PRODUCT OVERVIEW

Blend Uniformity

REVEAL™ E600 SERIES REVEAL™ E800 SERIES

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 blend uniformity without manual sampling; no QC lab analysis required
- Increase in manufacturing efficiency
- Automated report generation for every batch
- Prevent under/over blending
- Reduce blending time while ensuring uniformity

SUMMARY

Dry powder blending of pharmaceutical ingredients requires measurement of blend uniformity to determine that the end point has been reached and all powders are uniformly distributed. Typically, measurements are performed off line after manual sampling, or the blend uniformity is based solely on blending time. Both methods have a negative impact on the efficiency of the production process. The rise of continuous manufacturing necessitates real-time measurements for use in blending feedback controls.

PROZESS SOLUTION

Near-infrared (NIR) spectroscopy is well established as a PAT tool for measuring blend uniformity. The Prozess NIR Reveal E-Series measures via diffuse reflectance from the powder mixture and monitors the concentration of the API (or APIs) during every rotation of a bin blender, tracking the change in measured concentration over time. An internal accelerometer synchronizes measurements, so they are taken only when the powder blend is in a position to be measured. When the concentrations no longer change, the mixture is uniformly blended. Various statistical measures available in the Prozess software can be used to quantify this variation. Prozess supplies two NIR-based solutions for blend uniformity determination, covering different wavelength ranges and with different spectral resolution, measuring areas and measurement times.

For high potency APIs in low concentration formulations, Prozess also offers a light-induced fluorescence (LIF) Reveal E-Series analyzer for blend uniformity, which measures the change in concentration of the API by monitoring the fluorescence of the API as a result of ultraviolet (UV) excitation. This technique is very sensitive and well suited for blends of low dose API formulations. In all other respects the NIR and LIF solutions share operating features as well as the same user software.

Solutions designed for real-time blend uniformity measurements may be used in bin or V-blenders, feed hoppers, continuous blending systems or in the feed frame of tablet presses. Options are available for contact measurement probes or for measurements made through a window.

PROZESS TECHNOLOGIE

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PROCESS MEASUREMENT made simple

Blend Uniformity LIF

SYSTEM COMPONENTS

ENCLOSURE	• Instrument enclosure is 341 mm long x 266 mm wide x 146 mm high • Flexible conduit to Measuring Head: 1.6 m (other lengths available) • Can be mounted directly on blender
SPECTROMETER	• LIF spectrometer • Detection wavelength range: 300 - 1,000 nm • Spectral Resolution (approximate): 5 nm
PROCESS INTERFACE	• Connected to spectrometer with flexible conduit. • Working distance from measuring head to sample is adjustable • Made to attach with a 4" tri-clamp (sanitary) fitting on a blender unit. • Optimized for window measurements. Window kits sold separately. • Integrated trigger switch to control sampling during blender rotation • Measuring Head is 128 mm tall x 119 mm diameter
LED PUCK WITH 6 LEDS	• Holds LEDs in place inside the Measuring Head or Insertion Probe • Excitation wavelength(s) of LEDs can be specified at time of order • Standard LEDs are offered in wavelengths starting from 280 nm • Any combination of 6 LEDs can be ordered to accommodate various scenarios • LEDs and Fluorescence Filters are software controlled

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
BATTERIES / CHARGER	• Two hot swappable batteries for continuous operation • Allows system use for a minimum of 4 hours • IP65-compliant enclosures • Charge Status Indicators on batteries and charger • Recharges two batteries at a time • Recharger configured for 110/240 VAC, 50/60 Hz input
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

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Blend Uniformity NIR

SYSTEM COMPONENTS

ENCLOSURE	• Instrument enclosure is 341 mm long x 266 mm wide x 146 mm high • Flexible conduit to Measuring Head: 1.6 m (other lengths available) • Can be mounted directly on blender
SPECTROMETER	• NIR spectrometer • 1100 - 2100 nm diode array detector • Spectral resolution < 5 nm • Integrated tungsten halogen light source
PROCESS INTERFACE	• Connected to spectrometer with flexible conduit. • Working distance from measuring head to sample is adjustable • Adjustable spot size, 9 - 15 mm • Made to attach with a 4" tri-clamp (sanitary) fitting on a blender window • Optimized for window measurements. Window kits sold separately • Integrated trigger switch to control sampling during blender rotation • Measuring Head is 128 mm tall x 119 mm diameter

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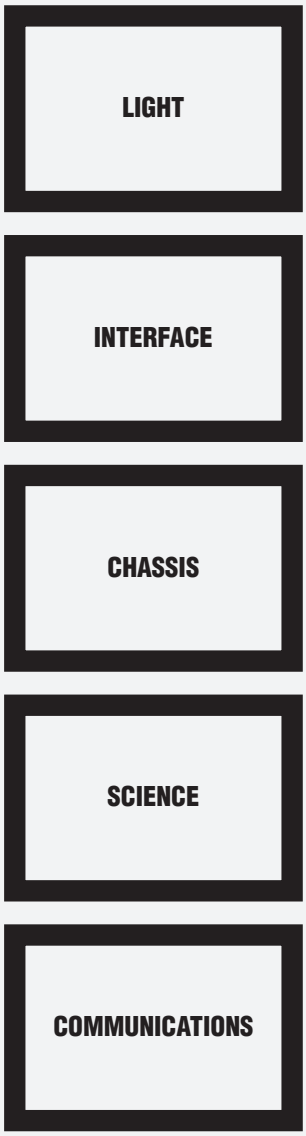
AN EXTENSIBLE PLATFORM



PROCESS MEASUREMENT
made simple

AVAILABLE OPTIONS

QUICK RELEASE INSTRUMENT MOUNTING BRACKET	• Includes a blender-side quick release bracket • Enables quick and easy attachment to blender/blender bin, as the bracket mates easily to the instrument • Quick release can be performed in seconds by a single person • Engineering Services available for fully custom blender/blender bin fit • Engineering Services available to assist with installation of bracket onto blender/blender bin
FLUSH DESIGN BLEND MONITOR WINDOW ASSEMBLY	• A 55 mm diameter clear aperture sapphire window sealed to a 316 stainless steel flange • The "inside" is completely flush with the bin lid surface to keep powders from sticking • The outside is an integrated 4" sanitary flange • Glass-filled PTFE seal • O-ring secondary seal (silicone as standard, other materials available on request) • Engineering Services available for modification of free issue blender lid • Engineering Services available for insertion of window assembly into lid • Engineering Services available for electro-polishing inside of finished lid • We provide Certification of Compliance for all components that have product contact
CALIBRATION / VALIDATION KIT	• 99% white reflectance standard • Black standard • Reflectance fluorescent standards, set of 4 • Wavelength standard • Window spacer assembly
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.

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AVAILABLE PROCESS INTERFACES

MEASURING HEAD	• Fiber coupled to enclosure with reinforced flexible conduit

DIMENSIONAL DRAWINGS

Blend Uniformity

REVEAL™ E-SERIES

All dimensions in mm