Stability-indicating spectrophotometric methods for determination of the anticoagulant drug apixaban in the presence of its hydrolytic degradation product

Mohamed Mohamed ,Tantawy MA, El-Ragehy NA, Hassan NY

Abstract

Apixaban (a novel anticoagulant agent) was subjected to a stress stability study including acid, alkali, oxidative, photolytic, and thermal degradation. The drug was found to be only liable to acidic and alkaline hydrolysis. The degradation product was then isolated and identified by IR and GC-mass spectrometry. Four spectrophotometric methods, namely; first derivative (D(1)), derivative ratio (DR), ratio difference (RD) and mean centering of ratio spectra (MCR), have been suggested for the determination of apixaban in presence of its hydrolytic degradation product. The proposed methods do not require any preliminary separation step. The accuracy, precision and linearity ranges of the proposed methods were determined, and the methods were validated as per ICH guidelines and the specificity was assessed by analyzing synthetic mixtures containing different percentages of the degradation product with the drug. The developed methods were successfully applied for the determination of apixaban in bulk powder and its tablet dosage form

Spectrochim Acta A Mol Biomol Spectrosc. 2016, January

Future University In Egypt (http://www.fue.edu.eg)

Copyright É 2026 [Future University in Egypt]. All rights reserved.