

2nd International Conference on

PHARMACEUTICAL CHEMISTRY

October 02-04, 2017 Barcelona, Spain

Method development and validation of lercanidipine in human plasma by liquid chromatography tandem - mass spectrometry

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Lercanidipine is an antihypertensive drug belonging to class of calcium channel blockers that is effective in treatment of patients with mild to moderate hypertension without affecting heart rate. The aim of this study was to obtain the optimum method and validate lercanidipine analysis in plasma using LC-MS/MS. Chromatographic separation was performed using Waters Acquity™ UPLC C18 1.7 μm (2.1 x 100 mm) column with mobile phase a mixture of 0.1% formic acid - methanol (20:80 v/v) with isocratic elution, the column temperature was 30°C with 0.2 mL/min flow rate and amlodipine as internal standard. Mass detection was performed on Waters Xevo TQD equipped with an electrospray ionization source in the MRM mode. Lercanidipine was detected at m/z 612.11 > 280.27 and amlodipine was detected at m/z 409.1 > 238.15. The optimum sample preparation was carried out by liquid-liquid extraction method using 5 mL mixture of n-hexane-ethyl acetate (50:50 v/v), vortexed for 3 mins, centrifuged at 4000 rpm for 20 mins, evaporated at 50°C for 30 mins, and reconstituted with 100 μL of mobile phase. This method was linear at concentration range of 0.025 to 10 ng/mL with $r \geq 0.9986$, and fulfills the acceptance of accuracy and precision within and between run in three days. In addition, this method fulfills the acceptance criteria for selectivity, carry over, stability, dilution integrity and matrix effects based on Guideline on Bioanalytical Method Validation by the EMA in 2011.

Biography

Yahdiana Harahap completed her PhD from the Department of Pharmacy, Institute Technology Bandung, Indonesia. She is currently the Head of Bioavailability and Bioequivalence laboratory Faculty of Pharmacy, Universitas Indonesia. Prior to this position, she was the Dean of Faculty of Pharmacy, Universitas Indonesia. She has published more than 50 papers published in both International and National Journals. She has been invited to be the speaker in many international conferences, especially in the field of BA/BE and Bioanalysis technique. She currently serves as an Expert at Indonesia National Agency of Drug and Food Control, specifically in BA/BE evaluation.

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