

Fluid Bed Drying



SUCCESS IN PHARMA

Prozess has established itself as a leader in the technically challenging and regulatory complex pharmaceutical sector, and includes 16 of the top 20 global Big Pharma companies as customers. We have delivered over 100+ systems into primarily Pharma applications.

FDA COMPLIANCE

Our software is fully compliant with the US FDA's strictest guidelines on electronic records and signatures, 21 CFR Part 11, and also is fully compliant with Good Automated Manufacturing Practices (GAMP).

PAT/QbD

Our success has been fueled, in large part, by leading manufacturing movements PAT (Process Analytical Technology) and QbD (Quality by Design). With pressure from the FDA (United States Food and Drug Administration), manufacturers are looking to Prozess solutions to enable them to produce products with consistent quality in a shorter production window, while shrinking waste and reducing overall production costs.

KEY BENEFITS

- Real-time determination of moisture content without manual sampling
- No off-line analyses required
- Prevent under/over-drying deviations
- Automated report generation for every batch
- Reduce waste, improve quality, and save time

SUMMARY

Pharmaceutical powders are often dried following a granulation process. The target moisture content depends on the specific formulation, and impacts subsequent processing steps. Currently, moisture content in the product may be inferred from exhaust moisture levels or simply from run times of the dryer. These techniques are indirect estimates of the moisture in the powder bed and are highly prone to error. Alternately, moisture content of the powder may be directly measured off-line using loss-on-drying or Karl Fischer titration techniques, both of which require samples to be removed from the dryer and several minutes per sample, reducing the process efficiency and risking over-drying.

PROZESS SOLUTION

Near-infrared (NIR) spectroscopy is well established as a PAT tool for directly measuring moisture content. The Prozess Reveal E-Series measures via diffuse reflectance from the powder mixture and directly monitors the concentration of water in the powder bed. When the water concentration reaches the target value, the drying process can be stopped automatically and the product removed for subsequent manufacturing operations. Various statistical measures available in the Prozess software can be used to quantify the moisture content and the moisture change over time. Measurement times are typically milliseconds, providing immediate feedback of the drying process, without removing any samples.

Solutions designed for real-time dryer measurements include measurements through a window or using an insertion type probe. Probes can include automation for cleaning or sample accumulation.



PROZESS
TECHNOLOGIE

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PROCESS MEASUREMENT
made simple

Drying

SYSTEM COMPONENTS

ENCLOSURE

- Instrument enclosure is 341 mm long x 266 mm wide x 146 mm high
- Configured for 110/240 VAC, 50/60 Hz input
- Flexible fiber optic connection to sample interface
- Hazardous area enclosures are available

SPECTROMETER

- NIR spectrometer
- 1100 - 2100 nm diode array detector
- Spectral resolution < 5 nm
- Integrated tungsten halogen light source

PROCESS INTERFACE

- Measuring Head
- Connected to spectrometer with flexible conduit
- Working distance from measuring head to sample is adjustable
- Adjustable spot size, 9 - 15 mm

KEY FEATURES

BUILT-IN NETWORKING CAPABILITY

- 10/100 Mbit Ethernet with sealed connector
- 802.11A/G/N wireless support
- Built in OPC

NOVAPAC™ / NOVAMATH™ SOFTWARE BUNDLE

- NovaPAC Software for real-time process analyzer control, measurement and data storage
- NovaMath Software for chemometric modelling and predictions

AUTOMATED SYSTEMS SUITABILITY

- Automated internal system suitability testing
- Rapidly verify wavelength accuracy and photometric accuracy
- Test schedule set by user through simple setting in the user interface

AC POWER SUPPLY

- For system use without batteries
- Configured for 110/240 VAC, 50/60 Hz input
- IP 65 compliant enclosure

FULL DOCUMENTATION PROVIDED

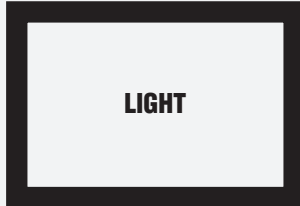
- User Manuals and appropriate certificates
- Executed Factory Acceptance Test (FAT) document

SYSTEM INTRODUCTION

- Execution of installation over a period of 1 to 1.5 days
- Includes acceptance testing to confirm system functionality following installation

Drying

AN EXTENSIBLE PLATFORM



LIGHT



INTERFACE



CHASSIS



SCIENCE



COMMUNICATIONS

PROCESS MEASUREMENT
made simple

AVAILABLE OPTIONS

QUICK RELEASE INSTRUMENT MOUNTING BRACKET

- Includes a bracket which mates instrument
- Enables quick and easy attachment to the drying area
- Quick Release can be performed in seconds by a single person

CALIBRATION / VALIDATION KIT

- 99% white reflectance standard
- Black standard
- Diffuse reflectance photometric standards, set of 8
- 1920a diffuse reflectance wavelength standard

INSTALLATION QUALIFICATION / OPERATIONAL QUALIFICATION

Execution of test plans to verify and document the installation and functional operation of the system at the time of execution.

- Includes 2 days of on-site IQ/OQ execution
- Comprehensive test protocol as evidence of proper test execution
- Full operational testing including: start-up, shut-down, general operation, instrument diagnostics, user accounts, security, and audit trail
- Execution of spectrometer validation routines

ANNUAL PREVENTIVE MAINTENANCE

Prozess Technologie's expert field service personnel can perform a suite of preventive maintenance services at your location.

- One on-site visit for scheduled preventive maintenance and system validation, normally completed in one day.
- All domestic travel time and expenses related to service visit are included. Please contact Prozess for international travel quotation.
- Preventive maintenance includes execution and acceptance of service test protocol. No parts or additional labor costs are included for repairs found to be necessary while carrying out the preventive maintenance.
- Requires that the system be available and accessible and that a full set of calibration standards to be available and within certification date.

AVAILABLE PROCESS INTERFACES

MEASURING HEAD

- Fiber coupled to enclosure with reinforced flexible conduit
- May be adapted to any installed window

HEATED INSERTION PROBE

- Fiber coupled to enclosure with reinforced flexible conduit
- May be adapted to many existing dryer ports
- Excellent for sticky substances
- Diffuse reflectance measurement
- Sapphire window
- Active heating control to reduce sticking
- Optional purge control

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DIMENSIONAL DRAWINGS

Drying



All dimensions in mm

