

# Synchronized Stability Indicating RP-LC Methods for Determination of Metolazone with Losartan Potassium or Spironolactone in Presence of Their Degradation Products

Mohamed Mohamed ,Hala E. Zaazaa, Rasha Abdel-Ghany , Mahmoud Sayed and Shimaa A. Atty

## Abstract

Two precise and selective stability-indicating RP-LC methods have been developed and validated for simultaneous determination of metolazone in its binary mixture with losartan potassium (method 1) and spironolactone (method 2) in the presence of their degradation products. For method 1, the chromatographic separation was achieved on Kromasil C18 column, the mobile phase consisted of a mixture of 0.1% ortho-phosphoric acid in acetonitrile and 0.1% ortho-phosphoric acid in water (28:72, v/v) pumped at flow rate 2 mL/min and UV detection at 235 nm. Linearity was determined over the concentration range of 2.616 mg/mL for metolazone and 40.6320 mg/mL for losartan potassium. For method 2, chromatographic separation of metolazone and spironolactone was achieved on a Symmetry C8 column using a mobile phase that consisted of acetonitrile, methanol, and 0.1% ortho-phosphoric acid in water in gradient mode pumped at a flow rate 1.5 mL/min with programmed wavelength detection. Linearity was determined over the concentration range of 2.616 mg/mL for metolazone and 20.6160 mg/mL for spironolactone. The suggested methods were proved to be highly selective, precise and accurate for simultaneous determination of the cited drugs in their combined pharmaceutical dosage form in the presence of their degradation products. The proposed methods were validated in compliance with ICH guidelines.

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