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## Formulation, evaluation and optimization of clofazimine self-micro emulsifying drug delivery system

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Clofazimine is BCS class II/IV drug with low solubility and high/low permeability which has low bioavailability and high intraand inter subject variability when given orally. In the present investigation, clofazimine containing micro emulsion is formed to increase its solubility. Various oil, surfactant and co-surfactants were screened for their emulsifying capacity of clofazimine from which capmul MCM, tween 20 and labrasol were selected as oil, emulsifier and co-emulsifier respectively. Pseudo ternary phase diagram was prepared to find out emulsification region for the preparation of the micro emulsion. The boundaries of the emulsification region was used as constrain point for the application of the simplex lattice design to optimize the formulation. Here concentration of oil, surfactant and co-surfactant were selected as independent variables whereas globule size, zeta potential and polydipersity index (PDI) were selected as dependent variables. The optimized formulation was containing 25% w/w capmul MCM, 45% w/w tween 20 and 30% w/w labrasol having globule size 119.5 nm, zeta potential -13.67 mV with 0.254 PDI, >90% release of CFZ is found within 60 min in 0.1N HCl as well as in 6.8 pH phosphate buffer. The *ex vivo* permeability of CFZ-SMEDDS was approximately 4 times more than plain CFZ suspension.

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