# Cleaning Validation

Using on-line UV-VIS spectroscopy for rinse monitoring with the new developed flowcell R.V.P. (**R**eproducible **V**ariable **P**ath length)

Cleaning Validation is a critical aspect in pharmaceutical batch manufacturing. Production run campaigns are followed by downtime periods of 'Change-Over' and this can have a considerable impact on production capacity and profitability.

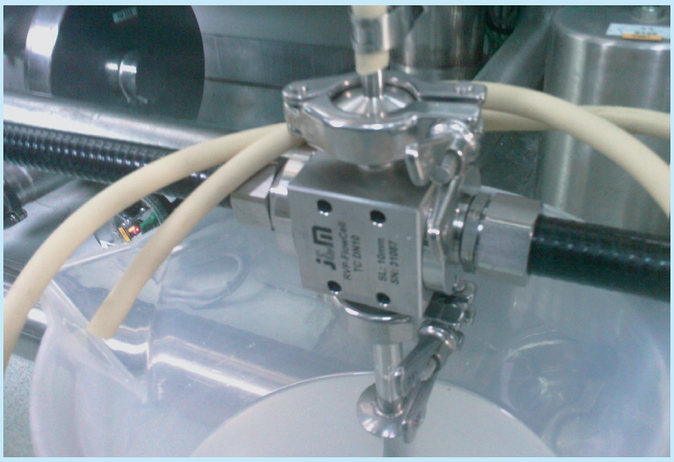
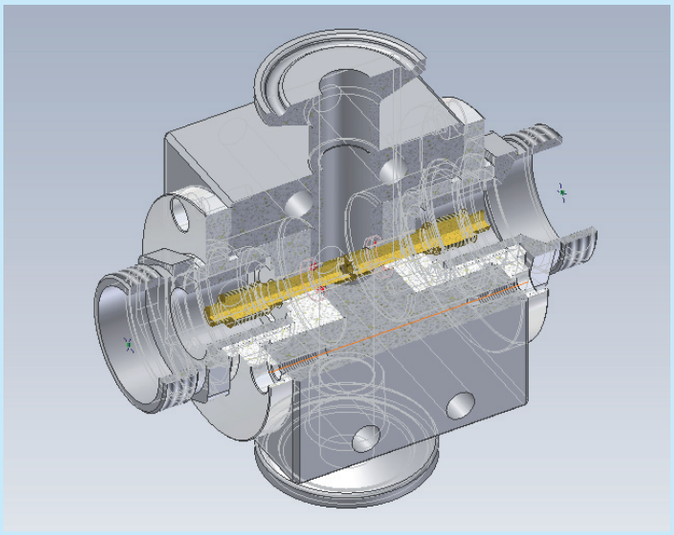


*Fig. 1: CV online installation in a pharmaceutical plant.*

Normally samples from the wash cycles are measured off-line by HPLC. This processes are time consuming and costly.

Using Process Analytical Technology (PAT) philosophies, is an alternative the installation of an on-line analyser. High sensitivity and fast response time allow the monitoring of cleaning processes in real time. A quick feed back is guaranteed that allows optimum cycle times, reducing dead times and saving costs.

On behalf of affiliated global pharmaceutical groups J&M Analytik AG designed around it´s new R.V.P.- flow cell both, close fitted or mobile analysers.



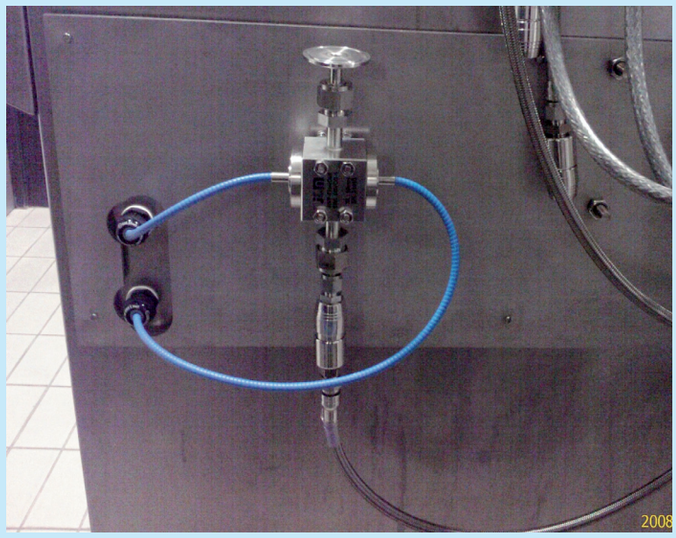



*Fig. 2 & Fig. 3: R.V.P. flow cell installed on a mobile CIP- analyzer for bypass operation.*

**In primary or secondary manufacturing plants, production equipment with cleaning in place (CIP) systems has to be thoroughly cleaned by a validated process before the next production cycle can start. An on- line CIP analyzer gives you quick feed back and ensures that your cycle times are optimal.**

## Applications

Process monitoring and controlling in chemical-, pharmaceutical-, food industries, biotechnology research and production, environmental monitoring, nearly unlimited (…

# Your approach to implement PAT for cleaning in place

| | PAT for cleaning process | QC Laboratory |
|---|---|---|
| Stage 1 | Use process analyzer(s) to visualize and gain insight in the cleaning process.<br>Optimize the cleaning process.<br>IMS, DART, UV, NIR, … | Development of innovative analytical technolo gies to reduce time for method development, validation and sample analysis e.g. UPLC,<br><br>Challenge process analyzer(s),<br>GMP-analysis of cleaning samples for release of equipment |
| Stage 2 | Routine monitoring of optimized cleaning process.<br>Evaluate performance of PAT tool(s). | GMP-analysis of cleaning samples for release of equipment. |
| Stage 3 | In-line cleaning analysis and immediate re-lease of equipment. | SWOP TEST |
| Stage 4 | Real-time control of cleaning process. | SWOP TEST |

*Fig. 3:*
*Typical mobil CIP process analyzer J&M detector inside*

*Fig. 4:*
*Typical laboratory setup (HPLC) J&M detector inside*

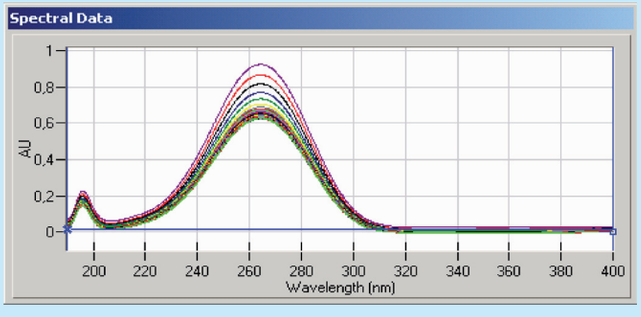



*Fig. 5*
*Graph shows the change in intensity over time in the entire wavelength range from 190 to 400 nm. The spectra were aquired every 5 sec.*

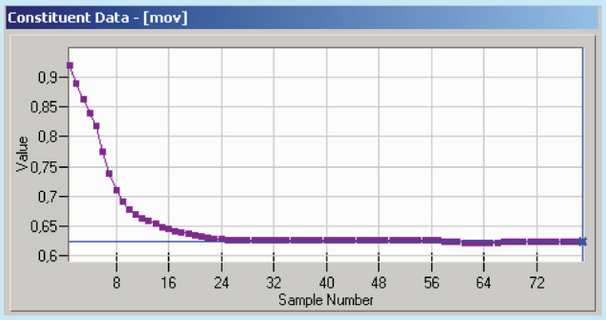



*Fig. 6*
*Graph shows the change in intensity over time for the wavelength at 265 nm.*

This example proves the advantages of using J&M instrumentation and software in online analysis applications like reaction monitoring, cleaning validation and blending or mixing procedures.

Please note:
Due to technological progress all specifications can be changed without a further note.