Sean Moore et al., Pharmacoeconomics 2017, 2:1(Suppl)
http://dx.doi.org/10.4172/2472-1042.C1.003



## End-point determination of isopropyl alcohol in lactose by near-infrared spectroscopy

**Sean Moore, Gavin Walker, Natalie Taupe** and **Monika Zacharska**
University of Limerick, Limerick; Sun Pharmaceuticals Industries Ltd, Cashel, Ireland

**Statement of the Problem**: The manufacturing steps of pharmaceutical tablets can broadly be divided into (1) granulation, (2) drying, (3) blending, (4) compression and (5) coating. Currently, monitoring of the drying process, in order to determine its end-point, is inefficient and time-consuming. The implementation of near-infrared (NIR) spectroscopy allows real-time control of the process, leading to an improved production capacity and reduced waste generation and costs. The purpose of this study was to develop and validate a method using NIR for measuring isopropyl alcohol (IPA) in lactose with subsequent potential for in/on-line measurement of this property during fluidized bed drying.

**Methodology**: Chemometric techniques were used to predict the amount of IPA in lactose from the NIR spectra. A partial least squares (PLS) model was constructed with the JMP Pro software using the normalized spectra of 48 calibration mixtures in the range of 1-12 wt.% of IPA in lactose over a spectral range of 1100-2500 nm. The model was validated using 11 unknown samples. The loss of IPA during drying of lactose at 30°C was monitored off-line by NIR and gas chromatography as a reference method.

**Findings**: The prediction capability of the PLS model was high with a correlation coefficient ($R^2$) of 99.6% and a root mean square error (RMSE) of 0.2%. The predicted values obtained during drying showed $R^2$=98.2% and RMSE=0.5%. The volatility of IPA poses challenges when handling and analyzing samples.

**Conclusions & Recommendations**: The use of NIR for monitoring desired properties, such as solvents, during different process steps offers an improvement of the overall manufacturing efficiency. Application of NIR spectroscopy for in/on-line monitoring at a commercial scale is required to further improve this technique and involve other manufacturing steps and product properties.

### Biography

Sean Moore has over 27 years' of experience in Medical Devices, Aerospace, and Electronics industries and has held various roles in continuous improvement, operations, engineering, manufacturing, R&D, metallurgical evaluation, chemical and heat treat processing and included interaction with the regulated bodies. His research is focused on the development of non-destructive testing methods in Medical Device and Pharmaceuticals. A method using Infrared technology was developed as part of the EI funding with NUIG to non-destructively quantify laser bonded polymers and a method to quantify API and excipient components of drug eluting stent coating, using Raman spectroscopy was funded and developed in-house in Abbott Vascular by the PI in collaboration with an Analytical Chemist.

Sean.Moore@ul.ie

**Notes:**