Application Note AN-NIR-073

Determination of water activity in tablets with the OMNIS NIR Analyzer

Fast, non-destructive measurements performed in seconds

Water activity (a_w), the partial vapor pressure of water in a substance divided by the vapor pressure of water in standard state, is expressed either as 0–100% equilibrium relative humidity (ERH) or scaled to 0–1 a_w. It is used to assess the safety, quality, and strength of non-sterile drug pharma products. In compounded preparations, a_w refers to water that is freely available to participate in reactions (e.g., hydrolysis) or provides an environment that supports microbiological growth. Typically, solid dosage pharmaceuticals are >0.70 a_w, indicating that microbial growth is unlikely [**1**]. Elevated a_w in powders affects flow, caking, compaction, and strength properties of solid dosage forms and it is used in the study of shelf-life, aging, and packaging requirements. Measuring a_w in the pharma environment is described in USP<1112> and USP<922> [**2**]. Dedicated instruments that measure a_w require up to 30 minutes per analysis, while the OMNIS NIR Analyzer delivers results in just a few seconds.

EXPERIMENTAL EQUIPMENT

In this study, 17 tablets of paracetamol with varying water activity (0.23–0.85 a_w) were measured on an OMNIS NIR Analyzer (Figure 1) to create a prediction model for quantification. Samples were measured in reflection mode (1000–2250 nm) in 15 mm vials using a flexible holder and single-point measurement.
The reference values were measured according to USP<922> Water Activity [3].

Figure 1. OMNIS NIR Analyzer Solid with 15 mm vial and Flexible holder OMNIS NIR.

Table 1. Hardware and software equipment overview.

Equipment	Article number
OMNIS NIR Analyzer Solid	2.1071.0010
Disposable vials, 15 mm, reflection	6.7402.110
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 water activity in paracetamol tablets. The quality of the prediction model was evaluated using the correlation diagram (Figure 3) 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.

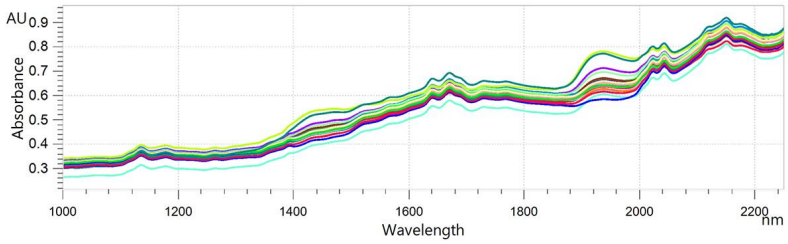

Figure 2. Stacked NIR spectra of paracetamol tablets analyzed on an OMNIS NIR Analyzer Solid.

RESULT WATER ACTIVITY IN PARACETAMOL TABLETS

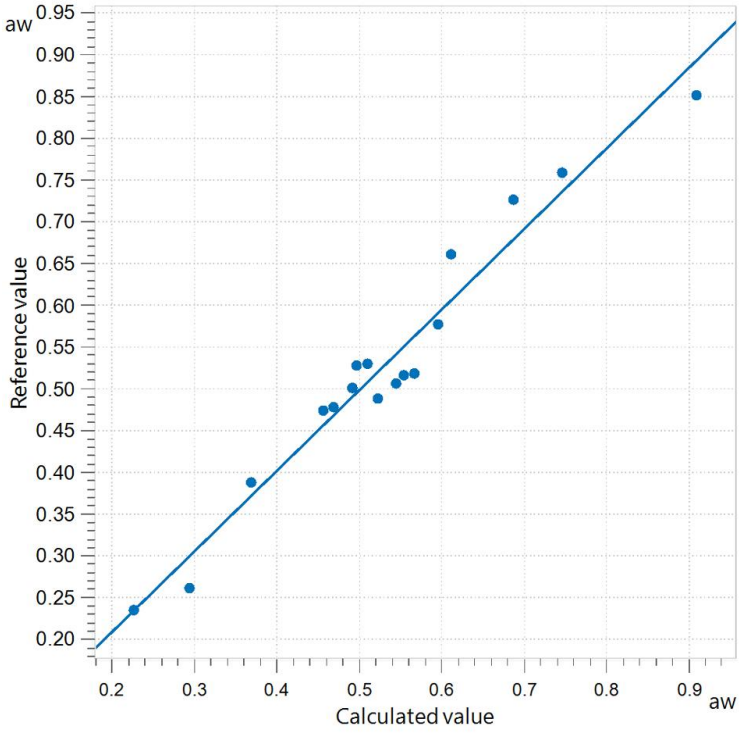

Figure 3. Correlation diagram and the respective figures of merit for the prediction of water activity using an OMNIS NIR Analyzer Solid. The reference water content was determined using a Novasina LabMaster-aw neo according to USP<922>.

R^2	SEC (a_w)	SECV (a_w)
0.958	0.0278	0.0322

CONCLUSION

This Application Note demonstrates the feasibility of determining a_w in paracetamol tablets quickly and easily. NIR spectroscopy offers users a fast, cost-effective, and highly accurate alternative to other standard water activity measurement options. Additionally, NIRS analysis is non-destructive, completely reagent-free, and gives results in only a few seconds.

REFERENCES

1. Pharmaceutical Trends: Water Activity Measurement - International Pharmaceutical Industry, 2021.
2. 〈922〉 Water Activity. DOI:10.31003/USPNF_M12475_02_01
3. *USP 922 Water Activity Measurement - Novasina - Excellent new Method.* https://www.novasina.ch/application/usp-922-water-activity/ (accessed 2024-08-27).

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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

15 mm

123 个可封的玻璃一次性品瓶,直径 15 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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