



## 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    |

## RESULT

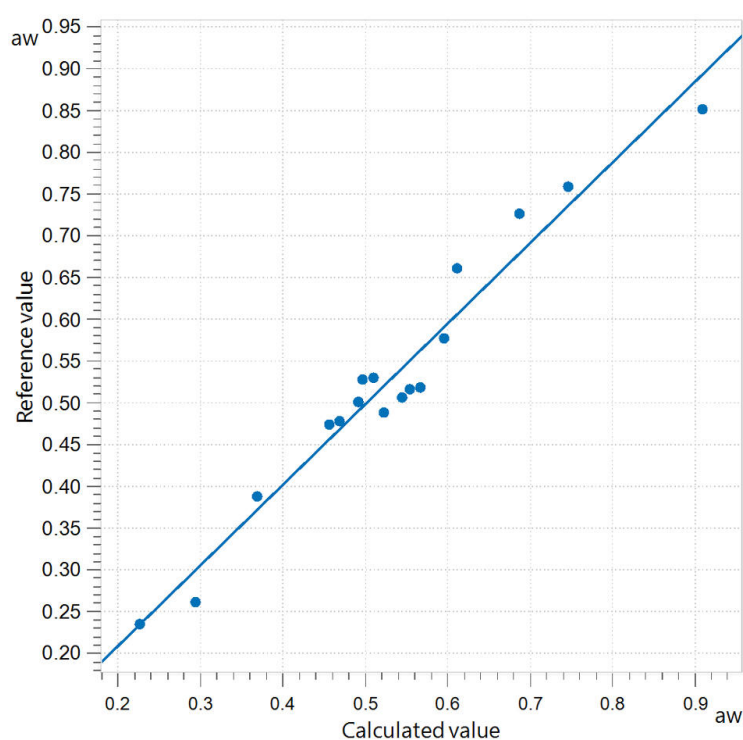
The measured NIR spectra (**Figure 2**) were used to create a quantification prediction model for the water activity in paracetamol tablets. The quality of the prediction model was evaluated using the correlation diagram (**Figure 3**) which

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

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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A WHOLE NEW LEVEL OF PERFORMANCE

### OMNIS

允许单机版 OMNIS 软件在一台 Windows™ 计算机上运行。

#### 特性:

- 该许可证已含有一份 OMNIS 设备许可证。
- 须通过万通许可授权平台进行激活。

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### Quant Development

用于在独立 OMNIS Software 安装套件中编写和编辑量化模型的软件许可证。