolved in minimum quantity of ethanol and mixed to the polymer mixture. The volume was made up to 100 ml with distilled water. Finally all the ingredients were then mixed properly with the Carbopol 934 gel with continuous stirring. Triethanolamine was added drop wise to the formulation for adjustment of required skin pH (6.8-7) and to obtain the gel of required consistency. The same method was followed for preparation of control sample without adding plant extracts. Turbidity and lumping occured in some batches (F1, F2, F6 and F7) of polymer based gel containing plant extracts. Hence, these batches were discarded and remaining batches (F3, F4 and F5) were considered for further studies.

(b) Hydroalcohalic gel Containing Extract: 1:2 proportions of Carbopol 934 and Sodium CMC were dispersed in 50 ml of distilled water with continuous stirring. 5 ml of distilled water was taken and required quantity of methyl paraben and propyl paraben were dissolved by heating on water bath. The solution was cooled and then propylene glycol 5 % w/v was added and mixed with first solution. Selected combinations of plant extract were dissolved in 30 ml of ethanol added then mixed to the above polymer mixture. The volume was made up to 100 ml with distilled water. Finally all the ingredients were then mixed properly with Carbopol 934 gel with continuous stirring. Triethanolamine was added drop wise to the formulation for adjustment of required skin pH (6.8-7) and to obtain the gel of required consistency. The same method was followed for preparation of control sample without adding any plant extracts**.**

Characterization and Evaluation of Formulation

All prepared formulations of gel were characterized for:

Physical Evaluation: Physical parameters such as color and appearance of the herbal gel were observedmanually.

Measurement of pH: The pH of various gel formulations was determined by using digital pH meter.

Spreadibility: Spreadibility was determined by the apparatus which consists of a wooden block, provided with pulley at one end.

S = M × L / T

Where, S = Spreadibility, M = Weight in the pan (tied to the upper slide), L = Length moved by the glass slide and T = Time (in sec.) taken to separate the slide completely each other.

Consistency: The measurement of consistency of the prepared gels was done by dropping a cone attached to a holding rod.

Homogeneity: All the developed gels were tested for homogeneity by visual inspection after setting the gels in the container.

Viscosity: Viscosity of gel was measured by using Brookfield viscometer with spindle No. 7 at 50 rpm at room temperature.

Drug content: 1 g of the prepared gel was mixed with 100ml of suitable solvent.

Compatibility studies: Fourier transformed infrared (FTIR) spectra technique has been used to study the physical and chemical interaction.

In-vitro drug release study of optimized formulation: Franz diffusion cell (fabricated in our Lab.) with a diameter 3.7 cm was used in in-vitro release studies.

Drug release kinetic modeling

The kinetics of Hydroalcoholic gel FH release was determined using the release kinetics method of drug release into various kinetic equations: zero order release kinetics, first order release kinetics and Higuchi model.

Accelerated Stability Studies

The optimized formulations were subjected to a stability testing for six months as per ICH norms at a temperature and RH of 40°C ± 2°C/75% RH ± 5% RH respectively.

Result and Discussion

Extraction of different plant

The dried powder of plants was extracted with 70% v/v hydro alcoholic solution. The solvents were removed by distillation under reduced pressure and the resulting semisolid mass was vacuum dried using rotary flash evaporator to obtain the extract. The percentage yields of various extract was presented in Table 1

Formulation ofTopical Polyherbal Gel

During the trial, the excipients concentrations of carbapol and Sodium CMC were gradually increased and then decreased as several problems like homogeneity, spreadibility and viscosity were encountered. These problems occurred in some of the batches (F1, F2, F6 and F7) of polymer based gel containing herbal extracts. Hence, these batches were discarded and remaining batches (F3, F4 and F5) were considered for further study.

Characterization and Evaluation ofTopical Polyherbal Gel

Developed herbal gels were brownish in color, translucent in appearance and homogeneous with absence

of lumps. Formulation F-5 had good values of spreadability, viscosity, pH, drug content and during the accelerated stability studies the appearance was clear and no significant variation in spreadability, pH and drug content was observed. Hence Hydroalcoholic gel was formulated from hydrogel F-5 formulation and its physiochemical study was found to be good.

Standard curve of Plant extract

Standard calibraction curve of plant extracts was determined by plotting absorbace vs concentraction at 234 nm. Table no.6.4 and Fig- shows the standard curve for herbal extract. The method obeyed Beer's law limit in the concentration range of 2-12 mcg/ml at 234 nm with a regression value of 0.998.6.8

In-vitro drug release study

Percentage drug release of gel formulation F3, F4, F5 and FH hydroalcoholic formulation containing plant extracts were observed to be- 14.59%, 16.25, 21.22 & 30.43 (at 30 min.) respectively and at 180 mint observed to be -51.34%, 52.45, 57.34% & 69.15 % (at 180 min.) respectively at 234 nm . It was observed that hydrogel F3, F4, F5 formulation gives50 % drug release at 180 mints while hydroalcoholic formulation FH gives 50% drugs below at 90 mint. Also it was observed that addition of ethanol in formulation increase the release by increasing permeation properties of gel

Stability Study

The formulated gels were subjected to stability studies. No color fading was observed for all prepared gels. The pH of all formulations remained unchanged and was found to be within the range of 6.2-7.2. The viscosity and spreadability of all gels remained unaltered and found to be within the range. The drug content was found to be in the limit 90%-103% for all gel formulation.

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Table 1 : Extract Value of plant Extract

Plant extracts	E1	E2	E3
Trigonella foenum greacum (% w/w) Seed extract	2.5	5	2.5
Hibiscus rosa sinensis Linn(% w/w) flower extract	2.5	2.5	5
Eclipta alba (L.) (% w/w) leave extract	5	2.5	2.5
Allium cepa L. (% w/w) Bulb extract	0.5	0.5	0.5

Table 2: Formulations of polyherbal Gel containing plant extracts

Ingredient	F1	F2	F3	F4	F5	F6	F7	FH
Carbopol 934 (gm)	3	3	2	1	1	-	1	1
Sodium CMC (gm)	-	1	1	1	2	3	3	2
Trigonella foenum extract (% w/w)	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Hibiscus rosa extract (% w/w)	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Eclipta alba extracts *(L.)* (% w/w)	5	5	5	5	5	5	5	5
Allium cepa extract L. (% w/w)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Propylene glycol 400 (%)	5	5	5	5	5	5	5	5
Lavandula oil	0.5ml	0.5 ml	0.5ml	0.5 ml	0.5ml	0.5 ml	0.5ml	0.5ml
Methyl Paraben (0.5%) (ml)	0.2ml	0.2 ml	0.2 ml	0.2 ml	0.2 ml	0.2 ml	0.2 ml	0.2 ml
Propyl Paraben (0.2%) (ml)	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml
Triethanolamine ml)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Ethanol	-	-	-	-	-	-	-	30 ml
Distilled water (ml)	q.s. to 100ml	q.s. to 100ml	q.s. to 100ml	q.s. to 100ml	q.s. to 100ml	q.s. to 100ml	q.s. to 100ml	q.s. to 100ml

Table 3: Physical Evaluation of Optimized Formulations

Batch	Color	Appearance	Spreadibility (gm.cm/sec)	Consistency (60 mm)	Viscosity (cps)	pH	% Drug Content
F3	Greenish	Homogeneous	23.81	8	16915	7.00	99.95
F4	Greenish	Homogeneous	24.34	8	16995	7.00	99.97
F6	Greenish	Homogeneous	24.26	8	16994	7.00	99.95
FH	Greenish	Homogeneous	24.34	8	16924	7.00	99.95

Table 4: Calibration curve of plant Extracts at 234 nm

S. No	Concentration	Absorbance at 234nm
1	2	0.221
2	4	0.323
3	6	0.425
4	8	0.556
6	10	0.639
8	12	0.753

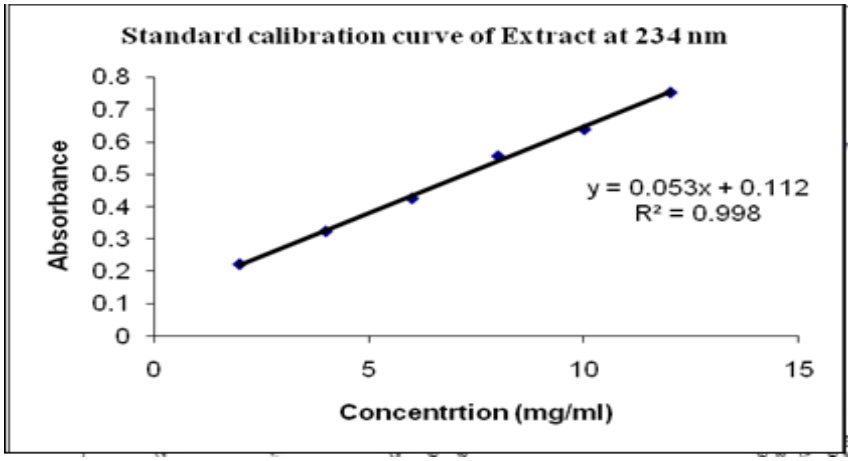

Figure 1: Calibration curve of plant Extracts at 234 nm

Table 5: % Drug release from Hydrogel, Hydroalcoholica Gel

Time	F3	F4	F5	FH
15	9.08	10.21	12.51	18.23
30	14.59	16.25	21.22	30.43
45	22.87	24.68	29.81	38.21
60	27.91	29.92	37.23	46.32
90	36.62	39.32	44.58	55.12
120	45.84	47.81	52.12	63.32
180	51.34	52.45	57.34	69.15

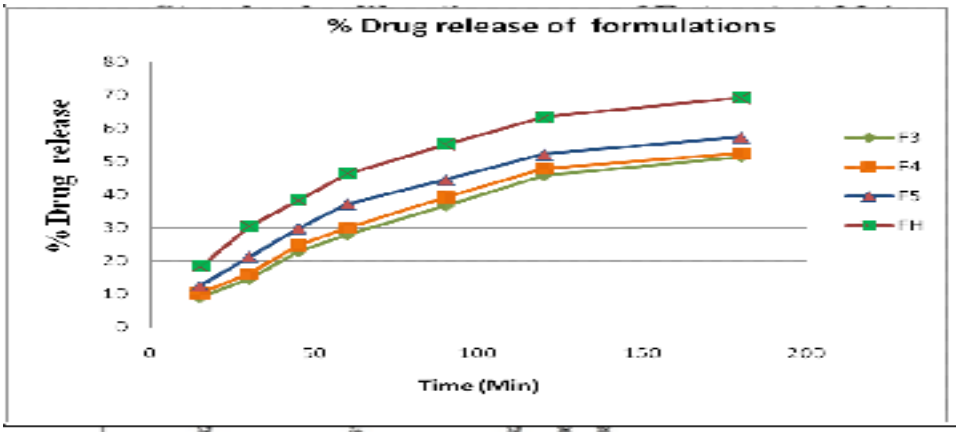

Figure 2: % Drug Release of Formulations