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.

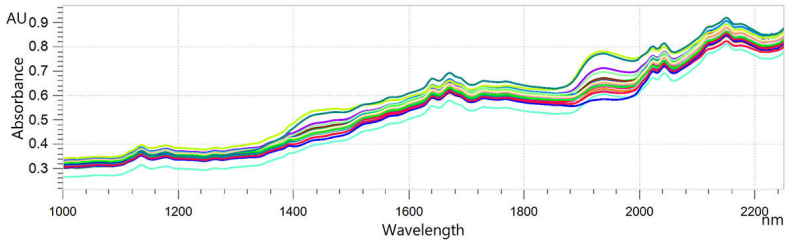

Figure 2. Stacked NIR spectra of paracetamol tablets analyzed on an OMNIS NIR Analyzer Solid.

RESULT WATER ACTIVITY IN PARACETAMOL TABLETS

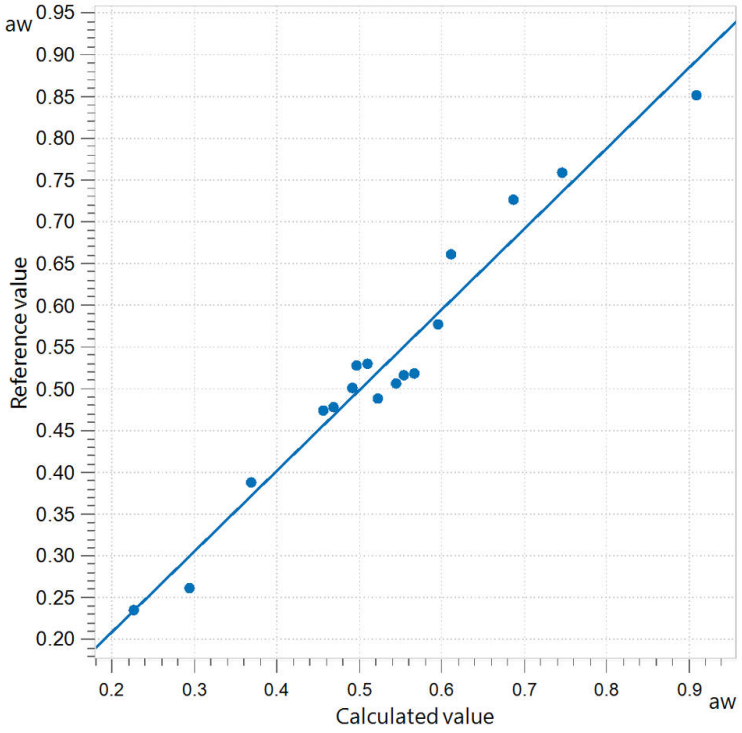

Figure 3. Correlation diagram and the respective figures of merit for the prediction of water activity using an OMNIS NIR Analyzer Solid. The reference water content was determined using a Novasina LabMaster-aw neo according to USP<922>.

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
3. *USP 922 Water Activity Measurement - Novasina - Excellent new Method.* https://www.novasina.ch/application/usp-922-water-activity/ (accessed 2024-08-27).

CONTACT

メトロームジャパン株式会社
143-0006 東京都大田区平和島6-1-1
null 東京流通センター アネックス9階
metrohm.jp@metrohm.jp

CONFIGURATION

OMNIS NIR Analyzer Solid

固体および粘性のサンフルのための近赤外スヘクトロメーター。

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) ソリューションてす。最新技術の適用と最新の OMNIS Software への統合は、この NIR スヘクトロメーターの速度、ユーサヒリティ、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秒未満て固体サンフルと粘性サンフルを測定
- 不均質なサンフルても再現性のある結果を得るための自動マルチホシション測定
- 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) との連結か容易
- 多数のサンフル容器に対応

15 mm

反射された固形物を分析するための直径 15mm の密封可能なカ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フルを調へるためのフレキシフルホルター、30 mm まて直径を調節てきます。

OMNIS

WindowsTMコンヒューター上のOMNISソフトウェアをスタントアローン操作することか可能になります。

特徴:

- ライセンスには、既に1つのOMNISテハイスライセンスか含まれています。
- メトローム・ライセンシンクホータルにて、アクティフ化する必要かあります。
- 他のコンヒューターに移行することはてきません。

Quant Development

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