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Dynamic X-ray micro-CT measurements of tablet disintegration

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Dynamic X-ray micro-CT was used to get a better mechanistic understanding of the disintegration process of pharmaceutical solid dosage forms (tablets or capsules). Dosage forms are the predominant form to control active pharmaceutical ingredients to a patient and typically consist out of compacted powder with added excipients. In order to deliver the active pharmaceutical ingredients to the patients, the compacted tablet needs to mechanically break up into smaller particles. Therefore, the admixture of excipients is essential as it controls the process of the drug release in the body and assures a high product quality. As a result, solid dosage forms are complex structures with high heterogeneities on different length scales. In order to simultaneously study the penetration of the water inside of the tablet, the disintegration and swelling, one needs to non-destructively and in full 3D visualize the process.

The tablet was compacted in a 6 mm die at a predetermined thickness to control the maximum in-die relative density (0.8) at Purdue University (Prof. Gonzalez Research Group). The formulation used was: MMC (89%) + APAP (9%) + MgSt (1%) + Cab-O-Sil (1%). MMC or MicroCrystalline Cellulose is widely used in pharmaceuticals, primarily as binder in oral tablets. The tablet was afterwards placed in the TESCAN UniTOM HR on a stryrofoam sample holder with a syringe pump attached. The pump added water at an injection rate of 2ml/min to the styrofoam. As a results, the water was absorbed by the tablet through capillary uptake at the bottom. This complete in-situ set up was mounted on the rotation stage of the TESCAN UniTOM HR and powered through the slipring of the system. By doing so, an endless, uninterrupted rotation of the complete in-situ set up was possible as fluid cable tangling was bypassed.

In order to capture the fast, mechanical dynamics of the disintegration process, a high temporal resolution was needed. The total time for complete disintegration of the tablet was 7 minutes. In the experiment, 100 uninterrupted tomograms at a temporal resolution of 4 seconds (200 projections/360°, 20 ms exposure time) per rotation could be obtained while water was absorbed inside the tablet. The voxel size of the scan was 13 µm, small enough to visualize the deformation mechanics inside of the sample.

The resulted reconstructed volumes clearly demonstrate the disintegration pattern of the samples. A crack forms at the bottom of the sample, opening upwards during the water absorption. The water front itself in not uniform throughout the complete sample and shows a faster absorption on the boundaries of the sample. Micro-cracks are developing throughout the sample, some of them filled with liquid while others remain dry. A more thorough investigation, including image analysis, is required to fully understand the behavior of the sample, but the principal disintegration mechanisms are captured throughout the process.

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References

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Time Block B (14:00-17:00 CET)

Participation

In person

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