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New spectrophotometric / chemometric assisted methods for the simultaneous determination of imatinib, gemifloxacin, nalbuphine and naproxen in pharmaceutical formulations and human urine.

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Abstract

In this paper, novel univariate and multivariate regression methods along with model-updating technique were developed and validated for the simultaneous determination of quaternary mixture of imatinib (IMB), gemifloxacin (GMI), nalbuphine (NLP) and naproxen (NAP). The univariate method is extended derivative ratio (EDR) which depends on measuring every drug in the quaternary mixture by using a ternary mixture of the other three drugs as divisor. Peak amplitudes were measured at 294 nm, 250 nm, 283 nm and 239 nm within linear concentration ranges of 4.0-17.0, 3.0-15.0, 4.0-80.0 and 1.0-6.0 μg mL^{-1} for IMB, GMI, NLP and NAB, respectively. Multivariate methods adopted are partial least squares (PLS) in original and derivative mode. These models were constructed for simultaneous determination of the studied drugs in the ranges of 4.0-8.0, 3.0-11.0, 10.0-18.0 and 1.0-3.0 μg mL^{-1} for IMB, GMI, NLP and NAB, respectively, by using eighteen mixtures as a calibration set and seven mixtures as a validation set. The root mean square error of predication (RMSEP) were 0.09 and 0.06 for IMB, 0.14 and 0.13 for GMI, 0.07 and 0.02 for NLP and 0.64 and 0.27 for NAP by PLS in original and derivative mode, respectively. Both models were successfully applied for analysis of IMB, GMI, NLP and NAP in their dosage forms. Updated PLS in derivative mode and EDR were applied for determination of the studied drugs in spiked human urine. The obtained results were statistically compared with those obtained by the reported methods giving a conclusion that there is no significant difference regarding accuracy and precision. The proposed methods were also applied to study the in-vitro drug release and the results were satisfactory.

Keywords: Univariate, Multivariate, partial least square, Model updating, Spiked human urine and Drug-dissolution test.

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