

标题: Using Terahertz Reflectance Spectroscopy to Quantify Drug Substance in Tablets

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摘要: The purpose of this research is to investigate the applicability of terahertz (THz) reflectance spectroscopy for quantification of drug substance in tablets, so as to demonstrate the feasibility for applying this technique to tableting process monitoring. In order to acquire a suitable absorbance spectrum for this purpose, it was necessary to enhance the reflection intensity. By using an aluminum plate as a mirror at the opposite surface of the tablet, a reasonable absorbance spectrum could be acquired to reflect the bulk information of the tablet. To assess the limit of tablet thickness, linearity between the tablet thickness and the absorbance value was investigated using lactose and mannitol tablets. Since linearity was found within 0.75-5.0 mm for both tablets using 0.4 and 0.8 THz region, it was confirmed that THz reflectance spectroscopy is applicable to tablets within at least 5.0 mm thickness. Mannitol tablets containing sodium salicylate as the model drug substance were used to investigate the quantitative performance of this technique. It was confirmed that the established calibration model was acceptable for this quantification because of the root-mean-squared error of cross-validation (RMSECV) being 1.95%. In order to evaluate the applicability of this technique, content quantitative performance in double layered tablets having active and placebo layers were assessed. Since this calibration model achieved the root-mean-squared error of prediction (RMSEP) of 1.42% for the double layered tablets, this technique was considered feasible even if the drug substance is localized in the tablets.

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