In-line UV Spectrometry Monitoring in Cleaning Validation

John Schallom, Brian Bosso, Paul Lopolito, Katie Frey, and Amy Thanavaro

Biopharmaceutical manufacturers rely heavily on non-specific, at-line analytical testing to confirm cleanliness of equipment surfaces through final rinse water analysis, potentially leading to false positives and problematic on-line or off-line testing. Spectroscopy methods, such as ultraviolet (UV) spectroscopy at 220 nm, can be used for continuous, in-line monitoring of the cleaning process. The sensitivity of the method can be improved by adjusting the sanitary flow path length. The authors performed interference and enhancement testing using a formulated alkaline and acid cleaner, as well as common biopharmaceutical process residues (such as monoclonal antibody drug substances, insulin drug product, and bovine serum albumin, which displays a cumulative effect like in total organic carbon analysis). Results showed that in-line monitoring capability of UV spectroscopy enables continuous monitoring of the entire cleaning cycle and applicability to quality by design, process analytical technology, process digitalization, and sustainability goals of a Pharma 4.0 manufacturing facility.

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Demonstration of equipment cleanliness through analytical testing is a critical part of cleaning validation and contamination control strategies. Health authorities require that equipment is visually clean and contaminant residues are reduced to scientifically justified limits (1–4). Contaminants can include residual product or intermediates, cleaning residues, excipients, particulates, and endotoxins. The scientifically justified limits are based on toxicological evaluation and health-based exposure limits (5–9). The European Commission's Annex 15, Section 10.6.1 states that biologics are "known to degrade and denature when exposed to pH extremes and/or heat;" these are common conditions in a cleaning process, and Section 10.6.2 supports non-specific methods, such as total organic carbon (TOC) and conductivity, when it is not feasible to test for specific product residues, such as when they are degraded (4). The incorporation of a scientifically justified (real-time, in-line) non-specific method such as conductivity or ultraviolet (UV) spectroscopy can aid in ensuring a state of control of a validated cleaning process by providing continuous process verification (10).

Equipment cleanliness requires that the validated cleaning steps have been followed and acceptable cleanliness has been demonstrated by analysis of samples through various techniques, including direct surface, swab, and rinse sampling (4,11). Each technique has advantages and disadvantages and can fit within the scope of a cleaning validation program. As a cleaning process matures into the continued monitoring phase, on-line rinse sampling (at-line or in-line) is advantageous, as it removes the requirement for collection and subsequent analysis of grab samples, decreases the turnaround time of the results, and improves the equipment release process. At-line sampling diverts an aliquot of the sample, often the final rinse water, to the instrument probe (12,13). In-line sampling involves having an instrument probe in the flow path of the fluid stream, providing continuous analysis (14,15).

Analytical methods for in-line and at-line rinse sampling include conductivity; TOC; chromatography methods, such as high-performance liquid chromatography (HPLC) or ultra-high-performance liquid chromatography (UHPLC); and

spectroscopic methods, such as UV and fluorescence. The selection and eventual validation of the analytical method depends on the soils being cleaned, including the cleaning agent, the range of the analytical method, and analyte interferences with other components in the soil (16). The International Council for Harmonisation's (ICH) Q2B document provides guidance on analytical method validation, which requires a specified analytical range, linearity, ruggedness, precision, accuracy, limit of quantitation (LOQ), limit of detection (LOD), and specificity for the analyte in the presence of expected components (17–19).

Conductivity is commonly used to demonstrate removal of cleaning agents but can have interferences with ionic species in buffers and some products. TOC is also a commonly used technique to show removal of product and cleaning agent and can have interferences with organic compounds, which are common in biopharmaceutical manufacturing. Elevated conductivity or TOC results require additional off-line testing to investigate the result and confirm the source of the contamination and risk to next batch or product, and patient.

UV spectroscopy is a common analytical technique used for monitoring chromatography and filtration steps in biopharma manufacturing, in cleaning processes of APIs, and in quality control for testing of raw materials, intermediates, and final product (15, 20–22). UV provides a semi-specific technique for detection of residual product and cleaning agent in cleaning applications.

UV analyses are performed by measuring transmittance of radiation through a sample and comparing against a blank solution. Absorbance of a sample is proportional to its concentration, and the distance the light must travel through the sample based on the Beer-Lambert law, $A = \varepsilon lc$, where A is the absorbance, ε is the extinction coefficient, which is a sample specific constant describing how much the sample is absorbing at a given wavelength, l is the pathlength, or the distance traveled by light through the sample, and c is the concentration of the solution. The pathlength of the sample, which is typically a fixed parameter in an analysis, can be modified to change the sensitivity of the method. A 1 cm pathlength is common in laboratory testing. Increasing the pathlength to 10 cm increases the absorbance 10-fold and can consequently decrease the LOD and LOQ.

Every compound has a different spectrum based on the structure. Selecting a wavelength for detection and monitoring can vary based on the highest overall peak in the spectrum or localized maximum. Previous studies have explored detection of cleaning agents by coupling HPLC or UHPLC with a UV detector (23). In these studies, a wavelength of 224 nm was selected based on the alkaline and acidic cleaner; these patented formulations include a chromophore to help with UV detection, either with a standalone detector or coupled with liquid chromatography. These cleaning agents have higher absorbance at the lower range—190–200 nm. However, because many organic molecules also absorb at this lower range, the inevitable interference outweighs the benefits of a higher absorbance. The localized maximum at 220 nm provides greater specificity compared with other compounds expected in the cleaning process.

These formulated alkaline and acid cleaners are composed of multiple components. To leverage one assay, such as in-line UV analysis, for the removal of the formulated cleaner, the following information should be available:

- composition of the formulated cleaner
- concentration of the analyte in the formulation
- rinse profile studies using specific and non-specific methods to demonstrate that all components rinse at the same rate
- rinse recovery of the analyte from the surface materials
- spray device coverage testing of the equipment and piping circuits
- toxicity evaluation of the formulated cleaner.

These studies have been discussed in detail in literature supporting cleaning validation and surface analysis (11,17).

Cleaning processes can degrade therapeutic macromolecules with pH extremes and high temperatures (4). This degradation can render the product biologically inactive. Biologically inactive products may no longer pose a toxicological challenge, but the degraded product needs to be removed from the equipment surface. HPLC, coupled with UV or mass spectrometry (MS), can provide information on whether or not the product is degraded. This approach requires at-line or grab sampling analysis, in addition to the time needed to perform the testing. Non-specific methods, such as TOC and conductivity, are not capable of differentiating intact from degraded products. For example, the TOC of a biologic API will detect native and degraded compounds, unless the product is degraded to an inorganic carbon. Additional studies are needed to demonstrate that product is degraded at those cleaning conditions (24–27). When analyzing protein degradation, sodium dodecyl sulfate polyacrylamide gel electrophoresis provides evidence of degradation by measuring the molecular weight of the sample. A sample is treated with a cleaning agent under the specified concentration, temperature, and time. This sample is analyzed alongside an untreated sample; the responses are compared to verify degradation.

A series of experiments were conducted by the authors to determine the feasibility of using in-line UV spectroscopy for the detection of residual biopharmaceutical drug substance or product and cleaning agent using in-line and standalone instruments. To use in-line UV for cleaning applications, several studies were performed to demonstrate that measurement of the cleaning agent and product can be validated with UV spectroscopy; the combination of cleaning agent and product do not enhance or depress the response; both intact and degraded product, in the presence and absence of cleaning agent, can be detected; comparable responses are observed between in-line and standalone UV detectors; and the real-time, in-line monitoring of product and cleaner is possible with UV spectroscopy.

Materials and methods

Spectrometric method development. Initial studies to determine the optimal wavelength and linear concentration range were carried out using a spectrophotometer (ThermoScientific GENESYS 50 UV-Vis) and 10 mm quartz cuvettes (Fisher Part # 14-958-

Table I. Summary of method qualification.

Formulated alkaline cleaner		Formulated acid cleaner	
Attribute	**Result**	**Attribute**	**Result**
Linear range	25–1000 ppm	Linear range	10–1000 ppm
Accuracy	90–111% recovery	Accuracy	99–103% recovery
Precision	0.1–2 %RSD[1]	Precision	0.3–6% RSD
Limit of detection	5 ppm	Limit of detection	5 ppm
Limit of quantitation	25 ppm	Limit of quantitation	10 ppm

1: RSD = Relative standard deviation. PPM is parts per million.

112). Spectra were collected from 190–400 nm for ~1000 ppm solutions of each cleaner diluted in type 1 water.

The range of the formulated cleaners was qualified from 25–1000 ppm (alkaline cleaner) and 10–1000 ppm (acidic cleaner) by characterizing the linearity and precision (repeatability) of the UV response. Accuracy of the analysis for concentrations calculated from measured UV absorbances was studied by quantitation of prepared samples via an external standards method. Linearity and precision studies were carried out by triplicate preparation and analysis of calibration curves across the concentration range of interest. Separate sample preparations, either alternate lots or concentrations within the linear range, were then prepared, analyzed, and quantitated using these calibration curves to assess the accuracy of the method. The LOQ, LOD, and specificity of the method was inferred based on the linearity, accuracy, and precision studies.

Model process soils. Model process soils were selected to encompass several product families in biopharmaceuticals that may use clean-in-place cleaning. A sample of bovine serum albumin (BSA), a standard for proteins in analytical methods, was purchased (EMD Millipore); samples previously studied for protein degradation (e.g., monoclonal antibody [mAb] and insulin) were also studied.

Each soil was diluted to concentrations across the analytical range studied for the alkaline cleaner and the UV response characterized. Additional preparations were made that contained 1:1 mixtures of the model soils and the alkaline cleaner. Spectra were collected for each solution, and absorbance at 220 nm monitored.

Product degradation. Effect of the degradation of the mAb on the UV measurement was studied by treatment of the mAb drug product with solutions of the alkaline cleaner at 1% and 3% concentration. Stock solutions were prepared and preheated to 60 °C. Once pre-heated, the mAb drug product was diluted with the degradation solutions 1:10 and temperature maintained for five minutes. To quench the reaction, the degradation solution was diluted to 100 mL with ambient temperature type 1 water.

For analysis via UV, solutions were diluted to cleaning agent concentrations ranging from 5–1000 ppm, and measurements made as described in the method development section.

In-line sensor–static measurement. A PX2 Photometer configured to monitor absorbance at 220 nm and a pathlength of 100 mm (10 cm) (EZ Cal Flow Cell) was provided for testing by Custom Sensors and Technology (Fenton, MO). Solutions of the alkaline and acid cleaner were prepared at concentrations ranging from 5–100 ppm. The measurement cell was configured with a fill port above the sensor and a drain port below to allow filling and draining of the chamber.

The sensor was blanked with type 1 water prior to sample solution absorbance measurement. UV absorbance was measured for approximately two minutes. The cell was rinsed with type 1 water between each measurement.

After data were collected with the PX2 photometer, the same solutions were analyzed on a spectrophotometer as previously described for comparison.

In-line sensor–dynamic measurement. The PX2 photometer was configured in the same manner as used during static measurement studies and was fitted on the drain port of a 60 L mixing vessel. Prior to testing, the sensor was blanked on deionized (DI) water from the source used to prepare cleaning and standard solutions.

The vessel was flushed with 10 ppm solutions of alkaline and acid cleaners for approximately two minutes via static spray ball, and the UV absorbance at 220 nm was monitored and compared with the established DI water baseline.

To study cleaning of the vessel, the interior surface was manually soiled with portions of the BSA and insulin samples characterized during the spectrophotometer studies. The vessel was then cleaned via a one-minute rinse with 1% (v/v) alkaline cleaner, immediately followed by a one-minute rinse with 1% (v/v) acid cleaner. The vessel was then rinsed with DI water. The real-time UV absorption at 220 nm was monitored throughout.

Results

Spectroscopic method development and qualification. Example spectra used for wavelength selection are provided in **Figure 1 (Located Online).** While neither spectrum exhibits a true peak, a local maximum is observed at 220 nm for each cleaner. As most organic compounds have some UV absorption character at and below 200 nm, selecting a longer wavelength improves the potential specificity of the method. Additionally, each cleaning agent used contained an analyzable surfactant with a chromophore having a characteristic absorbance at 224 nm. For method development

and qualification, cleaner concentrations were monitored via absorbance at 220 nm.

Using the collected linearity, precision, and accuracy data, the LOD and LOQ were established. The upper limit of the analytical range for each cleaner was 1000 ppm. A summary of the method qualification data is provided in **Table I.** For the alkaline cleaner, an LOD of 5 ppm and an LOQ of 25 ppm were established. For the acid cleaner, the LOD and LOQ were 5 and 10 ppm, respectively. UV spectroscopy is a non-specific method, and other components can contribute a response. Specificity studies are needed for process residues as described in the following section. The data support that both cleaners can be validated per ICH Q2 parameters (18).

Table II. Absorbance ratios of process soils against alkaline cleaner.

Soil	Absorbance @ 220 nm–soil/alkaline cleaner (average)
Monoclonal antibody	0.82
BSA	0.96
Insulin	0.60

Model process soils. The UV response at 220 nm for each soil was observed to be linear across a similar concentration range as the alkaline cleaner. For the cleaner and soil mixtures, an additive effect was observed for absorbance at 220 nm. Spectra demonstrating the additive effect are provided in **Figure 2 (Located Online).** This additive effect has been previously observed and characterized during UHPLC studies for analytes in different formulated cleaners (23). Another localized maximum specific for downstream protein determination was observed at 280 and 310 nm by Westwood *et al.* and Rathmore, *et al*., respectively (15,20).

Linearity of the UV response was retained when the cleaners and process soils were characterized in mixed solutions and the absorbance of the cleaner/soil mixture remained within the dynamic range of the spectrophotometer used. Absorbance curves for an alkaline cleaner, an insulin drug product, and a mixture of both components are provided in **Figure 3 (Located Online).**

The ratio of absorbance of the model process soil to cleaners ranged from 0.60 to 0.96, as shown in **Table II.** The combination of the cleaner and process soil is additive; the combination of the components does not enhance nor depress the response. As a non-specific method, all the signal needs to be attributed to the single worst-case component. While this attribution may lead to a bias to failing, the additive interaction of the process soil and cleaner supports the use of UV spectroscopy for the detection of residual amounts.

Product degradation. An example spectrum of the combined cleaner and degraded mAb drug product at an approximate ratio of 3.4:1 is provided in **Figure 4 (Located Online)**. The additive effect on measured absorbance previously observed was maintained for the degraded mAb. Additionally, the linearity of the response was preserved, as the absorbance measured remained within the dynamic range of the detector, despite the significantly greater drug product concentration relative to cleaner concentration. A plot of absorbance versus degraded mAb and cleaner solution is provided in **Figure 5 (Located Online)**.

In-line sensor–static measurement. The mean absorbance result was calculated for each two-minute measurement and then plotted as a function of cleaner concentration. A linear regression was performed and compared with a linear regression analysis for absorbance results for the same solutions characterized via spectrophotometer. Linearity was achieved for each cleaner across the range investigated with significantly greater absorbance observed for the longer pathlength cell compared with the spectrophotometer/cuvette measurements. Plots are provided in **Figure 6 (Located Online).**

In-line sensor–dynamic measurement. The absorbance measured for the 10 ppm cleaner solutions were significantly greater than the DI water baseline, indicating that it should be possible to detect cleaner residues at a typical limit concentration. Absorbance results when measured on the spectrometer were 0.112 and 0.138 for the alkaline and acidic cleaners, respectively. When measured on the PX2 photometer, absorbances were 0.306 and 1.432 for the same solutions. The response for the acidic cleaner in the PX2 photometer is as expected given the 10x pathlength compared with the cuvette. However, the alkaline cleaner is not proportional, potentially due to being below the proposed LOQ. Additionally, because the process has not been fully optimized, foam in the line could reduce the effective pathlength.

For the insulin drug product testing, the process can be clearly visualized in the UV absorbance data. As the 1% cleaning solutions were flushed through the system removing the soil, absorbance values greater than 4.0 were observed for both cleaners. During the rinse immediately following the cleaning process, UV absorbance was observed to rapidly return to baseline (<0.02 absorbance) in under one minute, indicating clearance of both the drug product soil as well as any cleaning agent residue. The same process profile was observed for the BSA cleaning study. **Figure 7 (Located Online)** shows the absorbance during the cleaning process steps.

Conclusion

FDA's *Guidance for Industry*: *PAT–A Framework for Innovative Pharmaceutical Development* was issued in 2004, and several theoretical and applied articles were published over the years utilizing current cleaning agents and on-line analytical technology (28–34). As the pharmaceutical industry strives toward Pharma 4.0 manufacturing and a digitalized cleaning process, the requirements for innovative formulated cleaners and in-line analytical sensors is paramount (35).

This article revisits the use of in-line UV spectroscopy with a sanitary flow cell at a specific wavelength to demonstrate cleaner removal. Interference and enhancement testing was performed using common biopharmaceutical process residues, such as native and denatured mAb drug substances, insulin drug product, and BSA, which displays a cumulative effect like TOC analysis. The in-line monitoring capability of UV enables real-time con-

tinuous monitoring of the entire cleaning cycle and applicability to quality by design, process analytical technology process digitalization, and sustainability goals of a Pharma 4.0 manufacturing facility.

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John Schallom is senior technical services Associate, STERIS. **Brian Bosso** is technical services manager, STERIS. **Paul Lopolito** is technical services director, STERIS. **Katie Frey** is formulation manager, STERIS. **Amy Thanavaro** is R&D scientific manager, STERIS.