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Bioavailability enhancement of sulpiride from a gastro retentive drug delivery system in rabbits

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The present study was aimed to develop, validate a simple reversed-phase high performance liquid chromatographic method for determination of sulpiride in plasma and also to evaluate in vivo performance of the optimized gastroretentive formulation in comparison with a non-gastroretentive reference product (Dogmatil®) using rabbits as an animal model. The HPLC system was operated at an excitation and emission wavelengths of 300 nm and 365 nm, respectively with the gain was set at 4 and sensitivity at medium. The mobile phase was consisted of 0.01 M phosphoric acid, acetonitrile and methanol (84:12:4, v/v) with addition of Triethylamine (0.15%v/v). The mobile phase pH was adjusted to 6 by using glacial acetic acid. The mobile phase was isocratically pumped at a flow rate of 1 mL/min. The analytical column Luna C18 (5 µm, 250 x 4.6 mm ID, Phenomenex, USA) fitted with a refillable guard column (Upchurch Scientific, Oak Harbour, WA, USA) packed with Perisorb RP-18 (30-40 µm, pellicular) was used for chromatographic separation. The mobile phase was filtered under vacuum through 0.45 µm nylon membrane filter (Whatman International, England) and degassed before used. The calibration curve was linear in the range of 15 to 4000 ng/ml with correlation coefficient (r) of 0.9999 (±0.0001). The intra-day accuracy ranged from -4.59% to 12.91% with a precision from 1.42% to 6.79%. The inter-day accuracy ranged from -1.86% to 6.29% with a precision from 4.21% to 13.91%. The extraction recovery values were found to be 95.99±9.44%, 96.12±11.94% and 93.49±5.13%, with precision of 9.84%, 12.42% and 5.49% respectively. The mean recovery for internal standard (metoclopramide) was 90.28±3.95%. The values of accuracy, precision and recovery obtained were within the acceptable limits as proposed by USFDA Bioanalytical Guidelines. For in vivo pharmacokinetics study a balanced two-way crossover design was used using 6 rabbits. The optimized formulation had higher Tmax, and AUC0-∞ values but lower Cmax value than non-gastroretentive reference product (Dogmatil® capsule). The bioavailability of sulpiride in the optimized gastroretentive dosage form was 2.20 times higher than the non-gastroretentive reference product (Dogmatil® capsule). In addition, the amount of drug released *in vitro* was correlated with the amount of drug absorbed *in vivo.*

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Applying lean manufacturing principles to a pharmaceutical site: Case study

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Reducing different types of waste and process improvement are shared targets of lean manufacturing and pharmaceutical guidelines (e.g. pharmaceutical quality system ICH Q10). In order to establish an integrated quality system we have used lean tools to discover areas for development and enhance continual improvement of our procedures. This project is carried out on the light of change management system to ensure adherence to cGMP and regulatory requirement in case of any variation is needed of process or system. Satisfactory results have been achieved supported with a finical analysis report.

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