White Paper

Agilent
Trusted Answers

USP <232>/<233> and ICH Q3D Elemental Impurities Analysis:

The Agilent ICP-OES Solution

Elemental Impurity Analysis Requirements

Worldwide, regulatory authorities are responsible for ensuring that pharmaceutical products are both effective and safe. To achieve this, potentially harmful contaminants—including elemental impurities—must be identified, and limits defined for the maximum allowable exposure to them. In February 2017, procedures for the analysis of elemental (inorganic) impurities in pharmaceutical products and ingredients were finalized. Existing wet chemical and colorimetric tests, such as European Pharmacopoeia Heavy Metals chapter 2.4.8 and United States Pharmacopeial Convention (USP) General Chapter <231>, have been replaced with instrumental methods. This methods provide specific, quantitative determination of individual elemental impurities in drug products and ingredients.

The USP, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and the European, Chinese, and Japanese Pharmacopoeias (Ph. Eur., CHP, and JP) have harmonized standards for measuring inorganic impurities in pharmaceuticals and their ingredients. The updated USP General Chapters USP<232> (Elemental Impurities – Limits) (*1*) and <233> (Elemental Impurities – Procedures)(*2*) were implemented in January 2018. The equivalent ICH method is defined in the Guideline for Elemental Impurities (Q3D)(*3*). ICH-Q3D has been in effect since June 2016 for new marketing authorization applications and has applied to previously authorized medicinal products since December 2017

The latest ICH Q3D and USP<232> chapters include catalyst elements, and other inorganic contaminants that may enter a drug product from raw materials, the manufacturing process, the environment, packaging, and container closure systems (CCS) (Figure 1). The maximum exposure limits are defined according to each impurity's toxicity and route of administration, rather than method capability, as was the case for the old colorimetric sulfide precipitate test in USP<231>.

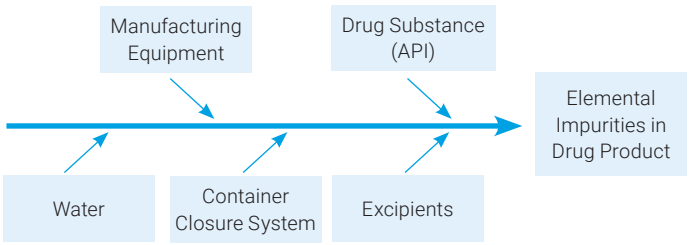

Figure 1. Potential sources of elemental impurities in drug products.

USP<233> recommends the use of modern instrumental techniques (Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES) or ICP-Mass Spectrometry (ICP-MS)), in place of the colorimetric test used in USP<231>. Alternative procedures may be used, provided they can be demonstrated to meet the performance requirements defined in the chapters. USP <233> also recommends the use of closed vessel sample digestion for solid samples, to ensure the quantitative recovery of all the regulated analytes, including volatile elements such as mercury.

Elemental Impurity Limits

The permitted daily exposure (PDE) limits for elemental impurities in drugs intended for oral, parenteral, and inhalational routes of administration, per the ICH and USP chapters, are shown in Table 1.

The potential toxicity of an elemental impurity is different depending on the route of exposure. Therefore, elemental impurities must be considered in a product risk assessment, appropriate for the intended route of administration of the final drug product. The likelihood of the element being naturally present (e.g. elements associated with a mineral-based raw material) or intentionally or unintentionally added (e.g. as a catalyst in chemical reactions, or via contamination from process equipment) must also be considered. The most harmful and ubiquitous Class 1 elements (Cd, Pb, As, and Hg) must be considered in the risk assessment for all drug products. Other elements, such as the Class 3 impurities, may need to be considered only if the drug is intended for parenteral or inhalational administration. The three classes are defined based on the toxicity of the elements and the likelihood of them occurring in drug products intended for each route of administration.

USP General Chapter <232> provides guidance on how a manufacturer should conduct the risk assessment to demonstrate compliance with the regulated limits for any given pharmaceutical product. Options include:

- direct analysis of the final drug formulation
- measurement of the level of impurities in each of the component materials used in the drug material
- review of test data or
- a risk assessment provided by a qualified raw material supplier.

If a risk assessment is performed, it must follow the guidelines defined in USP<232>, summarized in Table 1.

Table 1. The permitted daily exposure (PDE) limits for elemental impurities in drug products, according to their route of administration. Elements shaded in the table should be considered in product risk assessment. All elements listed should be included in risk assessment if naturally present or intentionally added.

ICH/USP Class	Element	Oral PDE (µg/day)	Parenteral PDE (µg/day)	Inhalational PDE (µg/day)
Class 1	Cd - Cadmium	5	2	2
	Pb - Lead	5	5	5
	As - Arsenic (inorganic)	15	15	2
	Hg - Mercury (inorganic)	30	3	1
Class 2A	Co - Cobalt	50	5	3
	V - Vanadium	100	10	1
	Ni - Nickel	200	20	5
Class 2B	Tl - Thallium	8	8	8
	Au - Gold	100	100	1
	Pd - Palladium	100	10	1
	Ir - Iridium	100	10	1
	Os - Osmium	100	10	1
	Rh - Rhodium	100	10	1
	Ru - Ruthenium	100	10	1
	Se - Selenium	150	80	130
	Ag - Silver	150	10	7
	Pt - Platinum	100	10	1
Class 3	Li - Lithium	550	250	25
	Sb - Antimony	1200	90	20
	Ba - Barium	1400	700	300
	Mo - Molybdenum	3000	1500	10
	Cu - Copper	3000	300	30
	Sn - Tin	6000	600	60
	Cr - Chromium	11000	1100	3

The J-value

The maximum level of elemental impurities in finished drug products is expressed as a maximum permitted daily exposure (PDE). This limit takes into account the concentration of the element present in the drug products, and the maximum recommended daily dose for the medicine.

Some materials require digestion or dilution in a solvent before analysis. For these materials, the PDE limit (in µg/day) must be converted to a concentration limit (in µg/L) as measured in the prepared sample. This conversion takes into account the dilution required to bring the analytes within the analytical range of the instrument and the maximum daily dosage.

The Target Concentration value in the prepared sample, referred to as the "J-value", defines the maximum permitted concentration limit for the analyte in the sample. The J value is calculated from:

$$J = \frac{PDE}{Total\ Dilution \times Max\ Daily\ Dose}$$

The Agilent ICP Expert software calculates the J-values for each analyte. The calculation is illustrated in Table 2 for the Class 1 elements Cd, Pb, As, and Hg, assuming a maximum dosage of 1 g/day and dilution factors of 10 x (e.g. 5 g in 50 mL) and 50 x (e.g. 2 g in 100 mL). Instrumental detection limits (IDLs) for a typical Agilent ICP-OES are also shown, for comparison.

Table 2. Example J value calculation and comparison instrument detection limits (IDLs).

Element	Oral Dose PDE (µg/day*)	J-value @ 10x Dil. (µg/L)	J-value @ 50x Dil. (µg/L)	Agilent ICP-OES IDLs*** (µg/L)
Cd	5	50	10	0.1
Pb	5	50	10	2.2
As**	15	150	30	3.7
Hg**	30	300	60	1.0

** Values apply to oral dose drugs with a daily dose of ≤ 10 g.*
*** Inorganic forms*
**** Axial-view*

The J-value is also used to define the calibration levels and QC concentrations. For example, calibrations must be prepared at concentration levels of between 0.5 and 1.5 J. Detectability (for Limit procedures) must be demonstrated using a sample spiked at 80% of the J value (0.8 J). Sspike recovery tests must also be performed at concentrations ranging from 50 to 150% of the J value (i.e. between 0.5 and 1.5 J).

Agilent's Complete Workflow for Implementing an Elemental Impurities Testing Capability

Sample preparation

The USP<233> chapter references several methods which can be used for the preparation of samples for analysis by the compendial procedures ICP-MS and ICP-OES. These include:

- Direct analysis.
- Dilution/solubilization in a suitable aqueous solvent, such as water or dilute acid.
- Dilution/solubilization in a suitable organic solvent, such as 2-butoxyethanol:water (25:75), DMSO or DGME.
- Indirect solution, preferably using closed-vessel microwave digestion with strong acids.

Most solid pharmaceutical materials can be digested using closed-vessel microwave digestion in nitric acid and hydrochloric acid. This procedure provides a sample digest in which all the regulated elements are stabilized in solution and can be analyzed directly by ICP-OES or ICP-MS, after appropriate dilution.

The inclusion of at least 0.5% HCl is strongly recommended for stabilization of all samples, as it ensures that elements such as Hg remain in solution. Addition of HCl is essential when platinum group elements (PGEs) such as Pt, Pd, and Os are included in the analysis. A higher level of HCl may be required for long-term stability of these elements.

Agilent works closely with all the leading microwave oven suppliers around the world, so pharmaceutical laboratories can select the most appropriate microwave to install, depending on their method requirements and the microwave oven supplier's local support capabilities.

Agilent ICP-OES instruments tolerate all common acid and organic solvent matrices, as well as other complex matrices, e.g. those produced by dissolving solid samples. These matrices can typically be measured without requiring high dilution factors. Agilent ICP-OES systems also have a robust vertical plasma, ensuring excellent stability and high sensitivity for all analytes.

The standard sample introduction configuration of Agilent ICP-OES systems tolerates a wide range of aqueous and acid stabilized sample types, including those containing up to 25% dissolved solids.

Similarly, for the analysis of samples that require the addition of hydrofluoric acid (HF) to ensure complete digestion, an inert sample introduction system is used. Such samples are unusual in most pharmaceutical laboratories, but this requirement may apply to some mineral-based excipients.

Understanding instrument performance and suitability

USP General Chapter <233> (Elemental Impurities -Procedures) recommends the use of either ICP-OES or ICP-MS to measure the levels of elemental impurities in drug products and ingredients. An alternative technique such as Flame Atomic Absorption Spectroscopy (FAAS) may be used if it has been validated and meets the acceptance criteria. FAAS may be appropriate for characterizing a few high concentrations elements in raw materials, but it is unlikley to be suitable for final drug product testing where the level of required analytes are too low to be accurately determined with the technique. For most pharmaceutical laboratories, a fast, multielement ICP technique will be preferred.

Selecting the best approach to elemental impurities testing will depend on the individual laboratory's specific requirements, starting with the decision whether to outsource the analysis to a qualified contract laboratory or bring the testing in-house. If you are evaluating and purchasing new instrumentation for this analysis for the first time, you will need to understand the performance capabilities of the instrumentation relative to the method requirements. Budget considerations may also be a factor, as will the skills and experience of the analysts in your lab.

Figure 2. The Agilent 5800 VDV (left) and 5900 SVDV ICP-OES (right).

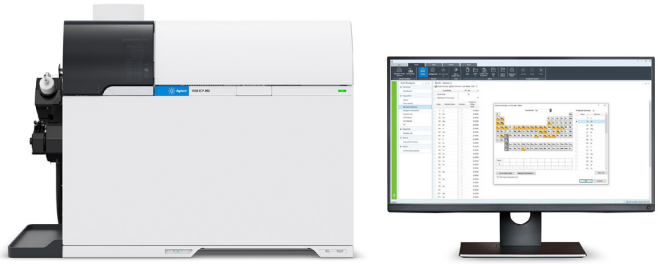

Figure 3. The Agilent 7850 ICP-MS configured for routine manufacturing QA/QC analysis.

ICP-OES or ICP-MS?

The key performance differentiators between ICP-OES and ICP-MS are:

Detection limits

ICP-MS has much better detection limits (DLs) than ICP-OES – around 3 orders of magnitude lower for most elements. This difference is partly offset by the better matrix tolerance of ICP-OES, which means samples may not need to be diluted as much before ICP-OES analysis. ICP-OES DLs may be sufficient for analysis of ingredients such as bulk raw materials (fillers, binders, and so on) and for oral medicines, where the PDE limits are higher. ICP-MS instruments achieve detection limits in the low parts per trillion range. These limits allow accurate determination of all required elements in all dosage forms, including drugs intended for parenteral or inhalation administration, where the PDE levels are typically one to two orders of magnitude lower than for oral medicines. For manufacturing facilities that produce a range of products, ICP-MS offers the flexibility to achieve the required limits for all regulated elements in all sample types.

Dilution

Dilution levels applied during sample preparation must also be considered. If samples must be highly diluted because they have high levels of dissolved solids e.g. sodium carbonate, or only small quantities of sample are available, then the sensitivity of an ICP-MS may be required to detect any elemental impurities in the resultant dilute solutions.

Ability to handle dissolved solids

Agilent ICP-OES instruments can tolerate high levels of dissolved solids with extended analysis being handled more easily than on ICP-MS. The Agilent 5800 VDV and 5900 SVDV ICP-OES instruments can measure samples with up to 25% total dissolved solids (TDS), so are a good choice for laboratories that measure bulk raw materials destined for use in oral medicines, where higher PDE limits apply. Agilent ICP-MS systems with Ultra High Matrix Introduction (UHMI) capability can handle samples that contain up to ~ 25% TDS. This is about 100 x higher than is typical for non-Agilent ICP-MS systems, which are usually limited to matrix levels of around 0.2%.

Speciation

For some elements, bio-availability and toxicity are highly dependent on the chemical form (oxidation state, organometallic complex, and so on) of the element. Of the analytes listed in the ICH/USP regulations, arsenic and mercury are of particular concern, and both are required analytes in all pharmaceutical products. For these two elements, the PDE limit refers to the inorganic form, because inorganic arsenic is the most toxic form, and inorganic mercury is considered the most likely form to be present in pharmaceutical materials.

If the measured concentration of arsenic (total of all forms) exceeds the Target Concentration, USP<232> suggests that a speciation analysis is performed to allow independent quantification of the inorganic As. If the inorganic As is found to be below the limit, the material would be considered to be compliant, even if the total As concentration exceeds the limit. The speciation of mercury should be established if the test material is likely to contain the more toxic methyl mercury species, which would normally be derived from marine material – fish, seaweed, etc. Otherwise, compliance with the regulations is established by determination of the total level of Hg, which is most likely to be in the inorganic mercuric (2^+) form.

Figure 4. Fully integrated Agilent LC-ICP-MS system for speciation analysis.

Speciation analysis is typically performed using a chromatographic technique such as liquid chromatography, coupled to an ICP-MS. Agilent LC-ICP-MS systems are widely used and fully integrated, allowing a simple and reliable approach to speciation of arsenic and mercury in pharmaceutical materials.

Speed of analysis

ICP-OES is a very fast technique, providing about twice the sample throughput of ICP-MS. ICP-OES can measure up to 2500 samples per 24 hours, compared to a maximum of around 1000 samples for ICP-MS. ICP-OES would therefore be the most suitable technique for laboratories that measure extremely high numbers of samples related to oral dosage medicines and where large dilution factors are not applied.

Cost and ease of operation

ICP-OES instruments are a lower capital cost for the laboratory and maintenance costs are also somewhat lower than for ICP-MS. There are generally fewer method variables to setup on ICP-OES, and experienced operators are more widely available. However, both Agilent ICP-OES and ICP-MS systems are provided with built in methods, and simplified workflows that enable novice operators to quickly learn the system

Why choose an Agilent ICP-OES?

Agilent 5800 and 5900 ICP-OES instruments are well suited to analyzing pharmaceutical samples using the USP and ICH methodology, offering functionality and performance such as:

- Tolerance to a wide range of sample matrices and high total matrix loads (up to 25% TDS). This robustness enables large amounts of sample to be digested with little dilution—satisfying the accuracy and precision requirements of ICH/USP regulations.
- Providing excellent long term signal stability to address the repeatability requirements of USP <233>.
- Providing "In method" confirmation of each element's concentration, ensuring confidence in results.
- Specificity of target analytes.

Vertical torch for measuring difficult samples

The torch of the 5800 and 5900 ICP-OES is designed for quick, easy, and reproducible installation. Its vertical orientation reduces the rate of crystalline particle deposition onto the injector. Particle deposition, which is commonly seen when measuring complex matrix samples with horizontal torches, quickly reduces instrument sensitivity. The vertical torch has high tolerance to complex matrix samples, delivering excellent short term precision and long term stability. It also needs to be cleaned less often, reducing maintenance time.

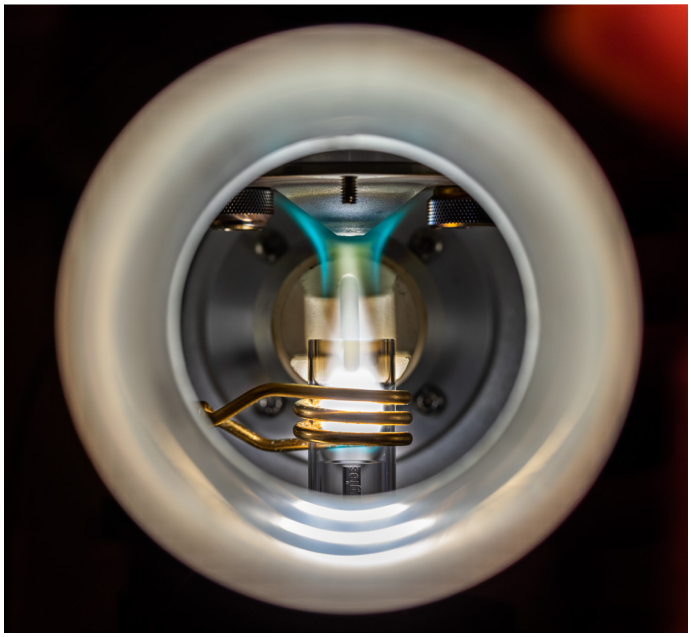

Figure 5. The vertical torch of the 5800/5900 is the ideal configuration for samples with high levels of dissolved solids, which are often deposited onto horizontal torches.

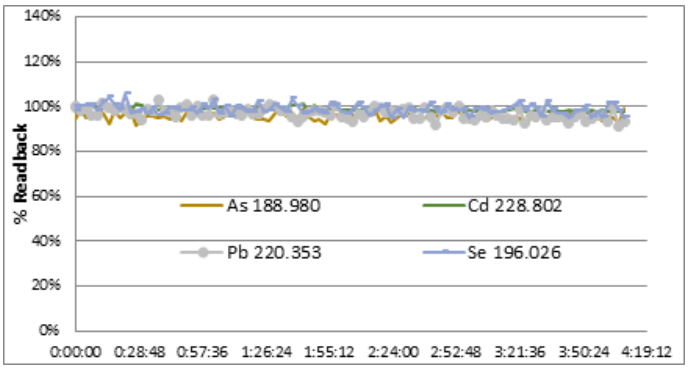

Figure 6. The vertical ICP-OES torch delivers excellent signal stability over long periods of time. This means sample analysis need not be interrupted for torch cleaning. The analysis shown above is of a four element 250 ppb spike in a 25% NaCl matrix. <3% RSD was achieved over four hrs.

Optics designed for accurate results

The 5800 VDV and 5900 SVDV ICP-OES have echelle-based optics with the Vista Chip III Charge Coupled Device (CCD) solid state detector. The detector measures >98% of the wavelength range between 167 and 785 nm in a single reading. This allows multiple alternate wavelengths for each element to be used for “in method” confirmation that the element's measured concentration was not affected by interference. This is done by simply using the data the detector already collected and provides the greatest level of confidence in the accuracy of the results.

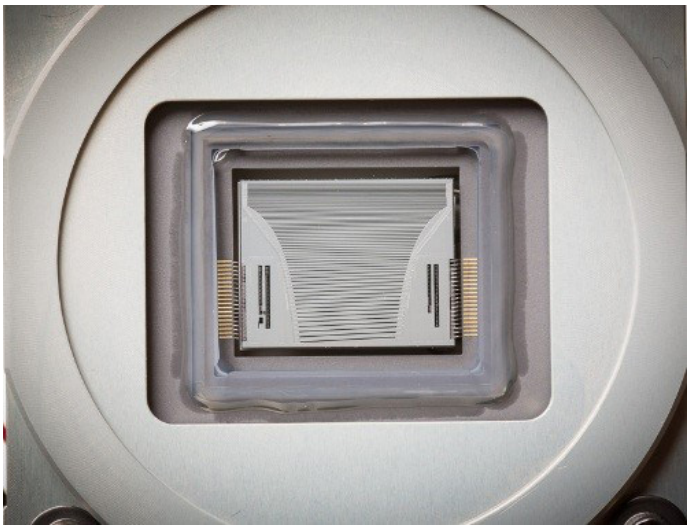

Figure 7. The detector is hermetically sealed, so an argon purge is not required when measuring UV wavelengths. The seal also extends the detector lifetime.

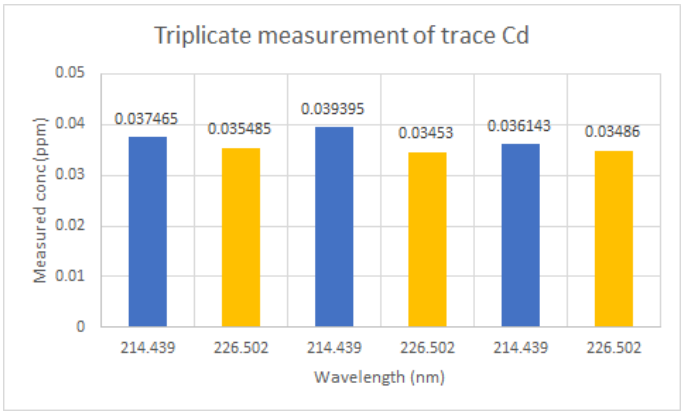

Figure 8. Triplicate measurement of trace Cd in solution with the 226.502 nm line used to confirm the results from the 214.439 nm line. The wide wavelength coverage of the CCD detector allows the use of other emission lines to confirm the measured concentration of each element. This is done within the method, without consuming extra time.

Maximum instrument uptime

The ICP Expert instrument control software includes a simple, intuitive dashboard display and automated performance checks. These provide live information about the health of the instrument, giving confidence that the instrument is performing to specification.

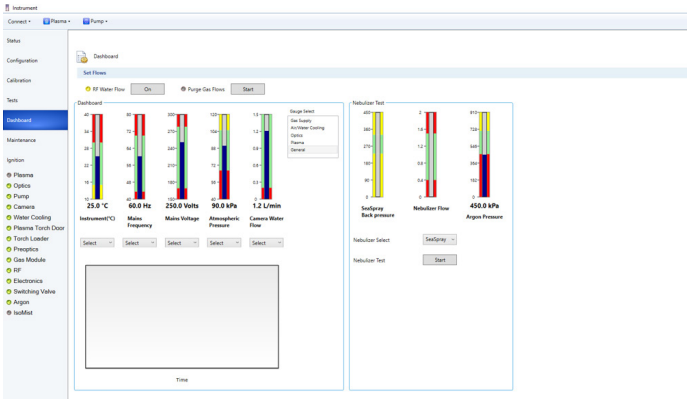

Figure 9. The ICP Expert software includes a live display of critical instrument parameters that provide at-a-glance confirmation that the instrument is operating correctly.

Vendor Qualification

Understanding and evaluating ICP instrument performance and then selecting a system suitable for your lab’s needs is a critical stage in setting up an elemental analysis capability within organization. As part of this process, a vendor qualification assessment would typically be carried out. This assessment should include a review of the vendor’s track record and experience, and seeking confirmation that the supplier has a suitable quality management system (QMS) in place. A QMS is used to manage the quality of products from design through to obsolescence/consumption.

Agilent has been a trusted supplier to the pharmaceutical industry for decades and our quality management is highly regarded. The processes and documentation within our product lifecycle (PLC) and ISO quality management systems ensure that our products are of consistent high quality and will perform as designed.

An Agilent ICP Expert 21 CRF 11 software kit is available that includes: The ICP Expert software that controls the Agilent ICP-OES systems; the Agilent Spectroscopy Database Administrator (SDA); and Agilent Spectroscopy Configuration Manager (SCM) software. The kit 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).

An example of a software quality certificate for ICP Expert is shown in Figure 10.

Agilent

Declaration of Software Quality

We herewith inform you that the software product/systems

Product Name	Revision Number
ICP Expert Software (G9292-64020) ICP Expert Pro Software (G9292-64021) ICP Expert 21 CFR 11 Software (G9292-64023) ICP Expert Automation Pack (G9569-64040)	Version 7.5.4

were developed according to the quality process and software product development life cycle established by the Life Science and Applied Markets Group (LSAG) of Agilent Technologies. Life cycle check-point details were reviewed and approved by the responsible management. The products were verified and validated to meet their functional and performance specifications and release criteria prior to release to shipment.

In order to fulfill the regulatory requirements of the users of this product according to current regulations and quality standards including, but not limited to, 21 CFR 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs), 21 CFR 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals), 21 CFR 58 (Good Laboratory Practice for Nonclinical Laboratory Studies), Agilent Technologies will make the source code and documentation available to an authorized governmental or regulatory agency for inspection at its facilities in Melbourne, Australia (terms and conditions to be negotiated).

Agilent Technologies will maintain possession of all documents and their reproductions and may require a confidential disclosure agreement to be provided by those requiring access to these documents.

Date: January/2021

Quality Manager Katherine McNamara

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Santa Clara, CA 95051, USA

Revision: T.02
Part Number: G9569-90018

Figure 10. An example of the Declaration of Product Validation certificate delivered with the ICP Expert 21 CFR Part 11 software kit.

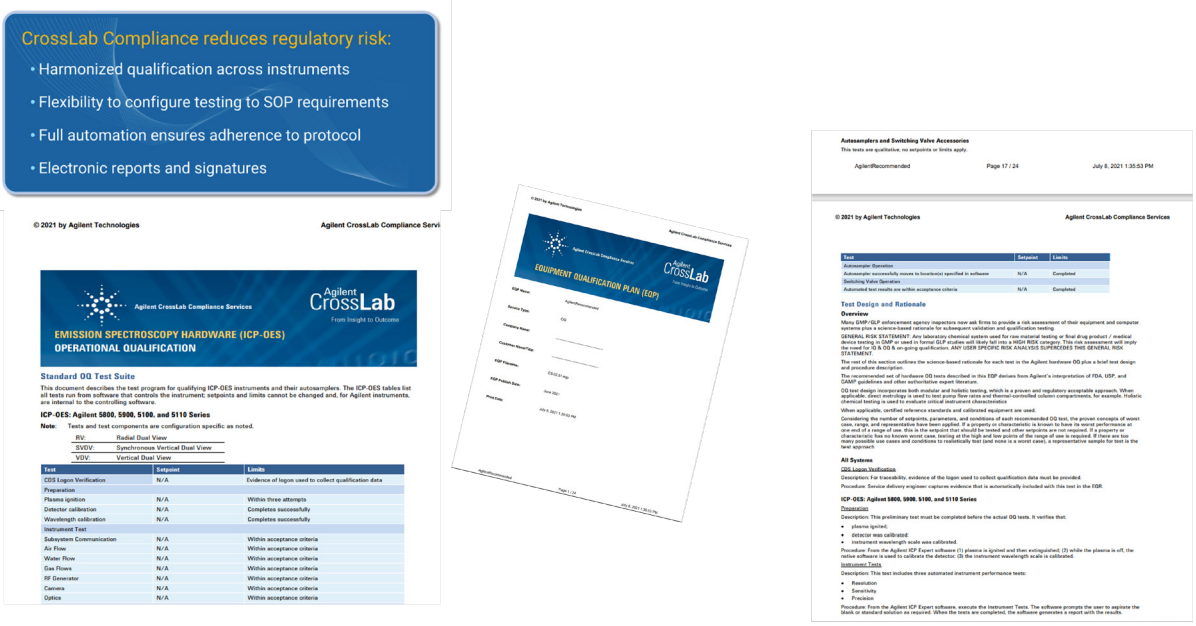

Figure 11. Agilent's CrossLab qualification services documentation.

Installation and operational qualification

While vendor and instrument selection is the first step in establishing a new analytical capability, the vendor's ability to deliver, install, and commission the instrument are also key factors in ensuring a smooth implementation. Qualification services (Installation Qualification (IQ) and Operational Qualification (OQ)), method setup and optimization, standard operating procedure (SOP) documentation, and operator training are essential steps in implementing an analytical facility in a regulated industry. After an instrument has been commissioned, Agilent provides applications expertise and documentation to ensure that the instrument is ready to go into production as quickly as possible.

Qualification services

Agilent provides a complete package of support services for pharmaceutical laboratories setting up an elemental impurities testing capability.

Our high levels of manufacturing quality control, combined with a worldwide organization of factory-trained support engineers, ensures fast installation and consistent, reliable instrument performance.

Once your instrument is installed, the Agilent CrossLAB automated compliance engine (ACE) delivers instrument qualification services, IQ/OQ. These services follow an automated, paperless Analytical Instrument Qualification (AIQ) process.

ACE provides fully traceable, audit-ready approval documents and equipment qualification reports (EQRs), reducing the risk of non-compliance (Figure 11).

Method Set Up and Documentation

The 5800 and 5900 ICP-OES instruments include pre-set methods for Elemental Impurity analysis in pharmaceutical samples, suitable for compliance with the requirements of ICH-Q3D and USP<232>/<233>. These methods can be loaded with a single click, sample details included, and the analysis performed.

The pre-set methods include settings for parameters such as plasma conditions, element emission wavelengths, integration times, and internal standards. This minimizes the time from analysis to reporting.

The method template can be modified to suit the specific requirements of a laboratory and saved as a new, custom method template (Figure 12).

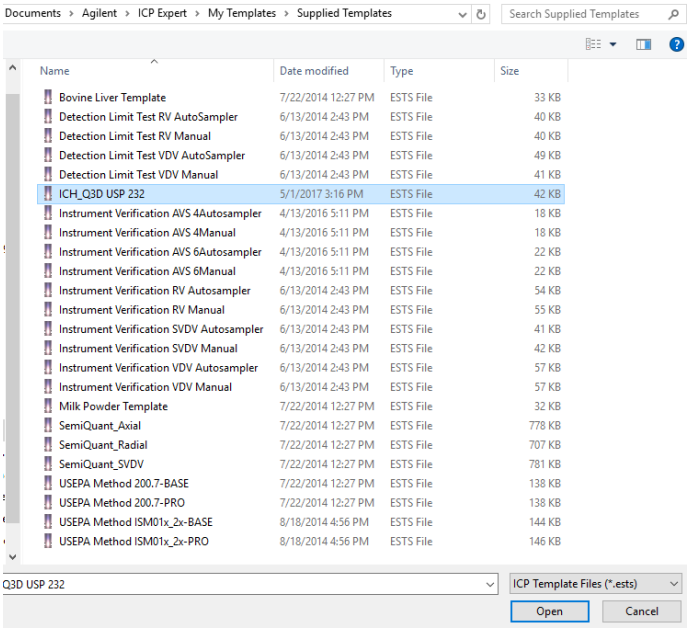

Figure 12. Agilent ICP-OES method templates suitable for elemental impurity analysis per USP <233>.

Ensuring Data Quality with Certified and Traceable Standards

The ability to validate the quality of analytical results is a critical Good Manufacturing Practice (GMP) requirement. Demonstrating data quality depends on the quality of the standards and reference materials used to calibrate the analytical equipment and confirm instrument performance using system suitability testing and ongoing analytical quality control (QC) solutions.

Agilent's ICH/USP certified reference materials (CRMs) are pre-mixed blends of elements at the appropriate relative concentrations for the oral and parenteral PDE limits defined in the ICH/USP methods (more CRMs are under development). The CRMs are traceable to NIST, giving a high level of confidence in the quantitative results generated by the Agilent ICP-OES or ICP-MS. Agilent premixed standards save you time and reduce errors by eliminating the need for you to prepare your own standards from single element standards.

Figure 13. Agilent has a kit containing standards that cover the full suite of regulated elements.

Agilent's CRMs for elemental impurity analysis are available as a kit containing five separate standards (including an internal standard mix) covering the full suite of regulated elements. Alternatively, each of the five solutions can be purchased separately, for example if only the Class 1 elements are being measured.

The standards are manufactured in an ISO Guide 34 compliant facility and certified in an ISO/IEC 17025 testing laboratory.

Table 3. The concentrations of elements in Agilent CRM standards for oral dosage drug products.

ICH/USP Class	Element	Oral PDE (µg/day)	Conc in Stock (µg/mL)
Class 1	Cd	5	5
	Pb	5	5
	As (inorganic)	15	15
	Hg (inorganic)	30	30
Class 2A	Co	50	50
	V	100	100
	Ni	200	200
Class 2B	Tl	8	8
	Au	100	100
	Pd	100	100
	Ir	100	100
	Os	100	100
	Rh	100	100
	Ru	100	100
	Se	150	150
	Ag	150	150
	Pt	100	100
Class 3	Li	550	550
	Sb	1200	1200
	Ba	1400	1400
	Mo	3000	3000
	Cu	3000	3000
	Sn	6000	6000
	Cr	11000	11000
	ICH/USP Target Elements Standard A		
	ICH/USP Target Elements Standard B		
	ICH/USP Target Elements Standard C		
	ICH/USP Target Elements Standard D		

Complying with Electronic Records and Electronic Signatures (ERES) Regulations

The US FDA has regulations in place to ensure the security, integrity, and traceability of electronic records. The FDA provides guidelines covering the criteria that they will use to judge whether electronic records and e-signatures can be accepted as equivalent to paper records and printed (handwritten) signatures. The regulations are described in Part 11 of Title 21 of the Code of Federal Regulations (21 CFR Part 11). The European Commission has similar regulations in place, as described in Annex 11: Computerised Systems of their Good Manufacturing Practice (GMP) rules.

Equivalent regulations that apply in other jurisdictions are described in the Pharmaceutical Inspection Convention/ Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMPs, China's GMPs and the chapter on computer systems of the Brazilian GMPs.

Agilent can provide a software solution for Part 11/Annex 11, and equivalent regulations to assist your laboratory in being compliant. From installation on the instrument control PC to distributed installation onto your servers, our solutions provide:

- Password protection for user access to the ICP-OES software.
- Configurable, multi-level access to software functions (defined by user privilege levels).
- Service plans to optimize instrument utilization and maximize productivity.
- Audit trail of user(s) logon/logoff, including detailed information on user actions within the ICP Expert software.
- Electronic signature protocols (user validation and reason) for specific actions.
- Secure storage of electronic records using the Agilent Spectroscopy Database Administrator (SDA). This provides secure database storage of data from a single Agilent ICP-OES. SDA can be installed on the instrument workstation PC or a network server.

Further information about Agilent's ICP-OES electronic records software solutions can be found in the publication titled "Support for 21 CFR Part 11 and Annex 11 Compliance: Agilent ICP Expert software and SDA/SCM", publication number 5991-6024EN.

Getting Support

Agilent ICP-OES systems include detailed operator training and documentation on key operations, workflows, and maintenance tasks, supporting Good Laboratory Practice (GLP) and GMP requirements. Extra application-specific training can be provided as part of the implementation package associated with setting up analysis methods following the Agilent elemental impurities SOP.

With our global network of Agilent offices and distributors, we have the capabilities to support even the most geographically diverse of pharmaceutical materials manufacturers. Whether you need support for a single instrument or multiple labs, Agilent can provide service support to help you solve problems quickly, increase uptime, and maximize the productivity of your team with:

- On-site maintenance, repair and qualification/ requalification services.
- Service agreements for all your systems and peripherals.
- Application training and consulting from our dedicated, worldwide network of specialists.

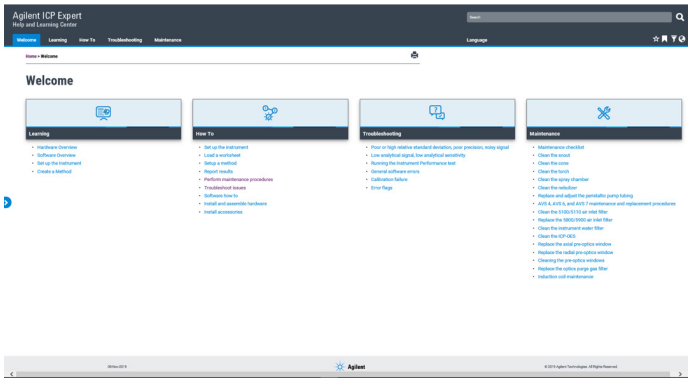

Figure 14. Agilent ICP-OES systems are delivered with extensive online help as well as eFamiliarization which steps the user through common workflows

The Agilent Service Guarantee provides the most secure guarantee in the industry. If your Agilent instrument requires service while covered by an Agilent service agreement, we guarantee repair or we will replace your instrument for free. No other manufacturer or service provider offers this level of commitment to keeping your lab running at maximum productivity.

References

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