Research Article

Formulation and Evaluation of Herbal Gel Conatining *Dalbergia sissoo* Roxb. Bark Extract

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ABSTRACT

Dalbergia sissoo Roxb. Fabaceae is used in the traditional medicine for the treatment of variety of ailments. The aim of present investigation was to formulate the herbal gel and evaluate is various pharmaceutical parameters of ethyl acetate extract of bark of *Dalbergia sissoo* Roxb. Gelling agent used in this study was 1% w/w concentration of carbopol-934. The ethyl acetate extracts were formulated and evaluated for pharmaceutical parameters such as pH, viscosity, extrudability, Spreadability and stability were also examined. The pH of the formulations was near about 6.8, which lies in the normal pH range of the skin. The preparation was stable under normal storage conditions and did not produce any sign and symptoms of skin irritation.

Keywords: Carbopol-934, *Dalbergia sissoo*, ethyl acetate extract, gel

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INTRODUCTION

India has rich tradition of plant based knowledge of healthcare. The use of the plant based medication is gradually becoming popular throughout the world [1]. Approximately, half of the world's best selling pharmaceutical agents are derived from natural products [2].

Topical application of gels at the pathological sites offer great advantage in a faster release of drug directly to the site of action independent of water solubility of the drug as compared to ointments and creams [3,4].

Dalbergia sissoo is a medium to large tree of about 25 meters high with grey-yellow trunk, longitudinal crack, and downcast twig. Leaves are leathery, pinnately compound, with about five alternate leaflets (**Fig. 1**). Leaf stalk measures about 15 cm long, each leaflet widest at the base to 6 cm long with a fine pointed tip. Flowers are whitish to pink, fragrant, nearly sessile up to 1.5 cm long and in dense clusters 5-10cm in length. Pods are oblong, flat, thin, strap like 4-8cm long, 1cm wide and light brown. It contain 1-5 flat bean shaped seeds 8-10 mm long [5]. It is an Indian medicinal plant which has a variety of uses in folk medicine Aphrodisiac, Abortifacient, Expectorant, Anthelmintic, Antipyretic, Emesis, Ulcers, Dysentery, Stomach troubles [6].

The present investigation involves the preparation of gel from the bark of Dalbergia sissoo ethyl acetate extract followed by the evaluation of pH, viscosity, spredability and for irritation activity.

Figure 1: Tree of *Dalbergia sissoo*

MATERIALS AND METHODS

Plant collection and Authentication

The fresh bark of the plant *Dalbergia sissoo* was collected from Komaneri, Tuticorin district, Tamil Nadu, India and it was botanically identified and authenticated by Dr.V.Chelladurai, Research Officer-Botany (Scientist-C), Central Council for Research in Ayurveda and Siddha, Government of India. The barks were pulverized to coarse powder using mechanical grinder. The sieved powder was used for evaluation and extraction purpose.

Preparation of extract

The powdered leaved were passed through 40 mesh sieves and stored in well closed container for further use. The dried powder bark (200g) were extracted with ethyl acetate in a Soxhlet apparatus followed by solvent recovery using rotary vacuum evaporator and thus yielded a semisolid extract respectively.

Formulation of Gel

Herbal gel was prepared using Carbopol 934 as a gelling agent in 1% w/w concentration with deionized water using mechanical stirrer. The pH of the gel was adjusted to neutral by addition of small quantities of triethanolomine with continuous stirring.1% w/w bark extract of Dalbergia sissoo was added to the gel and stirred for sufficient time for homogenous mixing of extract in gel base. Prepared gel was filled in collapsible tubes and stored at a cool and dry place. Physical parameters such as colour, appearance and feeling on application were recorded. pH of the gel was recorded using a pH meter.

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. Viscosity

Viscosity of the gel was measured by using Brookfield viscometer with spindle 7

D. Spreadability [7]

Spreadability was determined by the apparatus which consist of a wooden block, which was provided by at on end. 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 slides for 5minutes 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 80gm. With the help of string attached to the hook and time (in seconds) required by the top slide to cover a distance of 7.5cm noted. A shorter interval 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
T= Time (in sec.) taken to separate the slide completely each other.

E. Extrudability [8]

The gel formulations were filled in standard capped collapsible aluminium tubes and sealed by crimping to the end. The weights of the tubes were recorded. 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 the extruded gel was collected and weighed. The percent of the extruded gel was calculated (> 90% extrudability: excellent, >80% extrudability: good, >70% extrudability: fair)

F. Stability study [9]

The stability study was performed as per ICH guidelines 6. The formulated gel were filled in collapsible tubes and stored at different temparatures and humidity conditions,40 ºC ± 2ºC / 75% ± 5% RH for a period of three months and studied for appearance, pH and Spreadability.

APPLICATION OF HERBAL GEL AND DRAIZE SKIN IRRITATION TEST [10]

A protocol hard copy was submitted to the institutional animal ethical committee and got approval (Vide4/243/CPCSEA). The animals were conditioned to the normal diurnal and nocturnal rhythms. The animals were fed with leafy vegetables and water ad libitum. The average weight of rabbit was 2.5kgs. healthy male Albino Rabbits (white

2.5kg) are divided into 2 groups. 3 animals in each group.

The formulated gel was to be tested for irritancy. The animals were kept under standard laboratory conditions, at 25±1 and 55±5% relative humidity with a 12 h light/dark cycle.

PROCEDURE

Skin irritation studies were carried out in the presence of skin of rabbit. The hairs on the dorsal side of the rabbit are removed 1 day before performing experiment. Care was taken to avoid abrading the skin and only animals with healthy, intact skin are used for the study. About 0.5 g of herbal gel was apply to intact skin with patch for 4 hours. The herbal gel is removed after 4 hour exposure period and the formation for any erythema or edema is observed at 24, 48, and 72 hour thereafter. The observation is made for 14 days to determine any persistent or delayed effects.

GROUP I- Treated with the gel base (carbopol 934)

GROUP II- Treated with the gel from the best extract.

RESULTS AND DISCUSSION

The herbal gel was prepared and subjected to evaluation of the various parameters. The herbal gel was brownish yellow 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 6.5 to 6.8 and the gel was non-irritant upon application on the skin. Spreadability were also measured and found to be less variant than the initially prepared gel after performing stability study (**Table 1**). Extrudability was excellent after performing stability studies from that of the initially prepared gel (**Table 2**). The initial viscosities were recorded at 25°C are tabulated in (**Table 3**). Furthermore, the stability study's results revealed the preparation was stable under accelerated stability conditions.

The Draize skin test sensitivity showed that there was no sign of irritation such as redness or erythema indicating that the gel was no irritant (**Fig.2**).

Table 1: Spreadability of the Herbal Gel during the Evaluation Period (Mean ± SEM)

Evaluation Condition	Spredability (g.cm/sec)
Initial at 40˚C ±2˚C /75±5% RH	26.37±0.12
At 1month at 40˚C ±2˚C /75±5% RH	26.35±0.32
At 2month at 40˚C ±2˚C /75±5% RH	26.34±0.32
At 3month at 40˚C ±2˚C /75±5% RH	26.29±0.32

Table 2: Extrudability of the herbal gel at the time of preparation (Mean± SEM)

Extrudability	Mean of three tubes (Initial month)
Net wt of formulation tube (g)	12.33± 0.01
Wt. of gel extruded (g)	11.15±0.011
Extrudability amount percentage	90.34±0.07

Table 3: Viscosity of the Herbal Gel during Evaluation Period

Evaluation month	Viscosity (cps)
Initial	17000
At 1 month	17000
At 2 month	17000
At 3month	16500

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 *Dalbergia sissoo* bark extract at 1% concentrations. The studies revealed that the single herbal formulation consisting 1%

Dalbergia sissoo extract was non irritant and did not show any skin toxicity when applied topically in Rabbit.

Table 4: Skin Irritation Study

Name of the Group	Animal numbers	Grading	
Group I		7th day	14th day
	1	0	0
	2	0	0
	3	0	0
	1	0	0
Group II	2	0	0
	3	0	0

0-No erythema 1-Minimally Perceptible Erythema
2-Marked erythema 3-Fiery red erythema with edmea.

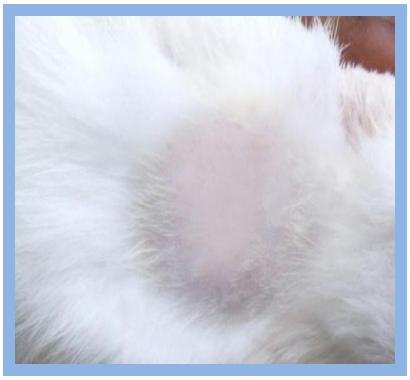
GROUP I

7th Day

14th Day

GROUP II

7th Day



14th Day

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