



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 ($0.23\text{--}0.85\ a_w$) 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

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

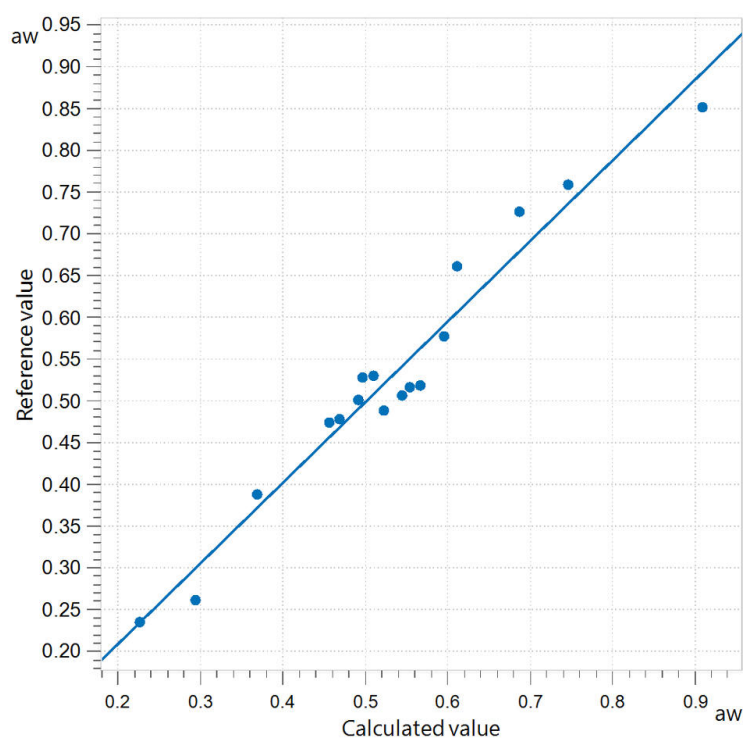


Figure 3. Correlation diagram and the respective figures of merit for the prediction of water activity using an OMNIS NIR Analyzer Solid. The reference water content was determined using a Novasina LabMaster-aw neo according to USP<922>.

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](https://doi.org/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

适合固体和粘性样品的近红外光谱仪。

OMNIS NIR Analyzer 是一种按照瑞士质量标准开发和生产的近红外光谱 (NIRS) 解决方案,用于整个生产链的常规分析。使用新技术和嵌入先进 OMNIS Software 反应在该 NIR 光谱仪的速度、可操作性和灵活使用上。

OMNIS NIR Analyzer Solid 的优点概览:

- 在 10 秒以内测量固体和粘性样品
- 自动化多位置测量,即使在样品不均匀时,也能够获得可重现的结果
- 方便地嵌入自动系统,或者与其它分析技术(滴定)关联
- 支持大量样品容器



15 mm

123 个可封闭的玻璃一次性样品瓶,直径为 15 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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