A simple high-performance liquid chromatographic assay for lumefantrine in plasma in the presence of efavirenz-based antiretroviral therapy

Ruth Ogboye¹ Julius Soyinka¹ Oluseye Bolaji¹ Adebanjo Adegbola¹

¹Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Obafemi Awolowo University, Ile-ife, Nigeria

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As per current treatment guidelines, artemether-lumefantrine, and efavirenz (EFV)-based antiretroviral therapy are recommended drugs for falciparum malaria and HIV infections, respectively. A liquid chromatography-ultraviolet detection (LC-UV) method for simultaneous quantification of lumefantrine and EFV was developed and validated for efficacy and pharmacokinetic clinical studies. Lumefantrine and EFV were separated using a 100 x 4.6 mm x 3 µm Fortis C 18 chromatographic column, and a multistep gradient mobile phase. Calibration was obtained with a series of standard solutions containing known concentrations of the chemical reference of both analytes prepared concomitantly in drug-free plasma. The assay was validated within the calibration ranges of 78.125 to 20000 ng/mL for lumefantrine and 187.15 to 24000 ng/mL for EFV. Stability assessment was carried out with or without heating the quality sample to 58°C for 45 min. The method was employed to measure the plasma concentrations of lumefantrine and EFV in a study conducted among malaria-HIV co-infected patients. Lumefantrine and EFV were well separated from each other and from the biological matrix. The method demonstrated a good recovery of 72.64% for lumefantrine and 117.17% for EFV. The intra- and inter-day accuracy presented as 95.36-105.14% for lumefantrine and 104.11-115% for EFV and precision ranged from 1.15 to 6.45% for lumefantrine and 0.43 to 13.12 for EFV, were within ±15% at the three quality control levels. The analytes from both quality control lots and samples collected from HIV-malaria co-infected individuals were found to be stable post-deactivation of infectious virus by heating to 58 °C for 45 min. The assay is accurate, precise and shown to simultaneously measure the lumefantrine and EFV in human plasma.