



New Japanese Pharmacopeia (JP 16) Water Testing Requirements

What You Need to Know

On April 1, 2011, the Japanese Pharmacopeia (JP) published changes in the JP 16 monograph that described new analytical testing requirements for Purified Water (PW) and Water for Injection (WFI). Pharmaceutical manufacturers shipping products to Japan must comply with these new requirements by September 30, 2012. These changes will directly affect the validation of new and existing Total Organic Carbon (TOC) analyzers used for either laboratory or on-line analysis.

Many current on-line TOC technologies may easily pass US or European pharmacopeia requirements, but not the more challenging JP tests.

The Challenge

The JP 16 2.59 monograph, *Testing for Total Organic Carbon*, specifies unique compounds for demonstrating calibration and suitability for laboratory and on-line TOC instruments. These include potassium hydrogen phthalate (KHP) for calibration testing and sodium dodecylbenzenesulfonate (SDBS) for suitability testing.^{1,2} Unfortunately, many existing analytical TOC methods may be incapable of accurately recovering these compounds or may require extensive modifications to do so. Of particular concern are many current on-line TOC technologies, which may easily pass US or European pharmacopeia requirements, but not the more challenging JP tests.³

Business Impact

Non-compliance with JP testing requirements could in some cases lead to:

- Delayed product disposition or shipment
- Increased investigation costs due to failed standard solutions testing
- Negative publicity

Solutions and Recommendations

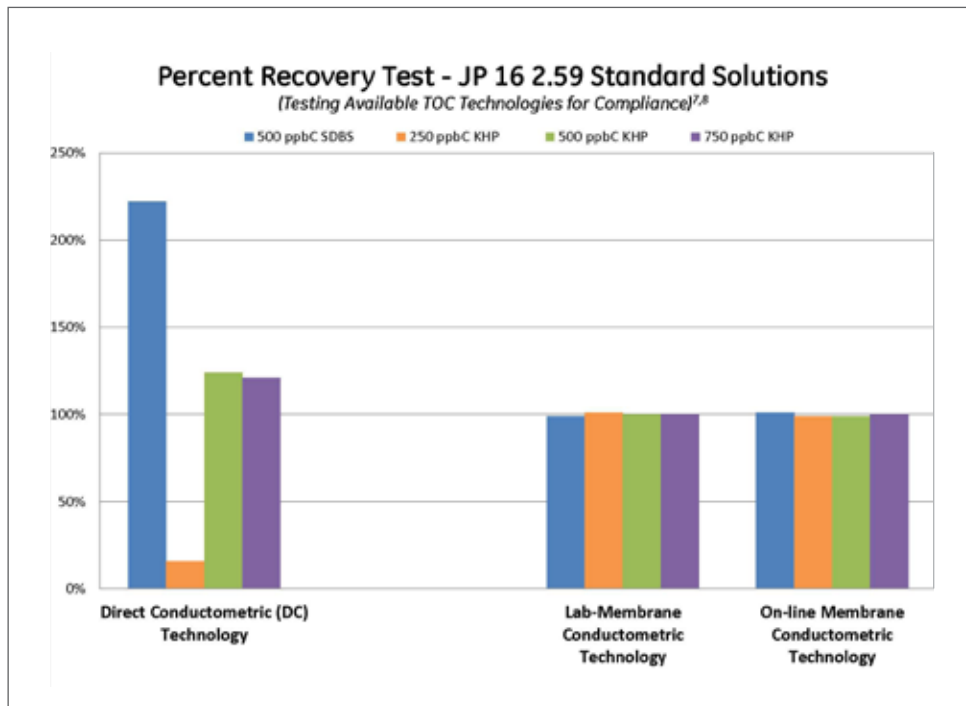
- Upgrade or replace existing non-compliant instrumentation with units capable of meeting the new JP requirements.
- Fully validate any new method to verify compliance with JP 16.

GE Analytical Instruments currently offers the robust Sievers 500 RL On-Line and Sievers 900 Laboratory TOC instruments that are fully compliant with JP 16 (all units are also USP and EP compliant). The instruments include JP 16-specific menus for simple operation, as well as complete validation documentation and service support. JP 16 reference standards are also currently available for shipment.

JP 16 General Chapter 8 cautions against using TOC methods that are susceptible to ionic interferences and suggests additional validation may be necessary.^{4,5} GE's unique measurement method is immune to interfering compounds, and therefore will avoid the need for this secondary testing.⁶

Supporting Data

The following table illustrates the challenge of meeting the new JP requirements — even when using the current generation of on-line TOC instrumentation. However, GE's Laboratory Membrane and On-line Membrane Conductometric technologies easily meet these new analytical requirements.



Our Promise

As the pharmaceutical regulatory environment continues to shift its focus from legacy approaches to risk mitigation and continuous quality assurance, rest assured that GE Analytical Instruments will be there to support your global regulatory needs.

Supporting References

1. GE Analytical Instruments, Application Note #300 00119: *Calibration of the Sievers 500 RL On-Line TOC Analyzer*. 2006.
2. GE Analytical Instruments, Application Note #300 00157: *Calibration Stability of the Sievers 900 Series TOC Analyzers*. 2005.
3. Kauffman, J.S. "Validating On-line TOC Analyzers for Real-Time Release." *Pharmaceutical Manufacturing*, November/December 2006.
4. "Quality Control of Water for Pharmaceutical Use," in *The Japanese Pharmacopoeia*, Sixteenth Edition, 2011, ch. G8, pp. 2246–2253.
5. "Validation of Analytical Procedures," in *The Japanese Pharmacopoeia*, Sixteenth Edition, 2011, ch. G1, pp. 2148–2151.
6. GE Analytical Instruments, Application Note #300 00221. *Compliance with JP 16 TOC Requirements Using the Sievers 900 and 500 RL TOC Analyzers and Standards*. 2010.
7. GE Analytical Instruments, *Test Plan: Feasibility Testing of On-line Instruments*. 2012.
8. GE Analytical Instruments, Test Document #100 01102: *JP 16 Capability Testing of the Hach/Ultra PAT700 On-line TOC Analyzer*. 2012.



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