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.

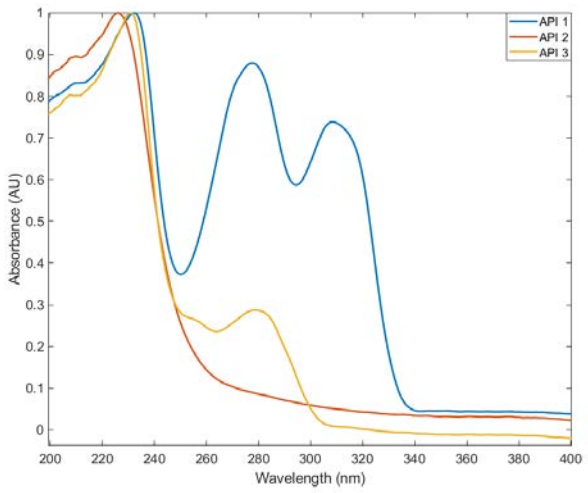


Figure 1: API Fingerprint of different APIs

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?

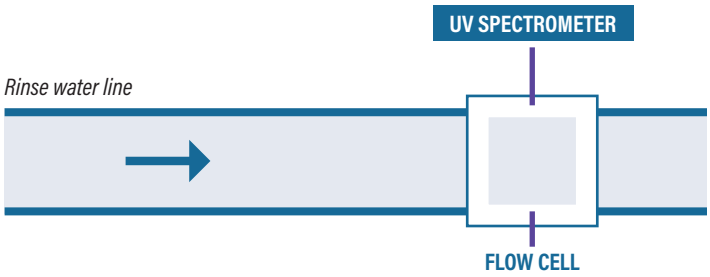
Each API has a unique UV absorbance fingerprint. By measuring the rinse water in-line with our UV-Vis spectrometer ASURYAN residues are detected at the few-ppm level — and the contaminating molecule is identified, not just flagged.

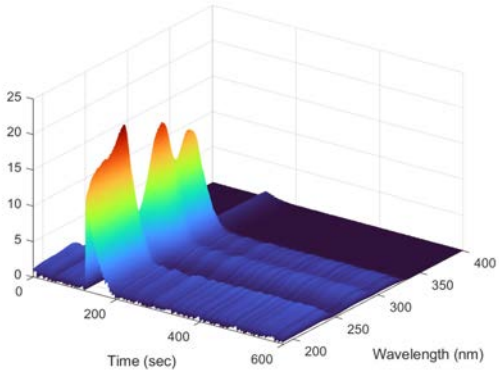
Asuryan delivers a continuous, sampling-free measurement directly on the discharge line. Cleaning campaigns are released in seconds rather than hours or days, with traceable spectral evidence for each batch — meeting GMP and audit requirements without lab turnaround.

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

Real time cleaning control of a vessel with API

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:
+33 4 80 78 01 40

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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FRANCE
Indatech
1900, Boulevard de la Lironde
34980 Montferrier-sur-Lez
Tél : +33 4 80 78 01 40
sales.indatech@chauvin-arnoux.com
www.indatech.eu

CHAUVIN ARNOUX GROUP