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(57) Abstract :

The present invention provides a quality by design (QbD) approach for validating HPLC method for Bamifylline hydrochloride in pharmaceutical dosage form. The Quality by Design (QbD) approach for validating analytical HPLC method has been validated according to ICH guidelines concerning linearity, precision, repeatability, specificity, robustness, accuracy, limit of detection (LOD) and limit of quantitation (LOQ). The method shows retention time 3.43min; Theoretical plates 3248; Tailing factor 1.184; linearity over the range 5–60µg/mL; Recovery values are consistently approximately 100%, with mean recoveries of 99.6%, 100.2%, and 99.8% respectively at 80%, 100%, and 120% levels; relative standard deviation (RSD) for repeatability, intermediate precision, and reproducibility are 0.34–1.89%, 0.62–1.87%, and 0.97–1.78%, respectively. The method exhibited excellent linearity, with a high correlation coefficient, confirming its suitability for quantification across the specified concentration range. The invention provides a conduction of forced degradation studies of Bamifylline hydrochloride under different stress conditions. The developed quality by design (QbD) approach for validating HPLC method for Bamifylline hydrochloride meets the necessary regulatory requirements and also provides a cost-effective, time-efficient tool for the consistent analysis of Bamifylline HCl, contributing to its quality control in pharmaceutical preparations.

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