Development and validation of impurity-profiling UPLC method for the determination of sodium cromoglicate and tetryzolinehydrochloride: Application on rabbit aqueous humor

Hayam Lotfy, Hesham Salem, Nagiba Y. Hassan and Sarah S. Saleh

Professor of Analytical Chemistry

Abstract

tSodium cromoglicate (SCG), antihistaminic agent, and tetryzoline hydrochloride (TZH), a sympath-omimetic agent, are formulated together as an ophthalmic preparation. An ultra-performance liquid chromatographic method with UV detection (UPLC–UV) was developed and validated for the quantitative determination of SCG and TZH in rabbit aqueous humor. Due to the instability of both SCG and TZH under alkaline conditions, the UPLC method was applied for their determination in the presence of their possible degradation impurities. The separation was performed using C18 column (1.7 μm particle size) and isocratic elution system with methanol: 1% o-phosphoric acid (65: 35, v/v). The optimum flow rate was 0.5 ml/min and the detection was done at 230 nm. The suggested method was validated in compliance with the ICH guidelines and was successfully applied for determination of sodium cromoglicate (SCG) and tetryzoline HCl (TZH) as prepared synthetically in laboratory mixtures, and in the presence of their alkali-induced degradation impurities. The suggested method was effectively applied to the determination of spiked rabbit aqueous humor samples as well as commercial pharmaceutical formulation.

Journal of Chromatography B - 2015, January