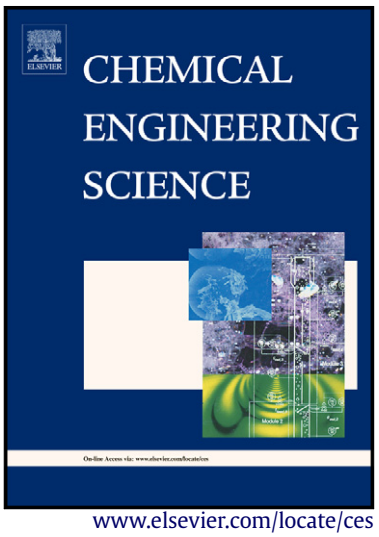

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Calibration-free In-Line Monitoring of Pellet Coating Processes via Optical Coherence Tomography

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ABSTRACT

The paper presents a new in-line measurement technique for determining the coating thickness and uniformity of pharmaceutical pellets during film-coating in a fluid-bed apparatus. Non-destructive and contact-free process monitoring was performed via an optical coherence tomography (OCT) sensor providing cross-section images. Through the OCT measurements, the coating thickness could be determined directly, without a chemometric calibration model required for the quantification. The direct integration of the OCT sensor head into the fluid-bed systems allowed continuous monitoring of the coating growth. Moreover, the in-line investigation of the intra- and inter-pellet coating uniformity was possible due to OCT's high acquisition rate. Results of the in-line OCT measurements were validated using both off-line OCT images and particle size analysis by performing an image analysis of samples that were periodically removed from the process during the production. Three batches were produced under the same process conditions demonstrating the reproducibility of the results. Rather