

Application Note AN-NIR-122

使用 OMNIS 奥秘一代近红外光谱仪量化乳糖中的水分

Fast, non-destructive determination of water with NIRS

Lactose is an important pharmaceutical product. Approximately 60% to 70% of pharmaceutical dosage forms contain lactose [1], and it is one of the largest pharmaceutical excipients by volume. Lactose can be used as a bulk filler for pharmaceutical tablets, as a binder to provide more strength to a dosage form, and it can also be added to facilitate the flow of a formulation during the production process. Moisture in lactose is undesirable at high levels as it causes the material to become sticky and bind to itself, forming hard clusters that may be difficult to break apart. USP specifies the water content range in lactose monohydrate from 4.5 % to 5.5 % [2].

The analysis of water in lactose is usually done with time-consuming methods. Near-infrared spectroscopy (NIRS) is a faster alternative. This Application Note shows the determination of water content in lactose with NIRS.

EXPERIMENTAL EQUIPMENT

In this study, samples of lactose with varying water content were analyzed to create a NIRS prediction model for quantification. Lactose monohydrate samples either spiked with water or dried in an oven were measured on an OMNIS NIRS Analyzer (Figure 1) in reflection mode (1000–2250 nm) in 19 mm vials using a flexible holder. Single measurement was selected as the measuring mode. Data acquisition and prediction model development were performed with OMNIS software.



Figure 1. The OMNIS NIR Analyzer Solid from Metrohm.

Table 1. Hardware and software equipment overview.

Equipment	Article number
OMNIS NIR Analyzer Solid	2.1071.0010
Disposible vials, 19 mm, reflection	6.7402.120
Flexible holder OMNIS NIR	6.07402.300
OMNIS Stand-Alone license	6.06003.010
Quant Development software license	6.06008.002

RESULT

The measured NIR spectra (Figure 2) were used to create a quantification prediction model for the percentage of water in lactose. The quality of the prediction model was evaluated using the correlation diagram which displays a very high correlation between the NIR prediction and the reference values. The respective figures of merit (FOM) display the expected precision and confirm the feasibility during routine analysis (Figure 3).

The water content of Hydranal Water Standard KF Oven, lactose monohydrate, (water content 5.10 ± 0.04 %) was predicted using the mentioned prediction model. The result is shown in the Table 2.

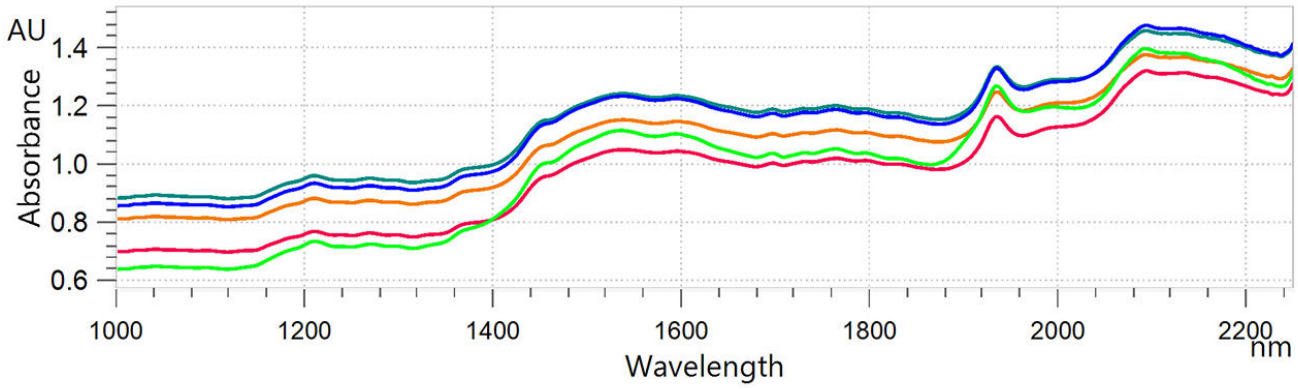


Figure 2. Overlaid NIR spectra of several lactose samples analyzed on an OMNIS NIR Analyzer Solid.

RESULT WATER CONTENT IN LACTOSE

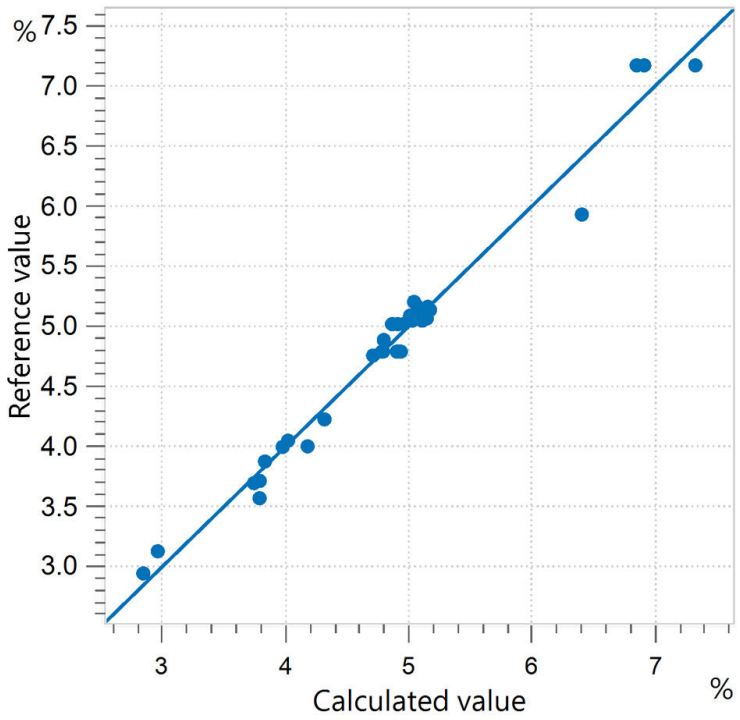


Figure 3. Correlation diagram and the respective figures of merit for the prediction of water in lactose using an OMNIS NIR Analyzer Solid. The reference water content was determined using a Karl Fischer (KF) oven method.

R^2	SEC (%)	SECV (%)
0.977	0.12	0.14

Table 2. Mean predicted water content for Hydranal Water Standard KF Oven, Lactose monohydrate, as determined with an OMNIS NIR Analyzer Solid (n = 3).

Hydranal Water Standard	
Water content (%)	5.1380
SD (rel) in %	0.029

CONCLUSION

This Application Note demonstrates the feasibility to determine water content in lactose quickly and easily. NIR spectroscopy offers users a fast, cost-effective, and highly accurate alternative to other standard testing methods. Additionally, NIRS analysis is non-destructive, completely reagent-free, and gives results in only a few seconds.

REFERENCES

1. Hebbink, G. A.; Dickhoff, B. H. J. Chapter 5 - Application of Lactose in the Pharmaceutical Industry. In *Lactose*; Paques, M., Lindner, C., Eds.; Academic Press, 2019; pp 175–229. DOI:10.1016/B978-0-12-811720-0.00005-2
2. Lactose Monohydrate. DOI:10.31003/USPNF_M44190_04_01

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CONFIGURATION



OMNIS NIR Analyzer Solid

用于固体物质和粘稠样品的近红外光谱仪。

OMNIS NIR Analyzer 按照瑞士质量标准开发和制造,是用于整个生产链中常规分析的近红外光谱 (NIRS) 解决方案。最新技术的应用以及与现代 OMNIS Software 的集成,体现在这款 NIR 光谱仪的速度、操作性和灵活应用上。

OMNIS NIR Analyzer Solid 的优势概览:

- 固体物质和粘稠样品测量时间小于 10 秒
- 自动多位置测量,确保即使在非均质样品中也能获得可重现的结果
- 可轻松集成至自动系统,或与其它分析技术(滴定)联用
- 支持多种样品容器



19 mm

225 个可封闭的玻璃一次性样品瓶,直径为 19 mm,适用于分析反射中的固体。适用于 XDS、DS2500 和 OMNIS 产品系列的 NIR 固体分析仪。



OMNIS NIR

可变直径高达 30 mm 的活动支架,用于通过反射检查样品。

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Quant Development

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