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Design of polymeric nanocapsules for raloxifene hydrochloride by multiple emulsion method (w/o/w) using rotatable central composite design model

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Raloxifene HCl (RLX) is used in prevention and treatment of post-menopausal osteoporosis in women. It has poor oral bioavailability (less than 2%) and shows high inter-patient variability. The present study aimed at developing oral poly-[epsilon]-caprolactone (PCL) nanocapsules of RLX using modified multiple emulsion technique (w/o/w) to improve its oral bioavailability. The Rotatable Central Composite Design (RCCD) is used in the present study to understand the effects of process variables on two responses: particle size and entrapment efficiency (EE) of the nanocapsules. Three critical factors identified in the study were amount of polymer, amount of surfactant (Lutrol F-127) and ultrasonication time (at 30 W output). Particle size and zeta potential were measured by Malvern Zetasizer. Loading efficiency and EE were determined for the developed nanocapsules. *In-vitro* drug release profiling was done in pH 7.4 phosphate buffered saline. Further characterization of the polymeric nanocapsules was done by FT-IR and DSC. Response surface methodology was used to determine the influence of multiple factors on particle size and EE of formulations. The particle size ranged from 134 ± 4 nm to 230 ± 3 nm for different formulations. All the formulations carried negative surface charge. The EE values ranged from 43 ± 5% to 85 ± 3%. The experiments carried out at the center points indicated the reproducibility of the method with RSD less than 4% for both particle size and EE. From the analysis of data, it was shown that amount of PCL had linear effect on particle size of the nanocapsule, while EE was inversely affected by amount of surfactant and ultrasonication time. Drug was found to be compatible with the excipients used. *In-vitro* drug release showed biphasic release pattern, characterized by an initial burst release of RLX followed by slower and more continuous release up to 72 h. The optimized formulation provided particles with required particle size (below 250 nm) and high entrapment efficiency.

Biography

Punna Rao Ravi has completed his Ph.D. from Birla Institute of Technology and Science, Pilani, Rajasthan. He is currently working as Assistant Professor in Pharmacy Department, Birla Institute of Technology and Science-Pilani Hyderabad Campus. He has published more than 12 papers in reputed international journals.

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