



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.

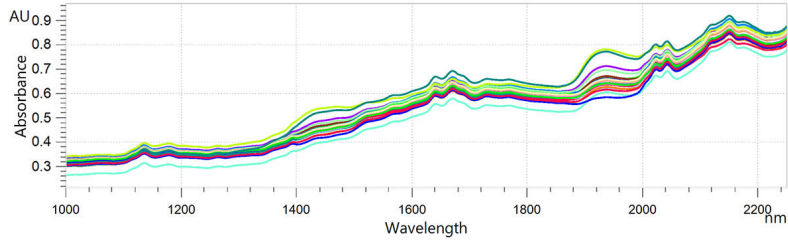
**Table 1.** Hardware and software equipment overview.

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

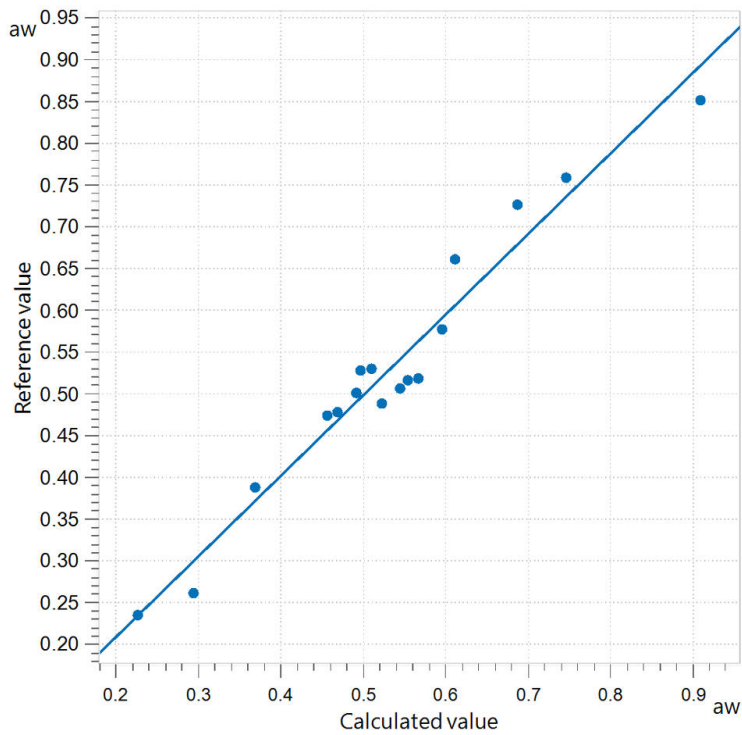
The measured NIR spectra (Figure 2) were used to create a quantification prediction model for the water activity in paracetamol tablets. The quality of the prediction model was evaluated using the correlation diagram (Figure 3) which displays a very high

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](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).

## CONTACT

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## CONFIGURATION



### OMNIS NIR Analyzer Solid

Espectrómetro del infrarrojo cercano para muestras sólidas y viscosas.

El OMNIS NIR Analyzer es la solución de espectroscopía del infrarrojo cercano (NIRS) desarrollada y producida conforme a los estándares de calidad suizos para los análisis de rutina a lo largo de toda la cadena de producción. El empleo de las tecnologías más avanzadas y la integración en el moderno OMNIS Software se reflejan en la velocidad, la manejabilidad y el uso flexible de estos espectrómetros NIR.

Información general sobre las ventajas del OMNIS NIR Analyzer Solid:

- Medidas de materias sólidas y muestras viscosas en menos de 10 segundos
- Medidas automatizadas en múltiples posiciones para obtener resultados reproducibles, incluso en muestras poco homogéneas
- Fácil integración en un sistema de automatización o vinculación con otras tecnologías de análisis (titulación)
- Compatible con numerosos recipientes de muestras



### Viales desechables, 15 mm, para reflexión

123 viales de vidrio desechables y cerrables con un diámetro de 15 mm para el análisis de sólidos en reflexión. Aptos para instrumentos de análisis de materia sólida de las familias de productos XDS, DS2500 y OMNIS.



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#### **Soporte flexible OMNIS NIR**

Soporte flexible con un diámetro variable de hasta 30 mm para el examen de muestras en viales en reflexión.

#### **Licencia "Stand-Alone" de OMNIS**

Habilita el modo "Stand-Alone" del software OMNIS en un ordenador con Windows™.

Características:

- Se incluye una licencia de los aparatos OMNIS.
- Debe activarse en el portal de licencias de Metrohm.
- No se puede aplicar a otro ordenador.

#### **Licencia de software de Quant Development**

Licencia de software para la creación y edición de modelos de cuantificación en una instalación de OMNIS Software "Stand-Alone".