Stability-Indicating RP-HPLC Methods for the Determination of Fluorometholone in Its Mixtures with Sodium Cromoglycate and Tetrahydrozoline Hydrochloride

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Abstract

Two stability-indicating reversed-phase liquid chromatographic methods were developed and validated for the determination of fluorometholone (FLU) in its mixtures with sodium cromoglycate (SCG) and tetrahydrozoline hydrochloride (THZ). The first HPLC method (Method 1) was based on isocratic elution of FLU and SCG along with their alkaline degradation products on a reversed phase C18 column (250 Ĭ 4.6 mm id)-ACE Generix 5, using a mobile phase consisting of methanol-water (70 : 30, v/v), pH adjusted to 2.5 using orthophosphoric acid at a flow rate of 1.2 mL min(-1) Quantitation was achieved with UV detection at 240 nm. The second HPLC method (Method 2) was based on isocratic elution of FLU, its alkaline degradation product and THZ on a reversed phase C8 column (250 Ĭ 4.6 mm)-ACE Generix 5, using a mobile phase consisting of acetonitrile-50 mM potassium dihydrogen orthophosphate (40 : 60, v/v) at a flow rate of 2 mL min(-1) Quantitation was achieved by applying dual-wavelength detection, where FLU and its alkaline degradation product were detected at 240 nm and THZ was detected at 215 nm at ambient temperatures. Linearity, accuracy and precision were found to be acceptable over the concentration range of 5-50 and 10-500 εg mL(-1) for FLU and SCG (Method 1) and over the concentration range of 5-80 and 5-60 εg mL(-1) for FLU and THZ (Method 2), respectively. Besides, the FLU alkaline degradation product was verified using IR, NMR and LC-MS spectroscopy. The two proposed methods could be successfully applied for the routine analysis of the studied drugs either in their pure bulk powders or in their pharmaceutical preparations without any preliminary separation step.

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