

Original Article

Formulation and Evaluation of Nasal Spray for the Treatment of Migraine Using Aromatherapy

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ABSTRACT

Objective: the main objective is to develop and formulate a non-toxic, user-friendly, and comfortable intranasal spray formulation of volatile oil for reducing migraine.

Materials and Methods: eucalyptus oil, Cween80, Span80, PEG400, nasal spray pumps, reagents and solvents of analytical grade were used. Microemulsions were prepared by water titration method. Nasal spray pumps were evaluated for spray pattern, shot weight and spray content. Invitro study was carried through cellulose acetate membrane respectively.

Results: Formulations were developed using (Smix) Cween 80: Span 80 in the ratios of 1:0.25 and 1:0.5, PEG 400 (0.5 gm). These were stable, clear with pH 6.27 and viscosity was 375.85cps. Vp6/100A exhibited the most consistent spray and uniform delivery amongst the tested pumps. The amount of drug diffused was 70% through cellulose acetate membrane within 24hrs.

Conclusion: Developed intranasal spray formulations containing eucalyptus oil showed potential to alleviate migraine.

Keywords: Migraine, Eucalyptus oil, Microemulsions, Blood Brain barrier, Intranasal.

1. INTRODUCTION:

Migraine headache appear to be caused by complex interplay of neurologic and vascular changes and show waves of neurologic changes in brain. Essential oils like eucalyptus oil and peppermint oil have been used for aromatherapy for the treatment of migraine. The major active ingredient of eucalyptus oil is cineole (eucalyptol) that has soothing, stimulant and antidepressant etc. Microemulsions have a much greater solubilizing capacity for non-polar organic compounds than aqueous micellar solutions and hence attempts are made to develop microemulsion of eucalyptus oil for intranasal delivery.

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2. MATERIALS AND METHODS

Eucalyptus oil, Cween80, Span80 and PEG400, nasal spray pump.

3. FORMULATION DEVELOPMENT OF EUCALYPTUS OIL MICROEMULSIONS

Eucalyptus oil microemulsions were prepared by combining hydrophilic and lipophilic surfactants namely Cween80, Span80 and Cosurfactant PEG400. Glycerin was added in the formulations as it acts as humectant for nasal formulations.

4. PHASE SOLUBILITY STUDIES AND MICROEMULSION FORMULATIONS

The pseudoternary phase diagrams of oil, surfactant, cosurfactant and water were constructed using water titration method. For solubility studies, the ratio of oil to the surfactant/cosurfactant mixture (Smix) was varied from 1:9-9:1 (w/w). Water was added drop wise to the oil-S mixture under vigorous stirring to form a clear and transparent microemulsion.

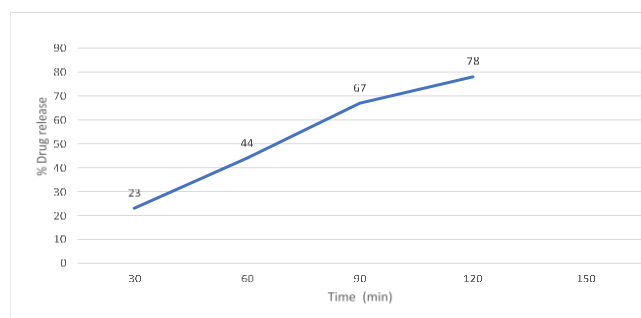
	Clarity Test	pH (4.5-6.5)	Viscosity	Centrifugation Test (4000 Rpm For 20 Min)	Stability
f1.	clear & transparent	5.6	364	passed – do not separate	stable
f2.	clear & transparent	5.5	359	passed – do not separate	stable
f3.	blurred	5.4	377	blurred – shows separation	not stable
f4.	blurred	5.4	384	blurred - shows separation	not stable
f5.	blurred	5.3	349	blurred - shows separation	not stable

Table: Evaluation of Optimized Microemulsion of Eucalyptus Oil:

effect needs to be further investigated by conducting detailed pharmacokinetics and clinical trials.

5. IN VITRO DIFFUSION STUDIES

The optimized formulations were subjected to release kinetic studies through sheep nasal mucosa in phosphate buffer: Cween80 (8:2) for a period of 4 h using franz diffusion apparatus.



6. FORMULATION AND EVALUATION OF NASAL SPRAYS

The nasal spray formulations of eucalyptus oil were evaluated for parameters like spray pattern, shot weight and content of eucalyptus oil per spray.

S. no	Parameter	Observation
1	Spray pattern	Spherically uniform
2	Shot weight	110 mg

7. CONCLUSION

Developed intranasal formulations showed potential in relieving migraine related headache. Essential oils can be used as an effective approach in alleviating the pain of migraine sufferers. Developed intranasal formulations provided comfort and soothing effect. Intranasal administration provides nose to brain targeting of essential oils for antimigraine effect. The

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