P3

Determination of batch-to-batch variation for fluidized bed granulation

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A batch-to-batch variation is an issue in fluidized bed granulation (Matero et al., 2007). The variation arises from process conditions, most notably from the relative humidity of ambient air. Therefore, building a reliable model for process monitoring is a complex task for batch granulation. However, multi-way models have been recognized as useful tools for the batch data to sum up the essential process behavior (Bro et al., 2004; Kourti, 2006). Our study aimed to develop a multi-way model for real-time granule water content and granule size determination during fluidized bed granulation, since these granule properties are the main characteristics of the granulation process. The model dimensions were different batches, process parameters and acoustic emission spectra. The bilinear multivariate methods have shown suitability of acoustic emission signals to monitor fluidized bed granulation (Matero et al., 2007). The model represented enables the granulation behavior profile determination and evaluation between batches according to the key granule properties.

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P4

Effects of formulation parameters and drug–polymer interactions on drug release from starch acetate matrix tablets

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The aim of this study was to determine formulation parameters that have the greatest impact on drug release. Another aim was to identify the interactions between drug and hydrophobic polymer matrix, and how they affect the drug release. Six different drug compounds, allopurinol, acyclovir, metronidazole, paracetamol, salicylamide and theophylline, were used in different formulations with starch acetate (DS 2.7) as a filler binder. Results indicate that formulation parameters describing directly or indirectly the structure of the matrix have the strongest impact. The importance of drug property based variables is significant but not as high as formulation parameters. The effect of water solubility and dissolution rate of the compound are obvious, but parameters describing the hydrophobic and hydrophilic regions of the molecule have a strong impact. Especially salicylamide seems to have a strong and sufficiently great hydrophobic region that interacts with starch acetate and impairs the drug release.

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P5

Quantitation of two enhancers in a pharmaceutical gel by near infrared spectroscopy

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Two near infrared spectroscopy (NIRS) models were developed for quantitative analysis of two enhancers, ethanol and propylene glycol, in a commercial pharmaceutical gel. For calibration, a separate sample set was prepared for each compound studied. The measurements were performed by transflectance technique, where a reflector was placed behind the sample. A multivariate analysis tool, PLS1 (Partial Least Squares) was used to calibrate both models. In calibration, NIRS spectra response was calibrated against property values obtained by gas chromatography (GC) analyses of the samples. For pre-treatment, a Multiplicative Scatter Correction (MSC) was used. The NIRS models were validated according to the Pharmacopoeia requirements. Over thirty commercial production batches of the drug product were analysed by the primary GC and the developed NIRS model. As a result, the developed NIRS models were found to be equivalent to the primary methods and suitable to be used in the Quality Control analyses.

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P6

3D drug concentration distribution motoring during USP2 dissolution testing

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In traditional dissolution testing drug concentration is monitored by taking samples from the dissolution vessel and analyzing them off line, e.g. with a spectrophotometer. Now a novel measuring method utilizing electrical impedance tomography (EIT) is studied. In EIT 3D drug concentration distribution is monitored non-intrusively and online. An array of metal electrodes is attached on the boundary of the dissolution vessel and a set of alternating electric currents is injected through electrodes and resulting voltages are measured. With