

Raw Material ID Analyzer



In order to successfully address the challenges associated with Operational Excellence programs and Process Analytical Technology initiatives, the pharmaceutical industry needs high performance integrated solutions for accurate and rapid analytical measurements in a strongly regulated environment.

There is a strong push within the pharmaceutical industry to focus on improving operational excellence by streamlining manufacturing processes. Raw material identification is a tedious and time-consuming task of the quality control (QC) laboratory and has significant impacts on operational and financial efficiency.

Furthermore, new regulations and cGMP trends are raising the bar in terms of the number of analyses to perform, which drastically complicates matters for QC laboratories.

The new FDA PAT initiative offers the opportunity to build rather than test quality into finished products. The key to building quality into a product is to focus on the relevant relationships between raw materials, manufacturing processes, and environmental variables and their effects on quality. To this end, FT-NIR techniques provide valuable information related to both physical (e.g. particle size, morphic form, etc.) and chemical attributes.

ABB has developed NIR solutions that not only greatly accelerate quality control of incoming raw materials but that can be fully validated. Analysis is done either directly at the unloading dock or in the laboratory. NIR analysis requires no sample preparation, is non-destructive, generates no waste matter, minimizes errors due to operator bias and greatly reduces exposure to potent drugs. The analyzer can be operated by non-skilled personnel and the analysis can be performed in 5 to 10 seconds! As a result, production cycle time is reduced, highly skilled personnel are free to manage other tasks and costly inventories are greatly reduced.

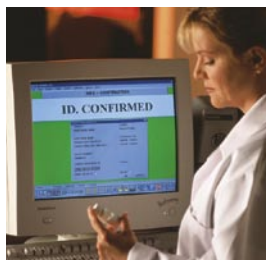
The ABB Solution

ABB's Raw Material ID analyzer is built around an industrial, permanently aligned FT-NIR spectrometer. The high precision of the permanent alignment enables raw material ID library transfer between instruments or after analyzer repair without any adjustments.

Solid and liquid (optional) raw materials can be identified using non-contact sampling accessories. For solids, the user can either use a diffuse reflectance fiber-optic probe for remote analysis through a disposable polyethylene sleeve, or can bring the sample to the analyzer and analyze it through polyethylene bags or disposable glass vials. Liquids can also be analyzed using disposable glass vials.

The analyzer is operated using ABB's AIRS software which is a highly visual and easy-to-use QA/QC operator interface. AIRS can

Analyze^{IT} FTLA2000-PH30



be used for both qualitative and quantitative analysis and includes reporting functions. The software is designed for use in a 21 CFR Part 11 compliant environment.

ABB services to make your life easy!

ABB offers Easyir, the most complete service package available on the market, in order to speed up implementation and make your life easier. This package offers library development and validation services, instrument maintenance and certification programs, equipment validation protocols, an exhaustive list of Standard Operating Procedures and detailed end-user software validation templates.

A flexible tool

The Raw Material ID analyzer is the perfect instrument for method development as it can be fitted with accessories for the analysis of tablets in the transmission mode, of pure and blended powders (blend uniformity), as well as, liquids, pastes, gels and creams. Any of these accessories can be added after the initial purchase and do not require the instrument to be shipped back to the factory.

Regulatory Compliance

The Raw Material ID analyzer is delivered with detailed Installation Qualification (IQ)

Features and benefits

Feature	Benefits
Individual PLS model for each material	Minimizes time required to maintain the library, saving many man-months per year.
AIRS software	Highly user-friendly and visual.
Non-contact sampling	No cross-contamination. No validation of cleaning procedures.
Pre-calibrated instruments	Can start analyzing within the first day.
PLS models	Probability of false positive ID less than 1 in 1 billion.
Easyir Service and Documentation package	Much faster implementation of the project (can save up to a year).
Confirmation analysis	Ability to determine labeling errors in addition to chemical ID.

Contact ABB and let us help you optimize your Raw Material Identification.

and Operation Qualification (OQ) protocols. It satisfies all relevant current Good Manufacturing Practice (cGMP) requirements and can be operated in a 21 CFR Part 11 fully compliant environment. In addition to a robust and accurate analyzer, customers who choose the ABB Analyze^{IT} solution benefit from ABB's experience and know-how for analyzer implementation in a pharmaceutical environment.

Advantages of ABB's Analyze^{IT} solution

The advantages of using ABB's FT-NIR instruments are numerous. Our analyzers show high intrinsic stability that eliminates the need for model maintenance. Measurements can be carried out in a non-contact mode, which eliminates tedious cleaning procedures and the risk of cross-contamination. Models are developed using the PLS algorithm, instead of PCA, in order to obtain the lowest probability of false positive identification and to allow building individual calibration models, which are easier to update than common models. Library transferability is guaranteed between instruments with same accessory model, notwithstanding instrument maintenance.



ABB Analytical and Advanced Solutions

585, boulevard Charest E., suite 300
Québec, Qc G1K 9H4
Canada
Phone: 418-877-2944
Fax: 418-877-2834
Email: ftir@ca.abb.com
www.abb.com/analytical

FTLA2000-PH30 B4218 2005-01

Copyright © 2004 by ABB Inc. All rights to trademarks reside with their respective owners. Specifications subject to change without notice. Pictures, schematics and other graphics contained herein are published for illustration purposes only and do not represent product configurations or functionality. User documentation accompanying the product is the exclusive source for functionality descriptions.