PRODUCT OVERVIEW

High Shear Wet Granulation

REVEAL™ E600 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 control of granulation process
- Direct measurement of powder in granulator
- Improve granulation consistency
- Prevent under/over granulation
- Automated report generation for every batch
- Reduce waste, improve quality, and save time

SUMMARY

Granulation is used to combine powders and form granules that are of a larger, uniform size, and is a process often employed in pharmaceutical product manufacturing. Granulation is typically followed by other processing steps, including drying. The granulation process is complex, with binders added wither as dry powders or as liquids. The granulation end point is affected by process and product variable. Process variables can be monitored and controlled, but some product variables, such as particle sizes and initial moisture content may be difficult to control. Typically the high shear wet granulation process is monitored by measuring the process variables such as speed, torque and current on the impeller motors. Changes in these parameters are used to infer the granulation end point. The granulation process may be stopped to visually assess the progress of the granulation during the wet massing phase. Variation due to differences in the process or the starting materials are typically not measured or controlled.

PROZESS SOLUTION

Near-infrared (NIR) spectroscopy is used to continuously monitor the high shear wet granulation process. NIR spectroscopy is uniquely able to monitor both the chemical changes in the product bed and the physical changes. Using an insertion probe, the Reveal E-Series can measure the rate at which the binder is added to the powder bed, and measure the transition from free water to bound water in the product. The rate of change is a predicator or the granulation end point during wet massing.

The granulation process is very dynamic with some changes occurring over very short times. The millisecond measurements time of the Reveal E-Series enable all changes to me measured accurately. Additionally, the Prozess software enables the system to be configured to simultaneously monitor physical changes in the product, such as changes in particle size. The relative change in particle size is also a measure of the granulation end point.

The insertion probe may enter the vessel through the lid or through the side walls, taking advantage of available ports. The probe includes a self-cleaning feature to reduce the risk of the granulate sticking to the probe face for consistent measurement throughout the granulation process.

PROZESS TECHNOLOGIE

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PROCESS MEASUREMENT made simple

High Shear Wet Granulation

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 • IP65-compliant enclosure
SPECTROMETER	• NIR spectrometer • 1100 - 2100 nm diode array detector • Spectral resolution < 5 nm • Integrated tungsten halogen light source
PROCESS INTERFACE	• Adapt to existing ports on granulator through side or top • Proprietary insertion probe with active control to prevent product adhesion

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

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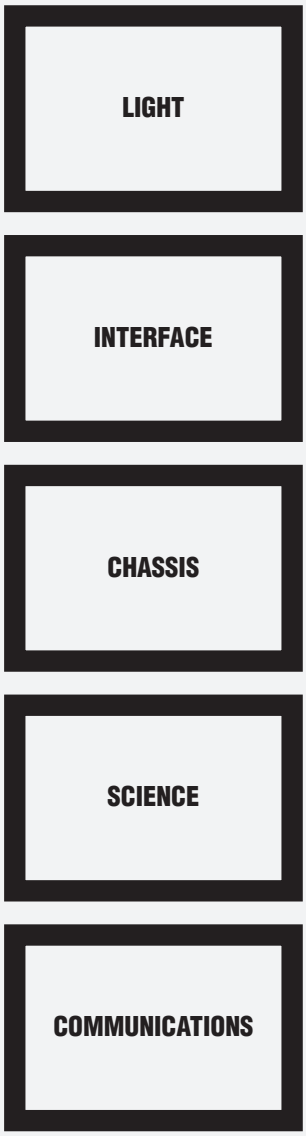
AN EXTENSIBLE PLATFORM



PROCESS MEASUREMENT
made simple

AVAILABLE OPTIONS

QUICK RELEASE INSTRUMENT MOUNTING BRACKET	• Includes a bracket which mates instrument • Enables quick and easy attachment to the granulation 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

HEATED INSERTION PROBE	• Fiber coupled to enclosure with reinforced flexible conduit • Use for contact measurement via insertion • Excellent for sticky substances • Diffuse reflectance measurement • Sapphire window • Active heating control to reduce sticking

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DIMENSIONAL DRAWINGS

High Shear Wet Granulation

REVEAL™ E-SERIES

All dimensions in mm