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Validated LC Method for the Estimation of Hydralazine Hydrochloride in Pharmaceutical Dosage Forms

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Abstract: A simple and specific liquid chromatographic method has been developed and validated for the estimation of hydralazine hydrochloride injection using HPLC. All the analytical parameters were determined as per ICH Q2B guidelines. Good chromatographic separation was achieved with Inertsil L10 packed column (4.6 mm x 150 mm, 5 µm particle size) at a wavelength of 230 nm using phosphate buffer and acetonitrile (77: 23) as mobile phase with a flow rate of 1.0 ml/ min. The resolution, between phthalazine and hydralazine hydrochloride peak is not less than 4.0. From the statistical treatment of the linearity data of Hydralazine HCl, it is clear that the response of Hydralazine HCl is linear between 50 % to 150 % level. The correlation coefficient is greater than 0.998. In addition, the analysis of residuals shows that the values are randomly scattered around zero, which fits, and well within the linear model. The developed method showed good linearity, reproducibility, precision and can be suitably applied for the routine quality control analysis in the estimation of commercial formulations.

Keywords: Hydralazine hydrochloride, HPLC, Validation, Estimation.

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