INTERNATIONAL JOURNAL OF ADVANCES IN PHARMACY, BIOLOGY AND CHEMISTRY

Research Article

Formulation and Evaluation of Herbal Gel containing *Eclipta alba Linn.,* leaves extract

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ABSTRACT

Present study deals with the development and characterization of *Eclipta alba Linn.,* medicinal herbal hydrogel preparation using leaf, carbopol 940, Methyl Paraben , Propylene glycol 400 ,Triethanolamine.The gel formulation was designed by using aqueous extract of *Eclipta alba Linn.,* leaves in concentration (1% and 5%) and evaluated using physiological measurements. All the prepared gel formulations were subjected for preliminary evaluation such as pH, Viscosity and Rheological studies, Spreadability, Drug content uniformity, Extrudabilty, and Skin irritation test. The optimized herbal gel formulation of the drug was subjected to accelerated stability studies at both 28°C, 30 °C and 35 °C for about 3 months. The pH of all the formulations was in the range of 6.45 to 6.67., which lies in the normal pH range of the skin. The drug content was in the range of 96.6 to 99.5 %. The formulations did not produce any skin irritation, i.e., erythema and edema for about a week, when applied over the skin. On the basis of evaluation study, it can be concluded that *Eclipta alba Linn.,* medicinal herbal hydrogel may be used for wound healing, antibacterial and antifungal activity.

Keywords: *Eclipta alba Linn.,,* Hydrogel, carbopol 940, Herbal formulation, antibacterial and antifungal .

1. INTRODUCTION

The whole plant of *Eclipta alba Linn*., belongs to the Asteraceae family and is widely cultivated weed throughout India, ascending up to 6,000 ft on the hills.*Eclipta alba Linn.*, is A slender, diffuse or suberect herb.Stems and branches are hairy. Leaves are Opposite, sessile, strigose and hairy, 2.5-7.5 cm long, oblong-lanceolate, subentire, acute, sparsely strigose with appressed hairs on both sides, Flowers are heads, involucral bracts, axillary, ray flowers ligulate; disk ones tubular[1]. Reports suggest that Wedelolactone and Luteolin, important constituents of *E.alba* have selectivity[2] and affinity towards Benzodiazepine binding site on GABA receptor [3]. Luteolin also inhibit the release of glutamate at cerebrocortical nerve terminals [4]. β-amyrin. From previous studies it was found that *Eclipta alba Linn.*, leaves showing the activities like anticancer[5], Haemostatic effect[6], Acute Seizure[7], antibacterial[8], acute oral toxicity[9] and antimicrobial[10].

Topical application has many advantages over the conventional dosage forms. In general, they are deemed more effective less toxic than conventional formulations due to the bilayer composition and structure. In the formulation of topical dosage forms, attempts are being made to utilize drug carriers that ensure adequate localization or penetration of the drug within or through the skin in order to enhance the local and minimize the systemic effects, or to ensure adequate percutaneous absorption[11]. The U.S.P. defines gels as a semisolid system consisting of dispersion made up of either small inorganic particle or large organic molecule enclosing and interpenetrated by liquid. Gels consist of two phase system in which inorganic particles are not dissolved but merely dispersed throughout the continuous

phase and large organic particles are dissolved in the continuous phase, randomly coiled in the flexible chains[12].

2. MATERIALS AND METHODS

2.1. Plant Materials

Collection, identification and authentication of raw *Eclipta alba Linn.*, was done. Fresh leaves of *Eclipta alba Linn.,* were collected in a street in Eluru, west godavari district, Andhra pradesh, India. In july and authenticated by department of botony, Acharya Nagarjuna university, guntur, India. A herbarium is maintained in sir crr College of Pharmacy, Eluru, Andhra Pradesh , India.

2.2. Chemicals

Carbopol 940 (Merck Ltd), Methyl Paraban (Sigma Aldrich Cmemicals), Propyl Paraben (WIN Medicare Pvt. Ltd), Propylene glycol-400 (SD Fine Chemical Ltd), Triethanolamine (SD Fine chemical Ltd).

2.3. Animals

Albino rats of either sex weighing between 200-250 g procured from swetha enterprises, were used for the present investigation. Animal Ethical Committee approved experimental protocol under guidelines of CPCSEA, New Delhi. The rats were housed at controlled temperature (25±2ºC) and 12hrs dark-light cycle and provided basal diet in the form of pellets, water ad libitum

2.4. Preparation of Topical Gel[13]

Different combinations of *Eclipta alba Linn.,* leaves of *aqueous* extract (1% & 5%) were tried with different types of polymers (Carbopol 940) using various formulae. The following few combination with Carbopol 940 resulted in the best gel formulation, which was smooth and stable. Control sample also was prepared for testing of animal to check the activity of control ingredients.

2.4.1. Method for Preparation of Gel Containing Extract

1 g of Carbopol 940 was dispersed in 50 ml of distilled water kept the beaker aside to swell the carbopol 940 for half an hour and then stirring should be done to mix the carbopol 940 to form gel. Take 5 ml of distilled water and required quantity of methyl paraben and propyl paraben were dissolved by heating on water bath. Solution was cooled and Propylene glycol 400 was added. Further required quantity of *Eclipta alba Linn.*, leaves extract was mixed to the above mixture and volume made up to 100 ml by adding remaining distilled water. Finally full mixed ingredients were mixed properly to the Carbopol 940 gel with continuous stirring and triethanolamine was added drop wise to the formulation for adjustment of required skin pH (6.8-7) and to obtain the gel at required consistency[14]. The same method was followed for preparation of control sample without adding any *Eclipta alba Linn.,* leaves extract.

Formulation

As per method described above the formulae were tabulated in Table 1. Along with control sample gel were prepared with addition of 1g and 5g of *Eclipta alba Linn.,* leaves extract to prepared 1% and 5% *Kigelia africana (Lam.) Benth .,* gel respectively.

2.5. EVALUATION OF TOPICAL GEL FORMULATION

2.5.1. Physical Evaluation

Physical parameters such as color and appearance were checked.

2.5.2. Measurement of pH

The pH of various gel formulations were determined by using digital pH meter. 2.5gm of gel was accurately weighed and dispersed in 25ml of distilled water and stored for two hours .The measurement of pH of each formulation was done.

2.5.3. Spreadibility[15]

Spreadibility was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end[10]. By this method spreadibility was measured on the basis of slip and drag characteristics of gels. An excess of gel (about 2g) under study was placed on this ground slide. The gel was then sandwiched between this slide and another glass slide having the dimension of fixed ground slide and provided with the hook. A. one kg weighted was placed on the top of the two slides for 5 minutes to expel air and to provide a uniform film of the gel between the slides. Excess of the gel was scrapped off from the edges. The top plate was then subjected to pull of 80 gm. With the help of string attached to the hook and the time (in seconds) required by the top slide to cover a distance of 7.5 cm be noted. A shorter interval

Indicate better spreadibility. Spreadibility was calculated using the following formula:

$$S = M \times L / T$$

Where,

S = Spreadibility,

M= Weight in the pan (tied to the upper slide)

L = Length moved by the glass slide

T = Time (in sec.) taken to separate the slide completely each other.

2.5.4. Stability Study

The stability study was performed as per ICH guidelines 6. The formulated gel were filled in the collapsible tubes and stored at different temperatures and humidity conditions, viz. 250 C ± 20C/ 60% ± 5% RH, 300 C ± 20C/ 65% ± 5% RH, 400 C ± 20C/ 75% ± 5% RH for a period of three months and studied for appearance, pH, and spreadibility.

2.5.5. Extrudabilty[16]

The gel formulation were filled in standard capped collapsible aluminium tubes and sealed by crimping to the end. The weight of tubes were recorded and the tubes were placed between two glass slides and were clamped. 500gm was placed over the slides and then the cap was removed. The amount of extruded gel was collected and weighed. The percent of extruded gel was calculated as

1. When it is greater than 90% then extrudability is excellent.
2.When it is greater than 80% then extrudability is good.
3. When it is 70% then extrudability is fair.

2.5.6. Viscosity[17]

Viscosities of gels were determined using Brookfield viscometer. Gels were tested for their rheological characteristics at 25^{o}C using Brookfield viscometer (DV-III programmable Rheometer). The measurement was made over the whole range of speed settings from 10rpm to 100rpm with 30seconds between 2 successive speeds and then in a descending orders.

2.5.7. APPLICATION OF HERBAL GEL AND SKIN IRRITATION STUDY

0.5 gm of the herbal gel was used as the test substance was applied to an area of approximately 6 cm2 of skin and covered with a gauze patch. The patch was loosely held in contact with the skin by means of a semi-occlusive dressing for the duration of 1 hour and gauze was removed. At the end of the exposure period, i.e., 1 hour, residual test substance was removed, without altering the existing response or integrity of the epidermis. Observations have recorded after removal of the patch. Control animals were prepared in the same manner and 0.5 gm of the gel base i.e., gel formulated using all ingredients except the herbal mixture was applied to the control animals and observations were made as similar to the test animals[14].The gel was applied to the skin once a day for 7 days and observed for any sensivity and the reaction if any was graded[18].

3. RESULTS AND DISCUSSIONS

The preliminary phytochemical analysis of the aqueous extracts of *Eclipta alba Linn.*, showed the presence of the major phytoconstituents like tannins, saponins, flavonoids, alkaloids, cardiac glycosides, terpenoids and reducing sugars.Moreover there are plenty of research studies proved the potent wound healing activities was due to the presence of flavonoids and terpenoids which serve as a defensive agent against any pathogen[19]. The various physicochemical properties of the prepared gel formulations are shown above. From the results it is clearly evident that all the gel formulations showed good gelling property and homogeneity. The pH of all the formulations was in the range compatible with normal pH range of the skin. The drug content released was also above average. The rheological behaviors of the gel formulations were studied with Brookfield viscometer. The results indicated the viscosity of gel formulations was consistent neither too thick nor too thin. A comparative study of viscosity and Spreadability showed that with increase in viscosity of the formulation, the Spreadability decreased and vice versa[20].

Table 1
Control and *Eclipta alba Linn.*, leaves aqueous extract formulation prepared with this ingredients along with quantity

S.N0	INGREDIENTS	Control	F_1	F_2
1.	Carbopol 940	1 gm	1 gm	1 gm
2.	Methyl Paraben (0.5%)	0.4 ml	0.2 ml	0.2 ml
3.	Propylene glycol 400 (5%)	5 ml	5 ml	5 ml
4.	Triethanolamine (q.s)	1.2ml	1.2ml	1.2ml
5.	Distilled water	Upto 100 ml	Upto 100ml	Upto 100ml
6.	E.A Extract (1%)	_	1g	_
7.	E.A Extract (5%)	_	_	5g

E.A= ***Eclipta alba Linn.***,

Table 2
Stability of developed gels at Initial month at 35^{0}C

Formulation	Colour	Appearance	pH	Spreadibility (Gm.cm/Sec)	Extrudability	Viscosity (Cps)
Control	White	Clear and Transparent	6.95 ±0.07	14.29 ± 1.32	Excellent	1638±30
F_1 -1% E.A Extract	Cream white	Clear and Transparent	6.77±0.05	14.19 ± 1.27	Excellent	1630±32.14
F_2 -5% E.A Extract	Cream white	Clear and Transparent	6.26±0.07	13.27 ± 0.56	Good	1622±21.12

Table 3
Stability of developed gels at second month at 30^{0}C

Formulation	Colour	Appearance	pH	Spreadibility (Gm.cm/Sec)	Extrudability	Viscosity (Cps)
Control	White	Clear and Transparent	6.99 ± 0.06	14.77 ± 1.32	Excellent	1640±40
F_1 -1% E.A Extract	Cream white	Clear and Transparent	6.87 ± 0.06	14.17 ± 1.27	Excellent	1629±31.14
F_2 -5% E.A Extract	Cream white	Clear and Transparent	6.56 ± 0.06	9.27 ± 0.56	Good	1622±21.12

Table 4
Stability of developed gels at third month at 28^{0}C

Formulation	Colour	Appearance	pH	Spreadibility (Gm.cm/Sec)	Extrudability	Viscosity (Cps)
Control	White	Clear and Transparent	6.99 ±0.06	14.39±1.32	Excellent	1640±40
F_1 -1% E.A Extract	Cream white	Clear and Transparent	6.6±0.06	14.29±1.27	Excellent	1727±50.33
F_2 -5% E.A Extract	Cream white	Clear and Transparent	6.6±0.06	11.27±0.56	Good	1660±40

Table 5
Skin Irritation Study Results.

TREATMENT	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
Control	A	A	A	A	A	A	A
F_1 -(1%)	A	A	A	A	A	A	A
F_6 -(5%)	A	A	A	A	A	A	A

A – No reaction, B – Slight patchy erythema, C –Slight but confluent or moderate but patchy erythema, D – Moderate erythema, E – Severe erythema with or without edema.

The herbal gel was prepared and subjected to evaluation of the various parameters. The herbal Gel was light brown in color and translucent in appearance and had a cool and smooth feeling on application. pH also maintained constant throughout the study which was found to be 6.9 to 7.0 and the gel was non-irritant upon application on the skin. Spreadibility were also measured and found to be less variant than the initially prepared gel after performing stability study. Further stability test for three months has been carried out and results revealed gel containing 5% *Eclipta alba Linn.*, leaves showed better stability than 1%. The gel was non-irritant upon application on to the skin. The control and experimental rats showed no signs of tremor, convulsion and reflex abnormalities.

4. CONCLUSION

The plant *Eclipta alba Linn.*, leaves was selected for the study, whose extract was very useful in the treatment of wounds. Literature survey revealed that this plant is used traditionally for various ailments, especially for its wound healing property. Extensive scientific studies were not performed on this plant. It is an attempt made to establish the herbal gel containing *Eclipta alba Linn.*, leaves extract at

various concentrations (1% and 5%). The studies revealed that the developed single herbal formulation consisting 1% *Eclipta alba Linn.*, leaves extract comparatively better than later other formulation but all the formulations were non irritant and did not show any skin toxicity when applied daily for 7 days in rats.Its antibacterial and antifungal property was not under taken for any scientific study with herbal gel. Hence the present work is performed.

5. ACKNOWLEDGEMENTS

The authors thanks to Management, Sir C R Reddy College of Pharmaceutical sciences , Eluru, Andhra preadesh, India for providing required facilities to carry out this research work.

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