Water Quality Standards Summary

Life Sciences and Healthcare Water Quality Standards:

1. USP (United States Pharmacopeia)
2. AAMI ST108:2023 (Association for the Advancement of Medical Instrumentation)
3. Clinical Laboratory Reagent Water (CLRW)
4. ASTM (American Society for Testing and Materials)

Below is a summary table of all these key standards. In the subsequent pages, each standard is broken out and information is provided on the purpose and use. Many of these standards overlap and can be somewhat interchangeable dependent on the application. Realistically, the best water quality standard is one designed by the end-user and considers the specific application and critical parameters, and the end user should be consulted when determining the targets.

Producing water to each standard is often done with equipment that is specifically designed to meet that quality and quality requirements. In many cases, multiple water qualities are needed, and it is common to design a central system that can meet the lower quality requirements and polish to the higher quality where it is required. Water Works can help design a system to meet standards and optimize for efficiency, sustainability, and total cost of operations. Please don't hesitate to reach out for consultation of any kind.

Quality Parameter	USP Purified Water	USP Water for Injection	ASTM Type I	ASTM Type II	ASTM Type III	ASTM Type IV	Clinical Lab Reagent Water	AAMI ST108:2023 Utility	AAMI ST108:2023 Critical
pH	–	–	–	–	–	5.0 - 8.0	–	6.5 - 9.5	5.0 - 7.5
Conductivity at 25° (µS/cm^2)	≤ 1.3	≤ 1.3	≤ 0.0555	≤ 1.0	≤ 0.25	≤ 5.0	–	< 500	< 10
Resistivity at 25° (Megohm)	–	–	≥ 18	≥ 1	≥ 4	≥ 0.2	≥ 10	–	–
Total Organic Carbon (ppb)	≤ 500	≤ 500	≤ 50	≤ 50	≤ 200	–	≤ 500	–	< 1000
Bacteria (CFU/mL)	≤ 100	≤ 0.1	Type A/B/C*	Type A/B/C*	Type A/B/C*	Type A/B/C*	< 10	< 500	< 10
Endotoxin (EU/mL)	–	≤ 0.25	Type A/B/C*	Type A/B/C*	Type A/B/C*	Type A/B/C*	–	–	< 10
Aluminum (ppm)	–	–	–	–	–	–	–	< 0.1	< 0.1
Chloride (ppm)	–	–	≤ 0.001	≤ 0.005	≤ 0.01	≤ 0.05	–	< 250	< 1.0
Copper (ppm)	–	–	–	–	–	–	–	< 0.1	< 0.1
Iron (ppm	–	–	–	–	–	–	–	< 0.1	< 0.1
Manganese (ppm)	–	–	–	–	–	–	–	< 0.1	< 0.1
Nitrate (ppm)	–	–	–	–	–	–	–	< 10	< 1.0
Phosphate (ppm)	–	–	–	–	–	–	–	< 5	< 1.0
Sodium (ppm)	–	–	≤ 0.001	≤ 0.005	≤ 0.01	≤ 0.05	–	–	–
Sulfate (ppm)	–	–	–	–	–	–	–	< 150	< 1.0
Silica (ppm)	–	–	≤ 0.003	≤ 0.003	≤ 0.5	–	–	< 50	< 1.0
Total Alkalinity as CaCO2 (ppm)	–	–	–	–	–	–	–	< 400	< 8.0
Total Hardness as CaCO2 (ppm)	–	–	–	–	–	–	–	< 150	< 1.0
Zinc	–	–	–	–	–	–	–	< 0.1	< 0.1

Quality Parameter (ASTM Specific)*	ASTM Type A	ASTM Type B	ASTM Type C
Max. Heterotropic Bacteria Count (CFU/100mL)	1	10	1000
Endotoxin EU/mL	< 0.03	< 0.25	N/A

1. USP (United States Pharmacopeia)

USP Purified Water

Purpose and Use: USP Purified Water is intended for use in the preparation of non-parenteral pharmaceuticals and is used in various pharmaceutical processes such as cleaning equipment and preparing bulk chemicals. It is one of the several types of water defined by the United States Pharmacopeia (USP) to ensure the quality and safety of pharmaceutical products.

USP Water for Injection (WFI)

Purpose and Use: USP Water for Injection (WFI) is a high-purity water that is primarily used in the pharmaceutical and biotechnology industries to produce parenteral (injectable) drugs. It is also used in the preparation of solutions for intravenous administration, as well as in the cleaning and rinsing of equipment and containers that come into contact with injectable products.

Production of WFI is typically produced by distillation or reverse osmosis followed by ultrafiltration, to ensure the highest levels of purity. The production process must be validated to consistently produce water that meets all the required specifications.

Quality Parameter	USP Purified Water (PW)	USP Water for Injection (WFI)
Conductivity at 25° (µS/cm^2)	≤ 1.3	≤ 1.3
Total Organic Carbon (ppb)	≤ 500	≤ 500
Bacteria (CFU/mL)	≤ 100	≤ 0.1
Endotoxin (EU/mL)	-	≤ 0.25

2. ASTM (American Society for Testing and Materials)

ASTM standards are often referenced in industrial, environmental, and research settings where specific purity levels are needed but may not necessarily align with pharmaceutical-grade requirements. *USP standards are primarily used for pharmaceutical and medical applications where sterility and absence of pyrogens are critical. ASTM standards provide a broad framework for water purity used in a variety of non-pharmaceutical settings, while USP standards are focused on ensuring the safety and efficacy of water used in medical and pharmaceutical contexts. However, because they have much overlap, the USP standards are more frequently used as a target over the ASTM standards.* Most modern central ultrapure water systems aim to meet USP Purified Water Standards. The USP specifications exceed ASTM Type II water specifications. In the case where a point of use requires ASTM Type I water, a desktop polisher is commonly used to polish the water to meet this standard.

Type I: Analytical procedures requiring minimal contamination, ultrapure water for critical applications (e.g., HPLC, ICP-MS).
Type II: H Laboratory experiments and general analyses high-purity water for general lab use (e.g., reagent preparation).
Type III: Preliminary cleaning processes. RO water for basic tasks (e.g., glassware washing).
Type IV: General laboratory water for non-critical tasks (e.g., rinsing glassware).

Quality Parameter	ASTM Type I	ASTM Type II	ASTM Type III	ASTM Type IV
pH	–	–	–	5.0 - 8.0
Conductivity at 25° (µS/cm^2)	≤ 0.0555	≤ 1.0	≤ 0.25	≤ 5.0
Resistivity at 25° (Megohm)	≥ 18	≥ 1	≥ 4	≥ 0.2
Total Organic Carbon (ppb)	≤ 50	≤ 50	≤ 200	–
Bacteria (CFU/mL)	Type A/B/C*	Type A/B/C*	Type A/B/C*	Type A/B/C*
Endotoxin (EU/mL)	Type A/B/C*	Type A/B/C*	Type A/B/C*	Type A/B/C*
Aluminum (ppm)	–	–	–	–
Chloride (ppm)	≤ 0.001	≤ 0.005	≤ 0.01	≤ 0.05
Copper (ppm)	–	–	–	–
Iron (ppm	–	–	–	–
Manganese (ppm)	–	–	–	–
Nitrate (ppm)	–	–	–	–
Phosphate (ppm)	–	–	–	–
Sodium (ppm)	≤ 0.001	≤ 0.005	≤ 0.01	≤ 0.05
Sulfate (ppm)	–	–	–	–
Silica (ppm)	≤ 0.003	≤ 0.003	≤ 0.5	–

For endotoxin and bacteria standards an additional note can be made for "Type A/B/C" on the standards shown below:

Quality Parameter (ASTM Specific)*	ASTM Type A	ASTM Type B	ASTM Type C
Max. Heterotropic Bacteria Count (CFU/100mL)	1	10	1000
Endotoxin EU/mL	< 0.03	< 0.25	N/A

3. Clinical Laboratory Reagent Water (CLRW)

Purpose and Use: Clinical Laboratory Reagent Water (CLRW) is a high-purity water specifically designed for use in clinical laboratories. It is used in various diagnostic and analytical procedures to ensure accurate and reliable test results. The water quality standards for CLRW are defined by the Clinical and Laboratory Standards Institute (CLSI).

Quality Parameter	Clinical Lab Reagent Water
Resistivity at 25° (Megohm)	**≥ 10**
Total Organic Carbon (ppb)	**≤ 500**
Bacteria (CFU/mL)	**< 10**

4. AAMI ST108:2023 (Association for the Advancement of Medical Instrumentation)

Purpose and Use: This standard primarily applies to healthcare facilities using water in the sterilization of medical devices. The primary goal of AAMI ST108 is to ensure that water used in cleaning, disinfecting, and sterilizing medical devices meets specific quality criteria to prevent

contamination and ensure patient safety. The standard emphasizes the importance of water quality in all stages of medical device processing, from initial washing to final rinsing and steam sterilization. This standard is commonly referenced in hospital sterile process departments (SPD) where sterilization equipment will have two connections, one for critical water, and one for utility water.

Quality Parameter	AAMI ST108:2023 Utility	AAMI ST108:2023 Critical
pH	6.5 - 9.5	5.0 - 7.5
Conductivity at 25° (µS/cm^2)	< 500	< 10
Resistivity at 25° (Megohm)	–	–
Total Organic Carbon (ppb)	–	< 1000
Bacteria (CFU/mL)	< 500	< 10
Endotoxin (EU/mL)	–	< 10
Aluminum (ppm)	< 0.1	< 0.1
Chloride (ppm)	< 250	< 1.0
Copper (ppm)	< 0.1	< 0.1
Iron (ppm	< 0.1	< 0.1
Manganese (ppm)	< 0.1	< 0.1
Nitrate (ppm)	< 10	< 1.0
Phosphate (ppm)	< 5	< 1.0
Sodium (ppm)	–	–
Sulfate (ppm)	< 150	< 1.0
Silica (ppm)	< 50	< 1.0
Total Alkalinity as CaCO2 (ppm)	< 400	< 8.0
Total Hardness as CaCO2 (ppm)	< 150	< 1.0
Zinc	< 0.1	< 0.1

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Water Quality Conversion Chart

	Resistivity	Conductivity	Dissolved Solids	Grains Per Gallon	Ph	
	Ω =ohms	µS = Microseimens mS = Miliseimens	TDS (ppm or mg/l as CaCo3)	GPG 1 Grain = 17.1 ppm	Max	Min
Quality →	18 M Ω	0.056 µS	0.028	0.000	7.8	6.2
	17 M Ω	0.058 µS	0.029	0.002	7.8	6.2
	16 M Ω	0.063 µS	0.031	0,002	7.9	6.1
	15 M Ω	0.066 µS	0.033	0.002	7.9	6.1
	14 M Ω	0.071 µS	0.036	0.002	7.9	6.1
	13 M Ω	0.077 µS	0.038	0.002	7.9	6.1
	12 M Ω	0.083 µS	0.042	0.002	8.0	6.0
	11 M Ω	0.091 µS	0.045	0.003	8.0	6.0
	10 M Ω	0.1 µS	0.05	0.003	8.1	5.9
	9 M Ω	0.11 µS	0.055	0.003	8.1	5.9
	8 M Ω	0.125 µS	0.063	0.004	8.2	5.8
	7 M Ω	0.143 µS	0.0715	0.004	8.3	5.7
	6 M Ω	0.167 µS	0.0835	0.005	8.3	5.7
	5 M Ω	0.2 µS	0.1	0.006	8.4	5.6
	4 M Ω	0.250 µS	0.125	0.007	8.5	5.5
	3 M Ω	0.333 µS	0.1665	0.010	8.6	5.4
← Less Dissolved Solids	2 M Ω	0.5 µS	0.25	0.015	8.8	5.2
	1 M Ω QC Light	1 µS	0.5	0.029	9.1	4.9
	900 K Ω	1.11 µS	0.55	0.032	9.2	4.8
	800 K Ω	1.25 µS	0.625	0.037	9.2	4.7
	700 K Ω	1.43 µS	0.715	0.042	9.3	4.6
	600 K Ω	1.67 µS	0.835	0.049	9.4	4.5
	500 K Ω	2 µS	1	0.058	9.5	4.4
	400 K Ω	2.5 µS	1.25	0.073	9.6	4.4
	300 K Ω	3.3 µS	1.65	0.096	9.7	4.3
	200 K Ω QC Light	5 µS	2.5	0.146	9.7	4.3
	100 K Ω	10 µS	5	0.292	10.1	3.9
	50 K Ω	20 µS	10	0.585	10.4	3.6
	40 K Ω	25 µS	12.5	0.731	10.5	3.5
	30 K Ω	33.3 µS	16.65	0.974	10.6	3.4
	20 K Ω QC Light	50 µS	25	1.462	10.8	3.2
	10 K Ω	100 µS	50	2.974	11.1	2.9
	5 K Ω	200 µS	100	5.848	11.4	2.6
	1 K Ω	1 mS	500	29.240	12.1	1.9