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Development and Optimization of Solid Lipid Nanoparticle Formulation for Enhanced Solubility of Ceritinib Using Box-Behnken Design

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Abstract

Background: Ceritinib is an anaplastic lymphoma kinase (ALK) inhibitor that exhibits low water solubility and poor drug compressibility hence depressed bioavailability. Objective: The objective of the current research is to develop ceritinib-loaded solid lipid nanoparticles (SLNs) for enhancing bioavailability.

Materials and Methods: Box–Behnken design (BBD) was employed to optimize variables in the formulation process of ceritinib-loaded SLNs containing three factors and evaluated at three levels. The independent variables include the ratio of drug to lipid (A), concentration of glyceryl monostearate (B), and Poloxamer-188 concentration (C), whereas dependent variables were particle size (Y1) and entrapment efficiency (Y2). The SLNs prepared by single emulsification and solvent evaporation method. Three optimized formulations of ceritinib SLN prepared using the BBD and subjected for physicochemical characterization.

Results: The formulation F1 with mean particle size (167.9 nm), polydispersity index (0.645), zeta potential ($-24.9 \pm 1.48\text{mV}$), and % entrapment efficiency (90.24%) is chosen for further investigation. The scanning electron microscopy study confirms a spherical shape.

Conclusion: The in vitro studies indicate a maximum drug release of 95.12% in 360 min for F1 which is much higher than of control (30.12% in 360 min). No significant difference (P

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