

FORMULATION AND EVALUATION OF TOPICAL HERBAL GEL FOR LOCAL INFLAMMATION

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ABSTRACT

Plant derived formulations and medicines have recently attracted great population interest towards their resourceful application. Medicinal plants being the richest source of bioactive compounds used in traditional and modern medicine have great significance with respect to formulations made out of ethanopharmacological background. Even in areas where modern medicine is available, the interest on herbal medicines and their utilization have been increasing rapidly in recent years. The present work is to formulate and evaluate the gel formulation of *Tridax procumbens* extracts. The ethanolic extracts were used for the formulation. After completion of formulation 006E it

was evaluated for its physicochemical parameters like colour, odour, pH, spreadability, extrudability, consistency, diffusion study, solubility, washability. Also the formulations were evaluated for its stability at various temperature conditions which shows no change in the irritancy, spreadability and diffusion study. Thus, it could become a media to use the medicinal properties of *Tridax procumbens* effectively and easily as a formulation forms like gel.

KEYWORDS: *Herbal gel, Inflammation, Tridax procumbens extract.*

1. INTRODUCTION

Herbal is a major component in all traditional medicine and a common element in Ayurvedic medicine. The traditional Indian systems of Ayurveda and Siddha medicines support the importance of medicinal plants to treat diseases. In India 70% of population is reported using traditional medicine for primary health care. Skin has been considered as promising route for administration of drug because of its accessibility and large surface area. Topical gel

preparations are intended for skin application or to certain mucosal surfaces for local action or percutaneous penetration of medicament.

Gels are typically semi-solid formulations having a liquid phase that has been thickened with other components. The liquid phase allows free diffusion of molecules through the polymers scaffold and hence release should be equivalent to that from a simple solution.

Tridax procumbens^[1] commonly known as tridax daisy is a species of flowering plant in the Asteraceae family. It is native to the tropical America, but it has been introduced to tropical, subtropical, and mild temperate regions worldwide. It is a spreading annual herb and grows up to 20 cm. *Tridax procumbens*^[2,3] has been studied for several potential therapeutic properties including antiviral, anti-inflammatory^[4-6] antibiotic, anti-microbial^[7], wound healing^[8], and antioxidant^[9,10] activities in *in vitro* studies and animal models. Keeping this in view, we have formulated a semisolid poultice preparation in the form of a gel, for topical anti – inflammatory activity. Formulation was prepared from rutin^[11] rich fraction of *Tridax procumbens* ethanolic extract having which shows significant anti-inflammatory action.

2. MATERIAL AND METHOD

2.1 Preparation of ethanolic extract: The plant material was collected locally, identified, authenticated and dried and further grinded to coarse powder for extraction. Hundred grams of powdered leaves were extracted with ethanol as a solvent by hot extraction method using soxhlet apparatus. The extract was cooled and filtered. The resulting extract was treated with lead acetate to precipitate tannins and filtered again. The filtrate was evaporated in vacuum to give a residue.

2.2 Formulation of topical preparation

The required quantity of polyvinyl alcohol (PVA) was slowly sprinkled into weighed amount of purified water with constant stirring to get the uniform dispersion and then kept overnight for hydration. The accurately weighted amounts of extract along with other additives are poured into the fixed amount of hydrated PVA dispersion with constant stirring. All the ingredients were blended using mechanical stirrer until the homogenous gel was formulated. The composition of herbal gel prepared from ethanolic extract of *tridax procumbens* is tabulated in the following table.

Table 1: Formulation table.

SR. NO	Ingredients	Quantity	%
1	PVA	8.247g	41.235
2	PEG	2.062g	10.31
3	CMC	0.515g	2.575
4	Gelatin	1.03g	5.15
5	Ethanollic Extract of <i>T.procumbens</i>	8.14g	40.7
6	Eucalyptus oil	0.01g	0.05

3. RESULTS

The herbal gel was prepared and subjected to evaluation of various parameters. The gel was yellowish in colour with a translucent appearance.

3.1 Viscosity^[12]

Gels were tested for their rheological characteristics at 25⁰C using Brookfield viscometer. The measurement was made over the whole range of speed settings from 10 rpm- 100 rpm with 30 seconds between 2 successive speeds and then in ascending orders.

3.2 Extrudability^[13]

The gel formulations were filled in standard capped collapsible aluminum 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. 500 gm. 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).

3.3 Spreadability^[14]

Spreadability was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end. By this method spreadability was measured on the basis of slip and drag characteristics of gels. An excess of gel (about 2 g) under study was placed on the ground slide. The gel was then sandwiched between this slide and another glass slide having the dimension of fixed ground slide and provided with a hook. A 1 kg weight was placed at 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 was noted. A shorter interval indicated better spreadability. 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 upper slide from the ground slide.

3.4 Stability study^[15]

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

3.5 pH^[16]: The digital pH meter was used to determine the pH of gel formulation. 2.5gm of gel was accurately weighed and dispersed in 25ml of distilled water and stored for two hours. The measurement of pH of formulation was carried out in triplicate.

3.6 Drug content uniformity

About 1 gm of gel was accurately weighed and transferred to 100ml volumetric flask to which about 70ml of methanol was added. After mixing, the volume was made up to 100ml with methanol. The content was filtered using filter paper. A quantity of 1ml was pipette out from the filtrate and suitably diluted with methanol. Then the extract was estimated spectrophotometrically by using Shimadzu UV/VIS spectrophotometer at 359 nm. Drug content uniformity with reference to Rutin as standard= 1.06%.

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 in tube (g)	15.62±0.011
Wt. of gel extruded (g)	14.32±0.014
Extrudability amount percentage	91.67±0.005

Table 3: Viscosity of the herbal gel at the time of preparation.

RPM	Viscosity (cps) – Initial month
50	132000
75	115000
100	78000
150	31,000

Table 4: Spreadability of the herbal gel during the evaluation period (Mean \pm SEM).

Evaluation Condition	Spreadability (g.cm/sec) Mean of three readings
Initial month	17.03 \pm 0.011
After 3 months at 25 \pm 2 °C/ 60 \pm 5% RH	17.01 \pm 0.011
After 3 months at 30 \pm 2 °C/ 65 \pm 5% RH	16.98 \pm 0.010
After 3 months at 40 \pm 2 °C/ 75 \pm 5% RH	16.92 \pm 0.011

Table 5: pH during the evaluation period.

pH	5.5
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4. CONCLUSION

Many formulations are made using ethanobotanical and ethanopharmacological background of the drugs used. The leaves extract of *Tridax procumbens* plant belongs to family Asteraceae was taken for this present study and formulated for the topical gel and its properties. Herbal gel formulation containing leaf extract of *Tridax procumbens* was successfully prepared with PVA and CMC as a gelling agent. The contents of developed herbal extract-based gel were propylene glycol as plasticizer, methyl and propyl paraben as preservative. The gel prepared using *Tridax procumbens* leaf extract was found to be good gel characteristics with respect to homogeneity, spreadability, pH, viscosity, extrudibility and stability. Further anti-microbial and pharmacological studies can be performed to for further evaluation.

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