RESEARCH ARTICLE

Formulation Development and Characterization of *Leonotis nepetaefolia* Extract Niosomal Gel for Anti-inflammatory Activity

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ABSTRACT

Inflammation is caused when the microorganism enters in our body and settles at specific tissue or sometimes may circulate into the bloodstream. *Leonotis nepetaefolia* (LN) flower extract contains various phytochemicals out of which saponins and flavonoids are main constituents. As such the phytochemicals have less permeability in the skin, therefore to enhance them these are loaded in niosomes. In the present work, the extract obtained from flowers of LN was taken to develop niosomal gel. The prepared niosomal gel was evaluated for to determine particle size, EE and zeta potential. Also, the anti-inflammatory activity was reported in the present paper. The study indicates that the niosomal gel possesses significant anti-inflammatory activity.

Keywords: Niosomes, Gel, Plant extract, Anti-inflammatory activity, *Leonotis nepetaefolia.*

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INTRODUCTION

Inflammation is a condition that involves immune cells, blood vessels and various molecular mediators which may affect the biological response of tissue against pathogens or damaged cells or by some irritants. There are various drugs that are used to treat inflammation by may have severe side effects like gastric irritation when used for prolonged duration. Also, several dosage forms such as cream, ointment, gel are available in the market for the treatment of the same.[1] Medicinal plant are safe and have no no adverse effects and have varied therapeutic uses.[2] Various NDDS such as phytosomes, nanoparticles, Niosomes, ethosomes, liposomes etc, when loaded with herbal extract, showed significantly enhanced permeation in skin and also decreased dose dumping and drug degradation.[3] Keeping the same in mind an attempt was made to formulate and evaluate the niosomes loaded with flower extract of *Leonotis nepetaefolia.* LN belongs to the family Lamiaceae and rich in alkaloids, saponins, flavonoids and glycosides. Pharmacologically the plant possesses anti-fungal activity, analgesic activity, anti-diabetic activity and anti-inflammatory activity.[4]

MATERIAL AND METHODS

Extraction of Plant Material

Approximately 250 gm of dried flowers of *Leonotis nepetaefolia* (after collection from local area of Malwa region and authentication by a Botanist) were extracted in a soxhlet apparatus using ethanol as a solvent. The extract obtained was dried in a desecrator.[5]

Preparation of Niosomes

Concentration of span and cholesterol was obtained from design software, a 3^2 factorial design was selected for the analysis and the influences of these factors were shown in Table 1. The niosomes of LN was prepared by thin hydration method (Tables 1 and 2). Span 60 and cholesterol was firstly dissolved in chloroform and then both the mixture was heated

Table 1: Factors and values

Independent variables	*Levels*			*Dependent variables*
	-1	0	+1	Particle size, Zeta potential, PDI, EE
Span 60	250	375	500	
Cholesterol	150	200	250	

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Table 2: Composition of LN niosomes

Formulation code	*Span 60 (gm)*	*$CHCl_3$ (mL)*	*Cholesterol (gm)*	*LN extract (gm)*	*Phosphate buffer (mL)*
NF-1	0.25	10	0.15	0.5	10
NF-2	0.375	10	0.15	0.5	10
NF-3	0.5	10	0.15	0.5	10
NF-4	0.25	10	0.2	0.5	10
NF-5	0.375	10	0.2	0.5	10
NF-6	0.5	10	0.2	0.5	10
NF-7	0.25	10	0.25	0.5	10
NF-8	0.375	10	0.25	0.5	10
NF-9	0.5	10	0.25	0.5	10

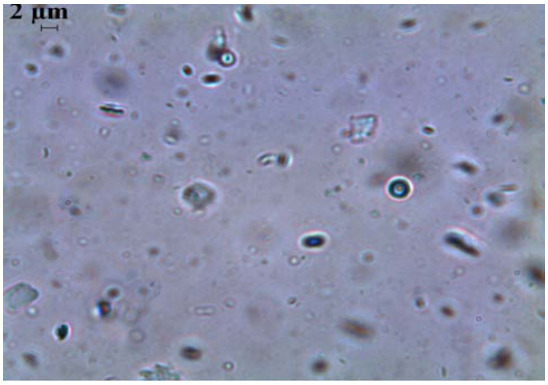
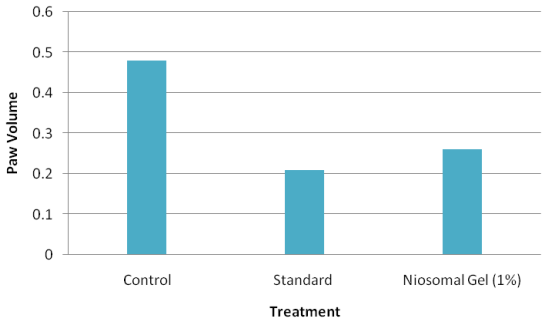


Figure 1: LN extract loaded niosomes (NF-5)



Graph 1: Paw volume of gel

Table 3: Characterization of LN extract niosomes

Formulation code	*Particle size in nm*	*PDI*	*ZV in mv*	*EE in %*
NF-1	220.3	.368	-29.3	57.43
NF-2	234.3	0.371	-29.1	60.81
NF-3	244.9	0.338	-30.8	62.46
NF-4	239.4	0.374	-31.2	63.90
NF-5	257.4	0.382	-30.3	66.89
NF-6	243.7	0.373	-29.7	63.42
NF-7	239.5	0.368	-28.4	64.65
NF-8	249.2	0.339	-30.6	63.93
NF-9	245.6	0.348	-31.2	62.20

Table 4: Characterization of CGL and NGL

Formulation code	*pH*	*Spreadability (gm/cm^2)*	*Viscosity (cps)*	*Drug content (%)*
Conventional gel (CGL)	6.1	14.32	4284.6	84.58
Niosomal gel (NGL)	6.5	15.69	4916.9	86.39

Table 5: Paw volume of standard and niosomal gel

S. No.	*Treatment*	*Paw volume after 120 mts*
1.	Control	0.48 ± 0.11
2.	Standard (Diclofenac Gel-1%)	0.21 ± 0.06
3.	Niosomal Gel (1%)	0.26 ± 0.03

at 50°C until the thin film was obtained. Then the film was hydrated using phosphate buffer 10 mL, pH 5.5 which having extract in it with gentle shaking for 3 hours.[6]

Characterization of Niosomes

The formulated niosomes were evaluated to determine the size, PDI, zeta potential and EE as per the standard procedure mentioned.[6]

Development and Evaluation of Niosomal Gel

The extract of LN gel about 10% w/w was developed using niosomal suspension and carbopol 934 (1%). Triethanolamine was added with stirring to obtain gel-like consistency. The prepared gel was evaluated for spreadability, viscosity, pH and drug content as per standard procedure. Drug content was determined at 335 nm.[6]

Anti-inflammatory Activity

Anti-inflammatory activity was determined using paw odema measurement in carrageenan-induced model in rats. The animal study protocol was approved by IAEC having Approval No. OU/IAEC/Pharmay/37. For the study albino rata (male or female) having weight 180 to 200 gm were used. Three groups control, standard and treated were made. Control was given with gel base 500 mg/kgbw, standard were given with 1% diclofenac gel 10 mg/kgbw and treated were given 1% niosomal gel 500 mg/kgbw. At the dorsal surface of the right paw of animal gel was applied and a carrageenan solution 1% wv in NS was given after 30 minutes. After a specific time interval paw volume was measured.[7]

RESULTS AND DISCUSSION

Nine formulations containing LN flower extract were prepared using varying concentrations of span an cholesterol and were characterized. The results as listed in Table 3 clearly indicate that the formulation code NF-5 have a maximum %EE i.e., 66.89%. SEM image of NF-5 were also given in Figure 1. Further, CGL and NGL were off-white in color, clear, uniform and gritty-free in nature. The results of pH, spreadability, viscosity and drug content are listed in Table 3. The niosomal gel (NGL) was evaluated to screen the anti-inflammatory activity in albino rats. Results indicate as mentioned in Table 4 that the NGL has significant activity as compared with diclofenac in reducing inflammation (Graph 1) (Table 5).

CONCLUSION

From the results obtained it was concluded that the prepared niosomal gel has sound anti-inflammatory activity as compared with the diclofenac standard drug.

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