

Validation and Simultaneous Determination of Paracetamol and Caffeine in Pharmaceutical Formulations by RP–HPLC

by M. Prodan*, E. Gere-Paszti, O. Farkas, E. Forgacs

*Institute of Chemistry, Chemical Research Center, Hungarian Academy of Sciences,
P. O. Box 17. 1525 Budapest Hungary*

Key words: validation, paracetamol, caffeine, RP-HPLC, pharmaceutical formulation

The novel rapid reversed phase isocratic chromatographic method for simultaneous determination of paracetamol and caffeine in drug formulations has been developed. The analysis was performed with LiChroCART 250–4 Purospher RP–18 column (4.6 × 250 mm, particle size 5 µm) using methanol–water eluent (40:60) at the flow rate of 0.5 mL min^{−1}. For each component a dual wavelength detection mode: 249 and 273 nm has been applied. After the investigation of important validation categories, such as selectivity, precision and accuracy, the range of linearity, recovery and stability it has been established that the newly developed method meets the requirements of validation. Therefore, due to its high separation efficiency, its applicability to the routine quality control analyses, separation of impurities and other degradation products has been proved. Significant retention time delay between paracetamol and caffeine peaks enables to collect fractions for the further preparative processing.