INTEGRATION OF QUALITY BY DESIGN AND GREEN ANALYTICAL APPROACHES FOR ROBUST AND SUSTAINABLE ANALYSIS OF PITOLISANT BY HPLC

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ABSTRACT

The present work focuses on developing and validating a stability-detecting High Performance Liquid Chromatographic technique for pitolisant, utilizing Quality by Design approach while evaluating its environmental sustainability. Central composite design as a part of response surface methodology was used to systematically improve the experimental parameters. Successful separation of pitolisant was accomplished on a Waters X-Bridge C18 column at 269 nm detection wavelength. The optimal chromatographic conditions, identified by the desirability function technique, employed a mobile phase of ethanol and ammonium acetate buffer pH 3.5 in 50:50 V/V, with a flow rate of 1.1 mL min^{-1}. The developed method was rigorously verified in accordance with ICH Q2(R2) criteria and subsequently assessed as per ICH Q1A(R2) to confirm its stability-indicating properties. To evaluate the, overall ecological sustainability of the analytical method, analytical greenness and green analytical procedure index were used. The concordance between these two greenness assessment tools substantiates the environment-friendly characteristics of the developed method.