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APPLICATION OF NIR SPECTROSCOPY FOR CONTENT UNIFORMITY DETERMINATION OF INTACT TABLETS: COMPARISON OF REFLECTION AND TRANSMISSION MODES OF NIR SPECTROSCOPY

Ahmed Shawky Abouzaid^{1,3}, Eman S Elzanfaly², Ahmed E El Gindy¹, Stephen W Hoag³ and Ahmed Ibrahim^{1,3}

¹Misr International University, Cairo, Egypt

²Cairo University, Cairo, Egypt

³University of Maryland, Baltimore, Maryland, USA

Content uniformity (CU) is a critical quality attribute in tablet manufacturing process. The active pharmaceutical ingredient (API) is usually determined by off-line techniques such as high performance liquid chromatography (HPLC) which is a slow, destructive technique and requires sample preparation. Therefore, near Infrared (NIR) spectroscopy was employed as a process analytical technology (PAT) tool to determine the API and consequently the content uniformity of tablets. NIR spectroscopy is a fast, non-destructive technique and requires minimal sample preparation. The purpose of this work was to develop and validate NIR reflectance and transmittance methods for the determination of the ibuprofen content (mg) for the content uniformity for ibuprofen tablet. Partial least squares (PLS) models for the NIR reflectance and transmittance was constructed by using calibration laboratory tablets with different ibuprofen (IBU) contents spanning from 146.47 mg to 243.91 mg. The predictive performance of the proposed methods was evaluated by traditional chemometric criteria. The corresponding values for the root mean square error of prediction (RMSEP) were equal to 0.96% and 1.83% for NIR reflectance and transmittance methods, respectively; besides using the chemometric criteria to compare analytical performance of proposed NIR methods. Moreover, the proposed NIR methods were successfully validated and implemented for the determination of the content uniformity for three batches that represent three levels of IBU content (160 mg, 200 mg and 240 mg).

shawky0225@gmail.com