6. Stability ï Indicating Methods for the Determination of Erdosteine In the Presence of Its Acid Degradation Products; Nadia M. Moustafa

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Abstract

Four accurate, sensitive, and reproducible stability-indicating methods for the determination of erdosteine in the presence of its acid degradation products are presented. The first method involves processing the spectra by using a first-derivative method at 229 nm in a concentration
range of 10ï70 εg/mL. The mean percentage recovery was 100.43 Ñ 0.977. The second method is based on ratio-spectra first derivative spectrophotometry at 227.4 and 255 nm over a concentration range of 10ï70 εg/mL. The mean percentage recovery was 99.65 Ñ 1.122%
and 100.02 Ñ 1.306% at 227.4 and 255 nm, respectively. The third method utilizes quantitative densitometric evaluation of the TLC of erdosteine in the presence of its acid degradation products, and uses methanolïchloroformïammonia (7 + 3 + 0.01, v/v/v) as the mobile phase.
TLC chromatograms were scanned at 235 nm. This method analyzes erdosteine in a concentration range of 2.4ï5.6 εg/spot, with a mean percentage recovery of 100.03 Ñ 1.015%. The fourth method is HPLC for the simultaneous determination of erdosteine in the presence of its acid
degradation products. The mobile phase consists of waterïmethanol (65 + 35, v/v). The standard curve of erdosteine showed good linearity over a concentration range of 10ï80 εg/mL, with a mean percentage recovery of 99.90 Ñ 1.207%. These methods were successfully applied
to the determination of erdosteine in bulk powder, laboratory-prepared mixtures containing different percentages of the degradation products, and pharmaceutical dosage forms. The validity of results was assessed by applying the standard addition technique. The results obtained agreed statistically
with those obtained by a reported method, showing no significant differences with respect to accuracy and precision.

Stability-Indicating Methods for the Determination of Erdosteine in the Presence of its Acid Degradation Products. Available from: https://www.researchgate.net/publication/261181729_Stability-Indicating_Methods_for_the_Determination_of_Erdosteine_in_the_Presence_of_its_Acid_Degradation_Products [accessed Dec 14, 2015].

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