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Formulation And Characterization of Herbal Gels

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ABSTRACT
Gels are three-dimensional, semi-solid polymeric compositions made up of a lot of liquid and a tiny quantity of solid that is spread throughout it. A solid, jelly-like material, herbal gel can range in consistency from soft and weak to firm and stiff. Numerous studies have been conducted on these topical preparations. Because of their natural origins, safety profiles, and medicinal potential, herbal gels have attracted a lot of interest lately. It is used topically for a number of ailments, including headaches. *Evodia rutaecarpa, Hypericum perforatum* and *Tanacetum parthenium* were combined to create the herbal gel. The herbal gel was shown to have the most potent effect on headaches. The creation of a unique herbal gel intended to provide topical therapy for headache disorders is described in this abstract. The produced gels were tested for homogeneity, toxicity, spreadability, pH, and physical appearance. The findings showed that the gel formulations were homogeneous and had a nice look. The spreadability values revealed that these herbal gels could be spread with little shear force. All formulations had a pH of about 6, which is within the skin's typical pH range. Under cold storage conditions, the preparation showed stability. Further study is necessary to completely comprehend the mechanism of action and to develop a formulation that can be helpful in the health sector.
Keywords: Plant extract, Herbal gel, Polyherbal formulations.

1. INTRODUCTION

Gels are semisolid systems made up of big organic molecules interspersed with liquid or suspensions of tiny inorganic particles. Gels can be based on organic solvents or water. Pastes are semisolid dosage forms made up of a considerable amount of finely distributed particles combined with one or more medicinal ingredients. A semisolid dosage form can be prepared using a variety of source ingredients. Beyond the standard pharmaceutical compounds like antioxidants, preservatives, and solubilizers, the fundamental components of a semisolid dosage form are specific to its makeup. The fundamental ingredients needed to create different semisolid dosage forms. When developing a formulation, the criteria for drug administration and the specific necessity to provide adequate emolliency or other quasi-medicinal properties to the formulation are taken into consideration when selecting appropriate raw ingredients. Semisolid dosage forms are typically used to deliver drugs locally. However, these forms have also been investigated in recent years for the systemic distribution of different medication compositions. The process of creating a semisolid dosage form that is appropriate requires choosing a drug carrier system that best suits the medication's physicochemical characteristics and necessary therapeutic use.

A gel is a system comprising at least two parts that is solid or semisolid and is made up of a condensed mass that is surrounded and permeated by a liquid. A gel is a soft material that resembles solid jelly and can range in consistency from soft and weak to firm and robust. Gels are described as a significantly diluted cross-linked system that, in its steady-state, shows no flow.

As an illustration: A gel would be something like fruit jelly. Another type of gel is gelatin that has been cooked and cooled. Gelatin's protein molecules crosslink to create a solid mesh with liquid-filled areas (Felton L et al, 2013). Based on the kind of bonding, gels might be irreversible or reversible. Whereas irreversible gels are often covalently bonded, reversible gels are typically hydrogen bonded systems. A gel can show up as a two-phase system with floccules of distinct particles, or it can show up as a single system with no obvious boundaries. The solvent penetrating into the gel causes swelling, which in turn causes the polymer network to stretch, maintain its shape, and entangle the drug particles within it. To raise the viscosity of a gel in its solution form, a certain concentration of polymer is needed. (**Labarre D *et al*, 2010**).

2. METHODOLOGY

2.1 Formulation development of polyherbal gel

After measuring 100 ml of water, dissolving the leaves of *Tanacetum parthenium, Hypericum perforatum, and Evodia rutaecarpa* measuring the amounts of methyl paraben, glycerin, and polyethylene glycol, the mixture was vigorously stirred using a mechanical stirrer, also known as a sonicator. Then, while stirring, Carbopol 934 was gradually added to the beaker holding the liquid above. A slow-moving triethanolamine solution was added to the mixture to neutralize it, and stirring was done continuously until the gel formed.

Table 2.1: Formulation of polyherbal gel

Ingredients (mg)	F1	F 2	F3
Tanacetum parthenium extract	400	400	400
Hypericum perforatum extract	400	400	400
Evodia rutaecarpa extract	400	400	400
Carbopol 934	1000	1500	2000
Polyethylene Glycol 600	0.2	0.2	0.2
Methyl Paraben	0.08	0.08	0.08
Triethanolamine	1.0	1.0	1.0
Distilled Water	100 ml	100 ml	100 ml

2.2 Evaluation of polyherbal gel

2.2.1 Appearance and consistency:

A visual examination of the texture of the polyherbal gel formulations was conducted, and the results are recorded in the results chapter.

2.2.2 Washability

The outcome chapter contains the findings of manual testing the degree and simplicity of water washing following the application of prepared formulations to the skin.

2.2.3 Extrudability

The polyherbal gel formulations were placed within aluminum collapsible tubes, which were then sealed. Pressure was used to extrude the material through the tubes, and the extrudability of the formulation was monitored.

2.2.4 Determination of Spreadability

Spreadability is the term used to describe how easily a gel sticks to skin following application. The medical effectiveness of a formulation is also influenced by its spread-value. The amount of time it takes for two slides to separate decreases with increasing spreadability. The average of six of these results was calculated for each formulation after the experiment was repeated.

$$\boldsymbol{Spreadability} = \frac{m * l}{t}$$

2.2.5 Determination of pH

A digital pH meter had been used to measure the anti-acne gels' pH. Twenty-five milliliters of filtered water were used to dissolve one gram of gel. The electrode was then immersed in the gel solution until a consistent reading was achieved. For each formulation, there were two pH measurements conducted.

2.2.6 Drug content

A 10ml volumetric flask containing one gram of gel combined with methanol was used to test the drug's composition. One milliliter of 2% AlCl3 solution and three milliliters of stock solution have been combined. After the mixture was vortexed for 15 seconds and the color creation was allowed to stand at 40°C for 30 minutes, the absorbance at 420 nm was measured using a spectrophotometer.

2.2.7 Viscosity

A digital viscometer made by Brookfield was used to determine the created gel's viscosity. Using spindle number six, the viscosity was tested at 10 rpm and 25–30 ºC ambient room temperature. a perfectly sized, mouth-fitting container that holds the ideal amount of gel. By using a big mouth container, the viscometer spindle may be kept inside the jar. The viscosity was tested once the reading stabilized.

2.2.8 *In vitro* diffusion profile

Franz diffusion cells were used for the in vitro diffusion studies of each formulation. constructed locally as an open-ended, cylindrical tube with a diffusion area of 3.8 cm^2, a height of 100 mm, and a size of 3.7 cm^2. For the cultivation of receptors, phosphate buffer (pH 7.4) was utilized. The network's average temperature was maintained at 37±1^{0}C. Following each withdrawal, the diffusion medium was replenished with an equivalent volume of new material. The total percentage release for each time period was calculated.

2.2.9 Skin Irritation Study

A 6 cm^2 skin area was treated with 0.5 gm of the herbal gel test component, and the area was covered with a gauze patch. The patch was kept in place for an hour by removing the gauze and applying a semi-occlusive dressing. The remaining test material was eliminated an hour after exposure without affecting the epidermis's integrity or reaction.

2.2.10. Stability Study

The stability investigation was carried out in accordance with the ICH guidelines. The resulting gel was put into collapsible tubes and kept for six months at different humidity and temperature levels: 250 C ± 20C / 60% ± 5% RH, 300 C ± 20C / 65% ± 5% RH, and 400 C ± 20C / 75% ± 5% RH. During this period, the gel's appearance, pH, viscosity, and spreadability were noted.

3. RESULT AND DISCUSSION

3.1 Evaluation of formulated Polyherbal gel

3.1.1 Physical Characteristics

It has been observed that the gel formulations mentioned above all have smooth textures, good homogeneity, no clogging, and clear colors. The gel compositions mentioned above offer good extrudability and washability.

Table 3.1: Results of Physical Characteristics

Formulation	Colour	Clogging	Homogeneity	Texture	Washability	Extrudability
F1	Green	Absent	Good	Smooth	Good	Good

F2	Green	Absent	Good	Smooth	Good	Good
F3	Green	Absent	Good	Smooth	Good	Good

3.1.2 Results of Spreadability

Table 3.2: Results of spreadability of polyherbal gel

S.N.	Formulation	Spreadability* (gcm/sec)
1	F1	13.07±0.26
2	F2	12.92±0.85
3	F3	12.19±0.41

3.1.3 Results of Viscosity

Gel viscosity was measured using a Brookfield viscometer type DV-II. Based on the slip and drug properties of the gels, the spreadability was measured and found to be between 12.19±0.41 and 13.07±0.26 gms/cm sec. It was discovered that the spreadabilities of F1, F2, and F3 were, respectively, 13.07±0.26, 12.92±0.85, and 12.19±0.41. In each of the aforementioned formulations, the spreadability of gels F1, F2, and F3 was measured at 13.07±0.26, 12.92±0.85, and 12.19±0.41. Spreadability was 13.25±0.46 in the F2 Formulation when the optimum formulation was chosen.

Table 3.3: Results of Viscosity of polyherbal gel

S.N.	Formulation	Viscosity* (cp)
1	F1	3429±75
2	F2	3251±18
3	F3	2983±64

3.1.4 Results of pH

The pH of a topical medication delivery system is crucial, and the findings of a study on herbal formulation's pH indicate that every formulation is appropriate for topical administration. The pH ranges of 6.95 to 7.08 that were acceptable for the manufactured polyherbal gels were met.

Table 3.4: Results of pH of polyherbal gel

S.N.	Formulation	pH
1	F1	6.97±0.02
2	F2	7.08±0.04
3	F3	6.95±0.02

Furthermore, the formulations' pH values fall between 6.99±0.02 and 7.02±0.04, meaning that they are safe to apply to skin and unlikely to cause irritation or other negative consequences.

The produced gel's pH values fell between 6.95±0.02 to 7.08, which is considered acceptable. For F2 (7.08±0.04), F3 (6.95±0.02), and F1 (6.97±0.02). Three formulations (F1, F2, and F3) in total were made utilizing various Carbopol 934 concentrations. The gel base was mixed with 250 mg of extract from *Tanacetum parthenium, Hypericum perforatum,* and *Evodia rutaecarpa* to achieve the required extract concentration. The pH, spreadability, viscosity, medication content, and extrudability of the topical gel were assessed. A digital pH meter was used to measure pH.

3.1.5 Results of flavonoid Content

In the above formulations of gel the percentage of flavonoid content in formulation F2 was found maximum (1.47±0.64/100mg).

Table 3.5: Results of flavonoid content in polyherbal gel using $AlCl_3$ method

S.N.	Formulation	Flavonoid Content (mg/100mg)
1	F1	1.39±0.22
2	F2	1.47±0.64
3	F3	1.28±0.57

3.2 Results of *In Vitro* Drug Release Study

3.2.1 *In vitro* drug release study of prepared polyherbal gel formulation

Table 3.6: *In vitro* drug release study of prepared Polyherbal gel formulation

S. No.	Time (hr)	% Cumulative Drug Release		
		F1	F2	F3
1	0.25	9.13	8.72	6.20
2	0.5	15.64	17.48	13.57
3	1	23.12	26.34	20.26
4	1.5	42.75	46.57	34.75
5	2	59.05	63.51	45.25
6	2.5	78.51	77.34	57.77
7	3	91.62	90.46	73.43
8	4	98.71	99.25	89.52

***In-vitro* drug release study of F1, F2 and F2**

3.2.2 Release Kinetics Regression values of formulation F2

Table 3.7 Release Kinetics Regression values of formulation F2

Formulation code	Zero order	First order	Higuchi	Korsmeyer-Peppas
F2	**0.891**	**0.874**	**0.968**	**0.971**

3.2.3 Results of Skin irritation study results

Table No 3.8: Results of Skin irritation study results

Treatment	Day I	Day II	Day III	Day IV	Day V	Day VI	Day VII
Control	A	A	A	A	A	A	A
Polyherbal Formulation (F2)	A	A	A	A	A	A	A

3.2.4 Results of Stability study of optimized formulation

Table 3.9: Results of Stability study of optimized Polyherbal formulation

Formulation Code	Months	Spreadability	pH
Polyherbal Formulation (F2)	**I**	12.61±0.25	7.08±0.04
	II	12.48±0.25	7.05±0.04
	III	12.55±0.25	7.01±0.04

CONCLUSION

According to the analysis, choosing medications and polymers carefully is necessary when creating a herbal gel formulation. According to compatibility testing, the selected polymer carbopol was compatible with extracts of *Tanacetum parthenium, Hypericum perforatum* and *Evodia rutaecarpa*. The polymer at varying concentrations affected the gel's pH, extrudability, and spreadability. A gel formulation with headache-causing qualities, stability, and homogeneity was created using carbopol. In conclusion, the development and evaluation of herbal gel's analgesic qualities present a potentially successful method of pain management. It is a beneficial natural ingredient for topical therapies because of its analgesic and pain-relieving qualities. A stable gel requires careful formulation and optimization, accounting for factors including concentration, excipients, and rheological properties. In order to determine how effectively the gel reduces headaches, eases pain, and creates safety profiles, extensive research is conducted, including both in vitro and in assessments. Future research might focus on enhancing bioavailability, exploring novel delivery systems, and conducting extensive studies to validate its effectiveness in a variety of pain conditions. All things considered, the creation and testing of herbal gel show promise as a potential supplement or replacement for traditional analgesics.

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