标题: A comparison of quality control methods for active coating processes

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摘要: Terahertz pulsed imaging (TPI) is a recent and nondestructive technique to quantify coating thickness of pharmaceutical tablet film coatings. In this study, TPI is used for the first time to quantify the progress of an active coating process. The dosage form consisted of a push-pull osmotic system comprising a two-layer tablet core with a functional film coating and a laser drilled hole. On top of this system an active coating was applied. The coating thickness data acquired by TPI and optical microscopy was compared to the quantification of the active pharmaceutical ingredient (API) via HPLC. Good correlation of TPI and HPLC data was shown for coating thicknesses up to 500 mu m. Due to the special structure of the dosage form, the TPI detection limit of 38 mu m layer thickness was circumvented by analysing the coating thickness of active coating and functional subcoat in one. Therefore it was possible to monitor the active coating process from the very beginning of the process. Optical microscopy was no suitable reference technique for TPI thickness measurements. The active coating showed deformation artefacts during sample preparation, which biased the subsequent thickness measurements. (C) 2012 Elsevier B.V. All rights reserved.

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