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IMPURITY PROFILING OF THIAMINE HYDROCHLORIDE INJECTION BY RP-HPLC AND CHARACTERIZATION OF DEGRADATION PRODUCT BY LC-MS/MS/QTOF

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Abstract

Objective: *To propose a comprehensive, simple, and affordable RP-HPLC method for impurity profiling and characterization of unknown degradation products of thiamine hydrochloride injectable formulation.*

Methods: *The chromatographic separation employs gradient mode using the octadecyl silane column using a mobile phase consisting of phosphate buffer with ion pair reagent, acetonitrile, and methanol delivered flow rate at 1.2 ml/min. The detection was carried out at 248 nm using empower software. LC-MS/MS/QTOF hyphenated technique was used for isolation and characterization of unknown degradation impurity. The performance of the method was systematically validated as per ICH Q2 (R1) guidelines.*

Results: *Degradation product observed in accelerated stability was characterized by LC-MS/MS/QTOF hyphenated technique and found m/z value 351.1604 and postulated as an oxidative degradation product of thiamine due to excipient interaction. The validated method was sensitive, selective, and specific data proves the method is precise and accurate from LOQ to 150% level and results are within 95-108% and less than 4.5% RSD. The developed method is linear from 0.03-58.83 µg/ml with a correlation coefficient of more than 0.990 and LOD and LOQ value ranged from 0.03 to1.51 µg/ml.*

Conclusion: *An efficient RP-HPLC method for impurity profiling of thiamine injectable formulation was successfully developed and unknown degradation product observed instability condition samples characterized by LC-MS/MS/QTOF technique. The validated method can be successfully employed for the impurity profiling of thiamine injectable in the quality control department.*

Author Keywords

Thiamine hydrochloride injection, RP-HPLC, Identification, Characterization, Degradation products, Validation, LC-MS-MS

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