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FAST QUANTITATIVE AND QUALITATIVE ANALYSIS OF PHARMACEUTICAL TABLETS BY NIR

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The implementation of NIR and chemometrics in the Pharmaceutical industries is still in strong progress, both regarding qualitative and quantitative applications and beneficial results are seen. Looking at the development so far, NIR will change the pharmaceutical industry even more in the future.

This presentation will address the experiences and progress achieved regarding the application and implementation of quantitative methods for determination of content uniformity and assay of tablets with less than 10% w/w of active, using Near Infrared transmittance spectroscopy in combination with PLS. Also qualitative methods for identification of the same tablets by Near Infrared reflectance spectroscopy will be discussed.

Four commercial tablet strengths are formulated and produced from two different compositions by direct compression. Three different strengths are dose proportional, i.e. fixed concentration by varying in size. The aim was to replace the conventional primary methods for analysing content uniformity, assay and identification by NIR.

Studies were performed on comparing transmittance versus reflectance spectroscopy for both applications on the dose proportional tablets. The model for determination of content uniformity and assay was developed to cover both coated and uncoated tablets, whereas the qualitative model was developed to identify coated tablets only. The impact of the tablet formulation, tablet size and coating, resulted in individual models for each composition The best calibration was achieved using diffuse reflectance for the identification purposes and diffuse transmittance for the quantitative determination of the active content within the tablets.

As NIR in combination with other techniques opens up the possibility of total quality management within the production, the transfer of the above-mentioned models from a laboratory based approach to an at-line approach at H.Lundbeck will be addressed too.