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Development and Validation of UV-Spectrophotometric and HPLC Method determination of Dofetilide in Formulation

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Abstract : A new, simple, specific and economic UV Spectrophotometric method and HPLC method for the estimation of Dofetilide content in bulk and laboratory prepared mixture. UV spectrophotometric detection was carried out at absorption maxima (λ_{max}) at 231nm using methanol as a solvent. The quantitation of drug was carried out using A1% 1cm at 231nm and Beer's law was obeyed in the concentration range of 2.5-20 µg/ml, with correlation coefficient value less than 1.The chromatographic separation was carried on a C-18 (250 mm × 4.6 mm, 5µ) column using an isocratic mode with a mixture of Acetonitrile:Phosphate Buffer (pH-7) in the ratio of 55:45% v/v as a mobile phase. The flow rate was 1.5ml/min, temperature is maintained at ambient and detection was made at 231 nm using Photodiode array (PDA) detector. The developed method was validated according to ICH guidelines and different analytical parameters such as linearity, precision, accuracy, specificity, limit of detection, limit of quantitation were determined. The percent amount of drug estimated was nearly 100%, found to be a good agreement with label claim of prepared laboratory mixture. The proposed method was validated for its accuracy, precision, robustness, ruggedness, linearity, limit of detection, limit of quantitation and was found to be in range (% RSD<2.0 and SD <±2.0). Both methods were validated and found to be simple, sensitive, accurate, and precise. The results of the study and statistical data proved the applicability of the present method in routine analysis of Dofetilide in bulk as well as laboratory prepared mixture.

Keywords : Dofetilide, UV Spectroscopy, HPLC, ICH guidelines.

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