



Parameter

USP 645 Water Conductivity, meter calibration verification

Sample Type

Ultrapure water, water for injection

Introduction

Water conductivity is used as a measure of water purity in the pharmaceutical industry. Three stages of testing are described in USP 645, each more involved than the last. If the requirements of Stage 1 or Stage 2 are met, the water meets the requirements of the test. Only if the water fails to pass all three Stages is the sample judged noncompliant.

As part of USP <645>, meter calibration must be verified by replacing the conductivity cell with NIST-traceable precision resistors (accurate to +/- 0.1% of the stated value). The Certificate of Analysis provided with each Orion conductivity calibration kit documents the NIST-traceability, the 0.1% tolerance, and actual conductance values for each resistor. Meter readings must agree with actual conductance values to within +/- 0.1 uS/cm.

Reference

USP <645> Water Conductivity, USP29-NF24, Page 2653, United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852-1790, USA. www.usp.org

Recommended Equipment

5Star benchtop pH/ISE/DO/conductivity meter (Orion 1010152); conductivity calibration kit for meter (Orion 1010001); printer (Orion 1010006) – optional

Meter Setup

Disconnect the electrode from the meter. Store electrode dry. Meter setup is the same as for Stage 1 and Stage 2 USP 645 testing – no changes are required in setup mode. However, in calibration mode, set the cell constant to 1.000 cm-1. To do this, press the “calibrate” key and when the cell constant is displayed, press the “digits” key within 5 seconds, before the meter goes into AutoCal mode. Note: do not perform an AutoCal at this time. Using the “scroll” and “digits” keys, adjust the display to 1.000.

Calibration

To verify meter calibration, use resistors A, B, C (nominal conductance values of 1, 10, 100 uS/cm) in the conductivity calibration kit. Plug the resistor into the meter in place of the conductivity electrode. Align the tabs on the resistor and meter and push the resistor firmly in place. (Improper alignment can damage the resistor and/or meter). Press “measure” and wait for the stable reading. Compare the displayed value to the actual conductance of the resistor, as documented on the Certificate of Analysis that comes with the kit. The displayed value should agree with the actual value within +/- 0.1 uS/cm.

Quality Control (QC)

Meter calibration verification should be performed regularly at a frequency that is in accordance with the user’s recommended QA/QC procedures.

Corrective Actions

Should the calibration verification fail to meet criteria, try one or more of the following corrective actions: 1) check the cell constant (in calibration mode) to verify that it has been set to 1.000 cm⁻¹; 2) check the meter setup to ensure all modes are set properly, especially that the temperature compensation is off and the reference temperature is set to 25 degrees C; 3) repeat the testing, pushing the resistors firmly into place and taking new measurements; 4) if the displayed readings are still out of range, contact our technical service department. See www.thermo.com for updated contact information.