QUALITY RISK ASSESSMENT AND DESIGNED EXPERIMENTS ORIENTED SIMULTANEOUS QUANTIFICATION OF ASPIRIN AND PANTOPRAZOLE SODIUM USING DRIFTS AND UFLC-DAD METHODS

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ABSTRACT

Systematized and reliable analytical methods are always of great advantage for the quality control of new drug products. Two new analytical methods were developed and validated using the multivariate approach to quantify a unique combination of aspirin and pantoprazole sodium. In the first method, emphasis was on non-destructive identification with quantification of aspirin and pantoprazole at their characteristic diffused reflectance-based infrared absorption band at 1747cm^{-1}(-C=O) and 1303cm^{-1} (-S-O), respectively. The second method relies on liquid chromatographic separation using a mobile phase of acetonitrile: phosphate buffer pH 3.5 (60:40 V/V) at a flow rate of 1.0 mL min^{-1} using a C-18 column. At 240 nm, the diode array detection was performed. Employing risk assessment revealed the risky method parameters that may influence the preciseness of the present methods. Nevertheless, these techniques were linear, sensitive and reliable for the quick and simultaneous measurement of the analytes in bulk and proposed fixed-dose commercial formulation.