Liquid chromatographic method for the analysis of buspirone HCl and its potential impurities.

Kartal M, Khedr A, Sakr A.

College of Pharmacy, University of Cincinnati, OH 45267-0004, USA.

An accurate, reproducible, and sensitive method for the determination of buspirone HCl and its potential impurities is developed and validated. The validated liquid chromatography method is conducted to meet the Food and Drug Administration/International Conference on Harmonization requirements for the analysis of buspirone HCl in the presence of its impurities. Five buspirone HCl potential impurities, including 1-(2-pyrimidinyl)-piperazine (I), propargyl chloride (II), 3,3'-tetramethylene glutarimide (III), propargyl glutarimide (IV), and the Mannich base-condensate of I-IV fumarate (V), are separated using a microBondapack C18 column by gradient elution with a flow rate 2.0 mL/min. The initial mobile phase composition is 90:10 (v/v) 10mM KH2PO4 (pH 6.1)-acetonitrile. After a 1-min initial hold, a linear gradient is performed in 26 min to 35:65 (v/v) 10mM KH2PO4 (pH 6.1)-acetonitrile. The samples are detected at 210 and 240 nm using a photo-diode array detector. The linear range of detection for buspirone HCl was between 1.25 ng/μL and 500 ng/μL, with a limit of quantification of 1.25 ng/μL. The linearity, range, peak purity, selectivity, system performance parameters, precision, accuracy, and robustness for all of the impurities were also shown to have acceptable values.

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