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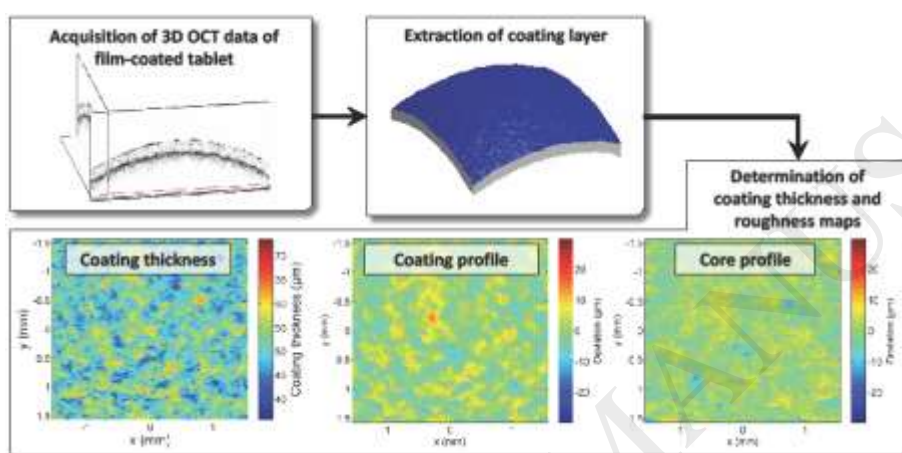
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Graphical abstract



ABSTRACT

This study demonstrates the use of optical coherence tomography (OCT) to simultaneously characterize the roughness of the tablet core and coating of pharmaceutical tablets. OCT is a high resolution non-destructive and contactless imaging methodology to characterize structural properties of solid dosage forms. Besides measuring the coating thickness, it also facilitates the analysis of the tablet core and coating roughness. An automated data evaluation algorithm extracts information about coating thickness, as well as tablet core and coating roughness. Samples removed periodically from a pan coating process were investigated, on the basis of thickness and profile maps of the tablet core and coating computed from about 480,000 depth measurements (i.e., 3D data) per sample. This data enables the calculation of the root mean square deviation, the skewness and the kurtosis of the assessed profiles. Analyzing these roughness parameters revealed that, for the given coating formulation, small valleys in the tablet core are filled with coating, whereas coarse features of the tablet core are still visible on the final film-coated tablet. Moreover, the impact of the tablet core roughness on the coating thickness is analyzed by correlating the tablet core profile and the coating thickness map. The presented measurement method and processing could be in the future transferred to in-line OCT measurements, to investigate core and coating roughness during the production of film-coated tablets.

Keywords: Optical coherence tomography, solid oral dosage form, coating, roughness, 3D thickness map

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