Lipid based formulation approach for BCS class-II drug: Modafinil in the treatment of ADHD

Hemal Tandel, Dhaval Shah, Jigar Vanza, Ambikanandan Misra


Abstract

The aim of study was to formulate self-micro emulsifying drug delivery systems for modafinil. It was also an objective to optimize formulation parameters and evaluate developed formulation for its in vitro, ex vivo and in vivo performances. Solubility of modafinil was determined in various vehicles (oil, surfactant and co-surfactant) and selected excipients were used for phase diagram. D-optimal mixture experimental design was applied to optimize the formulation variables; oil phase X1 (Clove oil), surfactant X2 (Tween-80) and co-surfactant X3 (Polyethylene glycol-400). The optimized batch had smaller globule size (<20 nm) and was stable for 3 months. The rate and extent of drug diffusion was studied using dialysis sac and rat tissue, study revealed that drug release from self-micro emulsified system were significantly higher than drug suspension. In vivo pharmacokinetic study revealed its higher Cmax, AUC and relative bioavailability (Fr) compared to the suspension and marketed formulation. Furthermore, this formulation demonstrated significant improvement (p < 0.05) in learning and memory capacities in water maze test in rat. Thus, the study confirmed ‘Self microemulsification drug delivery systems’ as a possible alternative to conventional oral formulations of modafinil to improve its oral bioavailability.