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NIR and Raman spectroscopy in quantification of three API's in solid pharmaceutical preparation

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The pharmaceuticals manufacture is one of the most regulated industrial sectors, these regulations require a high number of physical and chemical determinations. Techniques such as near infrared spectroscopy and Raman spectroscopy are being widely used in the pharmaceutical industry. The principal advantage of this technique is the possibility of obtaining information without sample preparation, and the possibility of analyzing samples in different matrices. The aim of the present study was, to develop a NIR and Raman method to determine the active content of three API's (6.8% w/w, 25% w/w and 25% w/w). Different spectral pretreatments were used for reducing spectral variabilities associated to physical characteristics of the samples. SNV was used to reduce scattering effects and second derivative treatment in combination with second polynomial Savitzky-Golay data point was used for normalization and baseline correction. Each model was developed with full subsets cross-validation and external validation (industrial and laboratory-made samples). Several prediction models were performed with various parameters and the best model was selected based on conventional criteria, R2, RMSECV, RMSEP among others. Finally, no significant differences were found between the NIR and Raman prediction and HPLC reference data of the validation and industrial samples, and the analytical parameters evaluated were within the stipulated margins. In addition, Raman spectroscopy, was possible to detect problems with the homogeneity of the active ingredients in the pharmaceutical product, which helped to improve the laboratory practices of the pharmaceutical industry.

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