YOUR PRESCRIPTION FOR ELEMENTAL IMPURITIES COMPLIANCE



PHARMACY

Refills: As many as needed Does Not Expire

0123456

TAKE DAILY FOR THE RELIEF OF

ICH Q3D and USP <232>/<233>

Prescriber: PerkinElmer, Inc.

ICH Q3D and USP <232>/<233> Solutions and Services Overview

THE RIGHT DOSE OF READINESS AT JUST THE RIGHT TIME

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceutical Products for Human Use (ICH) has completed its Guideline for Elemental Impurities. Known as ICH Q3D, the guideline provides a global policy on limiting metal impurities in drug products and their ingredients.

Q3D joins the existing ICH Q3 series Guidelines for controlling impurities present as organic, inorganic, and residual solvents. In combination with the U.S. Pharmacopeia's (USP) Chapters <232> and <233> on elemental impurities, they will redefine how the pharmaceutical and related supply-chain industries will measure, document, and comply with strict new standards to limit the presence of elemental impurities in drug products.

ICH Q3D will soon require a more demanding elemental impurities method be in place – and in operation – within your organization.

To help your company prepare for one of the most significant changes in pharmaceutical regulatory policy in over a century, think PerkinElmer. As an undisputed leader in Environmental and Human Health Science, PerkinElmer has the proven technology, expertise, and validation services your laboratory operations need to become fully compliant with the new Elemental Impurities Guidelines.

THE NEW CHAPTERS

MEASURING UP TO While USP's drug standards are enforceable in the United States through the Food and Drug Administration (FDA) these standards are reflected in the Food and Drug Administration (FDA), these standards are reflected in the regulatory expectations of more than 140 countries around the globe. Consequently, changes in USP chapters affect drug manufacturing globally.

A Comprehesive Approach



PerkinElmer offers a complete, integrated solution to ICH Q3D and USP <232>/<233> readiness, including:

- Fast, safe, and cost-effective sample preparation equipment
- Intelligent sample handling that includes automated auto-dilution systems for elemental impurities methods
- Choice of best-in-class ICP-MS/ICP-OES and software solutions
- Complete validation services
- Enhanced Security[™] software to help comply with 21 CFR Part 11

Raising the Bar



Our integrated USP Compliant Solution provides calibration and check standards for the analysis of impurities in pharmaceutical products and raw materials. Our premixed multi-element standards can be used to calibrate for each class and administration route as defined by the ICH, including the big four: arsenic, cadmium, lead, and mercury.

Precise Analysis



We have the method templates, expertise, and technology to provide your laboratory staff with the tools and knowledge they need to precisely measure levels of metals in pharmaceutical products at the limits defined by the ICH and USP guidelines.

USP and ICH Standards

In conjunction with our United States Pharmacopeia (USP) calibration standards, we offer 6 calibration standards for the analysis of metals in pharmaceutical materials and products following the International Conference on Harmonization (ICH) guidelines.

The ICH standards verify Elemental Impurities, Precious Metals Impurities and Parenteral Elemental Impurities. Couple our accurate and reliable ICH standards with your ICP-MS and you will remain compliant with the new and changing regulations.

USP <232>/<233> and ICH Q3D Toolkit



With the new USP/ICH Toolkit, you can rest assured that complying with these limits and procedures will be easier than ever. The Toolkit provides:

- Tools to assist with standard preparation and method development
- Method validation reporting tool with SOP and IQ/OQ
- Standard Operating Procedures (SOP)
- Sample preparation methods
- NexION[®] software information
- Pre-defined instrument methods and parameters

The Toolkit includes a J Value Calculator for accurate calculations of Target Limits (J values) of elemental impurities, making standard preparation and method development easier. It also helps improve efficiencies with the Method Validation Report Tool, which calculates and summarizes method validation data instantly.

THE END-TO-END SOLUTION THAT MAKES COMPLIANCE WORK

Tasked with elemental impurities determinations, today's highthroughput GMP pharmaceutical labs need a system that automates labor-intensive steps such as the preparation of calibration standards, dilution of samples, and the addition of internal standards. At the same time, these labs are generating large amounts of critical data that need to be properly managed. That is precisely what PerkinElmer's systems are designed to deliver.

SAMPLE PREPARATION



Titan MPS

USP Chapter <232> outlines three types of sample preparation:

- 1. Simple dissolution in water
- 2. Dissolution in organic solvent
- 3. Closed vessel digestion (to ensure accurate measurement of volatile Hg)

Preparing Insoluble Samples

For insoluble samples that require closed-vessel acid digestion, our Titan MPS[™] system is the ideal solution. This top-loading microwave employs a triple-interlocked lid that allows easy loading and removal of vessels, while the polymer-coated, stainless steel construction provides maximum corrosion resistance.

The Titan's Direct Temperature Control[™] (DTC) feature accurately measures the sample temperature in each vessel while Direct Pressure Control[™] (DPC) provides reference-vessel pressure sensing. Used together, DTC and DPC continually adjust microwave power to give safe, consistent digestions. Both technologies provide contact- and connection-free sensing and are included with every PerkinElmer Titan MPS system.

In addition, vessels are reusable and guaranteed for one year, delivering real savings on consumables.

AUTOSAMPLING



prep*FAST*

Automated Sample Dilution and Delivery For Faster, More Accurate Results

For automating the USP <233> process, our NexION® 2000 ICP-MS and Avio[™] 200 ICP-OES systems can be coupled with the prep*FAST* intelligent sampling system. This innovative inline system automatically prepares calibration standards, performs fast and accurate dilutions, and adds internal standards. The system's syringe-based delivery of all solutions ensures accurate dilution factors and constant total sample flow. Providing up to 200-fold, real-time dilutions with fewer errors, prep*FAST* also consumes less reagent volumes and provides fast uptake and washout with less risk of contamination. When coupled with prep*FAST*, PerkinElmer's high-performing ICP-MS or ICP-OES systems exceed all USP <233> validation criteria for stability, repeatability, ruggedness, and accuracy.

MEASUREMENT



NexION 2000 ICP-MS

Make Productivity a Priority

Our NexION[®] 2000 inductively coupled plasma mass spectrometer (ICP-MS) system is perfectly suited for implementing USP <232>/<233>. It includes an array of technical innovations that reduce background and interferences, optimize signal stability, minimize maintenance requirements and downtime, and generate better results. With its patented ion optic design (Triple Cone Interface and Quadrupole Ion Deflector), no maintenance is required of any components within the vacuum region, maximizing sample throughput and lowering operating costs. Plus, the NexION 2000 ICP-MS is engineered for less drift, better uptime, and dependable operation, thanks to its best-in-class stability. With the powerful built-in All Matrix Solution (AMS), samples can be run with high total dissolved solids (TDS), without manual dilution, increasing the matrix tolerance for high TDS. Last, but not least, NexION's Universal Cell Technology™ can operate in three different modes, offering additional interference removal techniques for your samples.



OPTIONS

Avio 200 ICP-OES

Innovative Features and Expanded Performance

Where appropriate, ICH and USP allows for the use of inductively coupled plasma optical emission spectroscopy (ICP-OES) technology. The effectiveness of ICP-OES depends on several factors including: sample type, sample preparation, detection limits, element lists, and testing protocols.

The world's smallest ICP-OES, the Avio 200 ICP-OES, delivers breakthrough performance using a series of cutting-edge technologies that enhance plasma stability, simplify method development, and dramatically reduce operating costs. Its patented Flat Plate[™] plasma technology utilizes maintenance-free induction plates and uses half the argon of helical coil systems, dramatically reducing operating costs. Dual viewing of the plasma allows the Avio 200 to provide a wide calibration range for all required elements in the same method, thus maximizing productivity. The built-in PlasmaCam[™] camera offers continuous viewing of the plasma, simplifying method development and enabling remote diagnostic capabilities for maximum uptime.

Alternative Solutions

We also offer alternative atomic spectroscopic techniques, such as flame or graphite furnace atomic absorption. These instruments can be used provided they meet USP's stringent requirements for accuracy, specificity, precision, repeatability, and other performance factors detailed in USP Chapter <1125>, "Validation of Compendial Procedures."

COMPLIANCE IS NOT THE MAIN THING, IT IS THE ONLY THING

Our 21 CFR Part 11 Compliant Software Solution

In the highly regulated pharmaceutical industry, data integrity is essential. With PerkinElmer's total solution approach to the provision of elemental impurities testing, that objective is much simpler to achieve.

Our innovative software is the perfect complement to its award-winning, elegant, and efficient hardware design. Featuring a simple, easy-to-use interface, it provides your lab with the ability to control and customize every aspect of the GMP laboratory and computer systems validation process. PerkinElmer's Enhanced Security software provides your laboratory the necessary tools to become 21 CFR Part 11 compliant.

Monitoring calibration, checking responses, and correcting problems are part of the software's automated quality control features that produce accurate and valid data even when running in unattended mode.

Providing an Added Layer of Confidence

The U.S. Food and Drug Administration's 21 CFR Part 11 covers overall system compliance and includes administrative, procedural, and technical elements – software cannot be compliant without these elements' development and implementation.

When coupled with the right policies and procedures, PerkinElmer's Enhanced Security software provides the tools that help your organization be 21 CFR Part 11 compliant with regard to the integrity, safety, and traceability of data generated in the determination of elemental impurities in your pharmaceutical drug products and excipients. User authenticity is verified to ensure that access is limited to authorized personnel only and that all permissions to perform certain tasks and access sensitive data are in place and tightly controlled.

Equally important, your company's proprietary data, methods, and parameters are kept in an encrypted, checksum-protected format to prevent tampering. Traceability is further enhanced through audit trails that capture file-, system-, and security-related events.





Developing a Collaborative Partnership

An experienced provider of laboratory services worldwide, PerkinElmer's OneSource[®] organization is uniquely positioned to deliver customizable services and a more profitable partnership for your business.

More than a traditional laboratory services company, OneSource becomes an integral part of your organization, delivering a level of technical and scientific support and expertise that provides your laboratory with a distinct competitive advantage.

Among the key features of OneSource is its comprehensive care and repair program for your entire operation that provides your business with huge benefits and cost efficiencies. OneSource also brings the most experienced professionals and advanced technologies to bear on the daunting operational challenges your organization faces every day -- from helping to streamline workflows and supporting computer systems to consulting on complex scientific issues.

IQ/OQ/CSV for ICP-MS

One key component of cGMP compliance is system qualification and computer systems validation. With our IQ/OQ/CSV solution the equipment installation, system operation, and computer systems are qualified and validated to meet internal and external requirements.



For more information on why PerkinElmer is the leader in trace metal analysis for more than 50 years, and what its ICH Q3D and USP <232>/<233> solutions can do for your organization, call or email your nearest PerkinElmer representative today.



Learn how to rapidly and efficiently implement ICH Q3D and USP <232>/<233> on elemental impurities in pharmaceutical products, visit: www.perkinelmer.com/USP232

PerkinElmer, Inc. 940 Winter Street Waltham, MA 02451 USA P: (800) 762-4000 or (+1) 203-925-4602 www.perkinelmer.com



For a complete listing of our global offices, visit www.perkinelmer.com/ContactUs

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