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Development and Validation of a Liquid Chromatographic Method for the Quantification of Related Substance in Gentamicin Drug Substances

Authors : Sofiqul Islam, V. Murugan, Prema Kumari, Hari

Abstract : Gentamicin is a broad spectrum water-soluble aminoglycoside antibiotics produced by the fermentation process of microorganism known as Micromonospora purpurea. It is widely used for the treatment of infection caused by both gram positive and gram negative bacteria. Gentamicin consists of a mixture of aminoglycoside components like C1, C1a, C2a, and C2. The molecular structure of Gentamicin and its related substances showed that it has lack of presence of chromophore group in the molecule due to which the detection of such components were quite critical and challenging. In this study, a simple Reversed Phase-High Performance Liquid Chromatographic (RP-HPLC) method using ultraviolet (UV) detector was developed and validated for quantification of the related substances present in Gentamicin drug substances. The method was achieved by using Thermo Scientific Hypersil Gold analytical column (150 x 4.6 mm, 5 µm particle size) with isocratic elution composed of methanol: water: glacial acetic acid: sodium hexane sulfonate in the ratio 70:25:5:3 % v/v/v/w as a mobile phase at a flow rate of 0.5 mL/min, column temperature was maintained at 30 °C and detection wavelength of 330 nm. The four components of Gentamicin namely Gentamicin C1, C1a, C2a, and C2 were well separated along with the related substance present in Gentamicin. The Limit of Quantification (LOQ) values were found to be at 0.0075 mg/mL. The accuracy of the method was quite satisfactory in which the % recovery was resulted between 95-105% for the related substances. The correlation coefficient (≥ 0.995) shows the linearity response against concentration over the range of Limit of Quantification (LOQ). Precision studies showed the % Relative Standard Deviation (RSD) values less than 5% for its related substance. The method was validated in accordance with the International Conference of Harmonization (ICH) guideline with various parameters like system suitability, specificity, precision, linearity, accuracy, limit of quantification, and robustness. This proposed method was easy and suitable for use for the quantification of related substances in routine analysis of Gentamicin formulations.

Keywords : reversed phase-high performance liquid chromatographic (RP-HPLC), high performance liquid chromatography, gentamicin, isocratic, ultraviolet
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