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Simple HPLC-MS/MS method for simultaneous determination of aripiprazole and dehydroaripiprazole in human plasma using microelution solid phase extraction

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A selective and accurate high pressure liquid chromatography-tandem mass spectrometry (HPLC-MS/MS) method has been developed and validated for simultaneous monitoring of Aripiprazole and its active metabolite Dehydroaripiprazole in human plasma using aripiprazole-d8 as the internal standard (IS). The analytes and IS were extracted from 200 µL of human plasma by solid-phase extraction using Oasis PRiME HLB 96-well µElution Plate, 3 mg sorbent per well (Waters, Madrid, Spain). Separations were carried out at 25°C in an ACE C18-PFP column (4.6 mm×100 mm and 3-µm particle size (SYMTA, Madrid, Spain) protected by a 0.2-µm on-line filter. The mobile phase consisted of a combination of 0.2% formic acid and 0.3% ammonia in MilliQ water pH=4.0 (solution A) and ACN (solution B) (65:35, v/v). The chromatogram was run under gradient conditions at a flow rate of 0.6 mL/min. Run time was 5 min followed by a re-equilibration time of 3 min, to give a total run time of 8 min. The volume injected into the chromatographic system was 5 µL. The analytes were detected using the mode multiple reaction monitoring in the positive ionization mode. The linearity of the method was established in the concentration range 0.15-110 ng/mL and 0.35-100 ng/mL for Aripiprazole and Dehydroaripiprazole, respectively. We validated the analytical method according to the recommendations of regulatory agencies through tests of precision, accuracy, recovery, matrix effect, stability, sensitivity and selectivity. The method was applied to 6 different bioequivalence studies of 10 mg aripiprazole formulation in 40 healthy Caucasian subjects.

Biography

Wojnicz A is currently pursuing PhD from Autonomous University of Madrid, Spain. She is a Bioanalyst Scientist, working at Analytical and Pharmacokinetic Unit of Clinical Pharmacology Service of 'Hospital Universitario de la Princesa', Madrid, Spain. She has spent 3-months period at Department of Pharmacy & Pharmaceutical Science and Biochemistry of University of California San Diego (UCSD) to improve her knowledge with experts in mass spectrometry. She has published more than 7 papers in reputed journals.

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