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Stability indicating RP-HPLC method for the determination of Tramadol Hydrochloride in Sterile Dosage form

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Abstract : A simple, well-organized and reproducible RP-HPLC method for determination of Tramadol Hydrochloride injection dosage form has been developed and validated. The Chromatographic Separation was carried out on Zorbax C_8 (250× 4.6 mm; 5µm) column using the mobile phase consists of buffer and Acetonitrile in the ratio 65:35. The mobile phase was flowed at the rate of 0.1 ml/min and effluent was detected at 270 nm. The retention time of Tramadol Hydrochloride was 4.273 min. The method was validated according to ICH guidelines and the acceptance criteria for specificity, linearity, accuracy, precision, robustness, and ruggedness were met in all cases. The method was linear in the range of 50µg/ml of Tramadol Hydrochloride. The percentage relative standard deviation for precision was found to be less than 2.0%.

Keywords: Tramadol Hydrochloride, RP-HPLC, Sterile dosage form, Stability indicating method.

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