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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 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, R^2 , RMSECV, and RMSEP among others. Finally, non-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, thanks to 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.

Biography

César Pino Torres is a student of the PhD program in Sciences and Analytical Technology imparted by the Pharmacy Faculty of the University of Concepcion, Chile. He is currently working on his doctoral thesis called "Development and Implementation of Spectroscopic and Chemometric Methodologies for quality controls and productive processes of drugs in the Pharmaceutical Industry". His love for the analysis of pharmaceuticals started in his formation as a Pharmaceutical Chemist, his major. His goal as professional and as future scientist is to implement in the Chilean pharmaceutical industry the use of spectroscopic techniques, which poorly developed in Chile. At 27 he has published "Chemical characterization of sub-bituminous coal from the Arauco province - Chile" and the second paper is about to be published.

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