Abstract:

In last decades the process of drug development was very fast and results in producing innumerable APIs that proves to be therapeutically active. Multiple active pharmaceutical ingredients (API) were developed for various diseases. But many of these APIs are dropped from the development pipeline because of their low aqueous solubility as well as poor membrane permeability. In order to improve bioavailability and clinical acceptability of these drugs a novel formulation strategy is need of the time. Microemulsion based lipoidal preparation bears much hope for such drugs. These nanolipoidal dispersions are thermodynamically stable emulsions in nature and are isotropic clear fine oil-in-water dispersions, having droplet size range of 5 to 50 nm. Cilnidipine, a 1, 4 dihydropyridine antihypertensive is poorly bioavailable and belongs to BCS class II. The present study was carried out to develop and evaluate a Cilnidipine loaded SMEDDS for enhanced pharmacokinetic parameters. Another potential aim of this study was to reduce the dose of the drug in order to counter the dose dependent toxicities related to chronic use. The SMEDDS was prepared by low energy method. A pseudo ternary phase diagram was developed using Triacetin, Tween 20 and Transcutol HP as oil, surfactants, and co-surfactants respectively. The statistically optimized formulation was obtained and was evaluated for relevant *in vitro* and *in vivo* characterizations. Globule size, zeta potential and PDI of the optimized formulation was found to be 9.045nm,-2.32mv and 0.203 respectively, indicating stable and uniformly distributed microemulsion nature of the formulation. Developed SMEDDS of viscosity 31 cps was found to be clear in 500 times dilution in water, acidic buffer P^H1.2 and phosphate buffer P^H 6.8. Selection of the optimized SMEDDS was followed by various formulation characteristics, including goat intestinal membrane permeability. The *In- vitro* dissolution study of optimized SMEDDS using LCMS/MS exhibited much better result as compared to the marketed tablet of Cilnidipine. *In-vivo* characterizations of the optimized SMEDDS shows significantly better pharmacokinetic parameters in Wister rats and showed almost 2.44 times enhanced relative bioavailability as compared to the marketed tablet of Cilnidipine which was observed to be correlating to our findings with Non-invasive blood pressure parameter of Wister rats.