

Validated spectrofluorimetric methods for the determination of apixaban and tirofiban hydrochloride in pharmaceutical formulations.

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Abstract

Apixaban and Tirofiban Hydrochloride are low molecular weight anticoagulants. The two drugs exhibit native fluorescence that allow the development of simple and valid spectrofluorimetric methods for the determination of Apixaban at $\lambda_{ex}/\lambda_{em} = 284/450$ nm and tirofiban HCl at $\lambda_{ex}/\lambda_{em} = 227/300$ nm in aqueous media. Different experimental parameters affecting fluorescence intensities were carefully studied and optimized. The fluorescence intensity-concentration plots were linear over the ranges of 2.0×10^{-6} g ml⁻¹ for apixaban and 2.0×10^{-7} g ml⁻¹ for tirofiban HCl. The limits of detection were 0.017 and 0.019 g ml⁻¹ and quantification limits were 0.057 and 0.066 g ml⁻¹ for apixaban and tirofiban HCl, respectively. The fluorescence quantum yield of apixaban and tirofiban were calculated with values of 0.43 and 0.49. Method validation was evaluated for linearity, specificity, accuracy, precision and robustness as per ICH guidelines. The proposed spectrofluorimetric methods were successfully applied for the determination of apixaban in Eliquis tablets and tirofiban HCl in Aggrastat intravenous infusion. Tolerance ratio was tested to study the effect of foreign interferences from dosage forms excipients. Using Student's t and F tests, revealed no statistically difference between the developed spectrofluorimetric methods and the comparison methods regarding the accuracy and precision, so can be contributed to the analysis of apixaban and tirofiban HCl in QC laboratories as an alternative method.

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