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Transdermal delivery of pravastatin loaded microemulsion based drug delivery system developed by central composite design

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The present study involves the formulation and optimization of microemulsion based Transdermal therapeutic system to improve the bioavailability of Pravastatin, an antilipidemic agent. It is a low bioavailable drug (18%). Drug-Excipient compatibility studies were conducted by FTIR. Capmul MCM was screened as oil phase; Tween 80 and Transcutol P were selected as surfactant and co-surfactant for microemulsions, due to their good solubilizing capacity of Pravastatin. Water titration method was used for the preparation of microemulsions to construct pseudo-ternary phase diagrams by using Chemix software. The microemulsion was optimized using a three-factor, three-level Central composite design, the independent variables selected were oil (Capmul), surfactant mixture (Tween 80 and Transcutol) and water, dependent variables selected were the size (Y1), flux (Y2), and Zeta potential (Y3). Mathematical equations and response surface plots were used to relate the dependent and independent variables. The prepared microemulsions were evaluated for various physicochemical parameters, ex vivo permeation studies by using Franz diffusion cells. All parameters were within the acceptable limits. Optimized formulation composition was selected by feasibility and grid search. The optimized formulation was showed flux 86.6 (µg/cm2/h), Zeta potential-33.8±15 mV, size 38±1.8 nm. The permeation of optimized microemulsion formulation showed 4.1 folds higher flux when compared with drug solution (21.08µg/cm2/h). Validation of the optimization study with 6 confirmatory runs indicated the high degree of prognostic ability of response surface methodology. The microemulsion-based Transdermal therapeutic system of Pravastatin was developed and optimized using Central composite statistical design and could provide an effective treatment in the management of Hyperlipidemia.