

In-Situ Nanostructure Monitoring by Small-and Wide-Angle X-ray Scattering

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Development of new drug formulations and quality control of pharmaceuticals requires knowledge on the nanostructure development both during their production and under various environmental conditions, such as temperature, humidity, and release conditions. This concerns the mostly crystalline, active ingredients as well as the frequently amorphous excipients. In extension of conventional X-ray powder diffraction, SWAXS (small-and wide-angle X-ray scattering) can provide valuable structural information on both components. Recent advances in X-ray small- and wide angle instrumentation have dramatically increased the practical usefulness of this method by allowing time-resolved nanostructure monitoring with a spatial resolution from 0.3 to 100 nm and a time-resolution down to seconds. The new Hecus System-3 SWAXS with the proprietary RotaCap allows to study the space-time development of sedimenting, heterogeneous reaction systems either under production or in degradation conditions. Full system automatization furthermore adds high-throughput capability for screening of multiple formulations. Examples for applications include: the time development of specific inner surface and crystallinity in inhaler powders based on lactose monohydrate, the characterization of mesoporous silicas under different production conditions, the temperature behavior of complex glyco-liposome formulations, and phase structure mapping of multicomponent, lipidic systems.