Application Note AN-NIR-122

使用 OMNIS 奥秘一代近外光量化乳糖中的水分

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.

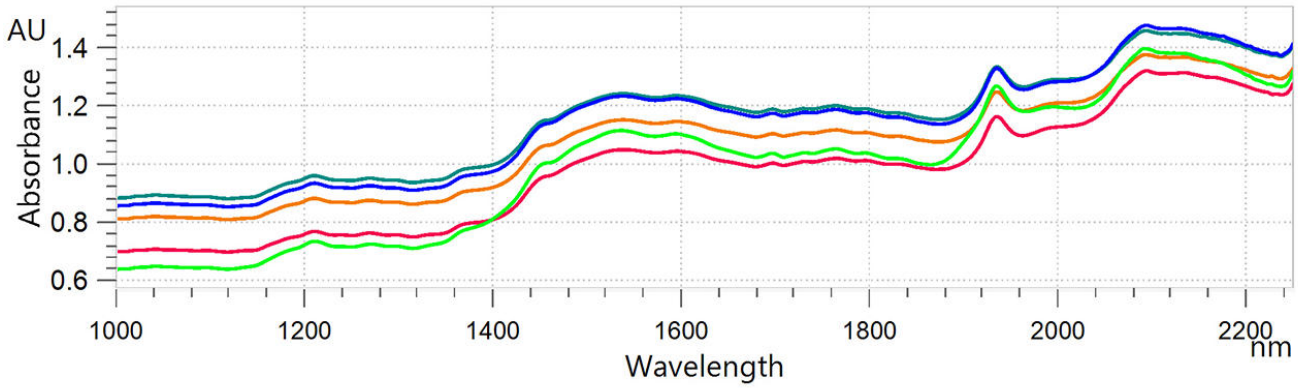

Figure 2. Overlaid NIR spectra of several lactose samples analyzed on an OMNIS NIR Analyzer Solid.

RESULT WATER CONTENT IN LACTOSE

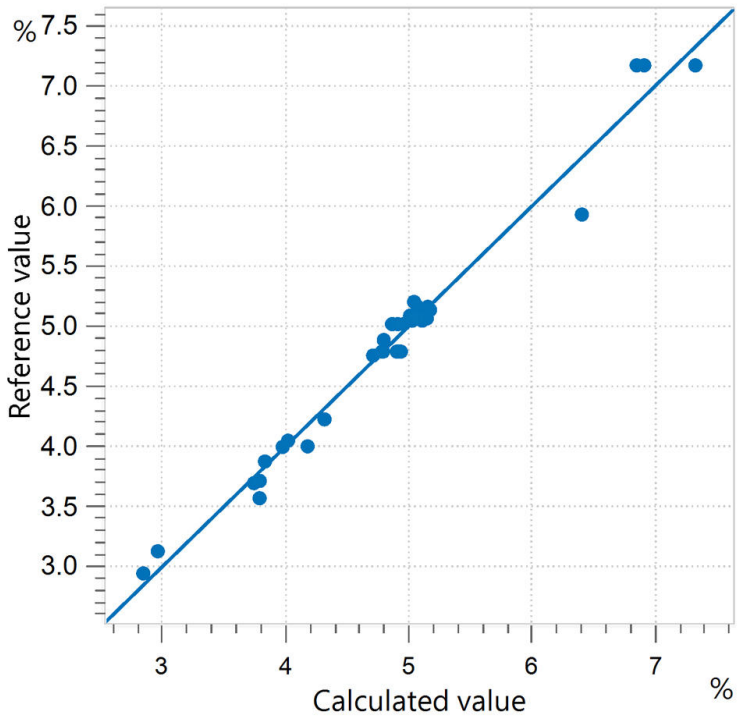

Figure 3. Correlation diagram and the respective figures of merit for the prediction of water in lactose using an OMNIS NIR Analyzer Solid. The reference water content was determined using a Karl Fischer (KF) oven method.

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

合固体和粘性品的近外光。

OMNIS NIR Analyzer 是一按照瑞士量准和生的近外光 (NIRS) 解决方案,用于整个生的常分析。使用新技和嵌入先 OMNIS Software 反在 NIR 光的速度、可操作性和活使用上。

OMNIS NIR Analyzer Solid 的点概:

- 在 10 秒以内量固体和粘性品
- 自化多位置量,即使在品不均匀,也能得可重的果
- 方便地嵌入自系,或者与其它分析技(滴定)
- 支持大量品容器

19 mm

225 个可封的玻璃一次性品瓶,直径 19 mm,用于分析反射中的固体。用于 XDS、DS2500 和 OMNIS 品系列的 NIR 固体分析。

OMNIS NIR

可直径高 30 mm 的活支架,用于通反射品。

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允机版 OMNIS 件在一台 WindowsTM 算机上行。

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- 不可再外算机上使用。

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Quant Development

用于在独立 OMNIS Software 安装套件中写和量化模型的件可。