



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.

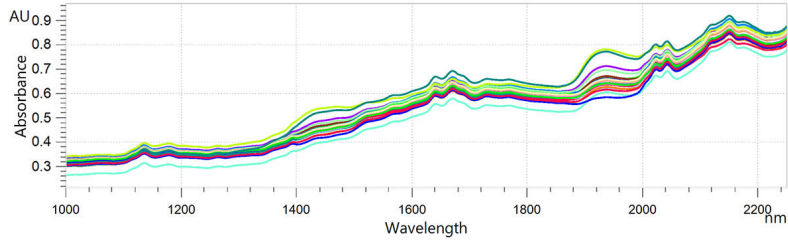


Figure 2. Stacked NIR spectra of paracetamol tablets analyzed on an OMNIS NIR Analyzer Solid.

RESULT WATER ACTIVITY IN PARACETAMOL TABLETS

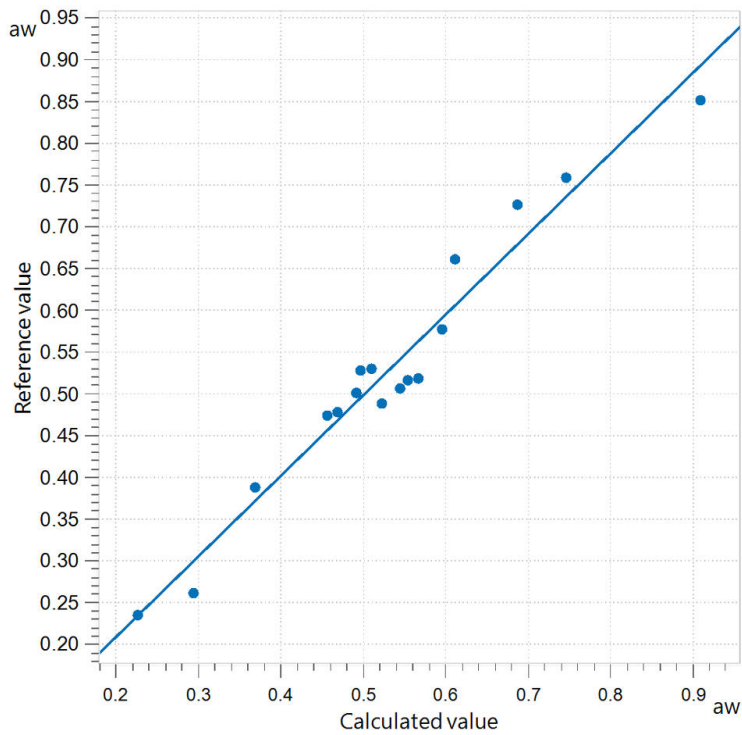


Figure 3. Correlation diagram and the respective figures of merit for the prediction of water activity using an OMNIS NIR Analyzer Solid. The reference water content was determined using a Novasina LabMaster-aw neo according to USP<922>.

| 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

Metrohm Korea Ltd.
8, 9, 5 (AJ)
05836 null

info@metrohm.kr

CONFIGURATION



OMNIS NIR Analyzer Solid

Near-infrared spectrometer for solid and viscous samples.

Developed and produced in accordance with Swiss quality standards, the OMNIS NIR Analyzer is the near-infrared spectroscopy (NIRS) solution for routine analysis along the entire production chain. Its application of the latest technologies and its integration in the modern OMNIS Software are reflected in its speed, operability and flexible utilization of this NIR spectrometer.

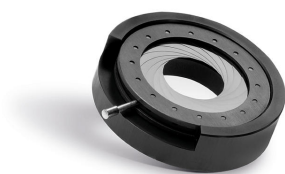
Overview of the advantages of the OMNIS NIR Analyzer Solid:

- Measurements of solids and viscous samples in less than 10 seconds
- Automated multi-position measurements for reproducible results, even with nonhomogeneous samples
- Simple integration in an automation system or link with additional analysis technologies (titration)
- Supports numerous sample vessels



Disposable vials, 15 mm, reflection

123 lockable disposable glass vials with a diameter of 15 mm for analyses of solids in reflection. Suitable for NIRS RapidContent (Solid) Analyzers of the XDS, DS2500 and OMNIS product families.



Flexible holder OMNIS NIR

Flexible holder with a variable diameter of up to 30 mm for the examination of samples in vials in reflection.

OMNIS

A WHOLE NEW LEVEL OF PERFORMANCE

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OMNIS Stand-Alone license

Enables stand-alone operation of the OMNIS software on a Windows™ computer.

Features:

- The license already includes one OMNIS instrument license.
- Must be activated via the Metrohm licensing portal.
- Not transferable to another computer.

Software license Quant Development

Software license for the creation and editing of quantification models in a stand-alone OMNIS Software installation.