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Spectroscopic Investigations of Drug Substances and Drug Formulations

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Different solid state characterization techniques have been widely used to gain a better understanding of the physical solid state characteristics of drug substances and drug formulations. In the past, physical characterization in the pharmaceutical industry mainly relied on x-ray powder diffraction, thermal analysis and microscopy. More recently, vibrational spectroscopic techniques such as infrared (IR), near-infrared (NIR), Raman and solid state nuclear magnetic resonance spectroscopy (SS-NMR) have attracted growing attention in both academia and industry. Even more recently, terahertz pulsed spectroscopy (TPS) has also been utilized to investigate pharmaceutical materials.

Spectroscopic techniques possess many advantages over other traditional analytical techniques, for instance the fact that they allow rapid, non-destructive measurements, suitable for use in the process analytical technology (PAT) setting. In this presentation recent examples of the use of spectroscopic techniques especially Raman spectroscopy, NIR and TPS on characterizing pharmaceutical compounds and formulations will be presented. Specific examples from our own work will be presented in this talk.

Using the example of the important anticonvulsant drug carbamazepine (CBZ), we will demonstrate that Raman spectroscopy combined with partial least squares (PLS) analyses can be used to quantify the conversion of CBZ polymorphs to the CBZ dihydrate in aqueous suspension. It was found that crystal morphology and polymorphic form have a large effect on the conversion, but that the conversion is not quantitative. An increased understanding of the influence of factors of this conversion such as defects, crystalline face differences, which are important to the physical stability of CBZ, can be obtained using a combination of spectroscopic and imaging techniques.