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A validated UPLC/ESI-MS/MS bio-analytical method for the quantification of Perindopril and Amlodipine in human plasma

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Background: In the present study, a validated UPLC/ESI-MS/MS method for the determination of combined dosage form of perindopril and amlodipine in human plasma sample was optimized. This method was responsive and an adequate amount to observe the low-dosage PK studies of perindopril and amlodipine in human plasma.

Methods: Chromatographic separation was achieved on a Waters ACQUITY UPLCTM BEH C18 (100.0 mmX2.1 mm; 1.7 µm) column. UPLC analysis consisted of mobile phase A for 0.1% formic acid in MilliQ water and mobile phase B for 0.1% formic acid in acetonitrile, which was degassed. The gradient elution with flow rate at 0.3 mL.min-1 of mobile phase was kept and 10 µL of sample was injected in each run. The total chromatographic run time was 5.5 min. Mass spectrometric detection was carried out in Multiple Reaction Monitoring (MRM) mode using electrospray ion source in positive ion polarity to profile the abundances using the transitions m/z 369 → m/z 172, and m/z 409 → m/z 238 for perindopril and amlodipine, respectively, and the transitions m/z 612.75 → m/z 280.30 for lercanidipine as internal standard. Argon was used as the collision gas at the pressure of 3.5X10-5 Torr. In this developed method, a high recovery of perindopril and amlodipine in plasma samples was proved with improved quality data in terms of increased detection limits and chromatographic resolution with greater sensitivity.

Conclusions: UPLC with MS/MS has the advantage over problems of poor chromatography, wearisome extraction steps, uncertain characterized peak and high injection load. As per FDA guidelines, the method is validated for its accuracy, robustness and reproducibility. Quantification of perindopril and amlodipine dosage forms by this method is time saving, cost effective and it can be used in clinical studies to quantify the drug content in human plasma samples.

Biography

Kalaiyarasi Duraisamy has completed her MPharmacy from The Tamilnadu Dr. MGR Medical University and pursuing part time PhD at JNTU, Hyderabad. She is working in a biopharmaceutical company and has more than 5 years of research experience in analytical R&D.

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