DOI: https://doi.org/10.53555/nnas.v2i4.680 **Publication URL: http://nnpub.org/index.php/AS/article/view/680**

FORMULATION AND EVALUATION OF HERBAL GEL CONTAINING KIGELIA AFRICANA(LAM.) BENTH., FRUITS EXTRACT

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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 efficiency are serious concerns in industrialized and developing countries. The present research has been undertaken with the aim to formulate and evaluate the herbal gel containing Kigelia africana(Lam.) Benth., fruits extract. The gel formulation was designed by using Carbapol 940, Kigelia africana(Lam.) Benth., fruits extract, propylene glycol, methyl paraben, propyl paraben and required amount of distilled water. The skin pH (6.8-7.1) was maintained by drop wise addition of Triethanolamine. 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 Kigelia africana(Lam.) Benth.**, fruits 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*.

Keywords: *Kigelia africana(Lam.) Benth., aqueous extract, Carbapol 940, herbal Gel, skin irritation.*

1. INTRODUCTION

The whole plant of Kigelia africana(Lam.) Benth., belongs to the *Bignoniaceae* family and is widely cultivated throughout tropical and subtropical regions of the world, mainly in India and SouthAfrica. This is highly valued in traditional Indian medicine and is one of the most extensively used plants in Ayurvedic Encyclopedia[1]. Whole fruits contains 6-hydroxyluteolin-7-alpha-glucoside and luteolin which are Flavanol glycoside derivatives. luteolin is the active principle of *Kigelia africana(Lam.) Benth.*, exhibits leg oedemas, dermal irritations and infections, mastitis and retained placenta, antibacterial and antifungal properties[2]. Kigelia africana(Lam.) Benth., has been used in traditional systems of medicine and also by traditional healers especially in South region of India for the treatment of dermal irritations since ancient times[3] .

Reports suggest that Luteolin, important constituents of Kigelia africana(Lam.) Benth., have selectivity and affinity towards Benzodiazepine binding site on GABA receptor. Luteolin also inhibit the release of glutamate at cerebro cortical nerve terminals[4].

Among the skin care formulations, single-phase gel is extensively used for cosmetic products due to its aesthetic appearance[5] .Moreover, organic macromolecules are uniformly distributed throughout a liquid in such a manner that no apparent boundaries exist between the dispersed macromolecules and the liquid[6]. An ideal formulation for acne should spread easily and leave minimal residue or oiliness as it is meant for large hairy surfaces like the chest and the back. Carbopol®940 used for the formulation is an excellent viscosity builder even at low concentration and does not support microbial growth. In addition, it provides good plastic flow properties with significant yield value. Propylene glycol is a water-miscible co-solvent for carbopol®940 and acts as a preservative, humectant, plasticizer or stabilizer in a variety of pharmaceutical formulations[7]. Its penetration enhancement capability has attributed to increased transdermal flux of many drugs[8].

2. MATERIALS AND METHODS

2.1. Plant Materials

Collection, identification and authentication of raw Kigelia africana (Lam.) Benth.Fresh fruits of Kigelia africana (Lam.) Benth. were collected in a street in Eluru, west godavari district, Andhra pradesh, India. In july and authenticated by department of botony, Acharya Nagarjuna university, guntur, India. A herbarium is maintained in sir crr College of Pharmacy, Eluru, Andhra Pradesh, India.

2.2. Chemicals

Carbopol 940 (Merck Ltd), Methyl Paraban (Sigma Aldrich Cmemicals), Propyl Paraben (WIN Medicare Pvt. Ltd), Propylene glycol-400 (SD Fine Chemical Ltd), Triethanolamine (SD Fine chemical Ltd).

2.3. Animals

Albino rats of either sex weighing between 200-250 g procured from swetha enterprises, 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

2.4. Preparation of Topical Gel[9]

Different combinations of *Kigelia africana (Lam.) Benth., aqueous* extract (1% & 5%) was tried with different types of polymers (Carbopol 940) using various formulae. The following few combination with Carbopol 940 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.

2.4.1. Method for Preparation of Gel Containing Extract

1 g of Carbopol 940 was dispersed in 50 ml of distilled water kept the beaker aside to swell the carbopol 940 for half an hour and then stirring should be done to mix the carbopol 940 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 Kigelia africana (Lam.) Benth ., fruit 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 940 gel with continuous stirring and triethanolamine was added drop wise to the formulation for adjustment of required skin pH (6.87) and to obtain the gel at required consistency. The same method was followed for preparation of control sample without adding any *Kigelia africana (Lam.) Benth., fruits* extract.

Formulation

As per method described above the formulae were tabulated in Table 1. Along with control sample gel were prepared with addition of 1g and 5g of *Kigelia africana (Lam.) Benth ., fruits* extract to prepared 1% and 5% *Kigelia africana (Lam.) Benth .,* gel respectively.

2.5. EVALUATION OF TOPICAL GEL FORMULATION

2.5.1. Physical Evaluation

Physical parameters such as color and appearance were checked.

2.5.2. Measurement of pH

The pH of various gel formulations were determined by using digital pH meter. 2.5gm of gel was accurately weighed and dispersed in 25ml of distilled water and stored for two hours .The measurement of pH of each formulation was done.

2.5.3. Spreadibility[11]

Spreadibility was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end[10]. 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.

2.5.4. 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.

2.5.5. Extrudabilty[12]

The gel formulation were filled in standard capped collapsible aluminium tubes and sealed by crimping to the end. The weight of tubes were recorded and 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 extruded gel was collected and weighed. The percent of extruded gel was calculated as 1. When it is greater than 90% then extrudability is excellent.
2.When it is greater than 80% then extrudability is good. 3. When it is 70% then extrudability is fair.

2.5.6. Viscosity[13]

Viscosities of gels were determined using Brookfield viscometer. Gels were tested for their rheological characteristics at 25^{o}C using Brookfield viscometer (DV-III programmable Rheometer). The measurement was made over the whole range of speed settings from 10rpm to 100rpm with 30seconds between 2 successive speeds and then in a descending orders.

2.5.7. 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 cm2 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[14].
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[15].

3. RESULTS AND DISCUSSIONS

The herbal gel was prepared and subjected to evaluation of the various parameters. The herbal Gel was light brown 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 6.9 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 5% Kigelia africana (Lam.) Benth., showed better stability than 1%. 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
Control and medicinal crude drugs aqueous extract formulation prepared with this ingredients along with quantity

S.N0	INGREDIENTS	Control	F_1	F_2
1.	Carbopol 934	1 gm	1 gm	1 gm
2.	Methyl Paraben (0.5%)	0.4 ml	0.2 ml	0.2 ml
3.	Propylene glycol 400 (5%)	5 ml	5 ml	5 ml
4.	Triethanolamine (q.s)	1.2ml	1.2ml	1.2ml
5.	Distilled water	Upto 100 ml	Upto 100ml	Upto 100ml
6.	K.A Extract (1%)	_	1g	_
7.	K.A Extract (5%)	_	_	5g

K. A=Kigelia Africana (Lam.) Benth

Physical evaluation of all formulations

TABLE: 2 Stability of developed gels at Initial month at 35^{0}C
TABLE: 3 Stability of developed gels at second month at 30^{0}C

FORMULATION	COLOUR	APPEARANCE	pH	SPREADIBILITY (GM.CM/SEC)	Extrudability	Viscosity (Cps)
Control	White	Clear and Transparent	6.95 ±0.07	14.29±1.32	Excellent	1638±30
F_1 -1% K.A Extract	Light brown	Clear and Transparent	6.67±0.06	13.62±1.05	Excellent	1617±20.13
F_2 -5% K.A Extract	Light brown	Clear and Transparent	6.45±0.06	11.29±1.35	Good	1638±19.14

TABLE: 4 Stability of developed gels at third month at 28^{0}C

FORMULATION	COLOUR	APPEARANCE	pH	SPREADIBILITY (GM.CM/SEC)	Extrudability	Viscosity (Cps)
Control	White	Clear and Transparent	6.99 ±0.06	14.39±1.32	Excellent	1640±40
F_1 -1% K.A Extract	Light brown	Clear and Transparent	6.6±0.06	14.62±1.05	Excellent	1613±23.09
F_2-5% K.A Extract	Light brown	Clear and Transparent	6.6±0.06	11.29±1.35	Good	1640±40

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_1 -(1%)	A	A	A	A	A	A	A
F_6 -(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.

4. CONCLUSION

The plant Kigelia africana (Lam.) Benth., was selected for the study, whose extract was very useful in the treatment of wounds. Literature survey revealed that this plant is used traditionally for various ailments, especially for its wound healing property. Extensive scientific studies were not performed on this plant. It is an attempt made to establish the herbal gel containing Kigelia africana (Lam.) Benth., fruits extract at various concentrations (1% and 5%). The studies revealed that the developed single herbal formulation consisting 5% Kigelia africana (Lam.) Benth., 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.Its antibacterial and antifungal property was not under taken for any scientific study with herbal gel. Hence the present work is performed.

5. ACKNOWLEDGEMENTS

The authors thanks to Management, Sir C R Reddy College of Pharmaceutical sciences, Eluru, Andhra preadesh, India for providing required facilities to carry out this research work.

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