

# NIRFlex N-500

## Solids Transmittance



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With NIRFlex Solids Transmittance, Buchi offers a powerful tool to fulfill a major request described in the pharmacopoeias to ensure consistency of dosage units in tablets – each unit in a batch should have an active ingredient content within a narrow range around the label claim. Unlike traditional time-consuming and costly HPLC methods, where only the active content is determined, the Buchi NIRFlex N-500 FT-NIR spectrometer offers a speedy, efficient, and non-destructive method with the ability to determine additional parameters simultaneously.

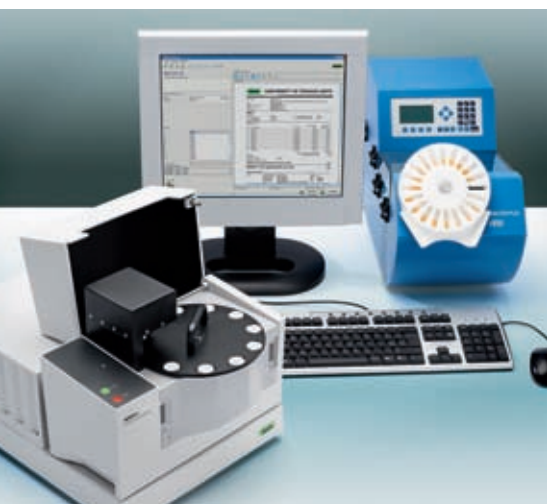
With FT-NIR, these kinds of measurements can be performed, using reflectance or transmittance techniques. Reflectance measurements primarily collect information from the surface area only. To get complete sample information it is necessary to perform transmittance measurements, especially for coated or multilayer tablets. For this purpose Buchi has developed a new measurement cell – NIRFlex Solids Transmittance.

## NIRFlex Solids Transmittance

NIRFlex Solids Transmittance is the latest addition to the range of sampling options for NIRFlex N-500. It is optimized to perform transmission measurements of solid dosage forms, like tablets or capsules, in a very simple and convenient way.

All typical samples like tablets, hard gelatin capsules, powders or soft gelatin capsules including semi-liquids or oily liquids can be measured with the same measurement option: NIRFlex Solids Transmittance. The extremely high dynamic photometric range of the system – one of its outstanding features – allows the generation of spectra with an optimized signal-to-noise ratio for all sample types. In addition, the sample plates are specially designed and coated to prevent stray light caused by light passing around the side of the tablets. All sample plates are customized for optimum measurement conditions for every kind of tablet.

The autosampler accepts up to thirty samples with a diameter of up to 12 mm. For samples larger than 12 mm, 10-place sample plates are available. The robust design of the measurement cell, with its fixed detector position and the direct drive of the sample plate assure high reproducibility and extremely long lifetime. The legendary robustness of Buchi NIR spectrometers guarantees seamless calibration transfer from one system to another. As a result, method development can be easily centralized.



Diffuse transmission measurements are very demanding applications, because only a very small part of the incident light is transmitted. Therefore care must be taken for good signal-to-noise ratio. The design of NIRFlex Solids Transmittance and its optimized detector ensure the best performance. NIRFlex Solids Transmittance uses a low energy source, which avoids any overheating of the samples, therefore enabling the investigation of temperature sensitive pharmaceutical active ingredients (API).



### NIRFlex Solids with Tablet Add-on

For reflectance measurements, NIRFlex Solids is the optimum solution. It is equipped with a small 10-place auto-sampler. The main function of this tablet add-on is to measure small tablet cores and uncoated samples.



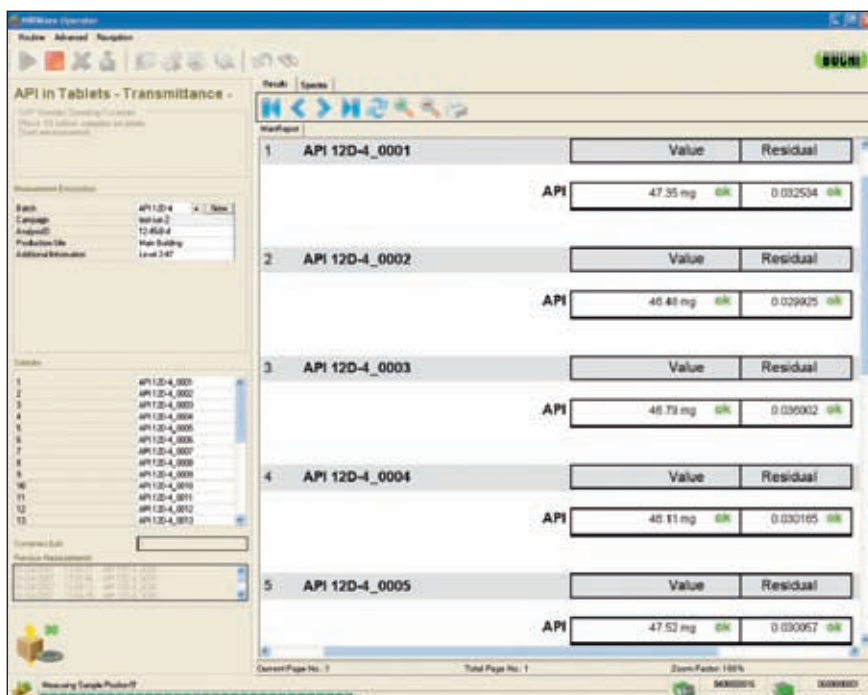
### NIRWare Software

The system uses the latest version of the NIRWare Software Suite **NIRWare 1.2**. Our customers are used to the ergonomic and intuitive use of Buchi products. That is one of the core features of the new NIRWare version 1.2.

The **Application Designer** of NIRWare 1.2 allows the development of all possible NIR applications with NIRFlex N-500 in an easy and convenient way – all within seconds. A wide range of settings ensures that the application can be specifically tailored to all of your needs.

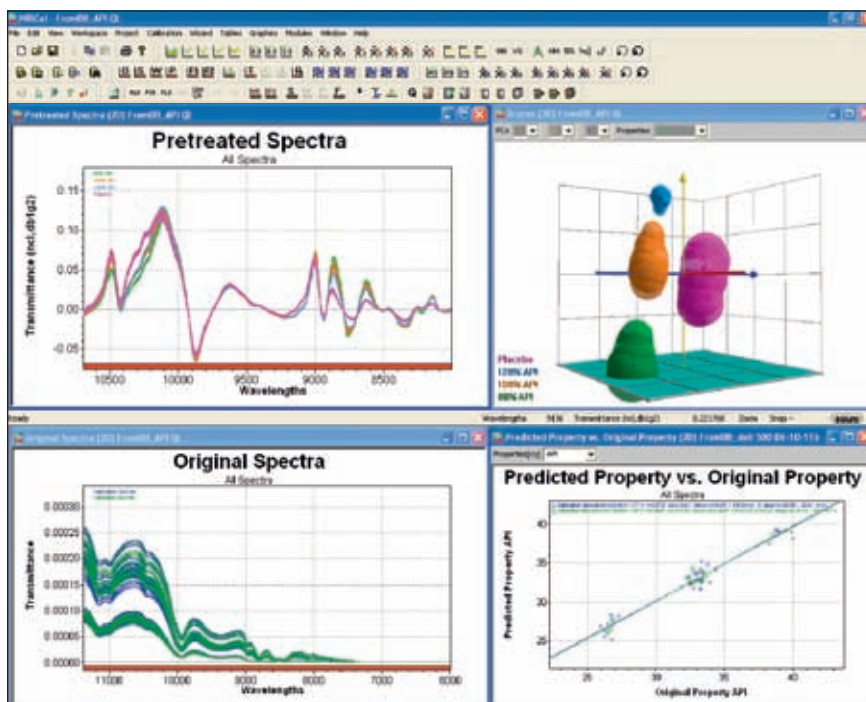
The **Operator** of NIRWare 1.2 is your daily tool when measuring with NIRFlex N-500. Its interface has a clear and intuitive structure, which can be tailored to every user's specific requirements including several entry fields for sample information and SOP information. One of its key features is that results are displayed directly in report format on the computer screen.

The database-oriented architecture of the software ensures full traceability and is fully compliant with **21 CFR Part 11**.



### NIRCal 5.2 for Chemometrics

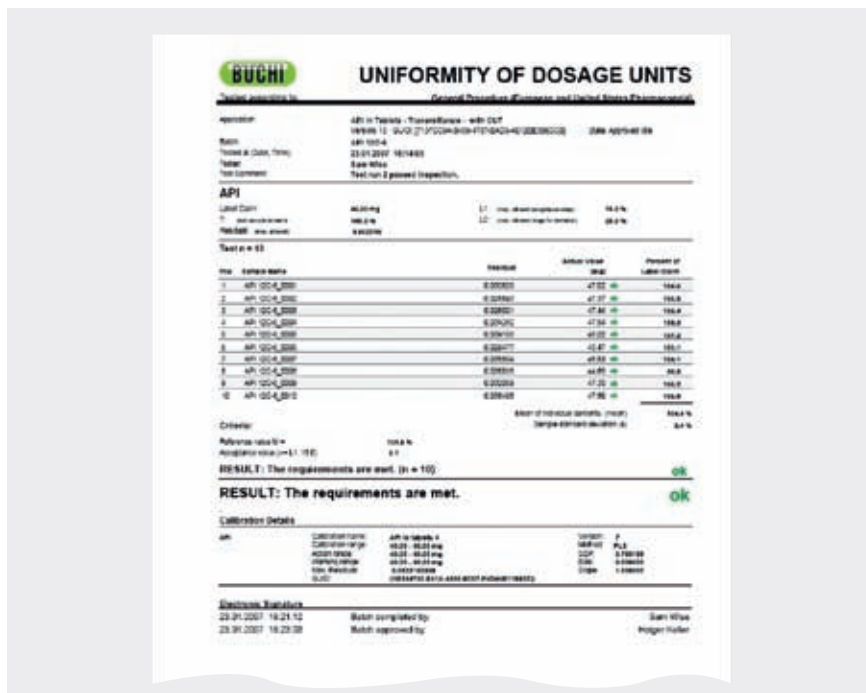
This very powerful software tool has been improved even further. One outstanding feature is the patented Calibration Wizard for quantitative and qualitative calibrations. You will be impressed by its speed and extended wavelength selection. With NIRCal, calibrations for identity control (e.g. Placebo-Verum) and quantitative calibrations for content determination (e.g. API, moisture, ...) can be developed quickly and straightforwardly.



### Content Uniformity Test

In pharmaceutical tablet production and quality control, one of the most important measurements is testing the “Uniformity of Dosage Units” as requested by pharmacopoeias. NIRWare 1.2 includes the most recent procedures and formulae according to the US Pharmacopeia, the European Pharmacopeia and the Japanese Pharmacopeia. The content uniformity test indicates the degree of uniformity in the amount of the drug substance of the blend from the assay of a defined number of tablets (typically 10). This test is required for batch release.

The Content Uniformity Test can be activated and configured in the NIRWare Application Designer. The procedure described in the pharmacopoeias is fully implemented and the resulting report summarizes the statistical results and parameters of the test.



API in Tablets - Transmittance - with CUT*	
Title	Value
Application name	API in Tablets - Transmittance - with CUT
Application type	Quantification
Application description	
License Key	
Content Uniformity Test Type according to	Enabled
CUT Procedure Name	Individual Monograph General Procedure (Japanese Pharmacopeia) General Procedure (European and United States Pharmacopeia) Disabled

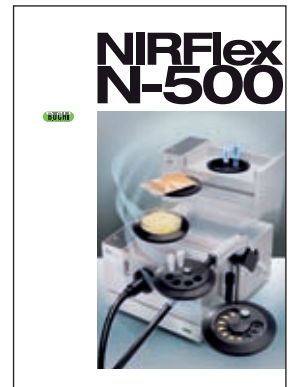
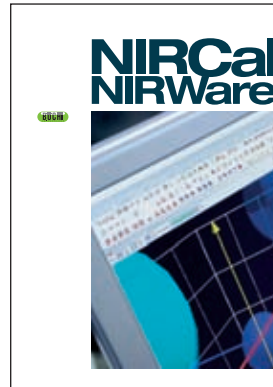
# Specifications

<b>Spectral range</b>	12'500 – 6'000 $\text{cm}^{-1}$ (default 11'520 – 6000 $\text{cm}^{-1}$ ) 800 – 1660 nm (default 870 – 1660 nm)
<b>Resolution</b>	8 $\text{cm}^{-1}$ (Boxcar apodization)
<b>Photometric dynamic range</b>	0 – 6 AU
<b>Wavelength accuracy</b>	+/- 0.2 $\text{cm}^{-1}$ (measured with HF gas cell at ambient temperature)
<b>Number of scans / sec</b>	2 - 4
<b>Typical signal-to-noise ratio</b>	(rms for spectral segments of 300 $\text{cm}^{-1}$ in the range of 10'100 – 6'500 $\text{cm}^{-1}$ )
<b>Open beam</b>	mean $2 * 10^{-5}$ AU (16 scans; 8 $\text{cm}^{-1}$ , Blackman apodization)
<b>5 mm Spectralon®</b>	mean $10 * 10^{-5}$ AU (64 scans; 8 $\text{cm}^{-1}$ , Blackman apodization)





**All our products comply with our philosophy of “Quality in your hands”. We strive to develop products and solutions that are solid, cleverly designed, convenient and easy to use in order to fulfill customer needs to the highest degree.**



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