

# Cleaning Validation



## 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

- Cleaning optimization, identify problem areas for cleaning, improve cleaning procedures
- Vessel release without off line testing
- Automated report generation for every batch
- Reduce solvent use
- Reduce cleaning times, know when to discharge solvent and move to the next cleaning step
- Reduce waste, improve cleaning, and save time

## SUMMARY

Production of pharmaceutical small molecule APIs entails the use of reaction vessels and typically includes sophisticated piping systems for the delivery and control of reactants and discharge of the finished product. Residual API must be removed from the vessels before they can be released for use in the manufacture of another API. Vessel cleaning entails the introduction of wash solutions or solvents into the vessels and piping. Typically, samples of the rinse solution must be removed from the system and taken to the laboratory for analysis of the residual API content in the rinsate. This greatly slows the cleaning process while adding to the laboratory test burden.

## PROZESS SOLUTION

Ultraviolet (UV) spectroscopy is capable of accurately measuring low API concentration in most rinse solvents. UV measurements have an advantage over measurements in other wavelength regions, as most solvents do not absorb UV light and therefore do not interfere with the measurement of the trace concentrations of API expected in the rinse solution.

The Reveal E-Series cleaning verification system utilizes UV light sources of various types and performs real-time measurements to quantify the concentration of API in rinse solutions. The Prozess software allows calibrations of absolute concentrations to be easily and exactly developed. The Reveal E-Series can measure over a broad range of concentrations covering the gross cleaning step early in the process and the final measurements at trace concentrations.

The system features internal system suitability tests to verify correct functionality on a user-selectable schedule. The system also incorporates automated lamp drift correction features for added long term stability and reliability.

A range of sample interface accessories are available. Both flow cells and insertion probes have been used successfully in cleaning verification installations.

The system and sampling accessories can be provided with hazardous area certifications for use in areas where potentially explosive solvent vapors may be present.

This same system finds application in other areas, beyond cleaning. Can be used for general purpose dilution monitoring of API. Equally applicable to large and small molecule API production.



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PROCESS MEASUREMENT  
made simple

# Cleaning Validation

## SYSTEM COMPONENTS

ENCLOSURE	<ul style="list-style-type: none"> <li>• Stainless steel</li> <li>• Dimension 510 mm x 406 mm x 205 mm</li> <li>• Configured for 110/240 VAC, 50/60 Hz input</li> <li>• Flexible fiber optic connection to sample interface</li> </ul>
SPECTROMETER	<ul style="list-style-type: none"> <li>• 190 nm to 600 nm or 190 nm to 1000 diode array detector</li> <li>• Spectral resolution &lt; 2 nm</li> <li>• Combined deuterium tungsten light source</li> </ul>
PROCESS INTERFACE	<ul style="list-style-type: none"> <li>• Select one sample interface to support intended application: Flow Cell, Insertion Probe, ATR Probe</li> </ul>

## KEY FEATURES

BUILT-IN NETWORKING CAPABILITY	<ul style="list-style-type: none"> <li>• 10/100 Mbit Ethernet with sealed connector</li> <li>• 802.11A/G/N wireless support</li> <li>• Built in OPC</li> </ul>
NOVAPAC™ / NOVAMATH™ SOFTWARE BUNDLE	<ul style="list-style-type: none"> <li>• NovaPAC Software for real-time process analyzer control, measurement and data storage</li> <li>• NovaMath Software for chemometric modelling and predictions</li> </ul>
AUTOMATED SYSTEMS SUITABILITY	<ul style="list-style-type: none"> <li>• Automated internal system suitability testing</li> <li>• Rapidly verify wavelength accuracy and photometric accuracy</li> <li>• Test schedule set by user through simple setting in the user interface</li> </ul>
LONG-TERM STABILITY	<ul style="list-style-type: none"> <li>• Automated internal lamp drift correction</li> <li>• Automatically compensates for lamp intensity changes over time</li> </ul>
FULL DOCUMENTATION PROVIDED	<ul style="list-style-type: none"> <li>• User Manuals and appropriate certificates</li> <li>• Executed Factory Acceptance Test (FAT) document</li> </ul>
SYSTEM INTRODUCTION	<ul style="list-style-type: none"> <li>• Execution of installation over a period of 1 to 1.5 days</li> <li>• Includes acceptance testing to confirm system functionality following installation</li> </ul>

## Cleaning Validation (Hazardous Area)

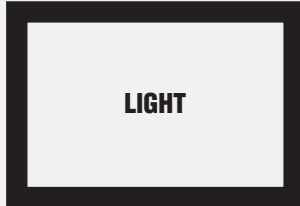
### SYSTEM COMPONENTS

ENCLOSURE	<ul style="list-style-type: none"> <li>• ATEX Zone 1, ATEX Zone 2; NEC Class I Division 1, NEC Class I Division 2 available</li> <li>• Stainless steel</li> <li>• Mobile cart option</li> <li>• Configured for 110/240 VAC, 50/60 Hz input</li> <li>• Flexible Fiber Optic Connection to Sample Interface</li> </ul>
SPECTROMETER	<ul style="list-style-type: none"> <li>• 190 nm to 600 nm, 190 nm to 1000 diode array detector</li> <li>• Spectral resolution &lt; 2 nm</li> <li>• Combined deuterium tungsten light source</li> </ul>
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MONITOR & TOUCH-SCREEN	<ul style="list-style-type: none"> <li>• Compatible with Hazardous Area operation</li> <li>• Operable with gloved-hand</li> </ul>
INDUSTRIAL COMPUTER	<ul style="list-style-type: none"> <li>• Integrated PC for real-time data acquisition, analytics and control</li> <li>• On-board storage</li> <li>• Windows 7</li> </ul>

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## AN EXTENSIBLE PLATFORM



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### AVAILABLE OPTIONS

#### MOBILITY

- Optional wheeled base
- Allows instrument to be easily moved
- Includes cord and fiber hook

#### MULTIPLEXING SUPPORT

- Measure up to four (4) separate channels
- Rapid and efficient switching times
- Independent control and configuration for each channel

#### I/O OPTIONS

- 4 - 20 mA outputs
- Contact closure relays
- Serial protocols

#### CALIBRATION / VALIDATION KIT

- Fiber coupled cuvette holder
- Photometric standards, set of 3
- Primary wavelength standard; Hg-Ar lamp
- Stray light standard set, potassium iodide

#### 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

#### INSERTION PROBE

- Fiber coupled to enclosure with reinforced flexible conduit
- Single pass or, double pass
- Available to accommodate a range of pressure and temperature conditions
- Available to support a range of material compatibility requirements
- Fixed or, variable path length
- Range of diameters, port sizes, piping adapters

#### FLOW CELL

- Fiber coupled to enclosure with reinforced flexible conduit
- Supports high flow rates and volumes
- Variety of pipe fittings and adapters available
- Fixed or, variable path length
- Available to accommodate a range of pressure and temperature conditions
- Available to support a range of material compatibility requirements

#### ATR PROBE

- Fiber coupled to enclosure with reinforced flexible conduit
- Available to accommodate a range of pressure and temperature conditions
- Available to support a range of material compatibility requirements

Cleaning Validation



All dimensions in mm

