Detecting counterfeit diabetes tablets by near infrared spectroscopy

R.S. Fernandes and K.M.G Lima*

Department of Chemical, UFRN, Natal, 59072-970, Brazil
*Corresponding author: kassio@ufrnet.br

Introduction

Glibenclamide (or glyburide), an oral hypoglycemic agent second generation sulfonylurea class, is used in tablets to control diabetes mellitus. The problem of counterfeit drugs is important all over the world. Rapid methods for detection of counterfeit drugs are of vital necessity. Visual control, dissociating tests or simple colour reaction tests reveal only very crude forgeries. The feasibility of information-rich NIR-measurements as an analytical method together with multivariate calibration for mathematical data processing for false drug detection is demonstrated. Thus, the objective of this work was to determine if NIRS could be used to discriminate between genuine and counterfeit diabetes tablets (glibenclamide).

Materials and Methods

NIR reflectance spectra (in triplicate) of 248 samples were measured using an FT-NIR Bomem MB 160 spectrophotometer in the 800-2500 nm range. Genuine tablets (n = 115) are referred to as subset N1 and counterfeit samples (n = 133) are referred to as subset N2. Each measured spectrum was the average of 50 scans obtained at a resolution of 8 cm^{-1}. Spectra, using full cross-validation, were treated and correlated with the hardness results by using The Unscrambler® 9.8 from Camo (Trondheim, Norway). The influence of various spectral pre-treatments [Savitzky-Golay smoothing, multiplicative scatter correction (MSC), first derivative (D1), second derivative (D2) separately and combined], regression methods (PLS-DA) and classification methods (SIMCA) on prediction error were compared.

Results and Discussion

The results showed that the correlation between the predicted category variable of calibration and validation and the measured category variable is significant with a correlation coefficient (r) over 0.98 and low SEC and SEP (< 0.05); the discriminant accuracy for genuine tablets and counterfeits tablets was 100% (deviation < 0.5) by the PLS-DA model based on the test set of samples; the discriminant accuracy by PLS-DA model was better than that by SIMCA model.

Conclusion

NIR spectroscopy was used to identify diabetes tablets as genuine or counterfeit with 100% accuracy using PLS-DA when using a broad near infrared wavelength range (800–2500 nm).

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