ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH

INNOVARE ACADEMIC SCIENCES Knowledge to Innovation

Vol 6, Issue 3, 2013

ISSN - 0974-2441

Research Article

FORMULATION AND EVALUATION OF HERBAL GEL CONTAINING LANTANA CAMARA LEAVES EXTRACT

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Received: 7 April 2013, Revised and Accepted: 7 May 2013

ABSTRACT

Herbal medicine has become an item of global importance both medicinal and economical. Although usage of these herbal medicines has increased, their quality, safety and efficiency are serious concerns in industrialized and developing countries. Herbal remedies are getting increasing patient compliance as they are devoid of typical side effects of allopathic medicines.

The present research has been undertaken with the aim to formulate and evaluate the herbal gel containing *Lantana camara* leaf extract. The gel formulation was designed by using Carbapol 940, *Lantana camara* leaf extract, propylene glycol, methyl paraben, propyl paraben and required amount of distilled water. The skin pH (6.8-7) was maintained by drop wise addition of Tri-ethanolamine.

The physicochemical Parameters of formulations (pH, Spreadibility, Stability etc.) were determined. Stability studies have carried out as per ICH guidelines for 3 months at different temperatures and humidity. The results showed that formulation containing *Lantana camara* leaf extract Show better stability. Further formulations have studied for skin irritation on animal model (Rat) and result showed that there was no skin irritation to animals.

Our literature survey revealed that the herbal gel of Leaves extracts from leaves of *Lantana Camara* was not investigated; hence these activities have been investigated in the present study.

Keywords: *Lantana camara,* hydroalcoholic extract, Carbapol 940, Gel.

INTRODUCTION

Finding healing power in plants is an ancient idea. It is estimated that there are 2, 50,000 to 5, 00,000 species of plants on earth·[1] a relatively small percentage (1-10 %) of these is used as food by humans and other animal species. It is possible that even more are used for medical purpose.[2] The literature survey reveals that plants like *Euphorbia prostrata, Santlaum album L, Achyranthus aspera L, Portulaca quadrifida L, Nelumbo nucifera, Nymphaea nuchali, Berberis asistata, Stephania japonica* have been used in treating piles. Such plants have flavonoids, triterpenoids, tannins, and saponin compounds. Literatures revealed that certain flavonoids are the potent inhibitors of cyclic AMP phosphodiesterase and this may be in part the explanation for their ability to inhibit platelet function. It has been supported in literature that flavonoids have been shown to chelate formation with metals, thereby inhibiting oxidation of ascorbic acid, protection of epinephrine by the inhibition of o-methyl transferase, which maintains the capillary tonus; it stimulate pituitary adrenal axis and inhibit platelet aggregation. Literature supports activity of tannins of protein precipating.[3-10] It has been revealed in literature that the leaves of *Lantana camara* have been shown to possess Antimotility effect in mice,[11] anti-hemorrhoid and anti inflammatory activity[13-23]. Aim of the present study was to formulate and evaluate of herbal gel containing *Lantana camara* leaves extract. Herbal gels with suitable rheological properties can facilitate the absorption of poorly absorbed drug by increasing the contact time of the drug with the skin. The main objective of this work was to investigate the importance of this feature for the anticipated in *vivo* contact time.

MATERIALS AND METHODS

Plant Materials

The plant of Lantana camara was collected from the university campus, Department of Pharmaceutical Sciences, Nagpur. The plant specimen was dried and its herbarium sheet was prepared and above material was given for botanically identification in Department of Botany, Rashtrasant Tukadoji Maharaj Nagpur University, and Nagpur. Specimen vouchers No. is 9101.

Chemicals

Sodium carboxy methyl cellulose (Merck Ltd),Carbopol 934 (Merck Ltd), Methyl Paraban (Suprim Cmemicals), Propyl Paraben (Suprim Cmemicals),Propylene glycol-400 (SD Fine Chemical Ltd),Triethanolamine (SD Fine chemical Ltd).

Animals

Albino rats of either sex weighing between 200-250 g procured from Mahaveera Enterprises, Hyderabad, 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

Preparation of Topical Gel

Different combinations of *Lantana camara* leaves extract (2.5% & 5%) were tried with different types of polymers (Sodium CMC, Carbopol 934) using various formulae. The following few combination with Carbopol 934 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.

Method for Preparation of Gel Containing Extract [30]

1 g of Carbopol 934 was dispersed in 50 ml of distilled water kept the beaker aside to swell the carbopol 934 for half an hour and then stirring should be done to mix the carbopol 934 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 *Lantana camara* 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 934 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. The

same method was followed for preparation of control sample without adding any *Lantana camara* 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 2.5g and 5g of *Lantana camara* leaves extract to prepared 2.5% and 5% *Lantana camara* gel respectively.

EVALUATION OF TOPICAL GEL FORMULATION

A. Physical Evaluation

Physical parameters such as color and appearance were checked.

B. Measurement of pH

pH of the gel was measured by using pH meter.

C. Spreadibility

Spreadibility was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end[31]. 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 × 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.

D. 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[30].

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 cm^2 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[32].

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 as[33]

RESULTS AND DISCUSSIONS

The herbal gel was prepared and subjected to evaluation of the various parameters. The herbal Gel was dark greenish 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 6.90 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 2.5% *Lantana Camara* showed better stability than 5%. 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

Table 1: Different formulations prepared with this ingredients along with quantity.

FORMULATIONS	INGREDIENTS	QUANTITY
Control	Carbopol 934	1 gm
	Methyl Paraben (0.5%)	0.2 ml
	Propyl Paraben (0.2%)	0.1 ml
	Propylene glycol 400 (5%)	5 ml
	Triethanolamine (q.s)	1.2ml
	Distilled water	Upto 100 ml

Table 2: Physical evaluation of all formulations at the time of gel formulation (initial month).

FORMULATION	COLOR	APPEARANCE	SPREADIBILITY (GM.CM/SEC)	pH
Control	White	Clear and Transparent	14.20	6.99
F- I (2.5%)	Greenish	Clear and Transparent	19.32	7.0
F – II (5%)	Greenish	Clear and Transparent	16.12	6.92

Table 3: 250 C ± 20C/ 60% ± 5% RH AT 2ND months.

FORMULATION	COLOR	APPEARANCE	SPREADIBILITY (GM.CM/SEC)	pH
Control	White	Clear and Transparent	14.12	6.99
F- I (2.5%)	Greenish	Clear and Transparent	19.90	7.0
F – II (5%)	Greenish	Clear and Transparent	17.01	6.92

Table 4: 300 C ± 20C/ 65% ± 5% RH AT 3RD months.

FORMULATION	COLOR	APPEARANCE	SPREADIBILITY (GM.CM/SEC)	pH
Control	White	Clear and Transparent	14.07	6.99
F- I (2.5%)	Greenish	Clear and Transparent	18.92	7.0
F – II (5%)	Greenish	Clear and Transparent	16.82	6.92

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- I (2.5%)	A	A	A	A	A	A	A
F – II (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.

CONCLUSION

Natural remedies are more acceptable in the belief that they are safer with fewer side effects than the synthetic ones. Herbal formulations have growing demand in the world market. It is an attempt made to establish the herbal gel containing *Lantana Camara* leaves extract at various concentrations (2.5% and 5%). The studies revealed that the developed single herbal formulation consisting 2.5% *Lantana Camara* 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.

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