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Dual working gastroretentive delivery system of poorly water soluble drug for pH-independent release modulation

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The study was aimed to design and develop gastroretentive drug delivery system combining two techniques mucoadhesion and floating. The final formulation was bilayer tablet comprising quetiapine fumarate as a model poorly water soluble drug. The upper layer (UL) of the tablet comprised of mucoadhesive polymer and floating sodium alginate beads while the lower layer (LL) was made up of drug, polymer and acidifier. Gas generating agents were incorporated into alginate beads to increase floating lag time. Optimization of both the layers was carried out by applying 3 x 2 full factorial design. The UL was optimized using two independent factors amount of alginate beads ($X1_{UL}$) and amount of polyox®303WSR ($X2_{UL}$) while LL was optimized using two independent factors: amount of HPMC K100M ($X1_{LL}$) and amount of fumaric acid ($X2_{LL}$). Tablets were prepared by direct compression technique. Intactness of beads was checked by SEM analysis. Floating lag time and mucoadhesive strength of the factorial batches were in the range 250 - 450 min and 0.3 - 0.6 N/cm^2, respectively. Total floating time of factorial batches was in the range 9 - 16 hr. The values of floating lag time, mucoadhesive strength and total floating time of the optimized batch were 350±15.2 min, 0.44±0.3 N/m^2 and 684±20.6 min, respectively. Matrix layer drug release showed good similarity with target drug release profile. The Fourier transform infrared spectroscopy illustrated stable nature of drug in the formulation and proved the absence of drug-excipient interactions. The formulation was found stable throughout the accelerated stability testing period of three months. In a nutshell, dual working gastroretentive systems can be developed as a platform for delivery of pH dependent poorly soluble drugs.

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