Executive Summary

New United States Pharmacopeia (USP) Sterile Water Testing Requirements

What You Need to Know

The United States Pharmacopeia (USP) published the removal of the legacy Oxidizable Substance Test for the water monographs, Sterile Water for Injection (WFI), Sterile Purified Water (PW), Sterile Water for Inhalation, and Sterile Water for Irrigation on April 1, 2012. The proposed revisions to these monographs describe new test requirements for Total Organic Carbon Chapter <643>. Pharmaceutical manufacturers are to prepare for these new requirements starting August 1, 2013.[1] These changes will directly affect the validation and intended use of new or existing total organic carbon (TOC) analyzers used for laboratory analysis.

TOC will replace the Oxidizable Substance Test for USP monographs Sterile WFI, Sterile PW, Sterile Water for Inhalation, and Sterile Water for Irrigation.

The Challenge

The USP Chapter <643>, Total Organic Carbon, includes a new section for sterile water, apparatus specifications, and specifies unique concentrations for demonstrating suitability for the TOC instruments. These include:

- A 100 ppb C limit of detection for the apparatus
- A maximum TOC level of 500 ppb C for the reagent water
- An 8 ppm C concentration for both the Sucrose (Rs) and 1,4-Benzoquinone (Rss) standard solutions[1]

Unfortunately, analyzers that are currently qualified for the current Bulk Water requirements for USP <643> will need to be re-verified to be suitable for the new compendial TOC method requirements, USP <643>. Although the Oxidizable Substance Test will be deleted 18-24 months after January 1, 2014, it will be the alternative to the new TOC test for "labeled" single-dose sterile water in packages or containers.

Business Impact

Non-compliance with the new USP <643> requirements could in some cases lead to:

- Delayed product disposition or shipment
- Increased investigation costs due to non-dedicated standards solutions mix up (e.g. Bulk Water vs. Sterile Water requirements)
- Negative publicity

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Solutions and Recommendations

- Request additional capital for dedicated TOC testing of sterile water
- Fully verify the compendial method requirements aligned with USP <1226>

GE Analytical Instruments offers the robust Sievers M9 Laboratory and Portable TOC Analyzers that are fully compliant with the new test requirements of USP <643> for Sterile Water (all units are also USP<643> Bulk Water compliant). Dedicated instruments for USP <643> Sterile Water include validation documentation and service support. USP <643> Sterile Water System Suitability, along with verification and calibration reference standards and sample containers are also available.

USP <643> specifies TOC instruments must have apparatus requirements that are unique to Sterile Water testing. GE's robust technology, documentation, support, and domain expertise will guide you to achieving compliance efficiently and effectively.

Supporting the Transition

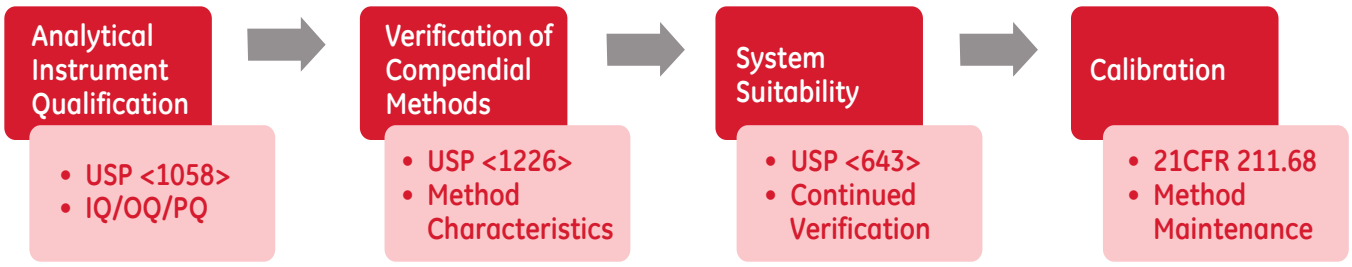
The graphic below illustrates a simple, clear, and compliant approach to ensure a successful transition to TOC analysis for Sterile Water as specified in USP <643>. GE's documentation is structured and focused on how to verify that the TOC method is suitable for its intended use so you can be up and running for this promulgation.

Our Promise

As the pharmaceutical regulatory environment continues to shift from legacy approaches to a focus on risk mitigation and continuous quality assurance, rest assured that GE Analytical Instruments will be there to support your global regulatory needs. Please contact us for more information.

Supporting References

1. United States Pharmacopeia, <643> *Total Organic Carbon PF, In-Process* Revision. April 2012.



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