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<AT>Hyperspectral Imaging using Near Infrared Spectroscopy to monitor coat thickness uniformity in the manufacture of a Transdermal Drug Delivery System

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<ABS-Head><ABS-HEAD>Graphical abstract
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<ABS-HEAD>Abstract
<ABS-P>Hyperspectral imaging using near infrared spectroscopy (NIRS) integrates spectroscopy and conventional imaging to obtain both spectral and spatial information of materials. The non-invasive and rapid nature of hyperspectral imaging using NIRS makes it a valuable process analytical technology (PAT) tool for in-process monitoring and control of the manufacturing process for transdermal drug delivery systems (TDS). The focus of this investigation was to develop and validate the use of Near Infra-red (NIR) hyperspectral imaging to monitor coat thickness uniformity, a critical quality attribute (CQA) for TDS. Chemometric analysis was used to process the hyperspectral image and a partial least square (PLS) model was developed to predict the coat thickness of the TDS. The goodness of model fit and prediction were 0.9933 and 0.9933, respectively, indicating an excellent fit to the training data and also good predictability. The % Prediction Error (%PE) for internal and external validation samples was less than 5% confirming the accuracy of the PLS model developed in the present study. The feasibility of the hyperspectral imaging as a real-time process analytical tool for continuous processing was also investigated. When the PLS model was applied to detect deliberate variation in coating thickness, it was able to predict both the small and large variations as well as identify coating defects such as non-uniform regions and presence of air bubbles.
<KWD>Keywords: hyperspectral; near-infrared; imaging; transdermal; chemometrics;

coating; thickness

<KWD>Abbreviations: NIRS, Near infrared spectroscopy; PAT, Process analytical technology; TDS, Transdermal drug delivery systems; NIR, Near Infra-red; CQA, Critical quality attribute; PLS, Partial least square; %PE, % Prediction error; MCT, mercury-cadmium-telluride; MC, Mean centering; SNV, Standard normal variate; PCA, Principle component analysis