Quantitative determination of diclofenac sodium and aminophylline in injection solutions by FT-Raman spectroscopy.

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Streszczenie

The FT-Raman quantification of diclofenac sodium and aminophylline commercial injection solutions was performed. The efficiency of various spectra treatment procedures including classical univariate intensity ratio and multivariate partial least squares (PLS) and principal component regression (PCR) methods was compared. First, the calibration models were built using unnormalised spectra. Next, spectra normalised by the intensity of a selected band of CH_3CN added as an internal standard to the studied samples were utilised. To compare the predictive ability of the models constructed, the relative standard error of prediction (RSEP) was calculated. The errors found for multivariate calibrations were a few times smaller than those for the univariate ones. Usually, the most effective was the PLS method, for which RSEP values of the order of 1–2% for calibration and 2–3% for testing data sets were obtained. Four commercial preparations of diclofenac sodium and one of aminophylline containing by weight, 2.4% of the active pharmaceutical ingredient (API) were quantified applying the developed models. Concentrations found from the Raman data analysis correlate with the declared values and the results of reference analyses. For the studied diclofenac sodium solutions they amount to 99.2–101.2% of the former and 101.2–102.4% of the latter quantities for the PLS models optimised for each medicine based on unnormalised spectra. These values for the aminophylline preparation were found to be 101.0 and 99.1%, respectively. It shows that the proposed procedure based on the chemometric treatment of FT-Raman spectra can be a fast and convenient alternative to the standard pharmacopoeial procedures of API quantification even in relatively diluted injection solutions.