Abstract

Online prediction of physical and chemical properties of pharmaceutical products using a SAM-Spec® sensor head combined with a hyperspectral imaging system

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Introduction

The production of solid dosage forms in the pharmaceutical industry involves several critical steps. During these steps, important chemical and physical parameters must be monitored in order to avoid out-of-specification products. The fluid bed drying application is a complex process in which variability in granule density and particle size distribution changes the spectra drastically and therefore generates difficulties with the classical NIR approach. In this study, active pharmaceutical ingredient (API) concentration was predicted while the physical attributes were calculated using scattering theory (calculation of the reduced scattering coefficient μs' and absorption coefficient μa).

Material and methods

Samples were measured using a new approach for sampling. This system was composed of a hyperspectral imager from SPECIM modified in order to simultaneously acquire 30 fibre channels. These fibres were connected on a specific probe having multipoint measurement in order to effect a spatially-resolved measurement. The head has an angle in order to be less sensitive to powder compaction. Each channel measured spectra at different distances (200 μm up to 6 mm) from the irradiation beam. The result obtained for a given sample was a 2D signal Wavelength x positions of the fibre. This 2D signal was then processed using nWay PLS and light simulation.

Results and Discussion

The two measuring solutions have demonstrated the ability to predict API and mean particle size. API determination coefficient, r^2, was 0.98 using n-PLS. Using scattering theory, the diffusion coefficient enabled a good correlation with the Malvern reference measurement of mean particle size D10 D50 D90 - R^2 between 0.8 and 0.9

Conclusion

API concentration was predicted accurately even at small concentrations. Mean particle size was predicted correctly using the scattering coefficient. The system enables on-line monitoring for uniformity, mean particle size and API concentration at several locations.

Reference paper as:
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