1.3 USP Purified Water and Water for Injection Criteria

The criteria presented below are condensed and / or excerpted from sections 643 and 645 of the United States Pharmacopoeia (USP), 25th edition.

1.3.1 Selected Criteria

Parameter	PW	WFI
pH	5.0 - 7.0	5.0 - 7.0
TOC	< 500 ppb	< 500 ppb
Total Bacteria Count	≤ 10 colony forming unit (cfu)/ml, pathogen free	≤ 10 cfu/ 100 ml, pathogen free
Endotoxin	Not Specified	≤ 0.25 EU/ml
Feed Water	Potable Water	Not Specified, but Health Canada regulations demand that PW be used

1.3.2 Conductivity / Resistivity

Stage 1 Procedure and Criteria:

Conductivity criteria for PW and WFI are the same. The conductivity criteria measured in-line, uncompensated for temperature, are listed below and are referred to as Stage 1 Criteria. If the Stage 1 Criteria are not met, a Stage 2 should be conducted, and then if necessary (Stage 2 failure) a Stage 3 test may be conducted.

Temperature (°C)	Conductivity (µS/cm)	Resistivity (MΩ-cm)	Temperature (°C)	Conductivity (µS/cm)	Resistivity (MΩ-cm)
0	0.6	1.67	45	1.8	0.56
5	0.8	1.25	50	1.9	0.53
10	0.9	1.11	55	2.1	0.48
15	1.0	1.00	60	2.2	0.45
20	1.1	0.91	65	2.4	0.42
25	1.3	0.77	70	2.5	0.40
30	1.4	0.71	75-90	2.7	0.37
35	1.5	0.67	95	2.9	0.34
40	1.7	0.59	100	3.1	0.32

Note that the USP defines the quality in terms of conductivity.

Stage 2 Procedure and Criteria:

Take a 100 ml (or more) sample, and vigorously stir in an open beaker maintaining the temperature at 25±1°C. Periodically observe the conductivity. When the change in conductivity (due to uptake of atmospheric CO_2) is less than a net of 0.1 µS/cm per 5 minutes, note the conductivity. If the conductivity is not greater than 2.1 µS/cm the water meets the requirements of the test for conductivity. If the conductivity is greater, proceed to Stage 3.

Stage 3 Procedure and Criteria:

This test is to be carried out within 5 minutes of the Stage 2 test on the same sample, while continuing to maintain the sample temperature at 25±1°C. Add 0.3 ml of saturated potassium chloride solution per 100 ml of sample to the sample and determine the pH to the nearest 0.1 pH unit as directed under USP section 791. If the pH is outside the range of 5.0 - 7.0 or if the end point conductivity measured in Stage 2 is greater than the conductivity criteria summarized in the table below, the water does not meet the criteria of the test for conductivity.

Stage 3 pH	Stage 2 Conductivity Limit (µS/cm)	Stage 3 pH	Stage 2 Conductivity Limit (µS/cm)
5.0	4.7	6.1	2.4
5.1	4.1	6.2	2.4
5.2	3.6	6.3	2.4
5.3	3.3	6.4	2.3
5.4	3.0	6.5	2.2
5.5	2.8	6.6	2.1
5.6	2.6	6.7	2.6
5.7	2.5	6.8	3.1
5.8	2.4	6.9	3.8
5.9	2.4	7.0	4.6
6.0	2.4		