



Application Note AN-NIR-078

药用多肽的自动水分分析

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

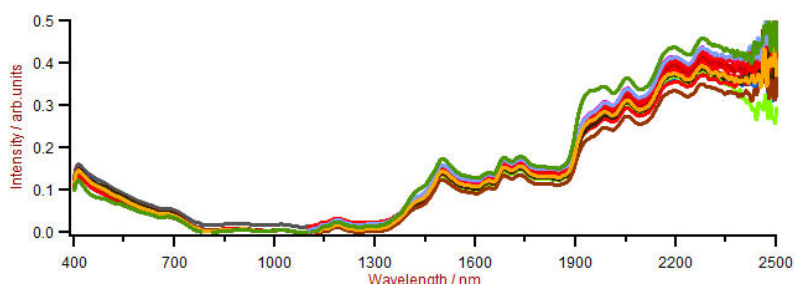


Figure 2. Protein samples measured with varying water content.

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%

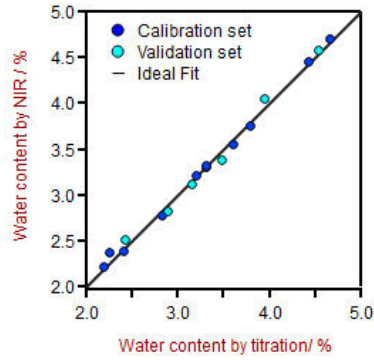


Figure 3. Correlation graph for moisture predicted by NIRS vs titration.

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CONFIGURATION



NIRS XDS Interactance OptiProbe Analyzer
坚固耐用的测量系统可用于监测工业设备和实验场所中的反应。

NIRS XDS Interactance OptiProbe Analyzer 分析仪可方便可靠地监控工业设备和实验场所中的化学反应。在方法开发以及生产过程的工艺放大等应用领域中, NIRS XDS Interactance OptiProbe 分析仪可提供不同样品的识别和品质测定的精确结果。在使用反射探针测量固体、高度散射液体和浆料的过程中, 分析水性制品、透明液体和溶剂时可使用透射反射探针。探针通过光纤与分析仪相连, 这样即使在恶劣或危险的过程环境条件下也可确保可靠地测量。



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泵,可用于自动处理大量常规样品系列以及完成复杂样品前处理或并列处理流程。除了内置的泵之外,还可再连接一台泵(隔膜泵或蠕动泵)和多达三台加液单元用来进行 LQH 加液处理。

由于其应用范围很广,因此必须根据具体应用来选择合适的样品盘、搅拌器、滴定头、机械臂和 Swing Head 以及样品容器并单独订购。

通过 Touch Control 实现单机控制。有以下 PC 控制用软件产品可供选择: 滴定软件 tiamo™、色谱分析软件 MagIC Net、伏安法软件 viva 或 OMNIS。



Vision Air 2.0 Complete

Vision Air – 通用的光谱分析软件。

Vision Air Complete 是用于监管规范环境的先进易用的软件解决方案。

Vision Air 优点一览:

- 便捷的软件应用和经过适配的用户界面保证了直观简单的操作方式
- 操作过程的创建与维护方式简单
- SQL 数据库,可安全且简单地管理数据

Vision Air Complete (66072208) 版本包含所有用于可见近红外光谱分析质量保证过程的应用:

- 仪器和数据管理应用
- 方法开发应用
- 常规分析应用

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)



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tiamoTM 3.0 light,用于控制滴定系统的计算机程序。

最多可连接两个万通仪器(Titrino、Titrand,等等),可不受限制地容纳天平和其他通用(也就是非万通仪器)仪器

具有大量模板的图形方法编辑器

个性化屏幕界面的布局管理器

含再评估功能的专业数据库

功能强大的报告生成器

作为 PDF、CSV、SLK 数据导出

无平行滴定

没有 LIMS 用 XML 格式数据导出

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