

# Formulation and Evaluation of Herbal Gel Containing *Clerodendron infortunatum* Leaves Extract

Sudipta Das<sup>1,2\*</sup>, Pallab K. Haldar<sup>2</sup>, Goutam Pramanik<sup>3</sup>

<sup>1</sup>Netaji Subhas Chandra Bose Institute of Pharmacy, Chakdaha – 741222, India

<sup>2</sup>Department of Pharmaceutical Technology, Jadavpur University, Kolkata –700032, India

<sup>3</sup>Bengal College of Pharmaceutical Science and Research, Durgapur – 713212, India

\*Corres.author: [sudipta\\_pharmacy@rediffmail.com](mailto:sudipta_pharmacy@rediffmail.com)

**Abstract:** The present research has been undertaken with the aim to formulate and evaluate the herbal gel containing *Clerodendron infortunatum* extract. The gel formulation was designed by using aqueous extract of *Clerodendron infortunatum* leaves in varied concentrations (2.5% and 5%) and evaluated using physiological measurements. The gel was prepared by using various polymer bases (Sodium CMC, Carbopol 934). Among them Carbopol 934 has given better gel formation. The gel was prepared by using Carbopol 934, *Clerodendron infortunatum* leaves extract, Propylene glycol 400, Methyl paraban, Propyl paraben and required amount of distilled water. Then skin pH (6.8-7) was maintained by drop wise addition of tri-ethanolamine. The physiochemical parameters of formulations (pH, viscosity, spreadability 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 2.5% *Clerodendron infortunatum* extract have better stability than other formulation. Further all formulations have studied for skin irritation on animal model (Rabbit) and result showed that there was no skin irritation to animals.

**Keywords:** *Clerodendron infortunatum*, Sodium CMC, Carbopol 934, Gel.

## INTRODUCTION

India has rich tradition of plant based knowledge of healthcare. The use of the plant based medication is gradually becoming popular through out the world<sup>1</sup>. Approximately, half of the world's twenty five best selling pharmaceutical agents are derived from natural products<sup>2</sup>. *Clerodendron infortunatum* Linn. (alternatively, *Clerodendrum infortunatum* Linn.) belonging to family Verbanaceae, have been used in Indian folk medicine as in the treatment of bronchitis, asthma, fever, disease of blood, certain skin diseases inflammation, burning sensation and epilepsy<sup>3</sup>. Previous investigation revealed that the leaves of *Clerodendron infortunatum* linn. have anti-inflammatory activity<sup>4</sup>. So the aim of the present study was to formulate and evaluate of herbal gel containing *Clerodendron infortunatum* leaves extract.

## MATERIALS AND METHODS

### Plant Materials

The plant *Clerodendron infortunatum* Linn. was collected in the month of November 2008 from the forest region of Midnapore, West Bengal, India. The taxonomical identification of the plant was done by Botanical Survey of India, Shibpur, India. The voucher specimen (PMU-4/JU/2008) has been preserved in Pharmacology Research Laboratory, Jadavpur University, Kolkata for future reference.

### Chemicals

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

### Animal Used

Healthy young adult albino rabbits (1.5-2 kgs) were maintained in identical laboratory conditions (25°- 30° C temperature and relative humidity of 55-65 % with alternate light and darkness 12 hours each) and fed with commercial pellet diet (Hindustan Lever, Kolkata, India) and water *ad libitum*. All procedures described were reviewed and approved by the Jadavpur University animal ethical committee (ref no. 367001/C/CPCACA).

### Preparation of Topical Gel

Different combinations of *Clerodendron infortunatum* 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

1 g of Carbopol 934 was 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. Cool the solution, then to that added Propylene glycol 400. Further required quantity of *C. infortunatum* 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 *C. infortunatum* leaves extract.

### Formulation

The method describes above and the formulae were tabulated in Table 1. Along with control sample gel were prepared with addition of 2.5g, 5g of *C. infortunatum* leaves extract to prepared 2.5% and 5% *C. infortunatum* 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. Spreadability

Spreadability was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end<sup>5</sup>. By this method spreadability 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 1 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 gms. 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 indicates better spreadability. Spreadability was calculated using the following formula:

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

Where, S = Spreadability, 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.

### D. Viscosity

Viscosity of gel was measured by using Brookfield viscometer with spindle.

### E. Stability Study

The stability study was performed as per ICH guidelines<sup>6</sup>. The formulated gel were filled in the collapsible tubes and stored at different temperatures and humidity conditions, viz.

25° C ± 2° C/ 60% ± 5% RH, 30° C ± 2° C/ 65% ± 5% RH, 40° C ± 2° C/ 75% ± 5% RH for a period of three months and studied for appearance, pH, viscosity and spreadability<sup>7</sup>.

## APPLICATION OF HERBAL GEL AND SKIN IRRITATION STUDY

0.5 gms of the herbal gel was used as the test substance was applied to an area of approximately 6 cm<sup>2</sup> 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 gms 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<sup>8</sup>.

The gel was applied to the skin once a day for 7 days and observed for any sensitivity and the reaction if any was graded as<sup>9</sup>:

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.

**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)	1.2 ml
	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)	P <sup>H</sup>
Control	White	Clear and Transparent	15.72	7.0
F- I (2.5%)	Greenish	Clear and Translucent	21.65	7.0
F – II (5%)	Greenish	Clear and Translucent	19.78	7.0

**Table 3: 25<sup>0</sup> C ± 2<sup>0</sup>C/ 60% ± 5% RH at 3<sup>rd</sup> months.**

Formulation	Appearance	Spreadibility (gm.cm/sec)	P <sup>H</sup>
Control	Clear and Transparent	15.23	6.98
F- I (2.5%)	Clear and Translucent	20.38	7.0
F – II (5%)	Clear and Translucent	18.67	6.92

**Table 4: 30<sup>0</sup> C ± 2<sup>0</sup>C/ 65% ± 5% RH at 3<sup>rd</sup> months.**

Formulation	Appearance	Spreadibility (gm.cm/sec)	P <sup>H</sup>
Control	Clear and Transparent	15.66	6.97
F- I (2.5%)	Clear and Translucent	21.22	6.98
F – II (5%)	Clear and Translucent	18.43	6.93

**Table 5: 40<sup>0</sup> C ± 2<sup>0</sup>C/ 75% ± 5% RH at 3<sup>rd</sup> months.**

Formulation	Appearance	Spreadibility (gm.cm/sec)	P <sup>H</sup>
Control	Clear and Transparent	14.87	6.95
F- I (2.5%)	Clear and Translucent	20.15	6.97
F – II (5%)	Clear and Translucent	17.46	6.91

**Table 6: 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

## RESULTS AND DISCUSSIONS

The herbal gel was greenish in color and translucent in appearance and gave smooth feel on application which was maintained after tested stability study (Table 2, 3, 4 &5). P<sup>H</sup> also maintained through out the study which was found 6.91 to 7.0. Spreadibility was also measured and found to be less variation with the initially prepared gel after performs the stability study (Table 2, 3, 4 &5). The initial viscosities of developed gels were measured using Brookfield viscometer with spindle. Further stability test for three months has been carried out and results revealed gel containing 2.5% *C. infortunatum* showed better stability than 5%. Initial viscosity for gel containing 2.5% and 5% *C. infortunatum* extract were 27390 cps and 29640 cps respectively and after stability study there were not much variation at different temperature and humidity. The gel was non-irritant upon application on to the skin (Table 6). The control and experimental rabbits showed no signs of tremor, convulsion and reflex abnormalities. The food intake per day had also found

normal during 7 days repeated dose dermal toxicity evaluation.

## 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 a very good attempt has made to establish the herbal gel containing *C. infortunatum* leaves extract at various concentrations (2.5% and 5%). The studies revealed that the developed single herbal formulation consisting 2.5% *C. infortunatum* 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 rabbits.

## ACKNOWLEDGEMENT

The financial assistance of Department of Pharmaceutical Technology, Jadavpur University, kolkata, India is gratefully acknowledged.

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