Formulation and Evaluation of Herbal Gel Containing Extract of *Calotropis gigantea* Leaves

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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 efficacy 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 Calotropis gigantea mother tincture. The gel formulation was designed by using Carbopol 934, Calotropis gigantea mother tincture, Polyethylene, Sodium Sulphite 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 such as pH, spreadability, viscosity and rheological studies, extrudability and drug content uniformity were determined. The results showed that the formulation containing Calotropis gigantea extract shows the drug content release which is above average. The pH of all formulations was found to be compatible with the normal pH range and so the chances of skin irritation are least.

Keywords: Calotropis gigantea mother tincture, Carbopol-934, herbal gel

1. Introduction

Calotropis gigantea R.Br (Asclepiadaceae) is a xerophytic, erect shrub, growing widely throughout the tropical and subtropical regions of Asia and Africa. This plant is popularly known because it produces large quantity of latex. The plant has potential pharmacological properties. Fractionation of the latex into its rubber and rubber-free fractions affords better insight into its potentials and limitations. A large quantity of latex can be easily collected from its green parts. The abundance of latex (containing alkaloids) in the green parts of the plant reinforces the idea that it produced and accumulated latex as a defense strategy against organisms such as bacteria, fungi and insects. Different plant parts have shown biological activities viz., antipyretic, anti-inflammatory, wound healing, analgesic, antidiarrhoeal, antioxidant and as an anti-diabetic, antinociceptive, fibrinogenolytic, anti-coagulant. Latex has good ovicidal and larvicidal properties etc. The prevalence of invasive, opportunistic microbial and fungal infections has increased at an alarming rate especially in immunecompromised individuals.

Although it appears to be a great array of antimicrobial and antifungal drugs, there is at present a quest for new generations of antimicrobial and antifungal compounds due to the low efficacy, side effects or resistance associated to the existing drugs. This plant has potential antimicrobial properties against microbial infections. Commercially available antimicrobial agents (antibiotics) are now used to treat diseases arising from microbial infections. A major problem encountered with antibiotics in clinical use is drug resistance, which mostly leads to treatment failure. Other problems with antibiotics include toxicity, high cost, low cost efficacy, etc. This necessitates a continuous search for new antimicrobial agents. Medicinal plants have no doubt remained the major sources of traditional medicine worldwide. This study attempts to determine the phytochemical analysis and antimicrobial effect of Calotropis gigantea. In this report, we provide new information on the antimicrobial activities of *C. gigantea* using known microbial pathogens as tested organisms.

2. Material and Method

Extraction of Plant Material:

Mother tincture

Mother tincture of *Calotropis gigantea* (homeopathic medicine of SBL).

Preparation of herbal gel

The required quantity of carbopol-934 was slowly sprinkled with continuous stirring into weighed amount of water to get a uniform dispersion and then kept overnight for hydration. The accurately weighed amounts of drug along with other additives were poured in the fixed amount of hydrated Carbopol-934 dispersion with constant mechanical stirring. The composition of herbal gel prepared from mother tincture of *Calotropis gigantea* tabulated in Table 1.

 Table 1: Composition of various gel formulations

 containing Calotronis signated extract

containing Catotropis giganiea extract						
Ingredients	F11	F12	F21	F22	F31	F32
Carbopol-934	1.5g	1.5g	1.0g	1.0g	0.75g	0.75g
Polyethylene	10g	10g	10g	10g	10g	10g
Triethanol Amine	1.5g	1.5g	1.5g	1.5g	1.5g	1.5g
Sodium Sulphite	0.1g	0.1g	0.1g	0.1g	0.1g	0.1g
Plant extract	1%	2%	1%	2%	1%	2%
Water up to (ml)	100	100	100	100	100	100

3. Evaluation of Herbal Gel

All the prepared gel formations were subjected for preliminary evaluations as follows:

A) pH

The pH of all the formulations was determined by using digital pH meter. 1.5gm of gel was accurately weighed and dispersed in 15ml of distilled water and stored for two hours.

The measurement of pH of each formulation was carried out in triplicate and the average values are represented in Table 2. The pH of dispersions was measured using pH meter.

fable 2: pH	values o	of gel	formulations	of	Calotropis
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gigantea						
Sr. no.	Formulations	pH value				
1	F11	7.3				
2	F12	7.4				
3	F21	7.2				
4	F22	7.0				
5	F31	6.7				
6	F32	6.5				

B) Viscosity and Rheological studies

Brookfield viscometer was used to determine the viscosities of gels. Rheological characteristics were tested at 25°C using Brookfield Viscometer (LVDV-II+P). The measurement was made over the whole range of speed settings from 10rpm to 100rpm with 30 seconds between two successive speeds and then in a descending order.

Table 3: Viscosity of gel formulation of Calotropis gigantea

Sr. No.	Formulation	Viscosity (cps)
1	F11	1887
2	F12	1895
3	F21	1703
4	F22	1688
5	F31	1622
6	F32	1614

C) Spreadability

Spreadability can be expressed as the extent of area to which the gel readily spreads on application to skin or affects part.

Spreadability is calculated by using the formula: S = ml/tWhere, m = weight tied to upper slide, l = length moved on glass slide and t = time taken to separate the slides completely from each other. Spreadability of different formulation was recorded as below.

Table 4: Spreadabilty of formulation

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Formulation	T1	T2	T3	Mean Time	Spreadability
F11	6.4	6.5	6.4	6.5	23.12
F12	6.8	6.7	6.6	6.7	24.63
F21	5.4	5.7	5.7	5.6	27.52
F22	5.8	5.6	5.7	5.7	29.36
F31	5.0	5.1	4.9	5.0	31.20
F32	5.2	5.1	5.2	5.2	32.90

D) Drug content uniformity

1 gm of gel was accurately weighed and transferred to 100ml volumetric flask to which about 70ml of methanol was added and stirred followed by making up volume to 100ml with methanol. The content was filtered using filter paper. A quantity of 1 ml was pipette out from the filtrate and suitably diluted with methanol. Then the extract was estimated using Jasco V630 spectrophotometer at respective λ_{max}

 Table 5: Drug content study of prepared topical gel

 formulation

Tormulation						
Sr. no	Formulation	% drug content				
1	F11	54.2				
2	F12	63.3				
3	F21	76.4				
4	F22	81.8				
5	F31	89.8				
6	F32	93.3				

E) Extrudability

Extrudability can be expressed as the force required to extrude material out of the tube; determining the consistency of preparation.

The extrudability was calculated using the following formula:

Extrudability = Applied weigh to extrude gel from tube (gm) / Area (cm^2) .

Formulation	Net wt. of	Wt. of gel	Extrudability	Grade
	formulation	extruded (g)	amount (%)	
	in tube (g)			
F11	2	1.48	75.3	++
F12	2	1.44	73.0	++
F21	2	1.59	80.2	++
F22	2	1.56	76.0	++
F31	2	1.71	84.3	++++
F32	2	1.69	86.7	++++

 Table 6: Extrudability of formulations

4. Results and Discussion

The various physicochemical properties of the prepared gel formulations are shown above. From the result it is clear that all the gel formulation shows good gelling property and homogeneity. The pH of all 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 also 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 the increase in the viscosity of formulation, the spreadability decreased and vice versa. Thus the gel formulation F32 has all the desirable properties that must be present in an ideal gel formulation.

5. Conclusion

This research work was carried out to develop a new topical herbal gel formulation for topical application. The prepared herbal gel was further evaluated for pH, viscosity, extrudability, spreadability and drug content uniformity. The optimized formulation F32 complies with all the parameters.

6. Future Prospects

Calotropis gigantea leaves have anti-microbial and antifungi properties and the extract of leaves of this plant cannot be applied directly on skin, so a suitable formulation is required to for application. As the formulation may comply

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with all the parameters of an idea gel, it can be compete with any herbal marketed formulation. In-vivo studies and invitro studies are needed to be carried out using suitable model to make it suitable for application on human skin as well as the anti-microbial and anti-fungal activity will be carried out on different microbes and they will be compare.

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