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Validated LC-MS method for determination of Tamsulosin in human plasma and its application in bioequivalence study

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An accurate, precise, and sensitive high-performance liquid chromatography tandem mass spectrometry (HPLC-MS/MS) assay was developed for the determination of Tamsulosin in human plasma samples to compare the bioavailability of 2 capsules (0.4 mg) oral formulations in 26 volunteers. Tamsulosin concentrations were analyzed by a rapid and selective and validated liquid chromatographic/tandem mass spectrometric method. Following protein-precipitation, the analyte and internal standard (metoprolol) were separated from human plasma using a gradient mobile phase on an Acquity® UPLC BEH C18 column. A TQD Waters tandem mass spectrometer equipped with IonSpray ionization source was used as detector and was operated in the positive ion mode. Multiple reaction monitoring using the precursor to product ion combinations of m/z 409.10>228.02 and m/z 268.10>72.05was performed to quantify Tamsulosin and internal standard, respectively. The method was linear in the concentration range of 0.40 – 28.00 ng/mL using 500 µL of plasma. The lower limit of quantification was 0.40 ng/mL. The intra- and inter-day relative standard deviation over the entire concentration range was less than 2.24%. Accuracy determined at three concentrations (1.20, 14.20, and 24.80 ng/mL for Tamsulosin) ranged from 1.03% to 4.59% in terms of relative error. Each plasma sample was chromatographed within 3.2 minutes. The bioequivalence study was an open- label randomized 2-period crossover trial with a 1-week washout period. Plasma samples were obtained over a 32-hour period. The bioequivalence between the two formulations was assessed by calculating individual peak plasma concentrations (C_{max}) and area under the curve (AUC_{0-32h}) ratios (test/reference). The statistical interval proposed was 80-125%, as established by international regulatory agencies.

Biography

Maricela Martinez-Delgado is currently is Head of Biopharmaceutical R&D Department in Dixpertia Investigación Biofarmacéutica y Farmacológica S. C., she has developed and validated over 50 analytical methods for determination of pharmaceutical molecules.