

PEMBROKE INSTRUMENTS, LLC

U.S. Product Information & Quotations

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ASURYAN

UV-VIS SPECTROSCOPY

CHAUVIN ARNOUX
INDATECH

Pharma Biotech



Cleaning validation: a critical challenge

How to ensure a perfect cleaning of process machines and vessels in the strictly regulated pharmaceutical and biotechnological industries ?

Demanding regulations

GMP frameworks (FDA 21 CFR 211, EMA Annex 15, ICH Q7) require that residues from previous batches stay below justified acceptance limits — typically in the ppm or ppb range for high-potency APIs (HPAPIs).

A single contamination event can trigger costly recalls and regulatory action, while tightening environmental discharge limits makes monitoring at source increasingly mandatory.

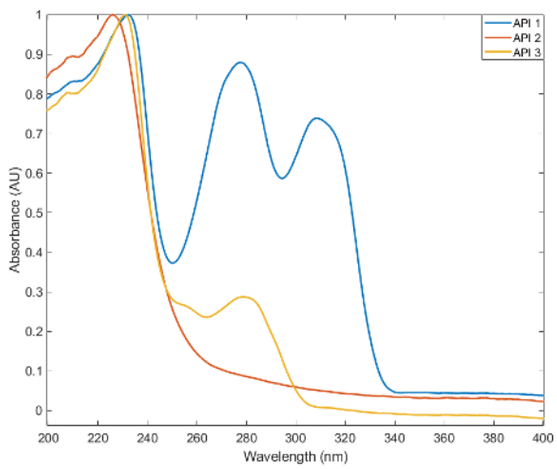


Figure 1: API Fingerprint of different APIs

Goals

Big Pharma

- Brand, patient & environmental safety are key
  — zero tolerance for cross-contamination
- High-value APIs & HPAPIs
  — ultra-low residue limits (ppm / ppb)
- Complex shared equipment
  — multi-product reactors, tanks and piping
- Tight wastewater limits
  — source monitoring of API discharge
- Need for sensitive, traceable, auditable analytical evidence

CDMO

- Frequent changeovers
  — dozens of APIs per year on the same line
- Downtime = lost revenue
  — every validation hour delays the next campaign
- Client audits & SLAs
  — traceable cleanliness evidence per sponsor
- Environmental compliance
  — control API discharge, avoid heavy fines
- Fast, versatile, robust solutions required to shorten cycle times

How?

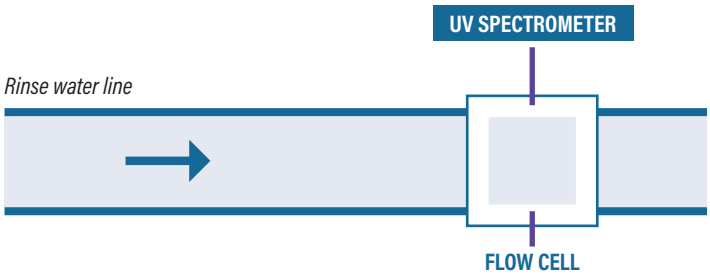
Each API has a unique UV absorbance fingerprint. By measuring the rinse water in-line with our UV-Vis spectrometer ASURYAN residues are detected at the few-ppm level — and the contaminating molecule is identified, not just flagged.

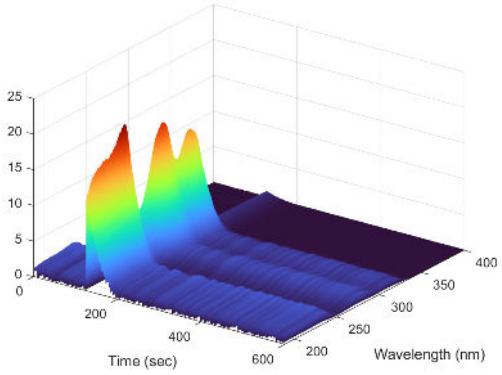
Asuryan delivers a continuous, sampling-free measurement directly on the discharge line. Cleaning campaigns are released in seconds rather than hours or days, with traceable spectral evidence for each batch — meeting GMP and audit requirements without lab turnaround.

The same instrument also tracks contamination in real time, capturing transient spikes that offline sampling could miss.

Qualification and quantification of vitamins in a blend in solution

Continuous in-line measurement of the rinse-water spectrum captures contamination as it appears and confirms its disappearance — providing direct, time-stamped evidence of cleaning effectiveness.





Several options to fit your process

Indatech offers a wide range of sensor options compatible with Asuryan, designed for the constraints of pharmaceutical production lines.

Flow cell | in-line measurement

- Optical paths up to 20 mm — ppm-level sensitivity
- Direct measurement through the rinse-water pipe
- Sanitary fittings, CIP/SIP compatible



Ideal for continuous monitoring on CIP loops, rinse circuits and shared multi-product equipment.

ATEX | Class I Div 1 certified

- Certified for explosive atmospheres
- Suitable for ethanol, acetone, IPA solvent lines
- Class I Div 1 / ATEX zones — installable in process areas



A key differentiator: very few competitors offer ATEX-certified UV-Vis on the production line.

The teams at INDATECH will be delighted to answer your questions by telephone:
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Advantages of Asuryan for cleaning validation

→ Ppm-level sensitivity:
well below regulatory acceptance limits, including HPAPI residues

→ API identification, not just detection:
UV fingerprint pinpoints the contamination source

→ Real-time, in-line, no sampling:
cleaning released in seconds vs. hours/days for TOC, HPLC or swab

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