

Computed Tomography analysis for process development and quality control of formulations

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The use of (micro-) Computed Tomography (CT) for the characterization of pharmaceutical materials has become increasingly important. CT gives valuable information about the morphology of tablets like e.g. porosity and porosity distribution; it helps in understanding the relationship between processing parameters and resulting morphology as well as the influence on drug product dissolution properties. CT provides a means to non-destructively visualize the internal structure of materials, which can be used to investigate the distribution homogeneity of drug delivery systems or other functional material in the formulation. CT can also be used to investigate the homogeneity of tablet coating in process development and quality control. The direct correlation with the phase composition of the formulation is often of paramount importance. Recent developments allow for a significant improved resolution in CT on an X-ray diffractometer. This enables to directly correlate high quality diffraction data with the morphology study on formulations.

We present the application of the CT set-up on different formulations. Application examples include the distribution analysis of MUPS in a tablet, wall thickness analysis of capsules, investigation of morphology and its homogeneity in pressed tablets and the analysis of the interior of capsules, e.g. the occurrence of compound aggregates and compound distributions.