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Design and Development of Mucoahesive Vaginal Drug Delivery System of Raloxifene Hydrochloride

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Abstract: Objective: Raloxifene hydrochloride is a selective estrogen receptor modulator with a very poor oral absolute bioavailability (2%) due to high hepatic first-pass metabolism. Mucoadhesive vaginal tablets of Raloxifene hydrochloride can bypass high hepatic first pass metabolism and also improve its solubility and dissolution behaviour.
Methods: Inclusion complex of drug with β-cyclodextrin was prepared by kneading method. Composition of the mucoadhesive tablet was optimized using 3^2 full factorial design where amount of sodium CMC (X_1) and amount of Polycarbophil (X_2) were taken as independent variables. Drug release at 6 hour (Q_6), mucoadhesive strength and swelling index were considered as dependent variables. The formulations of design batches were characterized for weight variation, hardness, thickness, friability, drug content, swelling index, *ex-vivo* mucoadhesive strength, surface pH, drug release at 6 hrs, *ex-vivo* residence time, drug release data modelling. Optimized batch was subjected to *ex-vivo* permeation study and short term stability study.
Results: The optimized formulation (F5) comprises 20 mg of sodium CMC and 15 mg of polycarbophil had shown mucoadhesive strength (0.343N), swelling index (36.04%) and % drug release at 6 hours (95.90%).ex-vivo permeation was found to be 47.93% at 6 hr. Results of drug release data modelling suggested zero order drug release kinetics (R2=0.9983) with case II transport release mechanism (n=0.9513) for optimised batch.
Conclusion: Raloxifene hydrochloride mucoadhesive tablet is a promising approach for the effective treatment of disease as it provides control drug release and bypasses the hepatic first pass metabolism.
Key words: osteoporosis, factorial design, Contour plot, β-cyclodextrin, phase solubility, Job's plot.

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