



Application Note AN-NIR-078

用多的自水分分析

Non-destructive quality control

The quantification of residual moisture in lyophilized pharmaceutical peptides is an important measure for quality control in the pharmaceutical industry. Analyses are routinely performed for process control and to ensure that production lots meet required specifications. For development purposes, such measurements are necessary during stability studies and to optimize the freeze-drying process (lyophilization).

Currently, Karl Fischer titration is widely used for moisture determination in routine analysis. However, measuring the water content by this method is time consuming and the sample is destroyed during analysis. This Application Note shows that near-infrared spectroscopy (NIRS) is a fast, reagentless, non destructive method to determine moisture content in lyophilized pharmaceutical products.

EXPERIMENTAL CONDITIONS

17 spectra of samples with varying moisture content were collected using a Metrohm NIRS XDS OptiProbe Analyzer in combination with the 815 Robotic Sample Processor. With the attached large sample rack, it was possible to automate measurements of up to 62 samples in series. The reference values were obtained by KF-titration. The data set consisting of spectra and lab values was split into a calibration set (11 samples) and validation set (6 samples). Outlier detection was performed on pre-treated spectra (2nd derivative) using a maximum distance in wavelength space algorithm.



Figure 1. The NIRS XDS OptiProbe Analyzer and the 815 Robotic Sample Processor.

Pre-processing	Algorithm	Validation type
2 nd derivative	PLS	Independent validation set

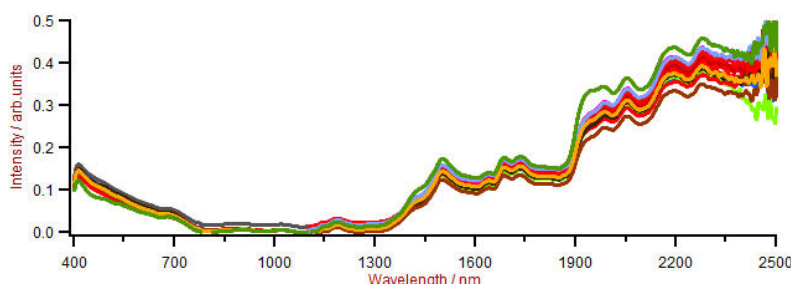


Figure 2. Protein samples measured with varying water content.

RESULT & CONCLUSION

The obtained correlation graph displays a very high correlation ($R^2 = 0.99$) between moisture predicted by NIRS and the KF-titration primary

method. SEC and SEV values are in the range of 0.060%, which proves that NIRS is a sensitive and suitable technique for moisture determination.

# Factors	R^2	SEC	SEV
2	0.99	0.054%	0.061%

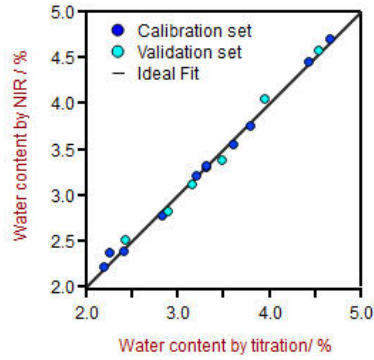


Figure 3. Correlation graph for moisture predicted by NIRS vs titration.

CONTACT

瑞士万通中国
北京市海淀区上地路1号院
1号楼7702
100085 北京

marketing@metrohm.com.cn

CONFIGURATION



NIRS XDS Interactance OptiProbe Analyzer
固耐用的量系可用于工和所中的反。

NIRS XDS Interactance OptiProbe Analyzer 分析可方便可靠地控工和所中的化学反。在方法以及生程的工放大等用域中,NIRS XDS Interactance OptiProbe 分析可提供不同品的和品定的精果。在使用反射探量固体、高度散射液体和料的程中,分析水性制品、透明液体和溶可使用透射反射探。探通光与分析相,即使在劣或危的程境条件下也可保可靠地量。



815 Robotic USB Sample Processor XL (1T/1P)

Robotic USB Sample Processor XL 包括一个工作站和一台内置的隔膜,可用于自理大量常品系列以及完成品前理或并列理流程。除了内置的之外,可再接一台(隔膜或蠕)和多三台加液元用来行 LQH 加液理。

由于其用范很广,因此必根据具体用来合的品、拌器、滴定、机械臂和 Swing Head 以及品容器并独。通 Touch Control 通 "stand alone" 控制。有以下 PC 控制用件品可供: 滴定件 tiamo™、色分析件 MagIC Net、伏安法件 viva 或 OMNIS。



Vision Air 2.0 Complete

Vision Air – 通用的光分析件。

Vision Air Complete 是用于管范境的先易用的件解决方案。

Vision Air 点一:

- 便捷的件用和配的用界面保了直的操作方式
- 操作程的建与方式
- SQL 数据,可安全且地管理数据

Vision Air Complete (66072208) 版本包含所有用于可近外光分析量保程的用:

- 器和数据管理用
- 方法用
- 常分析用

其它 Vision Air Complete 解决方案:

- 66072207 (Vision Air Network Complete)
- 66072209 (Vision Air Pharma Complete)
- 66072210 (Vision Air Pharma Network Complete)



tiamo 3.0 light USB1

tiamoTM 3.0 light,用于控制滴定系的计算机程序。

最多可接个万通器(Titrino、Titrand,等等),可不受限制地容天平和其他通用(也就是非万通器)器

具有大量模板的形方法段器

个性化屏幕界面的布局管理器

含再估功能的数据

功能大的告生成器

作 PDF、CSV、SLK 数据出

无平行滴定

没有 LIMS 用 XML 格式数据出

框言:德、英、法、意大利、西班牙、捷克、葡萄牙、
波、俄、斯洛伐克、日、繁体中文