Quantification of an active ingredient in tablets by NIR transmission measurements

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For the quality control of tablets several parameters have to be checked. The most important one is the content of an active ingredient which has to match a narrow range around the designated content. The only useful measurement mode is transmission which provides information of the complete tablet. A measurement in diffuse reflectance would register only the surface which is useless especially in case of a coated tablet.

In this work tablets for a clinical study (placebo/verum studies) with very low concentrations of the active ingredient were measured. The concentration range was 0 to 6 mg with a total weight of the tablets of 105 mg, leading to a highest concentration of the active component of 5.7 % by weight.

Especially the spectroscopic distinction between the placebo and the low dosage forms with 0.25 and 0.5 mg active agent requires an extraordinarily accurate sampling technique. Using the VECTOR 22/N-T in transmission mode allows the collection of the information from the complete tablets. A quantitative PLS-model with transmission spectra from the tablets described above shows that the active substance can be predicted with a RMSECV (root mean square error of cross validation) of 0.04% absolute for this special application.

The results are compared with those of measurements in diffuse reflectance using different accessories.