Meet USP<645> Water Conductivity Requirements and European Pharmacopoeia 2.2.38 Conductivity Test for USP & EP Purified Water and Water for Injection using:

The Insacal Conductivity Calibrator

For Pharmaceutical and Medical purposes the quality of water, as an excipient has been defined by the European Pharmacopoeia (EP) as well as the United States Pharmacopoeia (USP). In order to ship/sell your product in Europe or the United States of America, you must be able to prove that these requirements are met.

For Purified Water and Water for Injection (WFI) the USP defines the following requirements:

- Meter reports uncompensated Conductivity or uncompensated Resistivity.
- The display resolution is 0.1 µS/cm or better.
- The meter reads accurate 1 µS/cm when a 0.1% precision resistor replaces the sensor (to calibrate/verify the meter).
- The sensor cell constant is calibrated/verified to ±2%
- Temperature accurate to 2°C (effective USP 28)

How the Insacal improves your calibration obligations

- The Insacal is accurate to 0.37% of reading for cell constant determination with a test accuracy ratio of better than 4:1 (accuracy ranges from 0.25% to 1% depending on user measurement range and calibration option)
- Accredited by Danak with Traceability to DFM Standard Reference Materials SRM
- Compensated and Uncompensated Raw Values and Temperature readings are all simultaneously displayed to ensure accuracy
- Lightweight and portable for use in the Laboratory or in the Field
- Robust and made from suitable materials to ensure long term stability and accuracy

Insacal is the only Calibrator for Conductivity which is Accredited 17025 by Danak.


Insacal


Sensors


Calibration Tank


Calibration

Accessories

insacal™

The Conductivity Master Meter

For Regulatory Compliance

What is USP 645 and how does it affect me?

Are you utilising Water for Injection (WFI), Sterile Purified Water, Sterile Water for Irrigation, Sterile Water for Inhalation or Purified Steam?

Are you meeting your regulatory requirements on Conductivity Measurements and Calibrations?

USP Pharmaceuticals Water Conductivity Requirements

Stage 1:	Conductivity vs. Temperature Tables
Stage 2:	Conductivity Limit
Stage 3:	Conductivity vs. pH Tables

USP requirements since November 15, 1996 and EP requirements since July 2000

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USP<645> Goals

Fundamental Goals of the changes to USP Purified Water and WFI

- Maintain/Improve exisiting water quality
- Improve the reliability of the testing (using modern instrumentation)
- Reduce the number of tests
- Make allowances for on-line, in-line testing

The Three-Stage Philosophy

Stage 1: In-line Test:
A non-temperature compensated conductivity measurement corresponding to a measured temperature. If the conductivity does not exceed 1.3µS/cm @25˚C (or tabulated values in Table A), the test is complete. If not, go to Stage 2.

Stage 2: Lab Test:
Equilibrate a water sample with air. If the conductivity does not exceed 2.1µS/cm at 25˚C, the test is complete. If not, go to Stage 3.

Stage 3: Lab Test:
Add saturated KCl to the previous sample and measure the pH. If the conductivity does not exceed the allowable level of conductivity (measured in Stage 2) at that pHk, based on a Table B, the test is complete. If the conductivity exceeds that limit, the water test fails.

Advantages of on-line testing stage 1:

- Real-time process information for conductivity and temperature
- Immediate alarms and options
- Data may be logged, providing water history
- Easier and cost effective
- Eliminates sample collection, handling and transportation errors.
- In addition, temperature-compensated conductivity remains an excellent technique to observe water quality changes.

What is USP and how does it affect me?

USP<645> was published on September 15, 1996, became mandatory on November 15, 1996 and is continued in subsequent revisions.

Reccommendations of the Water Quality Committee (WQC) of the Pharmaceutical Research and Manufacturers of America (PhRMA formerly PMA) comprising leaders from major pharmaceutical companies were accepted to update antiquated testing standards for pharmaceutical waters such as USP Purified and Water for Injection (WFI). According to the WQC: "The exisiting USP monograph test for chloride, sulfate, calcium, ammonia and carbon dioxide were introduced into the USP in 1890 or before and may no longer be appropriate with regard to test methodology. While USP water monograph test methodologies for inorganic ions traditionally have been wet chemical methods, which are inexpensive and require little technical skill to perform, such attributes are offset by the qualitative and subjective nature of the antiquated tests.... the WQC of PMA proposes to replace them with a conductivity measurement."

Table A
Stage 1 Conductivity Limits as a Function of Temperature

Temperature (°C)	Stage 1 Conductivity Limit (µS/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

Table B
Stage 3 Conductivity Limits as a Function of pH

pH	Stage 3 Conductivity Limit (µS/cm)
5.0	4.7
5.1	4.1
5.2	3.6
5.3	3.3
5.4	3.0
5.5	2.8
5.6	2.6
5.7	2.5
5.8	2.4
5.9	2.4
6.0	2.4
6.1	2.4
6.2	2.4
6.3	2.4
6.4	2.3
6.5	2.2
6.6	2.1
6.7	2.6
6.8	3.1
6.9	3.8
7.0	4.6

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