

Chhabra GS, Banerjee SK. Stability indicating assay method development and validation of dronedarone hydrochloride in its bulk form by RP-HPLC. *Bull. Pharm. Res.* 2013;3(2):58-65.

Abstract: This study describes the development and validation of stability indicating HPLC method for dronedarone hydrochloride in its bulk form. Dronedarone was subjected to stress degradation under different conditions recommended by International Conference on Harmonization. The sample so generated was used to develop a stability indicating high performance liquid chromatographic method for dronedarone-HCl. The peak for dronedarone-HCl was well resolved from the peaks of degradation products, using a kromasil C18 (250 mm × 4.6 mm, 5 μm) column and mobile phase comprising of buffer:methanol (buffer:30 mM KH_2PO_4 + 1 ml triethylamine in 1 litre water, pH=3.6 adjusted with ortho-phosphoric acid) using the gradient method at a flow rate of 1 ml/min. Detection was carried out using a UV detector at 291 nm. The degradation product peak was well resolved from drug peak. The method proved to be specific to the drug and its degradation products. The developed HPLC method was validated with respect to linearity, accuracy, precision and robustness. All the results were found to be within the specification limit.

Key words: Dronedarone hydrochloride, HPLC, Stability indicating, Forced degradation, Validation.

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