LITHUANIAN UNIVERSITY OF HEALTH SCIENCES
FACULTY OF PHARMACY

international conference

ABSTRACT BOOK

CONTEMPORARY PHARMACY: ISSUES, CHALLENGES AND EXPECTATIONS 2026

March 27, 2026
Lithuania, Kaunas

Selection of conditions for impurities' determination in combined ibuprofen/caffeine syrup by HPLC

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Background: The production of fixed combinations is a modern trend in pharmaceutical manufacturing due to their advantages (1). Recently, a fairly large number of ibuprofen combinations have been present on the pharmaceutical market (2,3). At the same time, such dosage forms may have problems with both the bioavailability of the components and their potential interaction. That is why during the pharmaceutical development of such products it is very important to ensure the absence of any interaction between both the API and the excipients. For this purpose, it is important to have developed methods for the chromatographic separation of the API and impurities in such dosage forms.

Aim(s): To determine optimal conditions for determination of related substances for determination in combined ibuprofen/caffeine syrup.

Methods: Chromatographic determination was performed using an Agilent 1260 liquid chromatograph equipped with a diode array detector, autosampler, degasser, and a pump for mixing up to four components. ChemStation software was used for data acquisition and processing.

Results: During the experiment, the chromatography conditions were selected: stationary phase, a column 250 x 4.6 mm, filled with sorbent endcapped octylsilyl silica gel for chromatography R, with a particle size of 5 μm (for example, Waters Symmetry C8), mobile phase A: 6.8 g of potassium dihydrogen phosphate R and 0.4 g of sodium hexanesulfonate R are dissolved in 1000 ml of water R, the pH is adjusted to 3.0 with phosphoric acid R and mixed; mobile phase B: acetonitrile R, detection wavelength 210 nm, chromatography temperature 25 ° C, flow rate 1.0 ml / min, gradient chromatography mode. Also, during the development, the parameters of the suitability of the chromatographic system were determined.

Conclusion: The selected conditions allow for reliable separation of APIs in the composition of the dosage form with their potential impurities and excipients.

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