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Development and validation of a high-performance liquid chromatography-tandem-tandem mass spectrometry for quantitative determination of Fimasartan and Amlodipine in human plasma: Its application to a pharmacokinetic study of 60mg Fimasartan and 10mg Amlodipine

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A rapid, specific and fully validated high-performance liquid chromatography-electrospray ionization-tandem mass spectrometry (LC-MS/MS) method was developed for the determination of Fimasartan and Amlodipine using BR-A-563 and Clarithromycin as an internal standard, respectively. Liquid-liquid extraction (LLE) was carried out on 0.05 mL of human plasma using ethyl acetate and hexane for Fimasartan and 0.2 mL of human plasma using methyl tert-butyl ether (MTBE) and methyl chloride (MC) for Amlodipine. Detection was performed in positive ion multiple reaction monitoring (MRM) mode by monitoring the transitions: m/z 502.4 → 207.1 for Fimasartan, m/z 526.48 → 207.2 for BR-A-563, m/z 408.9 → 238.0 for Amlodipine and m/z 748.2→158.0 for Clarithromycin, respectively. Chromatographic separation was performed on Kinetex C18 (75 × 2.1 mm, 2.6 µm) using a mobile phase consisting of 0.05% formic acid- methanol (30:70, v/v) at a flow rate of 0.2 mL/min for Fimasartan and Luna C18 (50 × 2.0 mm, 3.0 µm) using a mobile phase consisting of 0.1% acetic acid-methanol (30:70, v/v) at a flow rate of 0.2 mL/min for Amlodipine. The linear calibration curves were 1-500 ng/mL for Fimasartan and 0.2-20 ng/mL for Amlodipine. The total runtime was 2.5 min for Fimasartan and 3 min for Amlodipine, retention time was about 1.6 and 1.0 min for Fimasartan and Amlodipine, respectively. The intra-day and inter-day reproducibility was less than 12% for each analyte. The proposed method shows good separation of analytes, without interference from endogenous substances. Fimasartan and Amlodipine were found to be stable under these conditions and the method was successfully applied to the pharmacokinetic study of complex tablet (Dukarb®, 60 mg Fimasartan and 10 mg Amlodipine).

Biography

Do-Hyung Kim majored in life sciences at Kyung Hee University in South Korea and had experience with many natural plants in Thailand and Indonesia. He is currently a master of medicine analysis at Kyung Hee University. He has a lot of experience in drug analysis and has a lot of experience in bioequivalence experiment, clinical experiment and pharmacokinetic experiment.

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