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FORMULATION AND EVALUATION OF HERBAL GEL CONTAINING *SESBANIA GRANDIFLORA* (L.) POIR. LEAF EXTRACT

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ABSTRACT

The present research has been undertaken with the aim to formulate and evaluate the herbal gel containing *Sesbania grandiflora* leaf extract. The gel formulation was designed by using ethyl acetate extract in varied concentrations and was evaluated using physiological measurements. The gel was prepared by using Carbopol 934, Sodium CMC, *Sesbania grandiflora* extract, Glycerin, Methyl paraben, 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 were carried out as per ICH guidelines for 3 months at different temperatures and humidity. The results showed that formulation F5 containing 2.5% *Sesbania grandiflora* extract have better stability than other formulation.

Key words: *Sesbania grandiflora*, Ethyl acetate extract, Sodium CMC, Carbopol 934, Gel.

INTRODUCTION

The use of medicinal plants as raw materials in the production of new drugs is ever increasing because of their potentials in combating the problem of drug resistance in micro-organisms. Demand for medicinal plants is increasing in both developing and developed countries. Research on medicinal plants is one of the leading areas of research globally[1].

Sesbania grandiflora (L.) Poir. commonly known as august (H), agati (S), rain tree (E) belongs to family Caesalpiniaceae is a medium size tree, with green, glabrous, twining branches having leaves, flowers white, reddish or pale creams. The other scientific names of sesbania are *Robinia grandiflora* Linn, *Aeshynomene grandiflora* Linn, *Sesban grandiflora* Poir, Agati *grandiflora* (L.) Desv. A small erect quick-growing short-lived soft-wooded tree sparsely branched. Bole straight and cylindrical, the wood white and soft. The tree is 5 to 12 meters in height. The leaves are 20 to 30 centimeters long, and pinnate having 20 to 40 pairs of leaflets, which are 2.5 to 3.5 centimeters long. The flowers are white and 7 to 9 centimeters long. The pods are linear, 20 to 60 centimeters long, 7 to 8 millimeters wide, pendulous, and somewhat curved, and contain many seeds.

The leaves are regular and rounded and the flowers white and large, very characteristic. The fruits look like flat, long and thin green beans. The tree thrives under full exposure to sunshine and is extremely frost sensitive[2-3].

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The active ingredients of sesbania are leucocyanidin and cyanidin present in seeds, oleanolic acid and its methyl ester and kaemferol-3-rutinoside which are present in flower. The bark contains tannins and gum. Saponin isolated from the seeds. Sesbanimide isolated from seeds[3-4].

All parts of *Sesbania grandiflora* are utilized for medicine in Southeastern Asia and India including preparations derived from the roots, bark, gum, leaves, flowers, and fruit. In Folk Medicine it is resorted to be aperient, diuretic, emetic, emmenagogue, febrifuge, laxative, and tonic. Agati is a folk remedy for bruises, catarrh, dysentery, eyes, fevers, headaches, smallpox, sores, sore throat and stomatitis. Different parts of this plant are used in Siddha system of Indian traditional medicine for the treatment of a wide spectrum of ailments including anemia, bronchitis, fever, headache, ophthalmia, nasal catarrh, inflammation, leprosy, gout and rheumatism. It also possesses anxiolytic, antiulcer, antioxidant, analgesic, antipyretic, antimicrobial, anticancer, anticonvulsive and hepatoprotective properties[5].

For topical treatment of dermatological disease as well as skin care, a wide variety of vehicles ranging from solids to semisolids and liquid preparations is available to clinicians and patients. Within the major group of semisolid preparations, the use of transparent gels has expanded both in cosmetics and in pharmaceutical preparations. A gel is colloid that is typically 99% wt liquid, which is immobilized by surface tension between it and a macromolecular network of fibers built from a small amount of a gelating substance present. Topical drug administration is a localized drug delivery system anywhere in the body through ophthalmic, rectal, vaginal and skin as topical routes. Skin is one of the most readily accessible organs of human body for topical administration and main route of topical drug delivery system. Numbers of medicated products are applied to the skin or mucous membrane that either enhance or restore a fundamental function of a skin or pharmacologically alter an action in the underlined tissues[6].

The various parts of *S. grandiflora* are used as medicine for many diseases and disorders. Keeping this fact and considering the folklore medicinal utility of the plant, the present work was undertaken to formulate the gel of ethyl acetate extract of leaves of *S. grandiflora.*

Material and methods

Collection of plant material

The plant *Sesbania grandiflora* was collected from Medicinal garden of UIPS, Ujjain, M.P. and was authenticated by Dr. S. N. Dwivedi, Prof. & Head, Department of Botany, Janata PG College, APS, University, Rewa, M.P. and Voucher specimen No. SD/SG/210 was deposited in our department.

Preparation of plant powder

The plant was dried under shade and then powdered coarsely with a mechanical grinder. The powder was passed through sieve No. 40 and stored in an airtight container for further use.

Preparation of extracts

About 250 g of dried powder leaf of plant was subjected to Soxhlet apparatus. It was fist defatted with petroleum ether then exhaustively extracted with ethyl acetate solvent in a Soxhlet apparatus for 36 hours. The temperature was maintained at (40-50^{o}C). 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.

Chemicals

Sodium carboxy methyl cellulose (Central Drug House (P.) Ltd.), Carbopol 934 (Merck Ltd),

Methyl Paraban (Suprim Chemicals), Propyl Paraben (Suprim Chemicals), Glycerin (SD Fine Chemical Ltd), Triethanolamine (SD Fine Chemical Ltd).

Preparation of Gel containing extract

Different 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. Cool the solution, then to that added glycerin and mixed it with fist solution. Further required quantity of *Sesbania grandiflora* plant extract was mixed to the above mixture and volume made upto 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 *Sesbania grandiflora* plant extract.[6]

Precipitation occurs in some of the batches (F1, F2, F6 and F7) of polymer based gel containing *Sesbania grandiflora* which could be due to the incompatibility in the system. Hence, these batches were discarded and remaining batches (F3, F4 and F5) were considered for further study (Table 1).

Evaluation of topical gel formulation[6]

Physical Evaluation

Physical parameters such as color and appearance were checked.

Measurement of pH

pH of the gel was measured by using pH meter.

Spreadibility

Spreadibility was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end. By this method spreadibility was measured on the basis of slip and drag characteristics of gels. An excess of gel (about 2 g) 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 g. 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 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 and

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

Homogeneity

All developed gels were tested for homogeneity by visual inspection after the gels have been set in the container. They were tested for their appearance and presence of any aggregates.

Viscosity

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

Stability study

The stability study was performed as per ICH guidelines. The formulated gel were filled in the collapsible tubes and stored at different temperatures and humidity conditions, viz. 25ºC ± 2ºC / 60% ± 5% RH, 30º C ± 2ºC / 65% ± 5% RH, 40ºC ± 2ºC / 75% ± 5% RH for a period of three months and studied for appearance, pH, viscosity and spreadibility.[7]

Table1: Formulation of topical gel of *Sesbania grandiflora* leaf extract

Ingredient	F_1	F_2	F_3	F_4	F_5	F_6	F_7
Carbopol 934 (g)	3	3	2	1	1	-	1
Sodium CMC (g)	-	1	1	1	2	3	3
Sesbania grandiflora Ethyl acetate leaf extract (% w/w)	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Glycerin (mL)	2	2	2	2	2	2	2
Methyl Paraben (0.5%) (mL)	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
Triethanolamine (mL)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Distilled water (mL)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

RESULTS AND DISCUSSION

During the trial, the excipients concentrations of carbapol and sodium CMC are gradually increasing and decreasing as a result several problems are coming like homogeneity, spreadibility and viscosity. These problems occured in some of the batches (F1, F2, F6 and F7) of polymer based gel containing *Sesbania grandiflora*. Hence, these batches were discarded and remaining batches (F3, F4 and F5) were considered for further study.

The developed herbal gel was greenish in color, translucent in appearance and showed good homogeneity with absence of lumps. The formulated F5 preparation was much clear and transparent as compared to F3 and F4 formulation.

The values of spreadability indicate that the gel is easily spreadable by small amount of shear. Spreadability of formulated gels (F3, F4 and F5) were 15.75, 19.78, 21.65 g cm/sec. Hence spreadability of F5 formulation was good as compared to F3 and F4 formulation. During the accelerated stability studies the appearance was clear and no significant variation in pH was observed and spreadability is 20.22 in F5 formulation after 3 months where as spreadability in F3 and F4 was 17.82 and 15.12 respectively. pH also maintained throughout the study which was found 6.91 to 7.0. The initial viscosities of developed gels were measured using Brookfield viscometer with spindle. The topical gel thus formulated was non-irritant upon application on to the skin.

Table 2: Physical evaluation of topical gel of Sesbania grandiflora leaf extract

Batch	Color	Appearance	Spreadibility (g.cm/sec)	Viscosity (dyn.s/cm^2)	pH
F3	Greenish	Homogeneous	15.75	$1.6*10^{-3}$	7
F4	Greenish	Homogeneous	19.78	$1.6*10^{-3}$	7
F5	Greenish	Homogeneous	21.65	$0.94*10^{-3}$	7

Table 3: Stability testing at 25^{o}C ± 2^{o}C/60% ± 5% RH (3rd months) of topical gel of *Sesbania grandiflora* leaf extract

Formulation	Color	Appearance	Spreadibility (g.cm/sec)	pH
F_3	Greenish	Homogeneous	15.65	7
F_4	Greenish	Homogeneous	18.40	6.98
F_5	Greenish	Homogeneous	20.38	7

Table 4: Stability testing at 30^{o}C ± 2^{o}C/65% ± 5% RH (3rd months) of topical gel of *Sesbania grandiflora* leaf extract

Formulation	Color	Appearance	Spreadibility (g.cm/sec)	pH
F_3	Greenish	Homogeneous	15.32	6.94
F_4	Greenish	Homogeneous	18.34	6.97
F_5	Greenish	Homogeneous	21.65	7

Table 5: Stability testing at 40^{o}C ± 2^{o}C/75% ± 5% RH (3rd months) of topical gel of *Sesbania grandiflora* leaf extract

Formulation	Color	Appearance	Spreadibility (g.cm/sec)	pH
F_3	Greenish	Homogeneous	15.12	6.91
F_4	Greenish	Homogeneous	17.82	6.96
F_5	Greenish	Homogeneous	20.22	6.98

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 Sesbania grandiflora extract. The studies revealed that the developed single herbal formulation F5 consisting Sesbania grandiflora extract comparatively better than later other formulations but all the formulations were non irritant though further pharmacological screening were may implied to test and investigate the safety profile of formulated gel to treat various inflammation of skin.

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