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 ∂ ex/∂ em = 284/450 nm and tirofiban HCl at ∂ ex/∂ 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 0.2ï6 εg mlī 1 for apixaban and 0.2ï5 εg mlī 1 for tirofiban HCl. The limits of detection were 0.017 and 0.019 εg mlī 1 and quantification limits were 0.057 and 0.066 εg mlī 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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