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Design and Development of Optimised Nanostructured Polymeric Systems of Raloxifene For Improved Biopharmaceutical Application in Breast Cancer: A Review

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Abstract: *Breast cancer remains the most common malignancy in women globally, accounting for approximately 36% of oncology cases, with over 2.089 million diagnoses reported in 2018. Its incidence is rising worldwide, particularly in industrialized nations, attributable to Western lifestyle factors such as poor diet, smoking, stress, and sedentary behavior. Early detection primarily relies on mammography, with high sensitivity (75–95%) and specificity (80–95%), especially in women aged 50–69 years, and supplemental screening techniques like MRI and ultrasonography. Despite advancements, therapeutic challenges persist due to hormone dependence, genetic predisposition, and treatment complications. Nanotechnology presents a promising avenue to enhance breast cancer treatment through optimized drug delivery platforms. Nanocarriers—including polymeric nanoparticles, liposomes, solid lipid nanoparticles (SLNs), dendrimers, and micelles—offer enhanced solubility, bioavailability, controlled release, and tumor targeting via surface modification and receptor-mediated uptake. Raloxifene, a selective estrogen receptor modulator with poor oral bioavailability (~2%), benefits significantly from encapsulation in nanocarriers to overcome solubility limitations and extensive first-pass metabolism. Nanostructured delivery systems documented for raloxifene include PLGA–PEG–PLGA nanomicelles, mPEG-PLA nanoparticles, chitosan-based systems, SLNs, cyclodextrin–chitosan composites, and hyaluronated chitosan nanoparticles, all uniformly demonstrating nanoscale size (100–200 nm), high encapsulation efficiency, amorphous drug dispersion, sustained release, and multi-fold-enhanced bioavailability in preclinical animal models. However, translation to clinical use is hindered by challenges such as complex manufacturing scale-up, reproducibility, stability, regulatory requirements, and nanotoxicity assessment. Future directions must focus on scalable, green manufacturing techniques, standardized characterization, real-world pharmacokinetics, and targeted, non-oral delivery routes. Integration of quality assurance frameworks and robust toxicological protocols with regulatory alignment will be essential for realizing the clinical potential of raloxifene-polymeric nanosystems in breast cancer therapy.*

Keywords: Breast cancer; Nanotechnology Drug Delivery; Ralpxifene; Nanoparticle

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