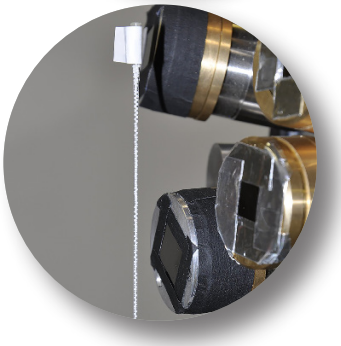
Case Study

Visualising coating integrity for bead drug products

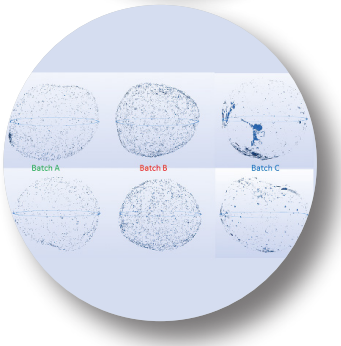
The Problem

Drug products in the pharmaceutical industry are commonly prepared in the form of discrete multi-particulate units. Bead products are a vehicle used in the development of controlled release drugs and are prepared by coating an inert spherical core with multiple layers, including that of the active ingredient. Components in each applied layer can have a significant impact on how the drug will be released and porosity of the layers is a critical feature related to observed dissolution behaviour. However accurate and highly resolved measurement of the physical integrity of these layers is a significant challenge in the development of advanced multi-particulate dosage forms.



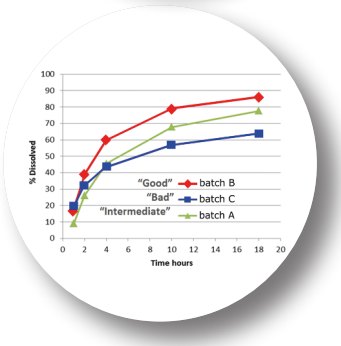
The Challenge

One Pfizer late stage candidate is layered onto an inert sugar core along with several other layers to create the final dosage form. Notable differences in dissolution rates between batches of beads had been observed at Pfizer and it was vital to both understand the reason for this and ensure consistent manufacture in the future. Previous surface and cross-sectional measurements using conventional SEM and benchtop X-ray microtomography had been attempted, but neither provided sufficient resolution. In this case the outer cellulose acetate layer is only ~ 7 µm thick and the pores within that layer are much smaller.



The Solution

High resolution X-ray tomography measurements were performed on the Diamond Manchester Imaging beamline I13-2 at the Diamond Light Source. Beads from 3 different production batches with varying dissolution profiles were mounted in glass capillaries for imaging. Tomographic analysis was successfully able to distinguish porosity differences between the different production batches and there was correlation between the porosity and the dissolution rate of the beads.



The Benefits

The non-destructive measurement of drug multi-particulates on I13-2 has enabled highly resolved data to be obtained. This has been used to successfully differentiate between different production batches and has highlighted the importance of the integrity of the bead coating in determining the dissolution rate.

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