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Lapatinib-loaded self- assembled Soluplus® polymeric micelles for breast cancer treatment by intravenous route

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Breast cancer is second leading cause of death among women. USFDA approved Lapatinib for HER2-positive breast cancer treatment; however, its clinical application is limited due to its poor aqueous solubility, large daily oral dose (1250 mg/day) and associated toxicities. Thus, we prepared Lapatinib-loaded self-assembled nanocolloidal polymeric micelles (LP-PMs) using Soluplus® and Pluronics F127 by a thin-film hydration method and hypothesized that a core-shell structure of PMs would enhance solubility and passively target tumors by enhanced permeation and retention effect. The prepared LP-PMs are intended for intravenous administration as no commercial intravenous product is available till date in market. Evaluation included solid state characterization confirming amorphization and encapsulation of drug with no typical incompatibility other than hydrogen bonding within formulation components. LP-PMs were optimized by Quality-by-Design approach. The LP-PMs had uniform size of 92.9±4.07 nm diameter with 5.06 mV zeta potential, and high drug encapsulation (approx. 87%). Further, *in vitro* release studies showed 36% and 60% of LP release from LP-PMs in 48 h in pH 7.4 and pH 5.0 release media, respectively, indicating sustained and preferentially higher release at acidic tumor site. It is noteworthy to mention that LP-PMs induced significantly less hemolysis than pure LP with no platelet aggregation; indicating their appreciable hemocompatibility and suitability for intravenous administration. On the other hand, LP-PMs showed higher efficacy for apoptosis induction in breast cancer cell lines (SKBr3) than pure drug. Conclusively, these findings indicate the greater potential of LP-PMs to serve as a promising intravenous alternative that can open the new route for breast cancer treatment.

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