

Research Article

Formulation and Evaluation of gel containing *Bacopa monnieri* L and *Portulaca oleracea* L.

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ABSTRACT

The aim of the study was to formulate the gel containing aqueous extract of *Bacopa monnieri* L & *Portulaca Oleracea* L. The gel was prepared by using aqueous extract of *Bacopa monnieri* L & *Portulaca Oleracea* L, Carbopol 934, glycerin, methyl paraben and triethanolmine. The skin pH was maintained by adjusting the pH of formulation at 7.0 (± 0.2). Physicochemical parameters of *Bacopa monnieri* L & *Portulaca Oleracea* L. gel formulation i.e. Colour, homogeneity, appearance, pH, viscosity, spreadability and microbiological activity were observed and documented, also stability studies were carried out as per ICH guidelines for 6 months. Experimental data for the gel formulations were found well within specification limit when exposed to accelerated condition 40°C/75% RH.

KEYWORDS

Bacopa monnieri L & *Portulaca Oleracea* L, pH, Stability, Viscosity, Microbiological.

1. INTRODUCTION

Plant species have been reported to have an effect against various skin disease. Medical practitioners can create many different formulas for different types of applications using herbal plant species. The use of medicinal plants in the creation of drugs is growing because of their therapeutic safety and effectiveness [1].

Bacopa monnieri L, commonly known as “Brahmi” and is a medical herb, found throughout the Indian subcontinent in wet and marshy places. The plant is used specially for insanity, nervous breakdown, dermatitis and in memory enhancement antiulcerogenic, adaptogenic activities and hepatoprotective effect against Morphine induced liver toxicity in rats. It helps in the prevention of neurological diseases and is also reported to possess antiinflammatory, analgesic, antipyretic, sedative, free radical scavenging and lipid peroxidative activities [2].

Portulaca Oleracea L, is an edible plant. It is also eaten as vegetable in some provinces of China. It has been reported to be rich in α -linolenic acid and β -carotene and has been reported to be a health food for patients with cardiovascular diseases. PO has many folkloric uses. It is used as antiseptic, anti-scorbutic, antispasmodic. In China, it is used as an anti-bacterial and anti-viral agent, and for the treatment of viral hepatitis and in diabetes management. Many studies have shown that this plant exhibits a wide range of pharmacological effects [3].

2. MATERIALS AND METHODS

2.1. Collection of Plant

Plants were collected from local area, Sangli. The plant was identified and authenticated by Dr. S.S. Sathe, an approved Botanist. A specimen voucher no. (RCP/SNG/203, 204) has been deposited in Department of Pharmacognosy, Rajarambapu College of Pharmacy, Kasegaon, Sangli, MS, India.

2.2. Extraction

Aqueous extract of leaves of *Bacopa monnieri* L & *Portulaca oleracea* L were prepared from shade dried. Aqueous extracts was prepared by 300g powder (twice) in 1500 ml of Distilled water for 30 min at 70⁰ C. The extract was filtered through Whatman filter paper (No.1) and then evaporated and concentrated on the water bath at atmospheric pressure to a semisolid condition. This was poured in Petri dish as thin layer in hot air oven (Lab Hosp) at 25⁰C for 8 hrs to obtain the extract with 10% yield.

Aqueous extract of leaves was prepared by using fresh part of leaf in preparation of gel.

2.3. Animals

Healthy male adult albino mice (25-30 g) obtained from the animal house of Appasaheb Birnale College of Pharmacy, Sangli, Maharashtra, India were used for the study. Mice were housed in polypropylene cages and fed on standard pellet diet and water ad libitum, and the room maintained under controlled condition (12 h light-dark cycle at 22±2°C). Animals were allowed to acclimatize for 7 days prior to experiments being carried out. Institutional ethics committee permission was obtained as per CPCSEA guidelines (Registration No: IAEC/ ABCP /15/2015-2016) for carrying out the study in animals.

2.4. Preparation of gel

The Gel was prepared using carbopol-934, glycerin, methyl paraben, Triethanolamine and water in a quantity sufficient to prepare 100 g of gel in case of blank gel. Water required in gel formulation was divided into two parts of ratio (25:75). In one part of 25%, extract (active) was dissolved and to this solution glycerin and methyl paraben was added and dissolved and in other part (75%) of water carbopol-940 was dissolved. Both the solutions were mixed properly in beaker and pH was adjusted to $7.0 \pm 0.2^\circ\text{C}$ with tri-ethanolamine.

Sr. No.	Ingredients	Quantity
1	<i>Bacopa monnieri</i> Linn	2.5%
2	<i>Portulaca oleracea</i> Linn	2.5%
3	Carbopol 934	3 gm
4	Glycerin	2 ml
5	Methyl paraben	0.2 ml
6	Triethanolmine	q. s.
7	Distilled Water	q. s.

2.5. Evaluation of topical gel formulation [4]:

2.5.1. Appearance and Homogeneity

Gel was tested for physical appearance and homogeneity by visual observation.

2.5.2. pH

The pH value of gel formulation was determined by using a pH meter (Sartorius, S0231)

2.5.3. Viscosity

The measurement of viscosity of prepared gel was done with Brookfield viscometer (DV-E viscometer).

2.5.4. Spreadability

The spreadability of gel formulation was determined by sensory evaluation, through feedback given by volunteers.

2.5.5. Microbiological Activity

Activity performed for specified Microorganisms *Escherichia coli*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

2.5.6. Stability Studies

Gel formulation is packed and subjected for stability study (Newtronic inc.) [5].

2.5.7. Storage conditions and time-points

Parameter	Accelerated	Long-term	Intermediate
Temperature	$40^\circ\text{C} \pm 2^\circ\text{C}$	$25^\circ\text{C} \pm 2^\circ\text{C}$	$30^\circ\text{C} \pm 2^\circ\text{C}$
Relative Humidity	$75 \% \pm 5 \%$	$60 \% \pm 5 \%$	$75 \% \pm 5 \%$

Test interval (months)	40°C ± 2°C / 75 ± 5% RH	25°C ± 2°C / 60 ± 5% RH *	30°C ± 2°C / 75 ± 5% RH*
0		A	
1	A	A	A
3	A	A	A
6	A	A	A

Note

1. Test results should comply with finished product shelf life In house specifications.
2. * In case of significant change observed at sample stored at 40°C ± 2°C & 75 % ± 5 % RH (accelerated condition) storage condition; perform the analysis of sample stored at 25°C ± 2°C / 60 ± 5% RH(Long-term) & 30°C ± 2°C / 75 ± 5% RH(Intermediate) storage condition.
3. A= Appearance, pH, Viscosity, Spreadability, homogeneity and microbiological activity

2.6. Skin irritation studies

The Wistar rats of either sex weighing 150-200 gm were used for this test. The intact skin was used. The hairs were removed from the rat 3 days before the experiment. The gels containing extracts were used on test animal. Gel base was applied on the back of animal taken as control. The animals were treated daily up to seven days and finally skin was examined visually for erythema and edema [6,7].

3. RESULTS AND DISCUSSION

The developed herbal gel was greenish in colour, translucent in appearance and showed good homogeneity with absence of lumps. The formulated gel was much clear and transparent. The values of Spreadability indicate that the gel is easily spreadable. Spreadability of gel 23.40 gm.cm/sec and 21.00 gm.cm/sec respectively. pH also maintained throughout the study which was found 7.0 and 7.1. The viscosity of developed gels was measured using Brookfield viscometer with spindle. Microbial tests of formulated gel of *Bacopa monnieri* L gel and *Portulaca Oleracea* L gel were found complies as per the acceptance criteria. The control and experimental rats showed no signs of inflammation, erythema, and edema.

Table 1. Evaluation of different parameters on formulated gel.

Parameters	Results for <i>Bacopa monnieri</i> L gel	Results for <i>Portulaca oleracea</i> L gel
Colour	Greenish	Greenish
Homogeneity	Good	Good
Appearance	Free from extraneous particles	Free from extraneous particles
pH	7.0	7.1
Viscosity (CPS)	4165	4520
Spreadability (gm.cm/sec)	Good	Good

Microbiological activity	Pass	Pass
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Table 2. Stability profile of *Bacopa monnieri* L gel formulation.

Evaluation	Initial	1 month	3 month	6 month
Colour	Greenish	Greenish	Greenish	Greenish
Homogeneity	Good	Good	Good	Good
Appearance	Complies	Complies	Complies	Complies
pH	7.0	7.0	6.8	6.9
Viscosity (cps)	4400	4350	4330	4200
Spreadability	Good	Good	Good	Good
Microbiological activity	Pass	Pass	Pass	Pass

Table 3. Stability profile of *Portulaca Oleracea* L gel formulation.

Evaluation	Initial	1 month	3 month	6 month
Colour	Greenish	Greenish	Greenish	Greenish
Homogeneity	Good	Good	Good	Good
Appearance	Complies	Complies	Complies	Complies
pH	7.1	7.1	7.0	6.8
Viscosity (cps)	4520	4425	4300	4050
Spreadability	Good	Good	Good	Good
Microbiological activity	Pass	Pass	Pass	Pass

Table 4. 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
<i>Bacopa monnieri</i> L gel	A	A	A	A	A	A	A
<i>Portulaca Oleracea</i> L gel	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

It is inferred from results that the *Bacopa monnieri* L and *Portulaca Oleracea* L (leaves) gel formulation are good in appearance, homogeneity and easily spreadable. When stored at Accelerated stability condition (40°C ± 2°C / 75 ± 5% RH) indicated that temperature and humidity has no impact on colour, appearance, homogeneity, pH, viscosity and spreadability.

Microbiological activity in the gel was found well within the acceptance limit, upon storage for 6 months at accelerated condition. The topical gel formulated was non irritant upon application on the skin.

5. REFERENCES

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