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ORIGINAL ARTICLE

Microemulsion Based Gel of Methylprednisolone for the Treatment of Eczema

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ABSTRACT
The present study enlightens to enhance the solubility and permeability of Methylprednisolone, a poorly soluble drug, by preparing a Microemulsion and then incorporate this microemulsion in to the gel. Methylprednisolone is steroid drug and used in treatment of eczema. Methylprednisolone loaded microemulsion were prepared by using Capmul MCM C8 EP as oil, Cremophore RH 40 as surfactant and Polyethylene glycol 600 as co-surfactant. Different Surfactant and cosurfactant (Smix) ratios were used to prepare the ternary phase diagram. Chemix software 4.1 was used to identify the efficient microemulsion region. The microemulsion formulation evaluated for globule size, poly dispersibility index, zeta potential, % transmittance, pH and assay. The microemulsion was incorporated into gel & the prepared gel was evaluated for viscosity. In future, the formulated microemulsion based gel can be tested for in vivo activity and clinical trials.
***Keywords**: Methylprednisolone, Eczema, Ternary phase diagram, Microemulsion based gel.*

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INTRODUCTION

Eczema, particularly dyshidrotic dermatitis, is a chronic inflammatory skin disorder characterized by erythema, pruritus, vesiculation, scaling, and recurrent flare-ups that significantly impair patients' quality of life. [1,2] Topical corticosteroids remain the mainstay of therapy due to their potent anti-inflammatory and immunosuppressive properties. Among them, methylprednisolone is widely used for managing inflammatory dermatoses because of its strong therapeutic efficacy and comparatively favorable safety profile. [3,4,5] However, its clinical effectiveness following topical administration is often limited by poor aqueous solubility and inadequate skin permeation, which restrict drug availability at the target site. Enhancing the solubility and transdermal delivery of poorly water-soluble drugs remains a major challenge in topical formulation development. Microemulsion systems have gained considerable attention as promising drug delivery platforms owing to their thermodynamic stability, transparency, ease of preparation, and ability to enhance drug solubilization. These systems, composed of oil, surfactant, co-surfactant, and aqueous phase, can improve drug partitioning into the stratum corneum and facilitate deeper penetration through the skin layers. Additionally, the small globule size of microemulsions increases surface area, thereby enhancing drug absorption. [6,7,8] Incorporating microemulsions into gel matrices further improves patient acceptability, ease of application, and residence time at the site of action. Microemulsion-based gels combine the advantages of enhanced permeation with the favorable rheological properties of gels, making them suitable for dermatological applications. Therefore, the present study focuses on the development and optimization of a methylprednisolone-loaded microemulsion system and its subsequent incorporation into a gel base to improve solubility, permeability, and overall therapeutic performance in the management of eczema. [9,10]

MATERIAL AND METHODS

MATERIALS:

Methylprednisolone was gifted by Apex Pharma, Vapi; Capmul MCM C8EP, Capmul MCM EP, Captex 200 P were received as gift samples from ABITEC corporation, USA; Maisine35, Labrafac PG, Labrafil-M-2125 were received as gift sample from Gattefosse, France; All other chemicals were purchased from Loba Chemie Pvt Ltd, Mumbai. All materials were of analytical grade.

METHODS:

Solubility Study

The solubility of methylprednisolone was determined in various experimental vehicles using the saturation solubility method. An excess amount of the drug was added to 1 g of each selected vehicle to ensure complete saturation. The mixtures were placed on a rotary shaker and agitated at 150 rpm for 72 hours at a controlled temperature of 37°C to achieve equilibrium. After equilibrium was established, the samples were centrifuged at 3000 rpm for 15 minutes to separate the undissolved drug from the supernatant. The clear supernatant was carefully collected and suitably diluted with an appropriate solvent. The concentration of dissolved methylprednisolone in each vehicle was then quantified using a UV–visible spectrophotometer. The measured absorbance values were used to calculate the saturation solubility of the drug in the respective vehicles. [11,12,13]

Development of pseudo ternary phase diagram

After identifying the most appropriate oil, surfactant, and co-surfactant based on their highest drug solubilizing capacity, pseudo-ternary phase diagrams were developed to delineate the extent and characteristics of the microemulsion region. The diagrams were constructed using the aqueous phase titration method. Various weight ratios of surfactant to co-surfactant (Smix) were prepared to investigate their effect on microemulsion formation. For each selected Smix ratio, predetermined proportions of water and Smix were mixed uniformly. The chosen oil phase was then incorporated slowly in a dropwise manner into the water–Smix mixture under continuous magnetic stirring maintained at 37°C. The titration process was continued until the system exhibited turbidity, which signified the transition from the microemulsion region to a biphasic system. All experimental observations were systematically recorded and utilized to plot pseudo-ternary phase diagrams using Chemix School software. These phase diagrams enabled precise identification of the microemulsion domain and assisted in optimizing the component concentrations for subsequent formulation development. [14,15,16,17]

Preparation of final methylprednisolone microemulsion

The optimized microemulsion formulation was selected from the pseudo-ternary phase diagram corresponding to the composition that exhibited the largest microemulsion region. This optimized formulation was subsequently employed for the development of a microemulsion-based gel. The Methylprednisolone-loaded microemulsion was prepared by initially dissolving the drug in the pre-determined Smix (surfactant and co-surfactant mixture) within a glass vial. The accurately weighed quantity of oil was then added to the same vial. All components were mixed thoroughly at ambient temperature until a clear and transparent microemulsion system was obtained. [18,19]

Evaluation of methylprednisolone microemulsion

Final microemulsion was evaluated for globule size, poly-dispersibility index, zeta potential by Zetasizer (Malvern Nano ZS, UK), % transmittance (UV 1800, Shimadzu Corporation, Japan), pH and drug content. [20,21]

Preparation of gel formulation

The microemulsion formulation was converted to gel formulation by adding 0.75% w/v Carbopol 934 with 3 hours stirring at 1000 rpm using mechanical stirrer. The final gel conversion was achieved by adding sufficient quantity of Triethanolamine to form gel. [22,23,24].

RESULTS AND DISCUSSION

It is observed that the drug shows highest solubility in oil - Capmul MCM C8 EP which is 148.44 ± 1.647 mg/g (Figure 1). Drug shows highest solubility of 376.68 ± 2.424 mg/g and 164.33 ± 1.355 mg/g in the surfactant (Figure 2) Cremophore RH 40 and cosurfactant PEG 600 (Figure 3).

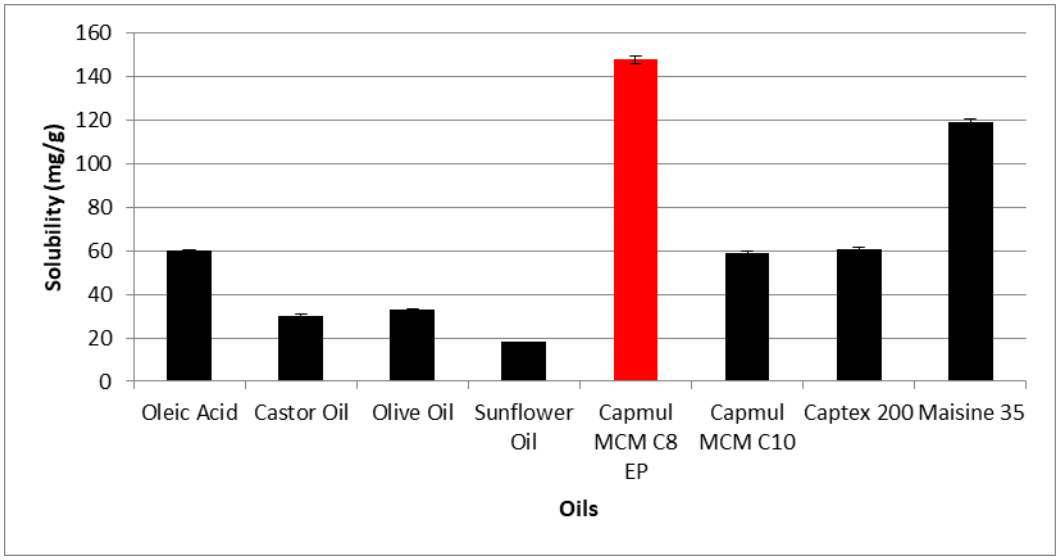

Figure 1. Solubility study of Methylprednisolone in different oils

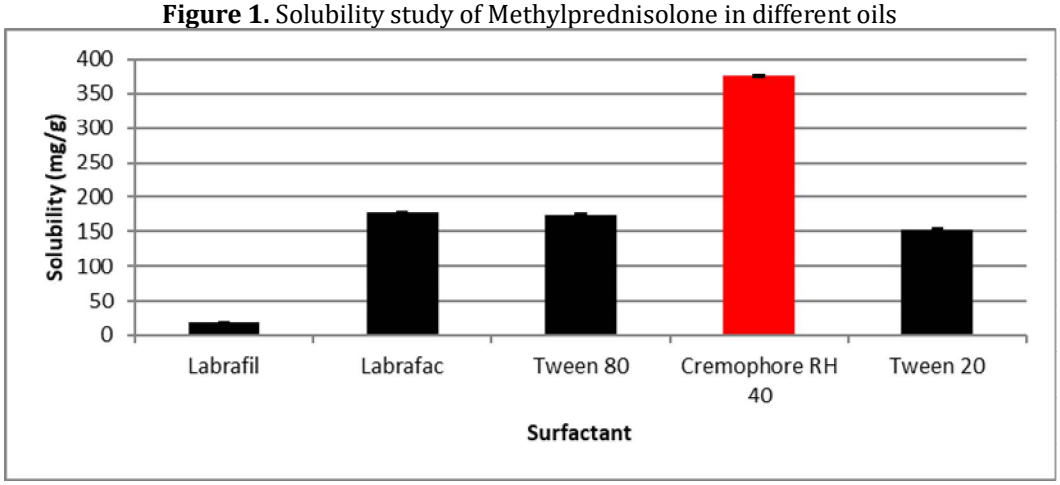

Figure 2. Solubility study of Methylprednisolone in different surfactants

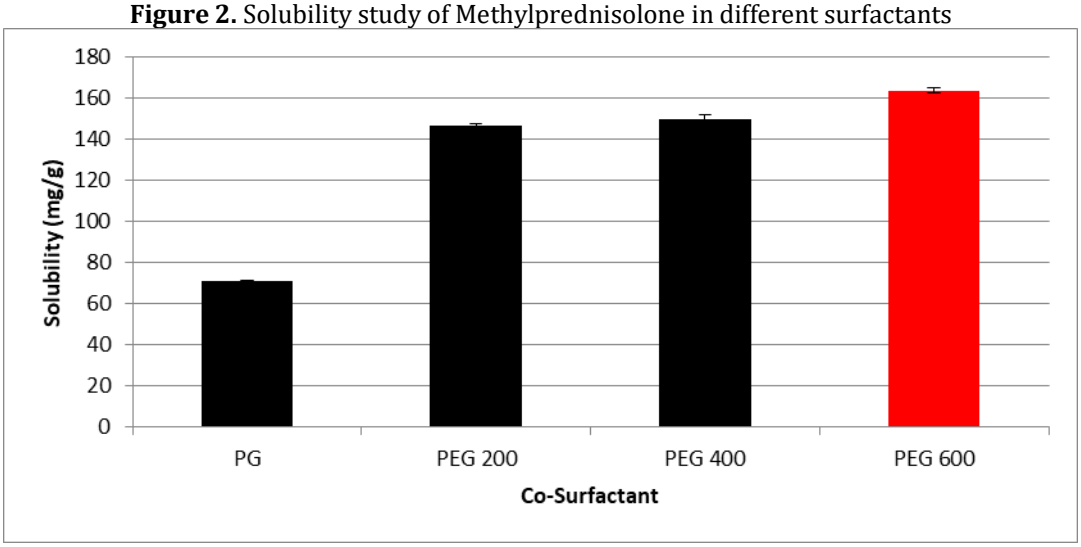

Figure 3. Solubility study of Methylprednisolone in different cosurfactants

Pseudo ternary phase diagram of the Smix ratio 3:1 showed highest emulsification range as shown in Figure 4. Therefore, it was selected for further product development.

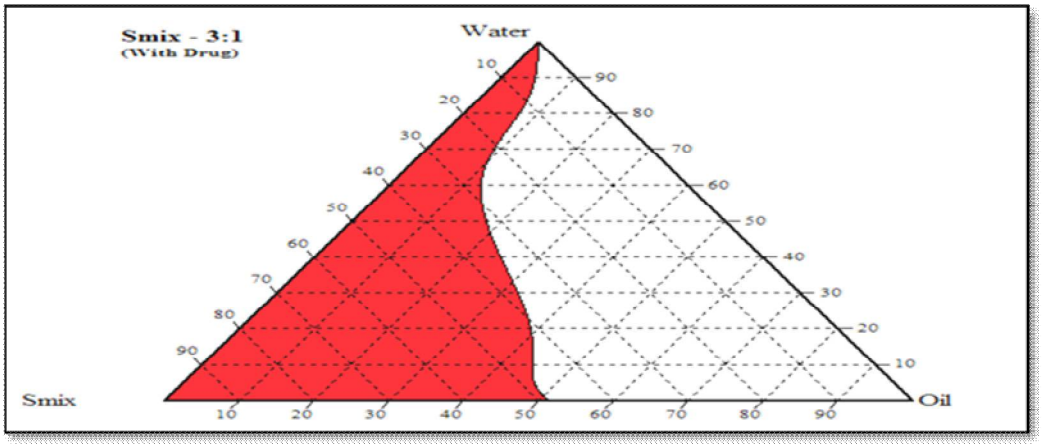

Figure 4. Ternary Phase Diagram of Methylprednisolone in Smix (3:1)

Globule size, poly-dispersibility index, zeta potential, % transmittance, pH and drug content of the formulation are given in Table 1. It is observed that the low globule size can help to achieve more drug delivery. [19,21,22]

Table 1: Evaluation of Methylprednisolone Microemulsion

Evaluation Parameter	Globule Size (nm)	Poly Dispersibility Index	Zeta Potential (mV)	% Transmittance	pH	Assay
Results	98.19 ± 2.46	0.249 ± 0.013	-32.7 ± 0.64	99.48 ± 0.37 %	6.2 ±0.2	99.27 ± 0.21

Poly dispersibility index is less than 0.3 which shows that the globules in the microemulsion are monodisperse. Zeta potential value shows the globules have enough surface charge to remain stable for long time. pH and assay results are also within acceptable criteria. Viscosity of the final gel formulation was evaluated by Brookfield viscometer and was found to be 53,272 ± 72.55 cP. [20,23,24]

CONCLUSION

Methylprednisolone is used for the treatment of eczema because it suppresses the immune system and decrease inflammation. Microemulsion based gel of methylprednisolone is prepared for faster absorption and patient compliance. The formulation is successfully prepared and is evaluated for various evaluation parameters. In the future, the formulation can be tested for *in vivo* activity and clinical trials.

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