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Formulation and Evaluation of Herbal Topical Gel Containing Leaves Extract of *Andrographis paniculata*

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ABSTRACT

Objective: The present study has been undertaken with the aim to formulate and evaluate the gel contaning leaf extract of Andrographis Paniculata.

Methodology and results: The formulation was designed by using alcoholic extract of leaves of Andrographis paniculata.The gel was prepared by using carbapol 934, triethanolamine, propylene glycol, methyl paraben, propyl paraben and required amount of distilled water. The prepared gel was evaluated for physical appearance, pH, spread ability, viscosity, extrudability, albumin denaturation assay and stability.

Conclusion: Carbopol gels with dried leaves extract of Andrographis paniculata could be prepared successfully.

Key words: Topical gel,Kalmegh, Spreadability, Albumin denaturation.

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INTRODUCTION

Andrographis paniculata (AP) commonly known as Kalmegh in Hindi, Kalamegha in Sanskrit and *Kalmegh*in Bengali is an erect herb belonging to family Acanthaceae. It is found in India especially in Tamil Nadu, Karnataka, Maharashtra, Orissa, Uttar Pradesh and Uttarakhand. *Andrographis paniculata* (Burm.f.) Nees is one of the important herbs among 17,000 higher plant species occurring in India, out of which more than 1000 species are used over several centuries in the traditional systems of medicine viz. Ayurveda, Siddha and Unani. Morphological characteristics could have different chemical constituents and physiological variation but also plants with similar morphological features and growing on the same site may have different contents of chemical constituents and physiological variation. *Andrographis paniculata* or Kalmegh is one of the most widely used plants in ayurvedic formulation. Crude and alcoholic extracts of AP have been reported to have wide variety of pharmacological activities. Topical application of gels at pathologic sites after great advantage in faster release of drug delivery to site of action. The present investigation involves the preparation of gel formulation of alcoholic extract of leaves of *Andrographis paniculata* followed by the evaluation for physical appearance, pH, viscosity, spread ability, extrudability, albumin denaturation assay and stability[1, 2].

MATERIALS AND METHODS

Carbopol 934 (Research-lab fine chem. industries Mumbai), Triethanolamine (Research-lab fine chem. industries Mumbai), Propylene glycol(Research-lab fine chem. industries Mumbai), Methyl paraben (Research-lab fine chem. industries Mumbai), Propyl Paraben (Lab and General exports Pvt. Ltd., Bangalore)

Preparation of ethanolic extracts:

The dried leaves of *Andrographis paniculata* were obtained from the local market. 20gm of dried leaves powder of *Andrographis paniculata* were macerated with 200 mL of alcohol in a round bottom flask, heated until it boiling then kept 15 min for cooling, stand for 2-3 hours separately. Thereafter, it was filtered rapidly taking precaution to minimize the loss of alcohol. Percentage of alcohol soluble extractive was calculated with reference to the air dried sample[1].

Method of preparation of gel containing extract:

The Carbopol934was dispersed in 10 ml of distilled water, kept the beaker aside for half an hour for it to swell and then stirring was done to form gel. Required quantity of methyl paraben, propyl paraben and triethanolamine was dissolved in propylene glycol. Triethanolamine was slowly added to the dispersion with continuous stirring. Further, required quantity of *Andrographis paniculata* leaves extract was mixed to the above mixture and volume was made up to 10ml by adding remaining distilled water. The composition of herbal gel prepared from ethanolic extract of *Andrographis paniculata* is tabulated in the following table[2, 3, 4].

Table 1: Formulation table

		Formulation		
Sr No	Ingredient	G1	G2	G3
1	Extract (g)	0.1	0.1	0.1
2	Carbapol 934(g)	0.05	0.1	0.2
3	Triethanolmine (ml)	0.5	0.5	0.5
4	Propyleneglycol(ml)	5	5	5
5	Methyl paraben(g)	0.02	0.02	0.02
6	Propyl paraben(g)	0.05	0.05	0.05
7	Water QS to (g`)	10	10	10

Fig. 1: Dried powder

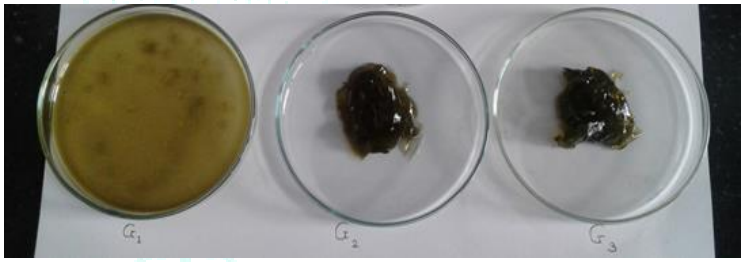

Fig. 2: Formulated gels

Evaluation of dried powder of *Andrographis paniculata*

Determination of Ash value

Total ash (TA) value: This value was determined using a minimum of 2.0-3.0 g of material in a furnace heated gradually to the ignition temperature of 650-700°C. Accurately 2 to 3 g of air–dried samples of *Andrographis paniculata* were weighed in a tared silica dish and incinerate at a temperature not exceeding 700°C until ash free from carbon is obtained. Then it was cooled and weighed. The process was repeated until at least two consecutive constant weights were obtained. The results are expressed as range or mean value standard deviation. The percentage of ash was calculated with reference to the air – dried drug.

Determination of acid insoluble ash (AIA): Above obtained ash was boiled with 25 mL of 2 M hydrochloric acid for 5 min, the insoluble matter was collected in a Gooch crucible or on an ash less filter paper, washed with hot water, ignited and cooled in desiccators. Then it was weighed. The percentage of acid insoluble ash was calculated with reference to the air-dried drug.

Determination of water soluble ash (WSA): Ash was boiled for 5 min. with 25 mL of water; the insoluble matter was collected in a Gooch crucible or on an ash less filter paper, washed with hot water, and ignited for 15 min at a temperature not exceeding 450°C. The weight of insoluble matter was subtracted from the weight of the ash, the difference in weight represent the water-soluble ash. The percentage of water-soluble ash was calculated with reference to the air-dried drug.

Loss on drying (LOD): Loss on drying of the air-dried samples of *Andrographis paniculata* was analyzed. This was carried out using a minimum of 0.5-1.0g of material. Accurately weighed quantity of sample was taken in a tared glass bottle and initial weight was taken. The sample was heated in an oven maintained at 105-110°C, for 3 h, after which the sample was allowed to cool to room temperature in desiccators, and subsequently weighed.

Phytochemical Investigation[3]:

Test for Alkaloids Crude extract was mixed with 2 ml of Wagner's reagent. Reddish brown colored precipitate indicated the presence of alkaloids**.**

Test for Cardiac Glycoside Keller-Kelliani test was performed to detect cardiac glycoside. Five ml of extract was treated with 2 ml of glacial acetic acid containing one drop of ferric chloride solution. This was underlayed with 1 ml of concentrated H2SO4. brown ring of the interface indicated a deoxysugar characteristic of cardenolides. A violet ring may appear below the brown ring, while in the acetic acid layer, a greenish ring may form just gradually throughout thin layer.

Test for Flavanoids Alkaline reagent test was performed to test the presence of flavonoids. Crude extract was mixed with 2 ml of 2% solution of NaOH. An intense yellow colour was formed which turned colourless on addition of few drops of diluted acid which indicated the presence of flavonoids.

Evaluation of herbal gel [3,4,5]:

Appearance and Homogeneity: Physical appearance and homogeneity of the prepared gels were evaluated by visual inspection[2].

pH: pH measurement of the gel was carried out using a digital pH meter by dipping the glass electrode completely into the gel system to cover the electrode. The measurement was carried out in triplicate and the average of the three readings was recorded[2].

Viscosity: Viscosity of gel was determined using Brookfield viscometer (Model CAP2000+)at 25^{0}C with a spindle speed of the viscometer rotated at 12 rpm.

Spreadablity: Two sets of glass slides of standard dimensions were taken. The herbal gel formulation was placed over one of the slides. The other slide was placed on the top of the gel, such that the gel was sandwiched between the two slides in an area occupied by a distance of 7.5 cm along the slides. 100 gm weight was placed on the upper slides so that the gel between the two slides was pressed uniformly to form a thin layer. The weight was removed and the excess of gel adhering to the slides was scrapped off. The two slides in position were fixed to a stand without slightest disturbance and in such a way that only upper slides to slip off freely by the force of weight tied on it. A 20 g weight was tied to the upper slide carefully. The time taken for the upper slide to travel the distance of 7.5 cm and separated away from the lower slide under the influence of the weight was noted. The experiment was repeated for three times and the mean time was taken for calculation[2].Spreadability was calculated by using the following formula:

$S = m \times l/t$

where, S= spreadability, m-weight tied to upper slides (20 g), l- length of the glass slide (7.5 cm), t- time taken in sec.

Extrudability: The gel formulations were filled in standard capped collapsible aluminum tubes and sealed by crimping to the end. The weights of tubes were recorded. The tubes were placed between two glass slides and were clamped. 500 gm was placed over the slides and then the cap was removed. The amount of the extruded gel was collected and weighed[3]. The percent of the extruded gel was (>90% extrudability: excellent, >80% extrudability: good,

>70% extrudability: fair).

In-Vitro Anti-inflammatory activity (Inhibition of Albumin): The extract was screened for anti-inflammatory activity by using inhibition of albumin denaturation technique. Test solutions containing different concentration of extract was mixed with 0.2 ml of egg albumin and 2.8ml of phosphate buffered saline (PBSpH6.4). The samples were incubated at 37^{0}C for 15 min and heated at 70^{0}C for 5 min. After cooling the absorbance was measured at 660nm in UV-Vis spectrophotometer. The percentage inhibition of protein denaturation was calculated using the formula [6, 7, 8] % inhibition= (Vt/Vc-1)*100

Were Vt=Absorbance of test sample and Vc =Absorbance of control

Stability study: Stability studies were performed as per ICH (International Conference on Harmonization) guidelines. The formulated gel was filled in the collapsible tubes and stored at different temperatures and humidity conditions, viz., 25°C ± 2°C and 60% ± 5% RH, 30°C ± 2°C and 65% ± 5% RH, 40°C ± 2°C and 75% ± 5% RH for a period of three months and studied for changes in appearance, pH and spreadability [2].

RESULTS AND DISCUSSION

The herbal gels were prepared and evaluated for various parameters. The gel was greenish in colour with translucent appearance. The pH of the gel formulations were in the range of 7.1 to 7.2. Viscosity and spreadability was measured to ensure uniform application of gel. Extrudability was excellent but was found that concentration of carbopol affects viscosity of the gel. Anti-inflammatory activity of the extracts was carried out by screening it for albumin inhibition method.

Table 2: Properties of Extract

Parameter	Observation
Colour	Green
Odour	Odourless
Appearance	Translucent
Extractive value	0.36 g

Table3: Determination of Ash values

Sr No	Parameters	Ash values (%w/w)
1	Total Ash	9%
2	Acid insoluble Ash	2.10%
3	Water soluble ash	1.50%
4	LOD	10.50%

Table 4: Results of phytochemical evaluation

Test	Observation	Result
Alkaloid	Reddish brown colored precipitate	Alkaloid present
Glycoside	Brown ring	Cardiac glycoside present
Flavonoid	Yellow color	Flavonoids Present

Table5: Evaluation of gel

Sr no.	Carbapol 934	Physical appearance of gel	pH	Viscosity (poise)	Spreadabality (g cm/sec)
1	0.05g	Green, smooth and Translucent	7.1	0.372	26.78
2	0.1g	Greenish, smooth and translucent	7.2	0.365	37.5
3	0.2g	Greenish Sticky	7.2	0.389	44.11

Table6: Extrudability in the initial month

Extrudability	Mean of three tubes
Net wt of formulation in tube (g)	12.34
Wt of gel extruded (g)	11.32
Extrudability (percentage)	91.73

Table7: Anti-inflammatory activity

Extract code	Absorbance values	Inhibition of denaturation (%)
Control	0.0939	-
E1	0.1139	21.3
E2	0.1772	88.71
E3	0.2443	160.17
E4	0.2889	207.66
E5	0.3074	277.36

Table8: Stability study of G2formulation

Parameters	At 25ºC ± 2ºCand 60% ± 5% RH			
	Months			
	0	1	2	3
Appearance	Homogeneous	Homogeneous	Homogeneous	Homogeneous
pH	7.2	7.2	7.2	7.2
Spreadability(g cm/sec)	37.5	37.5	37.5	37.5
At 30ºC±2ºC and65%±5%RH				
Appearance	Homogeneous	Homogeneous	Homogeneous	Homogeneous
pH	7.2	7.2	7.2	7.2
Spreadability(g cm/sec)	37.5	37.5	37.5	38.5
At 40ºC±2ºC and75%±5%RH				
Appearance	Homogeneous	Homogeneous	Homogeneous	Homogeneous
pH	7.2	7.2	7.2	7.2
Spreadability(g cm/sec)	37.5	37.5	38.5	38.5

CONCLUSION

The various properties of the prepared gel formulations were evaluated and it is inferred from results that the gel formulations are good in physical appearance, homogeneity and spreadability.

Further studies to be performed to confirm its anti-microbial and anti-inflammatory effects.

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