Forced degradation of mometasone furoate and development of two RP-HPLC methods for its determination with formoterol fumarate or salicylic acid

Ramzia Ibrahim, Marwa A. Fouad, Manal A. El-Shal, Enas Tolba

Professor of Pharmaceutical chemistry, Head of Pharmaceutical Chemistry Department.

Abstract
Two simple, selective and precise stability-indicating reversed-phase liquid chromatographic methods were developed and validated for the determination of mometasone furoate in two binary mixtures, with formoterol fumarate (Mixture 1) and salicylic acid (Mixture 2). Also, a forced degradation study of mometasone furoate was carried out including acid and alkali hydrolysis, oxidation, thermal and photo-degradation. For mixture 1, the method was based on isocratic elution using a mobile phase consisting of (Acetonitrile: 3 mM Sodium lauryl sulfate) (60:40, v/v) at a flow rate of 1 ml min⁻¹. Quantitation was achieved applying dual wavelength detection where mometasone furoate and its degradation products were detected at 247 nm and formoterol fumarate and its degradation product were detected at 214 nm at 30°C. For mixture 2 and for the forced degradation study, separation was based on isocratic elution of mometasone furoate, its degradation products and salicylic acid on a reversed phase C8 column using a mobile phase consisting of acetonitrile:water:methanol:glacial acetic acid (60:30:10:0.1, v/v) at a flow rate of 2 mL min⁻¹. Quantitation was achieved with UV detection at 240 nm. In addition, products from alkaline forced degradation of mometasone furoate were verified by LC–MS. Linearity, accuracy and precision were found to be acceptable over the concentration range of 10–800 μg mL⁻¹ and 5–60 μg mL⁻¹ for mometasone furoate and formoterol fumarate, respectively and over the concentration range of 5–320 μg mL⁻¹ and 20–1280 μg mL⁻¹ for mometasone furoate and salicylic acid.

Arabian Journal of Chemistry - 2015, January