Detecting counterfeit diabetes tablets by near-infrared spectroscopy

R.S Fernandes[1], K.M.G Lima[1*]

[1]Departament of Chemical, UFRN, Natal, 59072-970, Brazil
*Corresponding author: kassio@ufrnet.br

Introduction:

Glibenclamide or glyburide, oral hypoglycemic agent second generation sulfonylurea class, is used in the tablets to control diabetes mellitus. The problem of counterfeit drugs is important all over the world. Express-methods for detection of counterfeit drugs are of vital necessity. Visual control, dissociating tests or simple color reaction tests reveal only very rough forgeries. The feasibility of information-rich NIR-measurements as an analytical method together with multivariate calibration for mathematical data processing for false drugs 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. 115 genuine tablets, subset N1, and 133 counterfeit subset N2. Each measured spectra was the average of 50 scans, obtained with resolution of 8 cm^{-1}. Spectra and calibration set, full cross-validation tests 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] and regression methods (PLS-DA) and classification methods (SIMCA) on prediction error are 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 are 100% (deviation < 0.5) by the PLS-DA model based on the test set of samples; the discriminant accuracy by PLS-DA model is better than that by SIMCA model.

Conclusion:

NIRS 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).

Novelty statement:

This work indicating that the NIR diffuse reflectance spectroscopy method coupled with PLS-DA could be used to rapidly detect counterfeits tablets for diabetes treatment.

Summary:

This work was investigated the potential of NIR technique to detect counterfeits tablets for diabetes treatment using PLS-DA.