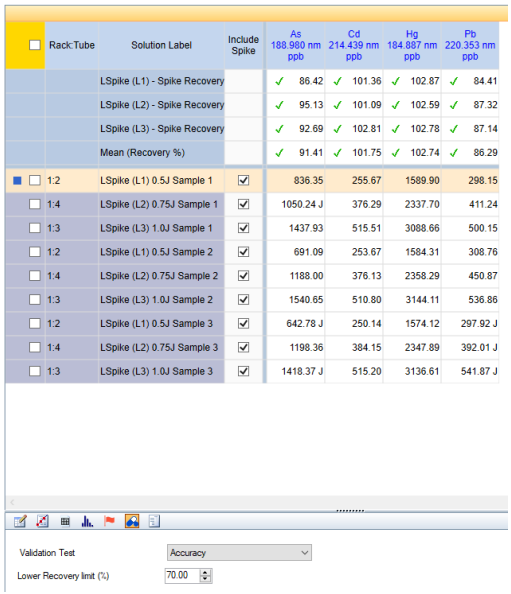
Simplified QC for Pharmaceutical Elemental Impurity Analysis

For ICP-OES

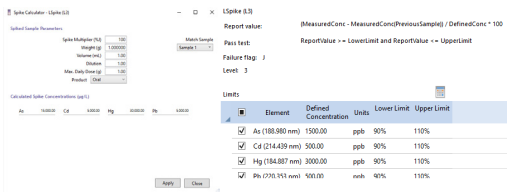


	Rack:Tube	Solution Label	Include Spike	As 188.980 nm ppb	Cd 214.439 nm ppb	Hg 184.887 nm ppb	Pb 220.353 nm ppb
		LSpike (L1) - Spike Recovery		✓ 86.42	✓ 101.36	✓ 102.87	✓ 84.41
		LSpike (L2) - Spike Recovery		✓ 95.13	✓ 101.09	✓ 102.59	✓ 87.32
		LSpike (L3) - Spike Recovery		✓ 92.69	✓ 102.81	✓ 102.78	✓ 87.14
		Mean (Recovery %)		✓ 91.41	✓ 101.75	✓ 102.74	✓ 86.29
■	1:2	LSpike (L1) 0.5J Sample 1	☑	836.35	255.67	1589.90	298.15
	1:4	LSpike (L2) 0.75J Sample 1	☑	1050.24 J	376.29	2337.70	411.24
	1:3	LSpike (L3) 1.0J Sample 1	☑	1437.93	515.51	3088.66	500.15
	1:2	LSpike (L1) 0.5J Sample 2	☑	691.09	253.67	1584.31	308.76
	1:4	LSpike (L2) 0.75J Sample 2	☑	1188.00	376.13	2358.29	450.87
	1:3	LSpike (L3) 1.0J Sample 2	☑	1540.65	510.80	3144.11	536.86
	1:2	LSpike (L1) 0.5J Sample 3	☑	642.78 J	250.14	1574.12	297.92 J
	1:4	LSpike (L2) 0.75J Sample 3	☑	1198.36	384.15	2347.89	392.01 J
	1:3	LSpike (L3) 1.0J Sample 3	☑	1418.37 J	515.20	3136.61	541.87 J

Validation Test: Accuracy

Lower Recovery limit (%): 70.00

Pass/Fail results are visually displayed for each element, allowing you to quickly see which samples are within the impurity limits.



The Spike Calculator feature in the ICP Expert software.

Expanded support for USP <232>/<233> and ICH Q3D methods supports compliance with elemental impurity analysis in pharmaceutical materials

The US Pharmacopeia (USP) and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) have released procedures that provide specific, quantitative determination of individual elemental impurities in drug products and ingredients. These procedures reference ICP-MS and ICP-OES as the suggested analytical techniques.

The Agilent ICP Expert software for the 5800 and 5900 ICP-OES instruments offers the following features that support compliance with the USP and ICH procedures.

Method validation tools

Pass/fail limits for acceptance criteria are flagged in the ICP Expert software. This includes the following validation tests for drug products:

- Accuracy
- Repeatability
- Detectability
- Ruggedness

The validation tests are easy-to-use and setup, with a pass or fail given for every element and wavelength, no calculations are required.

Spike calculator

- Facilitates setup and method development: helps to define calibration concentration levels and QC spike concentrations, based on “J-value”—the maximum permitted concentration limit for the analyte in a sample, corrected for sample preparation dilution.
- No calculations required: the maximum permitted concentration limits for analytes in a given sample are automatically applied

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PDE limits

Upon activation of USP/ICH specific support, permitted daily exposure levels (PDEs) are pre-populated for all the target analytes covered in USP <232> and ICH Q3D. This prevents the possible transcription errors associated with entering/transferring the values into the software.

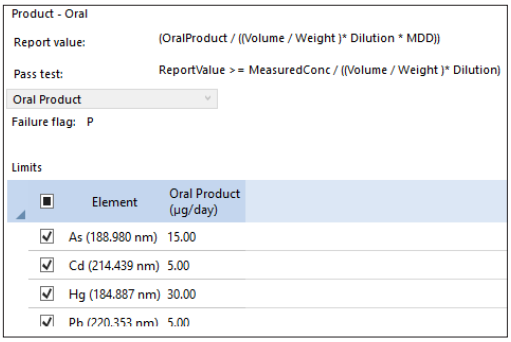
Supercharge your elemental impurity analysis

Move from installation to productive analysis quicker for your USP <232>, USP <233> and ICH Q3D analysis by starting with the purpose-designed template supplied with the ICP Expert software. This template has all the target analytes and spike solutions prepopulated to save method development time.

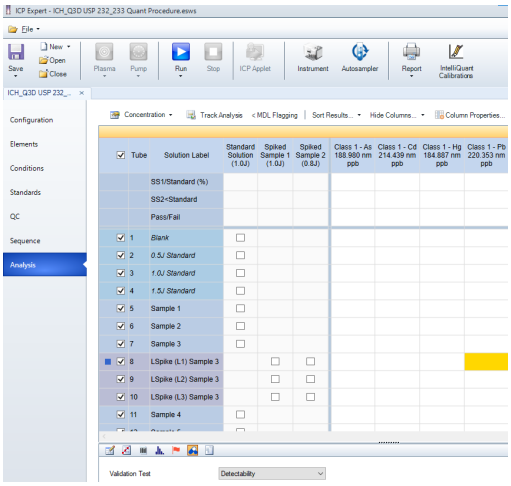
21 CFR Part 11 compliant

The ICP Expert expanded QC functionality is 21 CFR Part 11 compliant via the optional 21 CFR 11 extension pack. This is compatible with the Pro version of ICP Expert that includes; the Agilent Spectroscopy Database Administrator (SDA); and Agilent Spectroscopy Configuration Manager (SCM) software. The pack is qualified by Agilent as complying with the requirements of:

- 21 CFR 58 (Good Laboratory Practice)
- 21 CFR 210 (Good Manufacturing Practice for Drugs),
- or 21 CFR 211 (current Good Manufacturing Practice for finished pharmaceuticals)



Pre-populated PDE values are visible from the QC page.



Purpose-designed template for the USP/ICH Q3D quantitative procedure for elemental impurities analysis, with detectability test selected.

For more information visit:

www.agilent.com/chem/icp-oes

Available on Agilent 5800 and 5900 Instruments with ICP Expert 7.5 or later

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