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Prediction of ibuprofen tablet hardness using a nondestructive near infrared spectroscopy

Introduction: Tablet hardness highly affects the tablet quality. A higher hardness would decrease the disintegration time and the effectiveness of the drug. However, a lower hardness would lead to too friable tablets that would not bear the handling required for their packaging. Tablet hardness is usually determined by hardness tester, which is a destructive technique. Therefore, the NIR is currently used as a process analytical technology (PAT) tool to determine the tablet hardness, as it is simple, non-destructive and fast technique widely used in solid dosage manufacturing industry. Changes in the dosage form hardness are seen as sloping spectral baseline shifts in the NIR spectra, in which the absorbance increases as the hardness increases.

Aim: The study aimed to develop and validate NIR reflectance method to determine the ibuprofen tablet hardness. The tablet formulation consisting of ibuprofen (200 mg±5%) as active pharmaceutical ingredient, ludipress, kollidon CL and magnesium stearate were mixed and compressed at varying compression forces (8 kN, 10 kN and 12 kN). Targeted tablet weight was fixed at 350 mg with 10 mm in diameter. Partial least squares (PLS) models for the NIR reflectance spectra was constructed by using calibration laboratory tablets with different hardness values spanning from 12.4 kp to 16.4 kp. The predictive performance of the proposed NIR method was evaluated by traditional chemometric criteria.

Results: The corresponding values for the root mean squared error of calibration (RMSEC), of cross-validation (RMSECV) and of prediction (RMSEP) were equal to 1.81%, 2.51% and 0.99%, respectively.

Conclusion: In conclusion, the proposed NIR method was successfully validated and implemented for the prediction of the external ibuprofen tablet hardness. The most noticeable advantages of the proposed method over the conventional technique (hardness tester) are its non-destructive and rapid characteristics towards the analyzed samples.
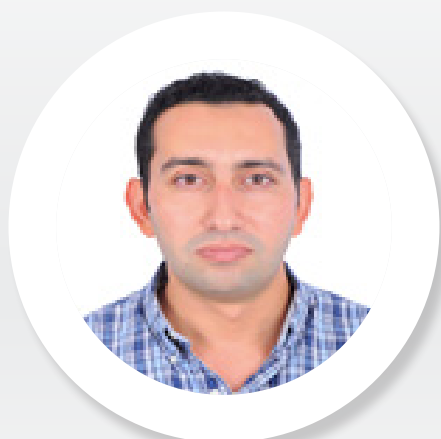
Recent Publications: A S Abouzaid, M Y Salem, E S Elzanfaly, AE El Gindy, S Hoag and A Ibrahim (2017) Screening the fluid bed granulation process variables and moisture content determination of pharmaceutical granules by NIR Spectroscopy. European Journal of Chemistry. doi:10.5155/eurjchem.8.3.265-272.1608.

Ahmed Shawky, Eman S Elzanfaly, Maissa Y Salem, Ahmed E El Gindy and Keith (2016) Using In-Line and Off-Line NIR Methodologies for Real-Time Predictions of Moisture Content and Particle Size in Fluid Bed Granulation. News medical Life sciences

Biography

Ahmed Shawky Abouzaid is a PhD student in Faculty of Pharmacy at Misr International University (MIU), Cairo, Egypt. In June 2004, he completed his Bachelor's degree in Pharmaceutical Sciences and was awarded with cumulative grade; 'Excellent with High Honor' from Faculty of Pharmacy, MIU. He obtained his MSc degree in Pharmaceutical Sciences, Faculty of Pharmacy, Cairo University, Egypt in 2014. He worked in MIU as a Teaching Assistant from 2004 to 2014. From 2014 to 2016, he obtained Internship for his PhD at School of Pharmacy, University of Maryland, Baltimore, USA. He is currently studying his PhD degree in Pharmaceutical department, under dissertation title "Applications of Near Infrared in Pharmaceutical Analysis". He has published two papers in reputed journals and four posters at international conferences.

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