Simultaneous Determination of Metformin, Vildagliptin and 3-amino-1-adamantanol in Human Plasma: Application to Pharmacokinetic Studies

Ramzia Ibrahim, Hassan M. E. Azzazyb, Ehab F. ElKadyc & Faten Faroukd*

Professor of Pharmaceutical chemistry, Head of Pharmaceutical Chemistry Department.

Abstract

Metformin (MET) and vildagliptin (VLD) are coformulated in tablets for the management of diabetes mellitus. The aim of this study is the development of a new fast ultraperformance liquid chromatography method with tandem mass detection (UPLC–MS/MS) for their simultaneous determination with 3-amino-1-adamantanol (starting compound for vildagliptin synthesis; VLI) in human plasma. Separation of MET, VLD, and VLI was performed on a 5 cm UPLC-C18 column using a mobile phase of 0.5% acetic acid in methanol and 0.02 M aqueous ammonium acetate (10:90, v/v). The injection volume was 10 µL and electrospray positive ionization was applied. Extraction from human plasma was carried out by acid precipitation of plasma proteins using pregabalin as an internal standard. The assay was validated according to ICH guidelines. The developed method is valid, fast, and simple and was successfully applied in pharmacokinetic studies in human volunteers.