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Validated RP-HPLC Method for the Simultaneous Determination of Tazobactam and Cefepime in Injectable Generic Combination Formulation

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ABSTRACT

In the present communication here we reported the development and validation of a new isocratic RP-HPLC method for the assay of tazobactam and cefepime in injectable generic combination form. The experimental operating factors influencing the maximum elution of these drugs were exclusively studied and optimized {Hypersil C_{18} column (250×4.6 mm, 5µ) using the mobile phase [KH₂PO₄ buffer (pH-3.5) and acetonitrile in the ratio of 45:55%v/v] with a flow rate of 1.0 mL min⁻¹ and UV detection at of 230 nm in ambient column temperature]. The retention times for tazobactam and cefepime were found to be 2.329 min and 4.252 min respectively. Linearity was observed over the concentration range of 10-30 µg mL⁻¹ for tazobactam and 50-150 µg mL⁻¹ for cefepime respectively. The limits of detection and quantitation of the proposed method were 0.00717 and 0.0239 µg mL⁻¹, for tazobactam and 0.0147 and 0.049µg mL⁻¹ for cefepime respectively. The values of other parameters precision, accuracy, sensitivity and robustness etc., are within the acceptance limits of ICH Q2 (R1) guidelines. The student's t and F-values at 95% confidence level did not exceed the tabulated t- and F-values, showing excellent agreement with those achieved by the reported methods. The validation results of the proposed method offered preferential advantages over most of the reported methods in terms of easy, precise, reliable, and economical.

Graphical Abstract



Figure 3. Calibration curve of tazobactam.

Keywords: RP-HPLC, Tazobactam, Cefepime, Validation, Injectable generic combination form, ICH Guidelines.