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Development and Evaluation of Herbal gel for the treatment of Inflammation

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Abstract

Inflammation is a pathophysiological response of living tissues to injuries that leads to the local accumulation of plasmatic fluid and blood cells. Although it is a defense mechanism, the complex events and mediators involved the inflammatory reaction can induce, maintain or aggravate many diseases. Therefore, the uses of anti-inflammatory agents are helpful in the therapeutic treatment of these pathologies. In this context, medicinal plants are widely used in folk medicine of many countries to treat different inflammatory conditions and, in particular, skin inflammations. Present work was designed to formulate herbal gel using extract of *Sarcosteema acidum* stem which provide better efficacy and to ensure biological evaluation of prepared herbal gel for safety and efficacy.

Keywords: Inflammation, Herbs, *Sarcosteema acidum,* Formulation, Evaluation, Gel

Introduction

Drug delivery through the skin has been a promising concept for a long time because the skin is easy to access, has a large surface area with vast exposure to the circulatory and lymphatic networks and the route is non-invasive. Gel consists of a natural or synthetic polymer forming a three-dimensional matrix throughout a dispersion medium or hydrophilic liquid. After application, the liquid evaporates leaving the drug entrapped in a thin film of the gel–forming matrix physically covering the skin. [1-2]

Many anti-inflammatory drugs (both NSAIDs and corticosteroids) have been developed but their safety profile studies have shown that none of them is clearly safe. They show wide ranges of adverse effects. Due to adverse reactions of synthetic and chemical medicines being observed round the globe, herbal medicines have made a comeback to improve our basic health needs. Many plants and herbs such as ginger, turmeric, olive oil, have been shown to exhibit potent anti-inflammatory effect.[3-5]

The presence of a network formed by the interlocking of particles of the gelling agent gives rise to the rigidity of a gel. The nature of the particles and the type of form that is responsible for the plant *Sarcostemma acidum* commonly known as Somlata is herb. The plant has the height of 2-4 feet and mostly occurs in India, Pakistan, Bhutan, and Africa. The plants have presence of latex in stem.[6-7]

There is utter need to formulate safe and effective anti-inflammatory formulation for the treatment of inflammation. The plant *Sarcosteema acidum* is selected because as per the literature it was reported to consist anti-inflammatory action. The formulation of same will be beneficial for the treatment of several types of inflammation.

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In the present work the formulation and evaluation of herbal gel of *Sarcosteema acidum* for antiinflammatory activity is planned.

Material and Methods

Selection, Collection and Authentication of Plant material

The plant *Sarcosteema acidum* was selected due to its importance in traditional system of medicine in the treatment of medicine. As per reported literature it was observed that the plant species has anti-inflammatory activity. It was also observed that no work has been reported on the formulation of the herb till date, therefore the present plant was selected. The dried stem and roots of herb *Sarcosteema acidum* was collected from the local area of Chopda, MH. The plant part (stem and roots) was authenticated by Dr. H. Ansari, Assistant Professor Botany Department, Science College, Chopda, (MH), a voucher specimen no. SA/S/2019-12 was coded for further reference.

Extraction of Plant material

The air dried and crushed stem and roots of *Sarcosteema acidum* (about 250 gm) was taken and extracted with ethanol as a solvent using soxhlet apparatus for 72 hr. After extraction the solvent was cooled and was filtered by whatsman filter paper size No.1. The extract was dried under reduced pressure using rotatary evaporator and was concentrated.[8-9]

Formulation of *In situ* Herbal gel[10-11]

The herbal gel of the stem and root extract of *Sarcosteema acidum* was prepared. The carbopol 934 was dissolved slowly in de-mineralized water with continues stirring for 1hr to avoid agglomeration. The beaker was kept aside. In another beaker xanthum gum and propylene glycol was taken and added. Both were dissolved in 10 ml of de-mineralized water with contious stirring for 10 min to insure homogenous solution. In third beaker HPMC K 100M was taken and 12 ml of de-mineralized water was added with continous stirring for 10 minutes. The solution of second beaker was added to beaker containing carbopal 934 with continues stirring for 10min and the pH was adjusted to 7.4. In the above mixture the HPMC K 100 M solutions were added with continue stirring for 10 min. The stirring was done to achieve clear and consistent gel base. To the clear gel base weighed quantity of extracts as specified in table 5.1 was added with continuous stirring and volume was adjusted with de-mineralized water. Eight different herbal gel formulations were prepared using ethanolic extracts of stem & roots of *Sarcosteema acidum* (EESAS) and (EESAR) as mentioned in Table 1.

Table 1: Formulation of different batches using stem & roots of *Sarcosteema acidum*

FC	EESAS	EESAR	C	HPMC	XG	PG	MP	PP	DMW
HG1	1	-	1	-	0.5	10	0.2	0.5	100
HG2	1	-	-	1	1	10	0.2	0.5	100
HG3	1	-	1.5	-	1.5	10	0.2	0.5	100
HG4	1	-	-	1.5	2	10	0.2	0.5	100
HG5	-	1	1	-	0.5	10	0.2	0.5	100
HG6	-	1	-	1	1	10	0.2	0.5	100
HG7	-	1	1.5	-	1.5	10	0.2	0.5	100
HG8	-	1	-	1.5	2	10	0.2	0.5	100

Evaluation Parameters of Herbal gel

The prepared formulations were evaluated for the following parameters:[10-11]

Physical evaluation

The physical evaluation of the formulation was done by evaluating clarity and transparency which was determined visually. The samples were observed in light at white background.

Determination of pH of Formulation

The pH meter was calibrated first and zero reading was recorded. The samples were taken in the beaker and the readings were taken from calibrated electrode. The procedure was repeated and three average reading was recorded.

Determination of Gelling capacity

Visual method was employed for determination of the gelling capacity. Near about 100µl of gel sample was taken in a vial. To the above freshly prepared artificial tear fuild was added and the solution and equilibrated at 35 ^{0}C. The procedure of gel formulation was assessed and time taken for the formation of gel was recorded.

Determination of Gelation temperature

Test-tube-inverting method was used to determine the gelation temperature of the samples. About 2 ml of the formulated gels was taken in a test tube and was kept on water bath. The temperature was kept at room temperature and increase gradually. The formulation was examined after every two minutes. The temperature at which the gel stops flowing was recorded. Three times the experiment was repeated and every reading was reported.

Determination of Viscosity of gel

The viscosity of the gel formulation was determined by Brookfield viscometer using spindle no 01 at 20 rpm at temperature 4 °C and 37°C. About 15ml of the gel formulation was taken in beaker and spindle was immersed in the formulation. The reading was recorded at initial and after rotation at different temperature. The reading was recorded thrice.

Determination of Syringeability

The syringeability studies was done on the gel formulation. It was done to check the flowing ability through 21 gauge needle The syringeability was checked for the ability of the flow property. The gel was kept at cold temperature and 1ml of gel was filled and the ability of gel to flow at normal pressure was observed.

Determination of Extrudability

The extrudability property of gel was determined to check the amount extrude from collapsible tube. Near about 20g of gel was place in collapsible tube and sealed. At the crimped end of collapsible tube the formulation was firmly presses. To prevent the rolling back of gel the clamps was applied. The cap of collapsible tube was taken off and formulation was force out. The formulation gets extruded which was collected and weighed in weighing bottle.

Determination of Spreadibility

The spreadibility was determined for all the gel formulation. The gel was placed on the glass slide and the empty glass slide was place on the top of gel containing slide. The formulation was placed in such as way that it was placed between two slides. The occupied distance of the slides was observed to be of 7.5 cm. The gel was placed between slide and pressed form thin uniform layer. The weight kept on the gel was removed. The excess gel observed in the slides was removed.

The two slides were fixed and on the upper glass slide the 20 ±0.5 g of the weight was tied. Due to weight the both the slides were separated which was recorded as time to complete the separation distance of 7.5 cm. The three readings were recorded and mean time was taken.

The spreadabilty was calculated as

$$S = m \times l/t$$

l is the length of slide (7.5 cm), m is the weight which is tied to slides and t is the time taken in second.

Determination of Drug content

The content of the formulation was estimated using UV-Visible spectrophotometer. Near about 1g of the gel formulation was taken in 50 ml of volumetric flask. The solution was make up to mark with methanol. The solution was shaked and filtered though whatman filter paper. The 0.1ml of the filterate was further diluted to 10ml with solvent and estimated at 560 nm.

Results and Discussion

Sarcosteema acidum commonly known as somlata belongs to family Asclepidiaceae have been evaluated for may pharmacological activity and the same has been reported in literature. The palnt species have been phytochemically screened and numbers of chemical constituents have been reported. The present work caries the results of formulation and evaluation of herbal gel containing two extracts of *S. acidum* The dried stem and root powder of *Sarcosteema acidum* was extracted with ethanol. The percentage yield of extract thus obtained has been mentioned in table 2.

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Table 2: Percentage yield of Extract

Sample Code	Weight of crude drug taken (gm)	Amount of extract obtained (gm)	% Yield of extract (w/w)
EESSA	100	10.28	10.28
EESAR	100	9.26	9.26

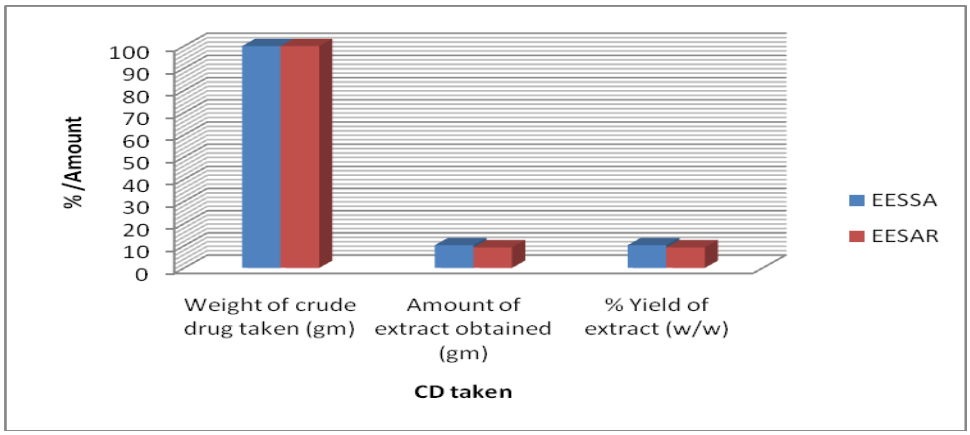

Fig. 1: Percentage yield of Extract

Evaluation of *In situ* Herbal gel

In the present study, an attempt was made to develop and evaluate herbal gel formulations of ethanlic extract of stem and root extract *S. acidum*. HG1 to 8 was formulated using different concentration of extract. The formulated herbal gel was evaluated for various parameters viz., physical appearance, pH, gelling capacity, gelation temperature, viscosity, Syringeability study, Extrudability, Spreadability and drug content. The result of evaluation parameters of formulated herbal gel was mentioned in table 3. Drug release profile was studied for all the formulated batches.

Table 3: Evaluation parameters of herbal gel

Evaluation Parameters	Formulations							
	HG1	HG2	HG3	HG4	HG5	HG6	HG7	HG8
Clarity	Unclear	Clear	Clear	Clear	Clear	Clear	Clear	Unclear
pH	7.14	7.07	7.10	7.05	7.01	6.98	7.03	7.12
Gelling capacity	+	++	++	+++	++++	++++	+++	+++
Gelation temperature	25.22	28.22	30.26	30.42	32.81	31.92	30.83	24.12
Viscosity (Poise)	0.3912	0.3810	0.3819	0.3879	0.3984	0.3817	0.3811	0.3310
Syringeability study	E	E	E	E	E	E	E	E
Extrudability (%)	94.18	96.58	97.57	98.18	99.83	97.51	98.21	92.18
Spreadability (gcm/sec)	57.40	62.40	69.34	70.48	72.49	69.39	67.41	58.40
Drug content (%)	88.32	91.32	94.22	95.92	99.82	92.10	89.48	87.22

++++= Excellent; +++=Very good, ++= Good, +=Satisfactory

The results of drug content of herbal gel for ethanolic extracts were indicated in Figure 2. The drug content was observed maximum in HG5 ehere as lowest in HG8, therefore the formulation code HG8 is chosen for further studies.

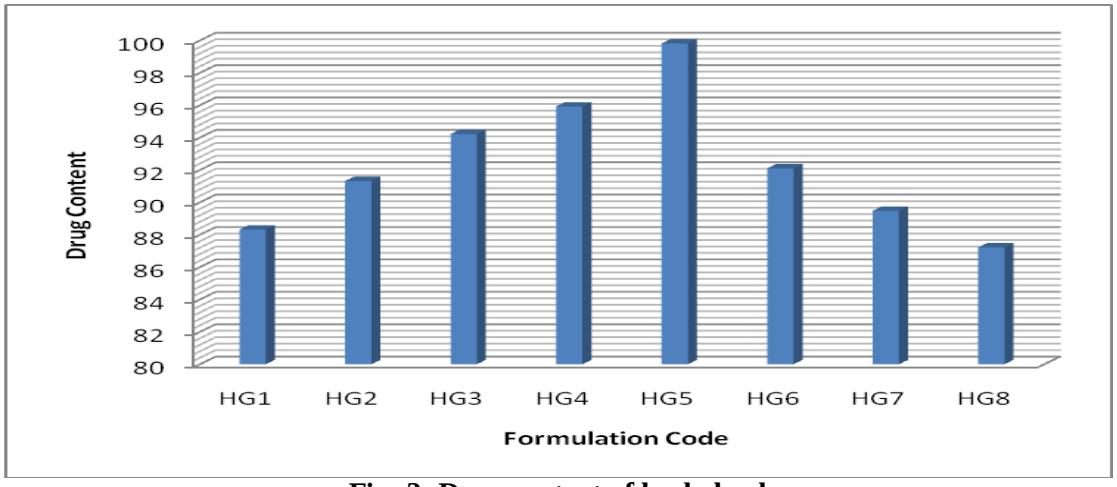

Fig. 2: Drug content of herbal gel

Conclusion

In the present work the herbal gel was formulated for effective and safe treatment used for the treatment of inflammation. The formulated herbal gel has passed the evaluation tests and are successful formulation for drug delivery. The *S. acidum* is medicinally important plant grown wildly in India and is useful in the treatment of inflammations by tribal's and rural people of India. Hence, the present plant is s selected to formulate herbal gel using *S. acidum* as active ingredients for the treatment of inflammation

The stem and root of plant were collected; dried and powdered plant material was extracted with ethanol. The percentage yield of ethanolic extract of stem and root was found to be 10.28 % w/w and 9.26% w/w respectively. Eight different batches of formulation (HG-1, HG-2, HG-3, HG-4, HG-5, HG-6, HG-7, HG-8) were prepared using ethanolic extract of *S. acidum* stem and roots.

HG-1 – HG-4 was formulated using ethanolic extract of stem and HG-5 – HG-8 was formulated using ethanolic extract of root. In above mentioned both the extract different proportion of Carbopol, HPMC and xanthum gum was added with different concentrations.

Various evaluation parameters such as physical appearance, pH, gelling capacity, gelation temperature, viscosity, Syringeability study, Extrudability, Spreadability and drug content were performed to evaluate the formulated herbal gel.

From the results observed it was concluded that all the prepared herbal gel i.e., HG-5 (ethanolic extract of root) has good clarity and transparency. The pH so obtained was within the limit as for most of the preparation indented to be used for skin. All the formulations were tested for pH value which was observed to be neutral in almost all cases 6.98-7.14 pH which has indicated that formulation has no skin irritation during application.

The gelling capacity and gelation temperature were found within the limit. The viscosity was found to be in limit. The ideal viscosity readings were reported between 0.38 and 0.39 poise which indicated the optimum herbal gel formulation using HPMC polymers.

The results of spreadibility showed that the formulations spreadable and were easily extrudable. This has indicated the excellent property of gel.

The drug content was found to be maximum of 99.82 (HG-5) followed by 98.21 (HG-7). From the data obtained it was concluded that the herbal gel formulated using ethanolic extract of roots of *S. acidum* was found to be more potent and efficacious than ethanolic extract of stem of extract of *S. acidum*.

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