

Publication

Assessment of diffuse transmission mode in near-infrared quantification—part I : The press effect on low-dose pharmaceutical tablets

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Quantitative applications for pharmaceutical solid dosage forms using near-infrared (NIR) spectroscopy are central to process analytical technology (PAT) manufacturing designs. A series of studies were conducted to evaluate the use of NIR transmission mode under various pharmaceutical settings. The spectral variability in relation to tablet physical parameters were investigated using placebo tablets with different thickness and porosity steps and both variables showed an exponential relationship with the detected transmittance signal drop. The drug content of 2.5% m/m folic acid tablets produced under extremely different compaction conditions was predicted and found to agree with UV assay results after inclusion of extreme physical outliers to the training sets. NIR transmission was also shown to traverse a wide section of the tablet by comparing relative blocking intensities from different regions of the tablet surface and >90% of the signal was detected through a central area of 7 mm diameters of the tablet surface. NIR Quantification of both film thickness and active ingredient for film-coated tablets are examined in part II of this study.

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