



Parameter

USP 645 Water Conductivity, Stage 1

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.

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 electrode (Orion 013016MD) with flow cell (included); conductivity calibration kit for meter (Orion 1010001); printer (Orion 1010006) – optional; Star Navigator Software (Orion 1010007) – optional.

Required Solutions

100 uS/cm conductivity standard (Orion 011008); deionized water (DI)

Meter Setup

Connect the electrode onto the meter. Set measurement mode to conductivity. In Setup mode, set temperature compensation to off, conductivity cell type to standard, read type to auto, cell constant to 0.100 (nominal), and reference temperature (tREF) to 25.

Electrode Storage, Soaking, and Rinsing

For overnight or longer, store electrodes clean and dry. Soaking in water is acceptable between measurements. Before testing, rinse the electrode thoroughly with DI water and shake off excess water.

Electrode Setup

The cell constant is printed on the conductivity electrode cable. On the meter, 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 match the cell constant from the cable.

Sample Preservation

For Stage 1 testing, no sample preservation is necessary. If the sample will be stored, it is common to store refrigerated.

Sample Preparation

No sample preparation is required for Stage 1 testing. The sample is tested at temperature without stirring, preferably as soon as possible after collection or in real-time by use of the provided flow cell.

Calibration

To verify cell constant, rinse electrode with 100 uS/cm conductivity standard and then test a fresh portion of the standard. Record the measured value and temperature. Compare to the conductivity standard table (Table 1, attached). If results are within 2% of expected, calibration is met. If not, see Corrective Actions, below. To verify meter calibration, use Orion 1010001. See associated application note.

Analysis

Place conductivity electrode (which has been rinsed and shaken dry) into the sample bottle. Gently and briefly (e.g., 3 seconds) stir with the probe. Tap electrode, if necessary, to dislodge any bubbles. Alternately, insert the electrode into the provided flow cell and connect the flow cell to the water line to be tested. Allow the flow cell to flush with several volumes of the test water. Press “measure” and wait for the reading to stabilize. This value is automatically logged and/or printed. Compare the measured temperature and conductivity readings to the Stage 1 values (Table 2, attached). Find the temperature value that is just lower than the measured value. If the measured conductivity is not greater than the value in the table, the water meets the requirements of the test for conductivity. If the conductivity is higher, conduct Stage 2 testing.

Quality Control (QC)

Recommended QC procedures include: verification of cell constant, meter calibration checks, and temperature measurement accuracy. See reference above for details.

Corrective Actions

Should the calibration verification fail to meet criteria, try one or more of the following corrective actions: 1) check the meter setup (see above) to ensure all modes are set properly; 2) rinse thoroughly & soak the electrode in DI water for 5 min; 3) rinse the electrode with a portion of the 100 uS/cm standard, then test a fresh bottle of 100 uS/cm conductivity standard; 4) clean the electrode with warm water & alkaline detergent for 10 to 30 min with stirring, then rinse & soak as in step 2 above, then rinse & test as in step 3 above; 5) only if steps 1-4 fail, recalibrate the electrode as described in log #23 on USP 645 Water Conductivity, Cell Constant Recalibration.



Table 1 - Chart of Standard Values in $\mu\text{S}/\text{cm}$ at Specified Temperatures for Orion 011008

Deg C	0.0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
18	86.4	86.6	86.8	87.0	87.2	87.4	87.6	87.8	88.0	88.2
19	88.3	88.5	88.7	88.9	89.1	89.3	89.5	89.7	89.9	90.1
20	90.3	90.5	90.7	90.9	91.0	91.2	91.4	91.6	91.8	92.0
21	92.2	92.4	92.6	92.8	93.0	93.2	93.4	93.6	93.8	94.0
22	94.2	94.4	94.6	94.7	94.9	95.1	95.3	95.5	95.7	95.9
23	96.1	96.3	96.5	96.7	96.9	97.1	97.3	97.5	97.7	97.9
24	98.1	98.3	98.5	98.7	98.9	99.1	99.3	99.5	99.7	99.9
25	100.1	100.3	100.5	100.7	100.9	101.1	101.3	101.5	101.7	101.9
26	102.1	102.3	102.5	102.7	102.9	103.1	103.3	103.5	103.7	103.9
27	104.1	104.3	104.5	104.7	104.9	105.1	105.3	105.5	105.7	105.9
28	106.1	106.3	106.5	106.7	106.9	107.1	107.3	107.5	107.8	108.0
29	108.2	108.4	108.6	108.8	109.0	109.2	109.4	109.6	109.8	110.0
30	110.2	110.4	110.6	110.8	111.0	111.2	111.4	111.6	111.9	112.1

To use the chart, read down and across to the measured temperature for the standard value at that temperature.

For example, at 25.4 degrees C, the standard should read 100.9 $\mu\text{S}/\text{cm}$ +/- 2%.

Table 2 - Stage 1: Temperature and Conductivity Requirements for USP <645>

Temperature (C)	Conductivity Requirement ($\mu\text{S}/\text{cm}$)
0	0.6
5	0.8
10	0.9
15	1.0
20	1.1
25	1.3
30	1.4
35	1.5
40	1.7
45	1.8
50	1.9
55	2.1
60	2.2
65	2.4
70	2.5
75	2.7
80	2.7
85	2.7
90	2.7
95	2.9
100	3.1