

Validated HPLC and Ultra-HPLC Methods for Determination of Dronedarone and Amiodarone Application for Counterfeit Drug Analysis

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Abstract

Two simple, accurate, and precise chromatographic methods have been developed and validated for the determination of dronedarone (DRO) HCl and amiodarone (AMI) HCl either alone or in binary mixtures due to the possibility of using AMI as a counterfeit of DRO because of its lower price. First, an RP-HPLC method is described for the simultaneous determination of DRO and AMI. Chromatographic isocratic elution based on potassium dihydrogen phosphate buffer with 0.1% triethylamine pH 8.0 methanol (10 + 90, v/v) at a flow rate of 2 mL/min with UV detection at 254 nm was performed. The second method is RP ultra-HPLC in which the chromatographic separation was achieved on an AcclaimTM RSLC 120 C18 using isocratic elution with potassium dihydrogen phosphate buffer with 0.1% triethylamine pH 8.0 methanol (5 + 95, v/v) at a flow rate of 1 mL/min with UV detection at 254 nm. Linearity, accuracy, and precision of the two methods were found to be acceptable over the concentration ranges of 7.6:2000 µg/mL for both DRO and AMI. The results were statistically compared using one-way analysis of variance. The optimized methods were validated and proved to be specific, robust, precise, and accurate for the QC of the drugs in their pharmaceutical preparations.

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