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A validated LC-MS/MS assay for the quantitative determination of hypophyllanthin and silibinin in human plasma: Application to a pharmacokinetic study in healthy volunteers

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A selective and sensitive liquid chromatography tandem mass spectrometry method (LC-MS/MS) has been developed for determination of Hypophyllanthin (HPT) and Silibinin (SBN) in human plasma. Sertraline hydrochloride was used as the internal standard (IS). Sample preparation involved liquid–liquid extraction by tert butyl metyl ether. Chromatographic separation was carried out on a C8 column ($3 \mu m$, $3.0 \times 50.0 mm$) with isocratic elution using a mobile phase of water:acetonitrile (10:90 v/v) at a flow rate of 0.6 mL/min. The detection was performed by tandem mass spectrometry with multiple reactions monitoring mode via electrospray ionization source in positive ionization mode. Analysis was carried out within 2.0 min over a linear concentration range of 1.00 -1000 and 1.00 – 500 ng/mL for HPT and SBN, respectively, and the LLOQ was 1 ng/ml for both compounds. The method was validated according to FDA guidelines for bioanalytical method validation and satisfactory results were obtained. This validated method was successfully applied to a pharmacokinetic study enrolling 20 male volunteers administered a single oral dose of Heptex vegetable capsules.

Biography

Said A Hassan is a Lecturer of Analytical Chemistry and Instrumental Analysis at Faculty of Pharmacy, Cairo University. In 2015, he was awarded the PhD degree in Analytical Chemistry. He finished the MSc in Analytical Chemistry in 2012 and was awarded the best master's thesis in Faculty of Pharmacy, Cairo University. He got the BSc in Pharmaceutical Science in Faculty of Pharmacy, Cairo University in 2007 graded Excellent with honor and ranked 8th in his class. He has experience in topics such as UV-VIS spectrophotometry, chromatographic techniques, capillary electrophoresis, chemometrics & electrochemical methods of analysis.

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