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Haitham AlRabiah, Mohammed A. Hamidaddin, Ibrahim A. Darwish

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Automated flow fluorescent noncompetitive immunoassay for measurement of human plasma levels of monoclonal antibodies used for immunotherapy of cancers with KinExA™ 3200 biosensor

Haitham AlRabiah[1], Mohammed A. Hamidaddin[1,2], Ibrahim A. Darwish[1]*

[1]Department of Pharmaceutical Chemistry, College of Pharmacy, King Saud University, P.O. Box 2457, Riyadh 11451, Saudi Arabia.

[2]Department of Medicinal and Analytical Chemistry, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

*Corresponding Author: Ibrahim A. Darwish, Prof. Fax: +966-114676220, Tel: +966-114677348, E-mail: idarwish@ksu.edu.sa

ABSTRACT

This study describes, for the first time, the development of an automated sensitive flow fluorescent noncompetitive immunoassay based on kinetic-exclusion analysis (KinExA) for the quantitative determination of human plasma levels of monoclonal antibodies (mAbs) used for cancer immunotherapy. The assay was adapted on KinExA™ 3200 biosensor and optimized and validated for bevacizumab (BEV) and cetuximab (CET), as representative examples of the mAbs, using their specific antigens. These antigens were the human vascular endothelial growth factor (VEGF) and epidermal growth factor receptor (EGFR) for BEV and CET, respectively. The limits of detection were 1.28 and 52.64 ng mL^{-1} for BEV and CET, respectively. The accuracy of the assay was demonstrated with analytical recovery of analytes from spiked plasma at 96.2 – 104.3 and 96.8 – 105.3% for of BEV and CET, respectively. The precision of the assay was satisfactory as shown by relative standard deviation (RSD) at 2.2 – 5.7 and 2.5 – 6.1% for