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SOLID LIPID NANOPARTICLES OF REBAMIPIDE: FORMULATION, CHARACTERIZATION AND IN VIVOPHARMACOKINETIC EVALUATION

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Abstract

Objective: Rebamipide (REB) is a gastroprotective agent used to treat ulcers and gastritis throughout the stomach. Rebamipide is a BCS class IV drug with low oral bioavailability of less than 10%. The objective of this study was to develop an REB-SLNs formulation for oral administration to improve the bioavailability of rebamipide.

Methods: The hot homogenization and ultrasonication methods were used to prepare the REB-SLNs. Lipids are dynasan 114, dynasan 116, dynasan 114, imwitor 900 P. Non-ionic surfactants are poloxamer 188, polysorbate 80, and lipoid E 80 act as an amphoteric stabilizing agent used in the formulation. Developed SLNs were evaluated for particle size, PDI, zeta potential, entrapment efficiency, drug content, in vitro release, stability studies, and in vivo pharmacokinetic profile.

Results: The optimized REB SLNs (F9) formulation prepared with Dynassan 114 contains an average particle size of 234±3.5 nm, PDI of 0.228±0.05, ZP of-24.58±2.63mV, drug content of 99.89±0.04%, and entrapment efficiency of 96.15±0.32%. DSC studies revealed that no interactions occurred between drugs and excipients. SEM studies showed that SLNs were nearly spherical. In vitro drug release of the optimized formulation, F9 was 91.61% in 24 h as sustained drug release. The optimized formulation was stable under refrigeration and room temperature for three months. Invivo pharmacokinetic studies of optimized formulation (F9) exhibited higher Cmax and AUC values relative to the coarse suspension.

Conclusion: Compared to the reference standard coarse suspension, the relative bioavailability of the developed formulation of REB-SLNs of dynasan 114 and combination of poloxamer 188 and polysorbate 80 (F9) was increased by 3.87 times.

Author Keywords

Solid lipid nanoparticles, Rebamipide, Bioavailability, Pharmacokinetics, Homogenization, and ultrasonication

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