DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULATION ESTIMATION OF ACETAMINOPHEN AND PAMABROM IN BULK AND IN TABLET DOSAGE FORM

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ABSTRACT

A simple, accurate and precise UV spectrophotometric methods and RP-HPLC method was developed and validated for simultaneous estimation of acetaminophen and pamabrom in bulk and tablet dosage form. In simultaneous equation method determination was carried out at 242.8 nm λ_{max} of Acetaminophen and 279 nm λ_{max} of pamabrom. The linearity range lies between 3.25-19.5 µg/ml for acetaminophen and 0.25-1.75 µg/ml for pamabrom at their respective wavelengths. Both the drugs were found in good agreement with the label claimed in the marketed formulation. In the tablets both the drugs were estimated as 97.24% and 102.11% Acetaminophen and Pamabrom respectively. Calibration curves were linear with correlation coefficient 0.999 and 0.998 over the concentration range of 3.75-19.5 µg/ml and 0.25-1.75 µg/ml for Acetaminophen and Pamabrom respectively. The RP-HPLC method for simultaneous estimation of Acetaminophen and Pamabrom was developed. The separation was achieved on a Phenomenex luna ODS C_{18} (250mm X 4.6 mm i.d., 5 µm particle size) with an isocratic mixture of Methanol:Water (50:50) pH-3.0. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection was kept at 265 nm. The retention time of Acetaminophen and Pamabrom was 2.9±0.2min and 4.8±0.2min respectively. The linearity of a simple, accurate, precise RP-HPLC method was developed

and validated for simultaneous estimation of Acetaminophen and Pamabrom in bulk and tablet dosage form. The proposed method was investigated in the range of 3.25-19.5µg/ml and 0.25-1.5µg/ml for Acetaminophen and Pamabrom, respectively. Correlation coefficient was 0.998 and 0.998 for Acetaminophen and Pamabrom, respectively. The limit of detection was 0.222µg/ml and 0.055µg/ml for Acetaminophen and Pamabrom respectively and the limit of quantification was 0.673µg/ml and 0.169µg/ml for Acetaminophen and Pamabrom, respectively.

Keywords: Acetaminophen, Pamabrome, UV Spectroscopic method, Simultaneous equation method and RP-HPLC