OPTIMIZATION OF VANKOMISIN BIOANALISIS METHOD IN SPIKED-HUMAN PLASMA AND ITS STABILITY TEST USING HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) UV DETECTOR

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ABSTRACT

Vancomycin is glycopeptide antibiotic with a narrow therapeutic index ranging from 10-40 µg/mL. Human plasma is used as matrix in this bioanalysis. The aim of this study was to obtain a more effective and efficient method of bioanalysis vancomycin, and know the stability of vancomycin in plasma during the preparation of samples, storage, until the analysis completed to achived the criteria prescribed by the European Medicines Agency (EMA) and the Center of Drug Evaluation and Research (CDER). The bioanalytical method used High Performance Liquid Chromatography with UV detector at 213 nm wavelength, mobile phase used buffer phosphate (KH_2PO_4) 5 mM pH 3 and methanol (80:20 v / v), flow rate 1.0 mL/min, 20 µL injection volume, stationary phase used C18 column (250 mm x 4.6 mm, 5 µm) with isocratic elution technique. Separation of compounds was carried out by liquid-liquid extraction using dichlorometan and HCl pH 3 and protein precipitation by methanol. The linearity test of vancomycin spiked-plasma calibration curve resulted in r = 0.9998 with a range of 0-60 µg/mL. The value of Lower Limit of Quantification (LLoQ) vancomycin in spiked-plasma was 2.59 µg/mL; Low Quality Control sample (QCL) 12,95 µg/mL and High Quality Control (QCH) 48 µg/mL. Based on the results of stability test vancomycin in spiked-plasma, frozen liquid, and post-preparation found that vancomycin stable in plasma for 21 days in storage -20°C and 24 hours at room temperature (25°C), while vancomycin stock solution stable for 30 days at storage 4°C and 24 hours at room temperature (25°C) with the %diff not exceeding ±15%.

Keywords: Vancomycin, spiked-plasma, Method Optimization, KCKT-UV, Stability Test.