

Water Quality Standards

Technical standards on water quality have been established by a number of organizations including the American Society for Testing and Materials (ASTM), International Organization for Standardization (ISO), United States Pharmacopoeia (USP) and the Clinical and Laboratory Standards Institute (CLSI) - previously known as the US National Committee for Clinical Laboratory Standards (NCCLS). CLSI outlines Clinical Laboratory Reagent Water (CLRW) guidelines.

ASTM Standards for Laboratory Reagent Water (ASTM D1193-91)

Measurement (unit)	Type I	Type II	Type III	Type IV
Resistivity (MΩ-cm)	> 18	> 1	> 4	> 0.2 (200KΩ)
Conductivity (µS/cm)	< 0.056	< 1	< 0.25	< 5.0
pH at 25°C	N/A	N/A	N/A	5.0 – 8.0
Total Organic Carbon (TOC) ppb or µg/L	<50	<50	<200	N/A
Sodium (ppb or µg/L)	< 1	< 5	< 10	< 50
Chloride (ppb or µg/L)	< 1	< 5	< 10	< 50
Silica (ppb or µg/L)	< 3	< 3	< 500	N/A

Additional ASTM Sub-Standards for Laboratory Reagent Water

Measurement (unit)	A	B	C
Heterotrophic Bacteria Count (CFU/ml)	< 1	< 10	< 1000
Endotoxin (units per ml)	< 0.03	< 0.25	N/A

ISO 3696 Standard

Parameter	Grade 1	Grade 2	Grade 3
Conductivity µS/cm (Temp Corrected)	< 0.1	< 0.1	< 5.0
pH at 25°C	N/A	N/A	5.0 – 7.0
Oxidizable matter Oxygen (O2) content mg/L	N/A	< 0.08	< 0.4
Absorbance at 254 nm and 1 cm optical path length, absorbance units	< 0.001	< 0.01	N/A
Residue after evaporation on heating at 110°C mg/kg	N/A	< 1	< 2
Silica (SiO2) mg/L	< 0.01	< 0.02	N/A

Water Quality Standards (cont.)

CLSI¹-CLRW Guidelines

Contaminant	Parameter and Unit	Type 3	Type2	Type1	CLRW
Ions	Resistivity (MΩ-cm)	> 0.05 (50 KΩ)	> 1	> 18	> 10
Organics	Total Organic Carbon (TOC) ppb	< 200	< 50	< 10	< 500
Pyrogens	(Eu/ML)	N/A	N/A	<0.03	---
Particles	Particles >0.2 μm (units/mL)	N/A	N/A	< 1 (0.22μ filtration required)	Include 0.22μ filtration
Colloids	Silica (ppb)	< 1000	< 100	< 10	---
Bacteria	Bacteria (cfu/ml)	< 1000	< 100	< 1	< 10

Laboratory Water Purity Specifications Consolidated Guidelines

Contaminant	Parameter and Unit	Type 1	Type 2	Type 3
Ions	Resistivity (MΩ-cm)	> 0.05 (50 KΩ)	> 1	> 0.05 (50 KΩ)
	Silica (ppb)	< 10	<100	<1000
Organics	Total Organic Carbon (TOC) ppb	< 20	< 50	< 200
Particles	Particles > 0.2 μm (#/ml)	< 1	N/A	N/A
Bacteria	Bacteria (cfu/ml)	< 1	< 100	< 1000
	Endotoxin (EU/mL)	< 0.001	N/A	N/A

USP Standards

Properties	USP Purified Water	USP Water for Injection & Highly Purified Water
Conductivity (μS/cm @ 25°C)	< 1.3	< 1.3
Total Organic Carbon (TOC) ppb or μg/L	< 500	< 500
Bacteria (guideline)	< 100 cfu/ml	< 10 cfu/ml
Endotoxin (EU/ml)	N/A	< 0.25 EU/ml