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A Novel Strategy for the Development and Validation of Bioanalytical Method for the Measurement of Baloxavir Marboxil using LC-API-MS/MS in Human Plasma**G.Raveendra Babu**

QIS College of Pharmacy, India

Using Liquid Chromatography-Atmospheric Pressure Ionization-Tandem Mass Spectrometry (LC-API-MS/MS), we have developed a sensitive and rapid method for quantifying Baloxavir marboxil in human plasma. We extracted baloxavir marboxil and our internal standard, baloxavir marboxil d4, from plasma samples using tert-butyl methyl ether (TBME) (liquid-liquid extraction). Mobile phase was 5 mM ammonium acetate buffer: methanol (25:75, v/v), and the upper layer was evaporated and reconstituted. To separate the components, we used a Zorbax SB C18 (504.6 mm, 3.5m) column and injected the reconstituted samples. Both Baloxavir marboxil and Baloxavir marboxil d4 were discovered using MS/MS in several reaction monitoring modes without significant interference from the human plasma matrix. The protonated precursor ion of baloxavir, $[M+H]^+$, had a mass of m/z 572.60, and the corresponding product ion had a mass of m/z 250.30. The protonated precursor ion ($[M+H]^+$) formed at m/z 576.60, and the corresponding product ion formed at m/z 254.30, when the internal standard was used. Over a range of 10.610-1229.080 ng/ml, the analyte's calibration curves were linear (R^2 0.9956, $n=6$). Baloxavir marboxil was shown to be stable in plasma for seven days at -70 degrees Celsius and fifteen hours at room temperature. It was also stable in the injector for forty-seven hours and after four freeze-thaw cycles. The new approach was validated in accordance with USFDA criteria, and we discovered that it was effective in identifying baloxavir marboxil in human plasma for pharmacokinetic investigations within predefined limits.

Keywords: Baloxavir; LC-API-MS/MS; Method Validation; Human Plasma; Stability studies**Biography**

Dr. G. Raveendra Babu is a Professor in the Department of Pharmaceutical Analysis at QIS College of Pharmacy in Ongole, Andhra Pradesh. He earned his Ph.D. from JNTU in Hyderabad. He published 65 research papers and three patents in national and international scientific journals. He is interested in drug bio-analytical and pharmacokinetic research.

upendragudimittla@gmail.com