

Monitoring powder uniformity of pharmaceutical blends using Near-infrared spectroscopy

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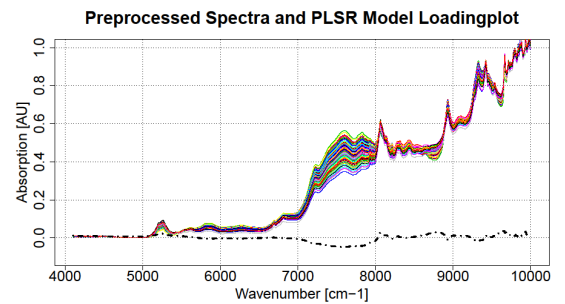
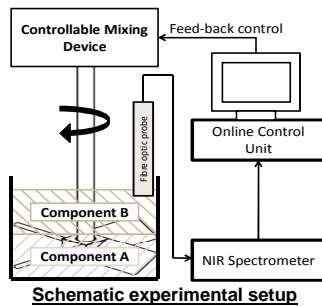


Introduction

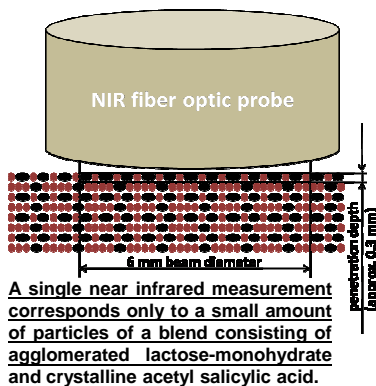
Blending processes are one of the key manufacturing steps in pharmaceutical preparation, as optimal blend homogeneity is crucial to ensure correct dosage. Near-infrared spectroscopy allows bypassing the traditional offline approach controlling the mixing end-point using HPLC or UV-VIS spectroscopic methods. By means of NIR spectroscopy, powder homogeneity can be directly evaluated during blending. NIR does thus ultimately facilitate knowledge based design of pharmaceutical production operations.

Methods

- Online NIR measurements ($10000 - 4100 \text{ cm}^{-1}$) allowing in-line analysis of strongly absorbing and highly scattering samples, e.g. powders or suspensions, without preparation
- Development of a Process Analytical Toolbox implementing powerful preprocessing functions and model building algorithms for analysis of multivariate collinear NIR data enabling online monitoring and process control

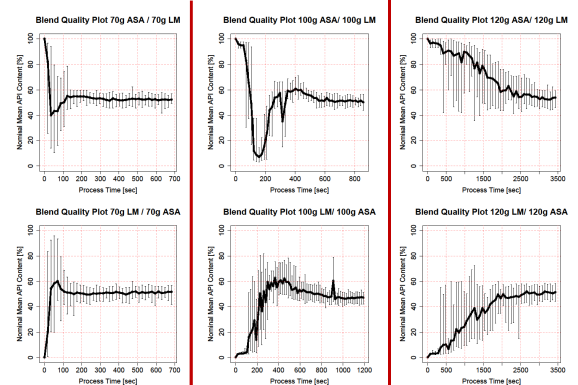


Results



Averaging subsequently recorded spectra or increasing recording time significantly improves model predictive performance.

Dependent on powder loading order and volume, different blender specific mixing kinetics have been identified.



Conclusions

- NIR spectroscopy proved to be suitable for quantitative online monitoring of powder blending processes.
- Monitoring pharmaceutical operations involving solid samples, NIR applications are limited by mixture sub sampling issues due to insufficiently large beam sizes.
- Optimal NIR spot size corresponds to the actual dosage of the end product.

References

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