



Application Note

In-Line Monitoring of Cleaning-in-Place with TIDAS P Pro Clean

With his novel “The Jungle”, which depicts the working and living conditions in the canned meat of Chicago in the year 1906, the author Upton Sinclair inspired the “Pure Food and Drugs Act” and with it laid the groundwork for all of today’s laws concerning Cleaning Validation (CV).



CV is the documented proof that a system or parts thereof are reproducibly cleaned below a known and accepted limit with a high degree of certainty. In the pharmaceutical industry Cleaning-in-Place (CIP) procedures are well established as a viable cleaning method. The cleaning takes place in



regularly timed intervals. After the cleaning, the process is usually validated using laboratory analytics. Often UV spectroscopy is used as a method for this validation.

The CIP-process can take up several hours, depending on the application. In many cases the cleaning process is run longer than actually necessary. This is done to ensure a complete and proper cleaning. However especially the disposal of the flushing water is a big part of the cleaning process costs. Through in-line monitoring and presentation of the measurement values in real time, the individual cleaning steps can be optimized. This saves time and money.

In the following graph the timing of a typical cleaning procedure is shown. The overall duration in this example is one hour:

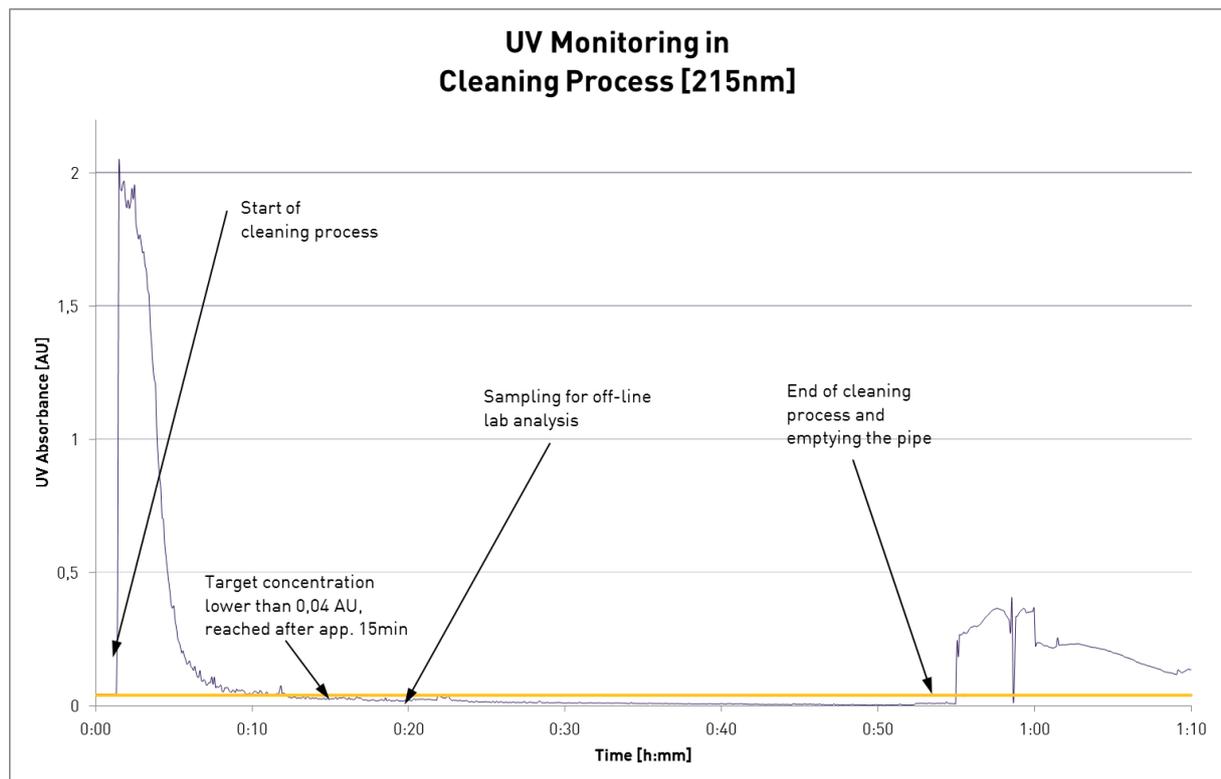


Figure 1: Timing of a CIP Process

After only a few minutes the concentration of active ingredient in the cleaning solution has already decreased dramatically. In fact the target concentration was already reached after approx. 15 minutes. Even the laboratory analysis taken after 20 minutes show that all parameters were already within the target values. This means in this case as much as 40 minutes of cleaning time could be saved.

In this example 1,500 litres of water were used (flow: 1,500 l/h). Here, the total water consumption could be lowered from 1,500 litres to just 600 litres. At a price of approx. 90 EUR/1,000 litres of flushing water, the costs can be lowered from 135 EUR to 54 EUR per flushing cycle. Furthermore the production line can be used again earlier.

Cleaning Validation with TIDAS P Pro Clean

The J&M TIDAS P Pro Clean system is ideal to monitor a CIP-process. This all-in-one solution consists of a spectrometer, a measurement cell, as well as the suitable evaluation software. It measures spectra of the cleaning solutions from 190 to 1100nm in transmission. The measurement systems of J&M are available as autonomous and mobile units and can also be firmly integrated in process lines.

Via various interfaces, the cleaning process can be directly transmitted to a process control unit. This makes an accurate and inexpensive monitoring in real time possible. Flushing times can be optimized. Costly and time consuming laboratory measurements are not necessary anymore. Total savings of 50 – 75 % are possible.

Control of the system, complete with data collection and evaluation is done with our easy-to-use TIDASDAQ software (21 CFR Part 11 compliant).

The measurement cells can be either immersion probes or flow cells. The measurements can take place either directly in the pipe or in a bypass. This will be implemented according to your wishes and requirements.



Figure 2: Example of a Flow Cell and of an Immersion Probe

The flow cells can be set to different path lengths with great reproducibility and can be installed directly in drainage pipe of the cleaning solution. The flow cell is connected to the spectrometer using fibre optics.

Spectroscopy is a precise and affordable tool to monitor a CIP-process in the pharmaceutical or chemical industry in real time. This way flush cycles can be optimized and as shown above savings in time and cost of sometimes over 50% can be achieved (depending on product and method of flushing).

About J&M

Since our foundation in 1987, J&M Analytik AG has offered innovative solutions and analytical systems for both laboratory and process analytics. J&M has gained a reputation in the field of fiber-optic measuring systems in the area of UV/VIS and NIR spectroscopy. The TIDAS® series of spectrometers are used with suitable accessories such as tailored measuring cells and fiber-optic probes in the chemical, pharmaceutical and food industry. Typical applications are the monitoring of cleaning, drying, and mixing processes as well as the determination of concentration of ingredients like fat and protein content in milk. Innovative products are constantly developed by working closely with both customers and partners. Our new developments in the area of networked, miniaturized fiber-optic probes based on LED technology will further advance the integration of spectroscopic analytics in the mass market.

To learn more, visit the J&M website at www.j-m.de.