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Pharmaceutical Powder Compaction and Dissolution Analytics by Laboratory Small and Wide Angle X-Ray Scattering (SWAXS)

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We investigate the compaction behavior of the most usual pharmaceutical excipients mixture (placebo) contained lactose monohydrate (LmH), microcrystalline cellulose (MCC), silicum dioxyd (SiO_2) and magnesium stearate (MgSt) with combined small- and wide-angle X-ray scattering (SWAXS). In general, the method is becoming an increasingly important technique in pharmaceutical solid-state characterization [1, 2]. Highly relevant questions of polymorphism in crystalline materials, stability and nanostructure of amorphous states, total inner surface in controlled-release formulations, stability and ageing formulations can be addressed by this technique. The information to be gained by SAXS expands largely the scope of conventional powder diffraction techniques. A particular advantage lies in the simultaneous observation of nano-scale (SAXS) and atomic scale (WAXS). With the development of high-brilliance laboratory SWAXS systems (Hecus S3MICROpix) the times for analysis have been greatly reduced, and hence the method can be applied to quality screening and process analytical technology (PAT). Furthermore, examples will be presented for technologically relevant systems, such as polymorphic forms of active ingredient carbamazepine, compactness of granulate, amorphous formulations of their coating lack, and dissolution behavior of pentoxifylline after process granulation. The results show, that an analysis in terms of robust SAXS parameters, such as total inner surface, scattering power intensity, Porod exponent and average correlations length, can provide highly valuable technological information about granulate compactness and dissolution behavior in correlation with tablets hardness.

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