

Smart Notes

Assist with compliance
with pharmaceutical
industry standards

pH Meters

Q A

How do I comply with the updated USP <791> requirements for pH measurements?

By using instrumentation with features that assist in complying with the method's new requirements.*

There has been a growing interest in the pharmaceutical industry surrounding the newly updated USP <791> standardized test method for pH measurement. USP <791> was established by the US Pharmacopeia for pH measurements used in the pharmaceutical, food and beverage, patient care, and dietary supplement industry.

In December 2014, a new version of USP <791> officially went into effect, which changed the pH measurement system requirements, instrumentation requirements and calibration requirements.

Thermo Scientific™ Orion™ pH meter kits are part of a high-quality pH test method designed to assist with compliance to USP <791> pH requirements.



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USP 791 pH Test Method

The USP 791 standardized test method outlines pH measurements for many pharmaceutical products. Pharmaceutical tests are performed not only to determine if the material's specifications are met, but also to address anticipated regulatory concerns, like drug compatibility, quality control or shelf life stability.

USP <791> Requirements**	General Recommendations*
Temperature Device: ± 1 °C	Verify against a NIST-traceable thermometer
Calibration Buffers: 2 Minimum	(USA Buffer Set) 3-point calibration with pH 4.01, 7.00, and 10.01 buffers, or 5-point calibration with pH 1.68, 4.01, 7.00, 10.01, and 12.46 buffers
Slope Value: 90 - 105 %	Slope is displayed on the meter screen when calibration is complete. Slope is also displayed in the meter calibration log.
Offset: ± 30 mV	Offset can be calculated by the meter, or Offset can be measured in pH 7 buffer, or Offset can be calculated by the analyst.
Verification: ± 0.05 pH	Analyze pH 6.86 buffer. Compare results to a table of buffer values at temperature. See table on page 10 of eBook.

* Consult with the SOP prepared by your internal quality or regulatory group when performing your testing per USP <791>

** For details and exact language, see: USP <791> pH General Chapter, The United States Pharmacopeial Convention, December 1, 2014. www.usp.org.

Summary

Conduct your pH testing using methods that adhere to the most updated standards followed by the pharmaceutical industry. Thermo Scientific Orion pH meter kits are part of a high-quality pH test method designed to assist with compliance to USP <791> pH requirements.



▶ Visit thermoscientific.com/orionmeters for product brochures and detailed applications notes.

thermoscientific.com/water

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