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Formulation and Evaluation of Herbal Gel Contains the Flower Extract of *Butea monosperma*

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ABSTRACT

There is a growing demand for herbal cosmetics in the world market and they are invaluable gifts of nature. Therefore, the basic intention of the present study was to design a proper formulation contain the flower extract of *Butea monosperma* (FEBM) with improved physical parameter. To accomplish this intention the herbal gel was prepared and subjected to evaluation of the various parameters. The cosmetic gel formulation was designed by using ethanolic extract of FEBM in varied concentration (0.5, 1 and 1.5%) using carbapol 940 as gelling agent and evaluated for various parameters. The study was also undertaken to evaluate the stability of gels. The prepared gels were evaluated for various physicochemical parameters such as physical observation, homogeneity, pH determination, viscosity, spreadability, extrudability, drug content, rate of drug permeability, stability as per ICH guidelines and HPTLC fingerprint profiles. All developed gels showed good homogeneity with absence of lumps. All gels were found to be stable with respective to their pH, viscosity and drug content. The extrudability and spreadability were also found to be less variant after stability study. The gels of *Butea monosperma* are radically permeable from skin of rats as demonstrate by the in-vitro permeation study. However, further preclinical studies of gel need to evaluate further confirming the reported biological activities. There is also need to evaluate effects especially in human phase, would be beneficial to assess its usefulness more exactly.

Keywords: *Butea monosperma*, gel, physicochemical properties, in-vitro permeation, stability.

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INTRODUCTION

A gel is a semisolid dosage form intended for skin application for local action as skin protectants, lubricants, emmmolients, drying agents, etc or for percutaneous absorption for specific action of medicament[1,2]. Delivery of drugs to the skin is an effective and targeted therapy for local dermatological disorders. This route of drug delivery has gained advantages over systemic drugs in that they deliver the medication directly to the targeted site, less likely to provoke side effects, bypasses the hepatic metabolism gastrointestinal irritation, and metabolic degradation associated with oral administration etc[2,3].

A gel is a semisolid system of at least two interpenetrating phases: a gelling agent and a liquid [4].The efficacy is often dependent on the composition of the vehicle. The ability of a drug in gel formulation to penetrate the skin and exert its effect depends on to consecutive physical events. The drug must first diffuse out of the vehicle to the skin surface and then, it must penetrate the natural barrier to enter into the site of action. Carbapol polymers are bearing very good water sorption property. They swell in water up to 1000 times their original volume and 10 times their original diameter to form a gel when exposed to a pH environment above 4.0 to 6.0[5].

Topical application of gels at pathological sites offer great advantage in a faster release of drug directly to site of action, independent of water solubility of the drug as compared to creams and ointments [6-10].

The present investigation involves the preparation of three gel formulations of *Butea monosperma* (ethanolic extract) followed by the evaluation for drug content, physical appearance, pH, extrudability. *Butea monosperma* is well known and it is used for relieving burning sensation, in treatment of gout, leprosy and other skin diseases. Chemical investigation showed that the flowers are rich source of flavanoids such as butein butin, butrine, isobutrine, coreopsin, isocoreopsin, monospermoside and the bright colour of the flowers are attributed due to presence of flavanoids [11].

MATERIALS AND METHODS

Collection of plant material and preparation of extract:

The flowers of *Butea monosperma* were collected from the Sakoli village, Nagpur region in the summer season. The flower was authenticated by Dr. N. M. Dongarwar of Botany Department; RTM Nagpur University, Nagpur India. A voucher specimen no. 9282 was deposited at Herbarium, Department of Botany, RTM Nagpur University Nagpur.

The flowers were dried in shade and then ground to produce coarse powder. The powder was

extracted with ethanol for 72 hrs by soxhlet apparatus. The extract was filtered using Whattman filter paper and then concentrated at 45^0C. The percent yield was found to be 9 % w/w. The extract were kept in sterile bottle and stored under refrigerated condition for further analysis.

Chemicals and Materials:

Carbapol 940, propylene glycol, methyl paraben, propyl paraben and other chemicals used were analytical grade.

Procedure of gel preparation:

The gel was prepared by using carbapol 940 as gelling agent. Weighed quantity of carbapol was soaked in specified quantity of water for 3 hrs. The extract dissolved in specified quantity of propylene glycol containing preservatives. This mixture was then added to the soaked carbapol dispersion and finally the pH was adjusted to neutral with sufficient quantity of triethanolamine.

Evaluation of gel:

The above formulated gel formulation was subjected to evaluation of following parameters.

Physical observation:

Physical parameters such as color, appearance and feeling on application were recorded. All formulations were observed visually for their clarity and color [12].

Homogeneity:

The homogeneity of all developed gels was checked visually for the presence of any aggregates or clumps and for appearance [13].

Determination of pH:

Accurately weighed 5 gm of gel was dispersed in 45ml of water to determine the pH of the suspension using digital in pH meter. The determinations were carried out in triplicate and the averages of three readings were noted [14].

Viscosity:

Viscosity of the gel was measured using Brookfield viscometer with spindle type 4 with 30 gear speed.

Determination of Spreadability:

It was determined by parallel plate method. Two glass slide of 10 x 20cm were selected. The gel formulation whose spreadability had to be determined were placed over one slide. The other slide was placed upon the top of the formulation such that the gel was sandwiched between the two slides across a length of 14.5 centimeters along the slide. Two slides are fixed to stand so that lower slide was remained fixed allowing the upper slide to slip off freely with the help of 50 gm weight.

The time required for the upper slide to separate out from lower slide was noted and spreadability was calculated as follows [15,16].

$$S=W \times L/T$$

Where, S=Spreadability,

L=length of the glass plate (14.5 cm),

W=Weight tied to upper plate (50gm),

T=Time taken to separate the slide completely from each other

Extrudability:

The formulations were filled into collapsible aluminium tubes and sealed by crimping machine. The weight of tubes was recorded. The tubes were placed between two glass slides weight500gm was placed on the slide and then cap was removed, the amount of extruded gel was concluded) after the gels were set in the container. The extrudability of formulation was determined as if the extrudability is >90% then it is excellent; >80% extrudability then it is good; >70 extrudability then it is fair [17].

Drug Content:

A specific quantity of gel, 200mg is extracted in 50ml of ethanol for 1 hr. This solution was then filtered, residue washed twice with ethanol and then volume produced to give 100 ml solution in volumetric flask. The drug content in this solution was then estimated spectrophotometrically at 269nm using ethanol as blank using calibrated curve [17].

Permeability studies:

Franz diffusion cell was used for In-vitro permeability studies. 0.5 gm gel was applied on pretreated skin of albino rat and then fixed in diffusion cell in between donor and receptor compartment containing 100ml of phosphate buffer 7.4 was used as diffusion medium and was maintained at $37^{o}\pm1^{o}$ and stirred at 500 rpm. At every 30 min the sample was withdrawn and replaced by equal volume of fresh buffer solution. The withdrawn were spectrophotometrically estimated at 269nm against respective blank[18].

Stability study:

All the selected formulations were subjected to a stability testing at different condition (at 30°C ± 2°C/65% RH ± 5% RH and 45°C ± 2°C/75% RH ± 5% RH) for three months as per ICH norms. All selected formulations were analyzed for the change in appearance, pH and drug content as per ICH norm[19].

HPTLC fingerprint profiles:

For HPTLC fingerprint profile, stock solution (1mg/ml) of each gel extracts was prepared in

methanol. 10ul of sample of each gel extracts were spotted on pre-coated Silica gel G60 F254 TLC plates using CAMAG Linomat V automatic sample spotter and the plate was developed in solvent systems to resolve polar and non-polar components of the fractions. The plates were scanned using TLC Scanner 3 (CAMAG) at 200 nm.

RESULTS AND DISCUSSION

There is a growing demand for herbal cosmetics in the world market and they are invaluable gifts of nature. Therefore, the basic intention of the present study was to design a proper formulation of *Butea monosperma* with improved physical parameter. To accomplish this intention the herbal gel was prepared and subjected to evaluation of the various parameters. Physical parameters such as color, appearance and feeling on application and other visual factors like clarity and colour of formulation are first thing decides the quality of formulation. Any change in physical observation with time reflects physical instability of formulation and make the product cosmetically unacceptable. The developed preparations were yellowish in color and translucent in appearance and had a cool and smooth feeling on application without any irritation. All developed gels showed good homogeneity with absence of lumps. The pH of the gel formulations were maintained constant throughout the study in the range of 6.5±0.23 to 6.7± 0.06, which lies in the normal pH range of the skin (Table 1). Viscosity is the most important parameter in the evaluation as it governs the many properties of the formulation such as, spreadability, pourability of the product from the container etc. Viscosity for respective gel was found to be 1627±23.09, 1613±23.09, and 1640±40 cps at 30 gear speed (Table 1).

The values of spreadability indicate that the gel is easily spreadable by small amount of shear. The results of spreadability were found to 9.29±1.27, 9.27±0.86 and 8.62±1.16 gm.cm/sec. for 0.5, 1% and 1.5% gels respectively (Table 1). Since packing of have gained considerable importance in delivery of desired quantity of formulation from the container, the measurement of extrudability becomes an important criteria. All Gel formulations had an excellent extrudability with>90% extrudability (Table 1).

Therapeutic efficacy of any topical formulation depends on its ability to deliver drugs to their sites of action from the skin surface for either local or systemic purposes. The rate-limiting step for topical delivery is the passage or diffusion through skin. In spite of the barrier function of the skin, topical drug delivery provides a convenient route of administration for a variety of clinical indications. The first challenge of developing an effective topical drug delivery system ultimately involves ensuring adequate drug permeability through the skin [20, 21]. The results of in-

vitro permeation of all developed gels through diffusion cells showed adequate permeation through skin with all formulations.

Evaluation of drug content data showed uniform distribution of drug in gel formulation (Table 1). Release profiles from various gel formulations across the membrane depicted that drug release increases as a function of time for all formulations (Table 1).

Table 1: Evaluation parameters of developed gels

Sr. No	Colour	Appearance	pH	Extrudability	Drug content (Mg)	Homogeneity	% Drug release in 6hrs	Spreadability (gm.cm/sec)	Viscosity (Cps)
F1	Bright yellow	Clear, Translucent	6.6±0.06	Excellent	99.13±0.12	Good, non-greasy	46%	9.29±1.27	1627± 23.09
F2	Bright yellow	Clear, Translucent	6.5±0.23	Excellent	99.73±0.12	Good, non-greasy	51%	9.27±0.86	1613± 23.09
F3	Bright yellow	Clear Translucent	6.7±0.06	Good	97.66±0.30	Good, non-greasy	42%	8.62±1.16	1640± 40

F1: 0.1% Gel, F2: 1% Gel, F3: 1.5% Gel; the values are in mean of three readings.

Table 2: Stability of developed gels at 45^0c

Sr. No.	Months	Appearance	pH	Viscosity	Drug content	Spreadability	Extrudability
F1	0	Clear and Translucent	6.6±0.06	1627±23.09	99.13±0.12	9.29±1.27	91.13±1.52
	1	Clear and Translucent	6.7±0.11	1680±40	98.6±0.35	8.50±0.70	90.23±0.73
	2	Clear and Translucent	6.7±0.06	1727±50.33	98.33±0.12	8.42±0.56	91.12±1.86
	3	Clear and Translucent	6.7±0.06	1760±40	98±0.2	8.24±0.66	88.18±1.74
F2	0	Clear and Translucent	6.5±0.23	1613±23.09	99.73±0.12	9.27±0.86	92.47±1.81
	1	Clear and Translucent	6.7±0.06	1640±40	99.4±0.2	8-48±0.22	91.97±0.73
	2	Clear and Translucent	6.5±0.12	1653±23.09	99.2±0.4	8.40±1.05	91.31±0.91
	3	Clear and Translucent	6.7±0.15	1680±40	98.33±0.12	8.41±0.71	90.16±1.01
F3	0	Clear and Translucent	6.7±0.06	1640±40	97.66±0.30	8.63±1.21	91.68±0.89
	1	Clear and Translucent	6.7±0.06	1693±23.09	97.4±0.2	8.43±0.66	91.38±0.18
	2	Clear and Translucent	6.7±0.15	1720±40	97.4±0.35	8.34±0.72	89.51±1.10
	3	Clear and Translucent	6.7±0.12	1787±23.09	97.13±0.12	8.20±0.79	89.29±0.41

F1: 0.1% Gel, F2: 1% Gel , F3: 1.5% Gel; the values are in mean of three readings

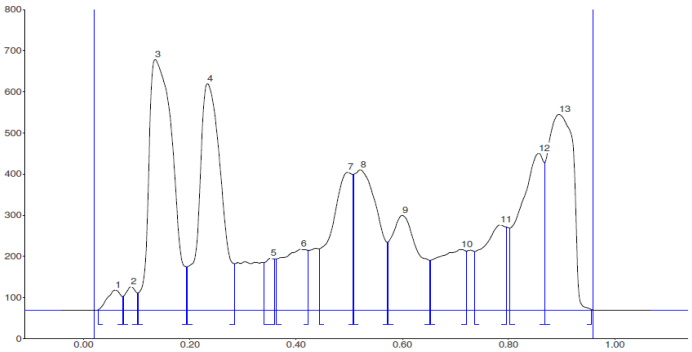
Table 3: Stability of developed gels at 30^0c

Sr. No.	Months	Appearance	pH	Viscosity (cps)	Drug content(%)	Spreadability (gm.cm/sec)	Extrudability
F1	0	Clear and Translucent	6.6±0.06	1627±23.09	99.13±0.12	9.29±1.27	91.13±1.52
	1	Clear and Translucent	6.7±0.20	1707±23.09	98.53±0.12	8.34±1.27	90.84±0.10
	2	Clear and Translucent	6.7±0.12	1800±40	98.4±0.2	8.07±0.71	90.56±0.37
	3	Clear and Translucent	6.7±0.15	1813±23.09	98.27±0.12	8.07±1.28	90.27±0.64
F2	0	Clear and Translucent	6.5±0.23	1613±23.09	99.73±0.12	9.27±0.86	92.47±1.81
	1	Clear and Translucent	6.5±0.12	1693±46.18	99.47±0.31	8.43±0.87	91.64±0.10
	2	Clear and Translucent	6.6±0.06	1760±40	99.27±0.2	8.13±0.94	91.49±0.26
	3	Clear and Translucent	6.8±0.15	1787±46.18	99.2±0.2	8.00±1.08	90.74±0.08
F3	0	Clear and Translucent	6.7±0.06	1640±40	97.66±0.30	8.63±1.16	91.69±0.89
	1	Clear and Translucent	6.8±0.12	1747±23.09	97.47±0.31	8.06±0.70	90.83±0.32
	2	Clear and Translucent	6.6±0.12	1800±40	97.33±0.23	7.99±0.57	90.42±0.95
	3	Clear and Translucent	6.7±0.15	1813±46.18	97.13±0.12	7.86±0.91	90.19±0.62

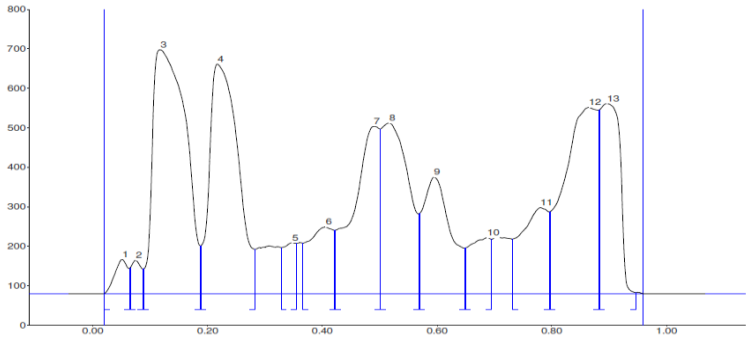
The stability test was carried out for three months and results revealed that the all gels showed better stability. During stability study, there was not much variation in viscosity after testing at different temperature conditions. Extrudability and spreadability were also measured and found to be less variant than the initially prepared gel after performing stability study. There was no significant change in pH values (Table 2 and 3).

Chromatographic fingerprinting is a chromatographic pattern of the extract of some common chemical components of pharmacological active or chemical characteristics. Authentication and identifications can be accurately obtained with the help chromatographic fingerprinting independently the concentrations of chemical characteristics constituents of the different samples of same herbal medicines. It could also demonstrate both the sameness and differences between various samples. In present study the HPTLC fingerprinting profile of gel extract of *Butea monosperma* was generated in solvent system in order to ascertain the total number of chemical moieties present in gel and stability of extract in gel. HPTLC fingerprint profile of extract of *Butea monosperma* gel was recorded (Figure 1).

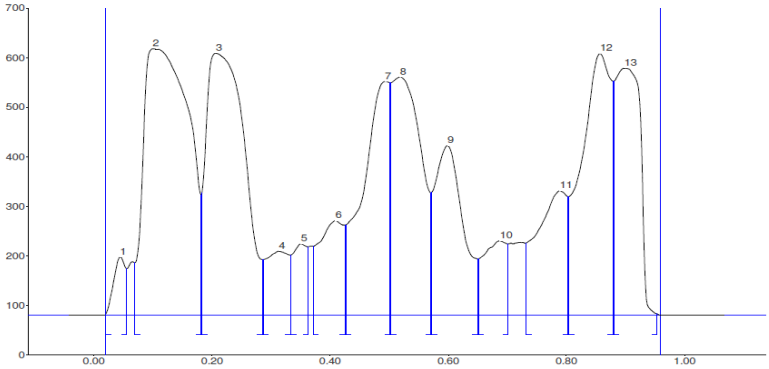
Chromatogram of 0.5% FEBM Gel



Chromatogram of 1.0% FEBM Gel



Chromatogram of 1.5% FEBM Gel



Mobile Phase: Ethyl acetate: Formic acid: Glacial acetic acid: Water (5:0.5:0.5:0.7)

Figure 1: TLC chromatograms of Gel extracts system scan at 200nm.

It is evident that the *Butea monosperma* has great potentials in treating a number of ailments where the free radicals have been reported to be the major factors contributing to the disorders. Earlier studies have also shown that the *Butea monosperma* possesses antifertility, antifungal, hepatoprotective, anti-inflammatory, antidiarrhoeal, anti-microbial, antiulcer properties etc.[22-27]. As per our knowledge there was not found any single report to developed and evaluate the topical *Butea monosperma* gel and this study will seems one of the first that developed and evaluate the gel containing flower extract of *Butea monosperma*. However, further preclinical

studies of gel need to evaluate further confirming the reported biological activities with reference to its topical applicability.

CONCLUSIONS

From the results of present study it concludes that the various concentrations of *Butea monosperma* gels are stable with respective to their pH, viscosity and drug content. The gels of *Butea monosperma* are also radically permeable from skin of rats as demonstrate by the in-vitro permeation study. However there is need to evaluate effects especially in human phase, would be beneficial to assess its usefulness more exactly.

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