

Optimization of Lercanidipine Nanocrystals Using Design of Experiments Approach

Authors : Dolly Gadhiya, Jayvadan Patel, Mihir Raval

Abstract : Lercanidipine hydrochloride is a calcium channel blockers used for treating angina pectoris and hypertension. Lercanidipine is a BCS Class II drug having poor aqueous solubility. Absolute bioavailability of Lercanidipine is very low and the main reason ascribed for this is poor aqueous solubility of the drug. Design and formulation of nanocrystals by media milling method was main focus of this study. In this present study preliminary optimization was carried out with one factor at a time (OFAT) approach. For this different parameters like size of milling beads, amount of zirconium beads, types of stabilizer, concentrations of stabilizer, concentrations of drug, stirring speeds and milling time were optimized on the basis of particle size, polydispersity index and zeta potential. From the OFAT model different levels for above parameters selected for Plackett - Burman Design (PBD). Plackett-Burman design having 13 runs involving 6 independent variables was carried out at higher and lower level. Based on statistical analysis of PBD it was found that concentration of stabilizer, concentration of drug and stirring speed have significant impact on particle size, PDI, zeta potential value and saturation solubility. These experimental designs for preparation of nanocrystals were applied successfully which shows increase in aqueous solubility and dissolution rate of Lercanidipine hydrochloride.

Keywords : Lercanidipine hydrochloride, nanocrystals, OFAT, Plackett Burman

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