



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.

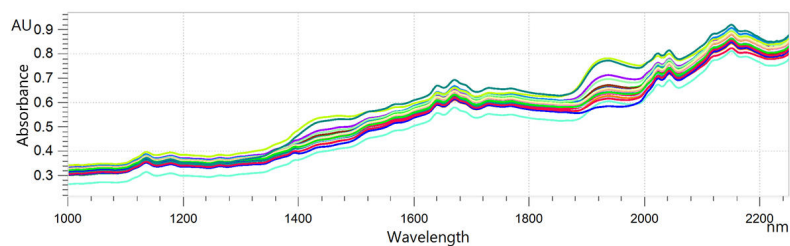


Figure 2. Stacked NIR spectra of paracetamol tablets analyzed on an OMNIS NIR Analyzer Solid.

RESULT WATER ACTIVITY IN PARACETAMOL TABLETS

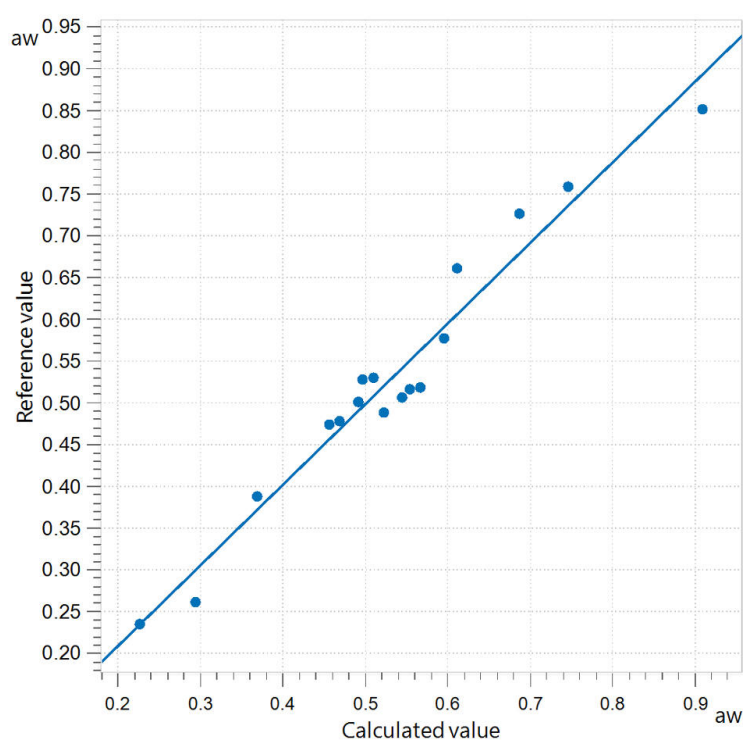


Figure 3. Correlation diagram and the respective figures of merit for the prediction of water activity using an OMNIS NIR Analyzer Solid. The reference water content was determined using a Novasina LabMaster-aw neo according to USP<922>.

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

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).

CONTACT

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CONFIGURATION



OMNIS NIR Analyzer Solid

固体および粘性のサンプルのための近赤外スペクトロメーター。

OMNIS NIR Analyzer は、スイスの品質基準に従って開発・製造された、生産チェーン全体に沿ったルーチン分析のための近赤外分光法 (NIRS) ソリューションです。最新技術の適用と最新の OMNIS Software への統合は、この NIR スペクトロメーターの速度、ユーザビリティ、柔軟な使用に反映されています。

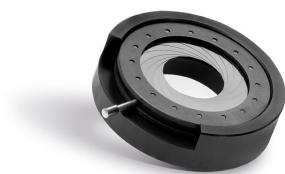
OMNIS NIR Analyzer Solid の利点の概要:

- 10秒未満で固体サンプルと粘性サンプルを測定
- 不均質なサンプルでも再現性のある結果を得るための自動マルチホジション測定
- オートメーションシステムへの統合、またはその他の分析技術 (滴定) との連結が容易
- 多数のサンプル容器に対応



15 mm

反射された固形物を分析するための直径 15mm の密封可能なガラス製使い捨てハイアル 123 個。製品ファミリー XDS、DS2500、OMNIS の NIR 固形物分析に適しています。



OMNIS NIR

反射中のハイアルのサンプルを調べるためのフレキシブルホルダー、30 mm まで直径を調節できます。

OMNIS

A WHOLE NEW LEVEL OF PERFORMANCE

OMNIS

Windows™ コンピューター上の OMNIS ソフトウェアをスタントアローン操作することが可能になります。

特徴:

- ライセンスには、既に1つのOMNISテハイスライセンスが含まれています。
- メトローム・ライセンシングポータルにて、アクティブ化する必要があります。
- 他のコンピューターに移行することはできません。

OMNIS

A WHOLE NEW LEVEL OF PERFORMANCE

Quant Development

スタントアローン型 OMNIS Software のインストールにおける定量化モデルの作成と編集のためのソフトウェアライセンス。