OUT WITH THE OLD, IN WITH THE NEW

News Letter

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Pharmaceuticals – Trace Metals

USP 232/233 Capabilities

From 1905 to 2016 United States Pharmacopeia (USP) 231 has been the accepted method for testing heavy metals in samples. Because of its limitations, USP 231 has been replaced with USP 232 Elemental Impurities Limits and USP 233 Elemental Impurities procedures.

USP 233 is an analytical procedure that must be used by 2018 by the pharmaceutical industry.

Benefits of Methods

Contact with manufacturing equipment, residual catalyst, and raw materials may create elemental impurities that could be present in drug products. USP 232/233 were implemented to redefine how heavy metals in samples are being tested. Referred to as procedure 1 and 2 they work hand and hand to evaluate the levels of the elemental impurities.

Detectability, repeatability, and specificity are what procedures 1 and 2 provide. Multi-element ICP-MS and ICP-OES are recommended because of high accuracy versus the subjective colorimetric test used in USP 231.

Validation

The method validation requirements of USP 233 can either be validated as a limit test or quantitative test. The limit test involves preciseness, and quantitative validation must demonstrate accuracy at 50%, 100%, and 150%. ICP-OES measures analytes by optical emissions over a concentration range that depends on the type of analyte.

ICP-MS measures mass fragments typically to a level of at least an order of magnitude better than ICP-OES. USP 233 states that the procedure must be able to unequivocally assess each target element in the presence of other sample components such as other analytes and matrix components.

Why the Change?

Impurities cause problems. Potential toxicity, unwanted side-effects, and the impact on drug stability can be a result of the existence of impurities in pharma-ceutical samples, which is why USP 232/233 are now being required.

Modernization. The new methods allow pharmaceutical labs across the globe to modernize their techniques and instrumentation.

Better methodology. To ensure complete digestion and retention of volatile elements the suggested sample preparation options that should be used, includes closed vessel microwave digestion.

MAS, LLC HAS VERIFIED USP 233 BY ICP-MS AND IS READY TO TEST YOUR SAMPLES.

Agilent 7500 ICP-MS

The Agilent ICP-MS offers a high temperature ICP source with a mass spectrometer, the ICP converts atoms of the element in the sample to ions, which are then separated and detected by the mass spectrometer. ICP-MS has many advantages one being the ability to handle both simple and complex matrices within a minimum of matrix interferences.

TRACE METALS	Cd	As	As
Rh	Ru	Cr	Pb
Ir	Os	Cu	Mo
Pd	Pt	Ni	V

Evolution of Science Methodology

"USP, with the support and assistance from both the FDA and the pharmaceutical industry, has made a tremendous impact on addressing and correcting the issues associated with outdated methodologies in documentary standards in the compendium."

-American Pharmaceutical Review

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