ELEMENTAL ANALYSIS & ELEMENTAL IMPURITY ANALYSIS

GMP SERVICES SUPPORTING PRODUCT IDENTITY CONFIRMATION, PURITY & QUALITY

Understanding the elemental composition of your raw materials, active pharmaceutical ingredients (APIs), and products is critical to ensuring quality control. Elemental impurity analysis is important to pharma development and commercial release

GMP Elemental analysis

Elemental composition analysis and elemental impurities analysis are key to ensuring the quality of a pharmaceutical.

Intertek offers Good Manufacturing Practice (cGMP) compliant laboratory services through strategic approaches, which includes options for semi-quantitative screening, method development and validation (as either a limit test or a quantitative test as dictated by the client's analytical needs) and routine analysis.

Elemental composition analysis

Understanding the elemental composition of your raw materials, active pharmaceutical ingredients (APIs), excipients or formulations is critical to ensuring quality control. Where the elemental composition is unknown, a strategic approach, which rationalises effort and expense, is required. Our analysts have significant experience in pharmaceutical organic and inorganic elemental analysis with coverage of almost the entire periodic table from trace levels to percent levels. Trace metals testing is a routine activity for our GMP laboratories and is carried out in accordance with pharmacopeia methods such as the United States Pharmacopeia (USP) Chapters USP <232> / USP <233> for elemental impurities or client specific methods.

ICH Q3D

ICH Q3D advocates the use of a risk-based approach to assessing the potential presence of elemental impurities in drug products. While such assessments are common within other aspects of pharmaceutical development, application to elemental impurity assessment presents new challenges.

While the guideline is ultimately intended to focus on final drug product quality, the actual risk assessment will touch all facets of the manufacture of a drug product.

ICH Q3D

CAME INTO EFFECT IN JUNE 2016 FOR NEW MARKETING AUTHORISATION APPLICATIONS

ICH Q3D comes into effect for authorised medicinal products in December 2017

Specific challenges include determining how to assess or quantify the risks associated with factors such as water, container-closure systems, and excipients. Defining where in the assessment process data may be required and identifying where risks can be determined to be negligible through a thorough scientific theoretical risk assessment also present significant questions.

Where the risk assessment identifies the need for testing, the level of the Permitted Daily Exposure (PDEs) for the element(s) of concern may also require the broader introduction of new, more sensitive, and specific analytical technology, adding still further to the complexity.

The guidance means introduction of new technologies specifically inductively coupled plasma techniques either with Optical emission spectroscopy (ICP-OES) or Mass Spectrometry (ICP-MS) detection.

With this new technology there is a requirement to meet new and specific limits for individual elements. The implementation of the ICH Q3D guideline can be adequately achieved through using an appropriate risk-based process combined with existing GMP standards.

A risk assessment should be performed to identify any elemental impurities that may potentially be present at significant levels in the drug product. Such an assessment is then used to define an appropriate control strategy.

Our ICH Q3D Solutions

Our elemental impurities experts and toxicologists can help you to develop a compliance strategy to achieve successful implementation of ICH Q3D requirements. We provide combined toxicological risk-assessment and testing compliance services to meet the requirements of the Guidelines. Testing programs can include screening studies and data to aid risk assessments, if this data does not already exist, or develop and validate methods tailored to the clients' specific products.

ELEMENTAL ANALYSIS
& ELEMENTAL IMPURITY ANALYSIS

intertek
Total Quality. Assured.

United States Pharmacopeia (USP) 232 and 233 elemental impurities

The United States Pharmacopeia (USP) has published in the Pharmacopeia Forum, (PF 42(2) [Mar-Apr 2016]) a proposed revision to the USP General Chapter <232>, Elemental Impurities – Limits. In the introduction to the revised chapter, it states "This chapter is being revised to address comments received and to further align this chapter with ICH Q3D.

The USP's Elemental Impurities Expert Panel approved a recommendation to the General Chapters - Chemical Analysis Expert Committee that this chapter be revised to align with the ICH Q3D Step 4 document to the greatest extent possible." The USP has added elements not previously listed in chapter <232> and adjusted its Permitted Daily Exposure in order to match those found in the Q3D guidance.

We offer elemental impurity analysis services according to USP General Chapter <232> and USP Chapter <233> which are GMP compliant and are conducted in accordance with these USP chapters to support your raw materials quality control testing, reference materials certification, stability testing and GMP batch release testing.

Intertek's technical resources

Our expertise in sample preparation ensures that we meet the challenges of difficult samples which have poor solubility enabling very low levels of detection (i.e. at toxicologically relevant levels, such as parts per billion or lower in solution). Our GMP facilities are equipped with both inductively coupled plasma – mass spectrometry (ICP-MS) or inductively coupled plasma – optical emission spectroscopy (ICP-OES) technologies.

Our GMP centers of excellence for elemental analysis are located in North America (Whitehouse, NJ) and Europe (Manchester, UK).

"The implementation of the ICH Q3D guideline can be adequately achieved through using an appropriate risk-based process combined with existing GMP standards.
A risk assessment can help identify any elemental impurities that may be present at significant levels in the drug product."

Total Quality Assurance

With over 20 years of elemental analysis and impurity analysis experience we offer Total Quality Assurance solutions for your drug substance or drug products. We apply the right strategies for your samples through cost effective and efficient services by utilising the latest technology for sample preparation and instrumentation. With Intertek as your quality assurance partner we can help you to overcome any challenge presented by sample type and sample matrices.

FOR MORE INFORMATION

Europe: +44 161 721 5247
North America: +1 800 967 5352

Europe: pharma.services@intertek.com
North America: icentre@intertek.com

intertek.com/pharmaceutical/analysis/elemental/