PAT Monitoring of Coating Pan by NIR: PLS Method Calibration

Approach

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INTRODUCTION

In this study the coating process in pan was taken in consideration, different coating materials were tested, the process was monitored by NIR to determine the weight gain and the coating thickness of the coated tablets in real time.

METHODS

The NIR device was positioned in the coating pan through the front door, attached to the spray bar in contact with the moving tablet bed.The coating process was replicated using two different coating agents (HPMC and PVA based ready-to-use coating systems) to demonstrate the independency from the material used. The NIR response was compared with manual measurements obtained by a precision micrometre and a digital scale at regular intervals. The data were analysed and processed using Unscrambler software. 3 batches per coating materials were used together to build a calibration curve, the measured samples were correlated with the NIR response by the PLS method.

CONCLUSION

The high R2 shows that there is a strong correlation between the real values and the response of the NIR, confirming that the model is robust.

A 4th batch was run for every coating agent as an «unknown» batch to verify the model.

The reproducibility and the precision of the PAT monitoring can allow process control without the need for constant sampling and at-line analysis. Future development of this study can lead to an integration of the PAT technology with the control software of the coating pan and a real time control of the process in terms of product characteristics instead of the process parameters. This integration can also be developed to design a continuous manufacturing process that must be kept constantly under control to guarantee the reproducibility of the final product.

**Keywords:** PAT, NIR device, Process monitoring, Continuous Manufacturing, Coating Pan, Coating, Andrea Gelain, Freund-Vector