STABILITY STUDY AND VALIDATED REVERSED PHASE LIQUID CHROMATOGRAPHIC METHOD FOR THE DETERMINATION OF TIROFIBAN HYDROCHLORIDE IN PRESENCE OF TYROSINE AS A PROCESS IMPURITY

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Abstract

Tirofiban hydrochloride was subjected to the degradation under conditions of hydrolysis (acidic and alkaline degradation), oxidative, thermal and photolytic degradation as prescribed by ICH. A simple and precise liquid chromatographic method has been developed and validated for the simultaneous determination of tirofiban hydrochloride monohydrate (TIR) and its synthetic starting material; tyrosine (TRS). All the chromatographic separations were achieved on Zorbax SB C18, 250 mmĬ4.6 mm i.d., 5εm column at a flow rate of 1 mL minï1. Isocratic elution based on 0.1 M phosphate buffer (pH 3) - acetonitrile (70:30, v/v) with UV detection at 227 nm was applied. For the stability study separation of TIR from its degradation products was achieved using 0.1 M phosphate buffer (pH 3) - acetonitrile (72:28, v/v) with UV detection at 210 nm. Method validation parameters namely, linearity, accuracy and precision were found to be acceptable over the concentration ranges of 10-250 εg mLï1 for TIR and 1-70 εg mLï1 for TRS. The minimum detection limits were 1.76 εg mLï1 for TIR and 0.13 εg mLï1 for TRS. The optimized method was validated and proved to be specific, robust and accurate for the quality control of the cited drug in drug substance and drug product

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