

Original Article

FORMULATION DESIGN AND OPTIMIZATION OF HERBAL GEL CONTAINING ALBIZIA
LEBBECK BARK EXTRACT

B. RAJESH, DAS SAUMYA, PATTANAYAK DHARMAJIT, M. PAVANI

Vikas College Of Pharmaceutical Sciences, Rayanigudem, Suryapet, Nalgonda(Dist),A. P
Email: rajeshbujji53@gmail.com

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ABSTRACT

Objective: Herbal gels are having a lot of advantages over conventional gels in minimizing side effects and increasing the therapeutic efficacy. The objective of the study is to formulate and evaluate topical gel formulations containing methanolic and Ethyl acetate (EA) extracts of *Albizia lebeck* (common name: Dirsina) bark which has been identified to have anti-inflammatory activity.

Methods: The gel formulations were fabricated using bark extracts with different solvents like (Methanol and Ethyl acetate). The different polymers like carbopol, sodium alginate in different ratios were used in formulating the gels. Dibutyl phthalate is used as permeation enhancer; Methyl paraben and propyl paraben are used as preservatives; glycerin is used as a humectant. The pH of the gel is maintained in the range of 6.8 -7 by using triethanolamine to prevent itching and irritation of the skin. The physicochemical parameters like pH, viscosity, spreadability, etc., have been studied. Diffusion studies have been carried out using Franz Diffusion cell. Stability studies and FTIR studies showed compatibility between polymer and extracts.

Results: It is observed that all the formulations showed good viscosity and spreadability. The formulation containing Sodium CMC+Sodium alginate of methanolic extract and Sodium CMC of E.A extract has showed better viscosity and spreadability compared to other formulations. The diffusion studies carried out for all the formulations shows satisfactory diffusion.

Conclusion: As the formulations contains the natural product as API it has very less side effects compared to other products and it is also very economical due to the wide spread availability of the plant.

Keywords: *Albizia lebeck*, Sodium CMC, Sodium alginate, Inflammation.

INTRODUCTION

Herbal medicine has become an item of global importance both medicinal and economical. Although usage of these herbal medicines has increased, their quality, safety and efficiency are serious concerns in industrialized and developing countries. Plants play a vital role in curing various ailments of the man and herbal remedies are getting increasing patient compliance as they are devoid of typical side effects of allopathic medicines. The allopathic system of medicine includes two conventional line of the treatment for rheumatoid arthritis, which come along with certain side effects. Hence, turning to safe, effective and time tested ayurvedic herbal drug formulations would be a preferable option. So there is need to investigate such drugs and their effective formulation for the better patient acceptance. Considering these facts present review aims to develop novel herbal gel containing the herb, viz *Albizia lebeck*[1]. So, herbal anti-inflammatory gels which is non-toxic, safe, and effective and improves patient compliance by the utilization of herbal extracts would be highly acceptable. *Albizia lebeck* is important drug in many herbal anti-inflammatory, analgesic formulations. The anti-inflammatory activity of the drug is well established by many scientific works. [2]

MATERIALS AND METHODS

Methods

The dried inner bark powder (250g) of *Albizia lebeck* was extracted with methanol (500ml) and Ethyl acetate (500ml) at room temperature by maceration for 7 days. Both containers were shaken/agitated from time to time to ensure better extraction. After maceration period the contents were filtered and filtrate were concentrated under reduced pressure by rotary flash evaporator. The concentrated extracts were dried in desiccators and stored in air tight containers. [3] The polymers used for the preparation of gels are Carboxy Methyl Cellulose Sodium (NaCMC), carbopol934 (CP), and sodium alginate (SA). Dibutyl phthalate (DBP) is used as a plasticizer and Triethanolamine (TEA) is used as an emulsifying agent. All the chemicals used are of analytical grade and procured from S.D fine

chemicals. Different preformulation studies which include characterization of extract, preparation of calibration curve and FTIR studies for estimation of drug polymer compatibility are performed. Herbal gels are formulated using various gelling agents in different concentrations. Preservatives, plasticizers, emulsifiers, humectants, etc. where incorporated in the formulation to obtain a stable product.[4]

Evaluation

The physical parameters such as color and appearance were observed. The pH of the gel was measured using electrode type pH meter. Viscosity of the gel was measured by using Brookfield viscometer. The proper maintenance of viscosity is necessary to ensure good drug delivery. Presence of any aggregate and homogeneity of the gel is visually inspected. For the determination of spreadability excess of sample is applied in between two glass slides and was compressed by using 1000g weight for 5min. Weight (50gm) was added to pan. The time required to separate the two slides, i.e. the time in which the upper glass slide moves over the lower plate was taken as measure of Spreadability (S).

S=ML/T

S=spreadability

M=weight on upper slide

L=length moved on glass slide

T=time taken for complete separation

The drug content of the gel was estimated spectrophotometrically using phosphate buffer pH 6.8.

The drug diffusion studies were performed by using Franz diffusion cell. The gel sample was applied on the dialysis membrane and then fixed in between donor and receptor compartment of diffusion cell. The receptor compartment contained phosphate

buffer (100ml) of pH 6.8. The temperature of diffusion medium was thermostatically controlled at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ by surrounding water in jacket and the medium was stirred by magnetic stirrer at 500rpm. The sample at predetermined intervals were withdrawn and replaced by equal volume of fresh fluid.

The samples withdrawn were spectrophotometrically analyzed at specified wavelength against their respective blank. The accelerated

stability studies were performed as per ICH guide lines at a temperature of $40^{\circ}\pm 2^{\circ}\text{C}$. [5]

RESULTS

The standard calibration graph for the ethyl acetate extract and methanolic extract was plotted and intercept was obtained. The graphs are shown in figure No. 2.

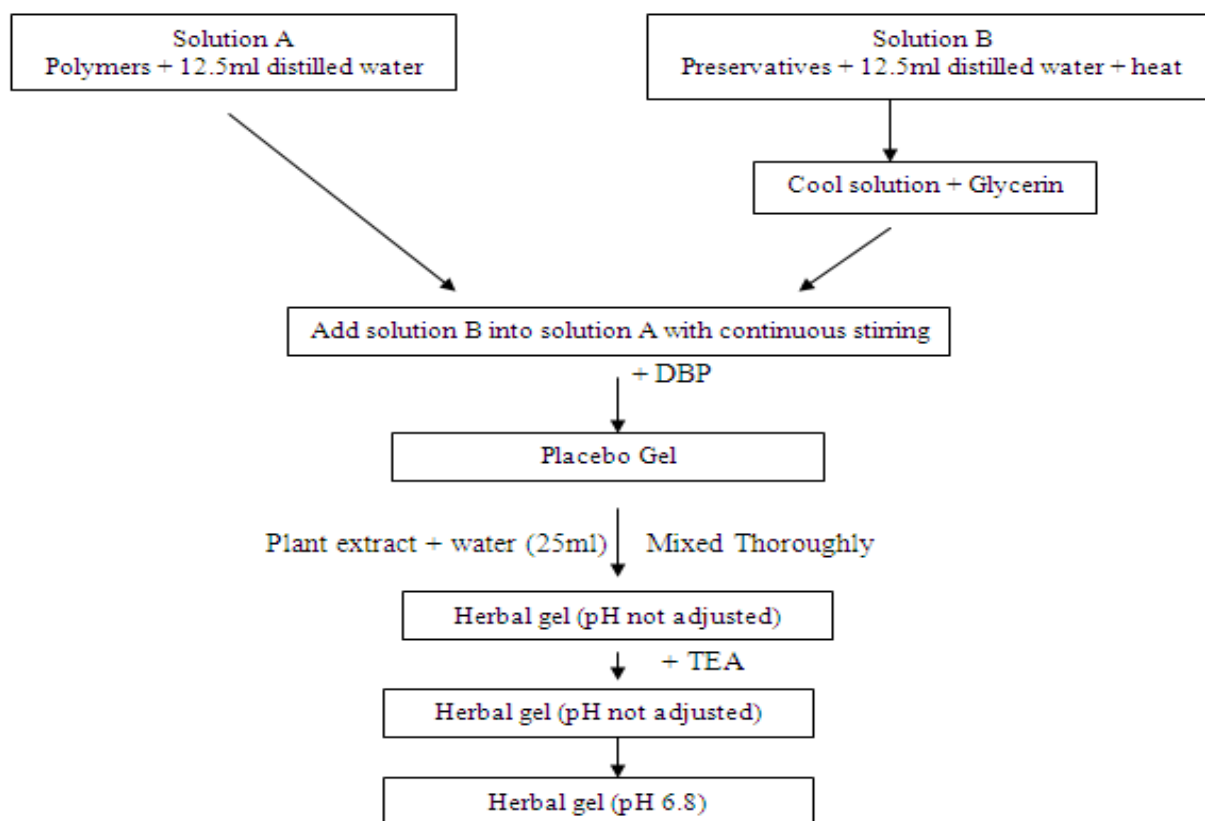


Fig. 1: Method of Preparation of Gels

Table 1: Formulation of herbal gels

Ingredients	FM ₁	FM ₂	FM ₃	FE ₁	FE ₂	FE ₃
Sod.CMC(g)	0.75	0.75	0.75	0.75	0.75	0.75
Carbopol(g)	-	0.75	-	-	0.75	-
Sodium Alginate(g)	-	-	0.75	-	-	0.75
<i>Albizia lebbek</i> Bark extract(g)	0.625	0.625	0.625	0.625	0.625	0.625
Glycerin(ml)	0.5	0.5	0.5	0.5	0.5	0.5
Methyl paraben(0.5%)(ml)	0.05	0.05	0.05	0.05	0.05	0.05
Propyl paraben(0.2%)(ml)	1.25	1.25	1.25	1.25	1.25	1.25
Triethanolamine(ml)	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Dibutyl phthalate(ml)	0.6	0.6	0.6	0.6	0.6	0.6
Distilled water(ml)	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Table 2: Results of Physical Evaluation

Formulations	Color	Appearance	Homogeneity	Viscosity (CPS)	Spreadability (g cm/sec)	Drug content (%)
FM ₁	Reddish brown	Clear and translucent	Good	8651	15.20	91.61
FM ₂	Light Reddish Brown	Clumpy and translucent	Good	9632	21.07	85.12
FM ₃	Reddish brown	Clear and translucent	Good	8976	16.75	97.36
FE ₁	Reddish brown	Clear and translucent	Good	8651	15.01	93.54
FE ₂	Light Reddish Brown	clumpy and translucent	Good	9632	21.75	82.11
FE ₃	Reddish brown	Clear and translucent	Good	8976	16.55	92.66

The drug diffusion studies were performed for the formulations containing both the extracts. All the formulations showed good drug release.

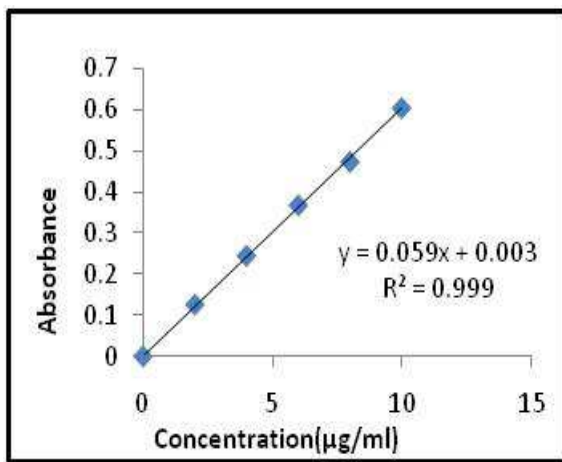
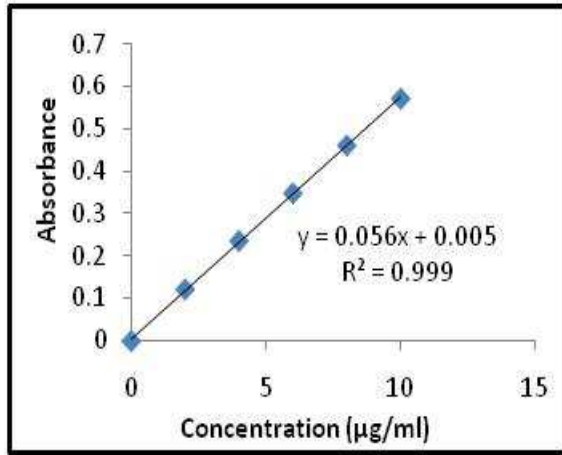


Fig. 2: Standard Calibration Curve of extract

Physical evaluations like visual inspection for color and appearance, homogeneity were carried out. Viscosity and spreadability was measured to ensure uniform application of gel. Drug content was estimated to ensure the uniformity of drug in the formulation. Results of the same are shown in table No. 2.

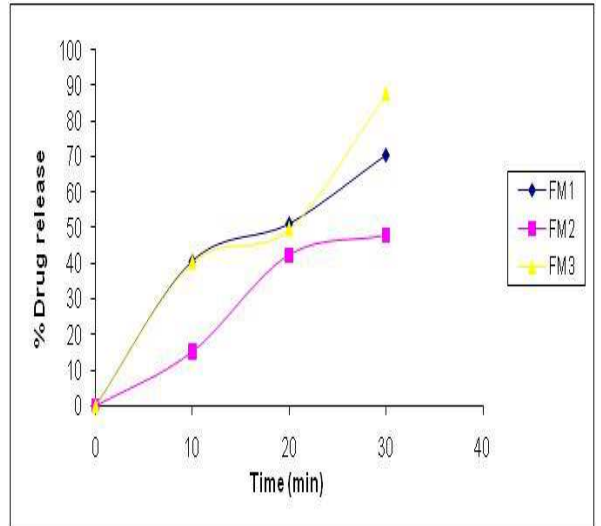


Fig. 3: Drug Diffusion Studies of gels containing Methanolic extract

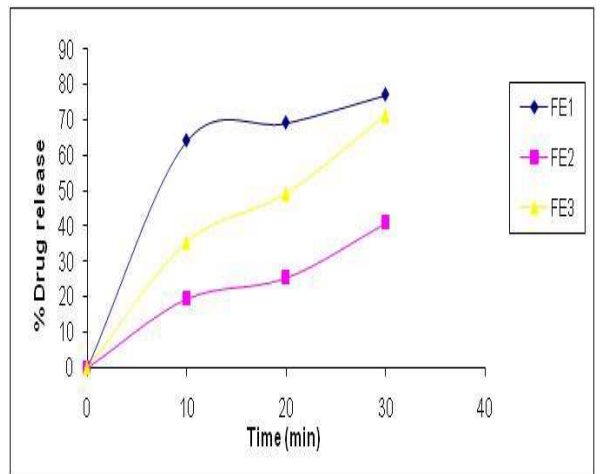


Fig. 4: Drug Diffusion Studies of gels containing Ethyl acetate extract

Table 3: Results of Stability studies

S.No.	Formulations	Weeks	pH	Spreadability	Drug content
1.	FM ₃	0	7.0	16.75	97.36
		2	7.0	16.88	97.36
		4	7.0	16.55	96.17
		6	7.0	16.11	95.54
2.	FE ₁	0	6.8	15.01	93.54
		2	6.8	15.48	93.54
		4	6.8	15.11	92.31
		6	6.8	14.75	91.67

DISCUSSIONS

The calibration curve of methanolic extract and ethyl acetate extract was observed at 268nm and 265nm respectively. Both of them got a R² value of 0.999. The FTIR studies confirmed that there is no considerable interaction in-between the extract and the polymer. The physical evaluation showed that all the gels obtained light brown to reddish brown coloration due to the plant extract. Formulation FM2 and FE2 formed clumps on storage which may be due to the presence of excess proportion of carbopol. All the gels were translucent in appearance. The pH of all the gels was

found to be in between 6.8-7. All formulations shown good homogeneity and viscosity. The viscosity of gels prepared by carbopol was high as compared to NaCMC and SA. The value of spreadability indicates the degree of shear required to apply the gel. NaCMC shown good spreadability as compared to carbopol and SA. Formulation FE1 showed the best spreadability. The results of physical evaluation is given in Table No.2. The percentage drug content of all the prepared gels were found to be in the range of 82.1% -97.36%. The observed values of drug content is mentioned in table No.2. All the prepared formulations showed good permeation studies. The gels prepared with the combination of

NaCMC and carbapol showed least permeability of 40.8%. The methanolic extract was found to have good diffusion property as compared to ethyl acetate. The drug release was found to be highest for the formulation FM3 due to the presence of NaCMC and SA. The stability studies were carried out for the formulation FM3. Results of stability studies are mentioned in Table No.3. Parameters like pH, spreadability, drug content, and permeation were studied. There was no significant change in the above parameters after acceleratory stability studies.

CONCLUSION

From the present investigation it can be concluded that proper selection of polymers is required for optimized drug delivery through transdermal route. The usage of herbal extract was found to be efficient in releasing the drug without fluctuations. The methanolic extract of *Albizia lebbek* showed good permeation. The

preservatives, humectants and permeation enhancers play a vital role in drug delivery through transdermal route.

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