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A Validated Reverse Phase HPLC Method for the Determination of Disodium EDTA in Meropenem Drug Substance with UV-Detection using Precolumn Derivatization Technique

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Abstract: This paper deals with development and validation of a high performance liquid chromatographic method for the quantitative determination of disodium EDTA (Ethylenediamine tetraacetic acid) in Meropenem active pharmaceutical ingredient (API). EDTA was derivatized with Ferric chloride solution by heating at 70 °C in water bath for about 20 minutes and the chromatographic separation achieved by injecting 100 µL of the derivatized mixture into a Waters HPLC system with photodiode array detector using a Phenomenex Luna C18(2) column (250 × 4.6 mm), 5 µ. The mobile phase consisting of 5% methanol and 95% of 0.7 g/L solution of Tetra butyl ammonium bromide and 4.6 g/L solution of sodium acetate trihydrate in water (pH adjusted to 4.0 with the help of acetic acid glacial) and a flow rate of 1 milliliter/minute. EDTA eluted at approximately 6 minutes. The method was suitably validated with respect to specificity, linearity of response, precision, accuracy, ruggedness, stability in analytical solution, limit of quantitation and detection and robustness for its intended use.

Keywords: EDTA, HPLC, precolumn derivatization, Meropenem, ferric chloride

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