Conference abstract PMS08

Linking Rheological Key Parameters of Pharmaceutical Powders to Mixing Properties

**O. SCHEIBELHOFFER¹, N. BALAK¹, D. M. KOLLER¹,
S. D. FRASER¹, T. FREEMAN², J. G. KHINAST^{1,3}**

¹ Research Center Pharmaceutical Engineering GmbH, Graz, Austria

² Freeman Technology, Worcestershire, United Kingdom

³ Institute for Process and Particle Engineering, University of Technology, Graz, Austria

E-mails: daniel.koller@rcpe.at (D. M. Koller), khinast@tugraz.at (J. G. Khinast)

Sci Pharm. 2010; 78: 635

doi:10.3797/scipharm.cespt.8.PMS08

The application of process analytical technology (PAT) has opened the possibility for continuous process monitoring and quality control in the pharmaceutical industry.

Transporting and mixing of pharmaceutical powders is a challenging task and changes significantly with the mixer type and with the process scale up. Therefore knowledge about the critical process parameters (CPPs) with respect to the powder and their influence on the mixing behavior are essential.

Traditional powder tests (e. g., shear cell, flow through a funnel, etc.) often lack reproducibility and depend strongly on the operator. In contrast to these powder characterization methods, here, an FT4 powder rheometer (Freeman Technology) was applied to determine standardized and repeatable results for powder properties, e. g., shear properties, permeability, cohesion, compressibility, etc.

Based on design of experiment (DoE), an experimental design was developed, testing a recent amount of parameters, which were evaluated for their responses on forming a uniform blend in a mixing process. Continuous process monitoring of the blending processes with near-infrared (NIR) spectroscopy allowed a non-destructive investigation of blend quality and mixing dynamics. Evaluation of the spectral data was performed with qualitative and quantitative multivariate data analysis (MVDA) methods, in order to look for correlations between FT4 parameters and blend quality.