

# WATER PURIFICATION STANDARDS

Laboratory Grade Water (CAP / NCCLS 1988)			
	Type I	Type II	Type III
Conductivity (MicroSiemens)	<0.1	<0.5	<10.0
Resistivity (Megohm-cm)	>10.0	>2.0	>1.0
Bacteria (CFU/ml)	<10.0	10	N/A
Silicate (mg/L)	<0.05	<0.1	<1.0
Total Solids (mg/L)	0.1	1	5
TOC (mg/L)	<0.05	<0.2	1
pH	-	-	5.0 - 8.0

ASTM Standard for Reagent Grade Water (D1193-99e1)				
	Type I	Type II	Type III	Type IV
Electrical Conductivity (MicroSiemens)	0.056	1	0.25	5
Electrical Resistivity (Megohm-cm)	18	1	4	0.2
Endotoxin(EU)	<0.03	0.25		
TOC (ug/L)	50	50	200	no limit
Sodium (ug/L)	1	5	10	50
Chlorides (ug/L)	1	5	10	50
Total Silica (ug/L)	3	3	500	no limit
pH				5.0 - 8.0
Special Reqmts	0.2 um membrane filter*	Prepared by distillation	0.45 um membrane filter	

	Type A	Type B	Type C
Heterotrophic Bacteria Count	10/1000 ml	10/100 ml	100/10ml

\* - Distillation or equal process followed by mixed bed ion exchange and 0.2 micron filter. Feedwater water to final polishing must have a maximum conductivity of 20 uS/cm at (25 C)

ASTM Standard for Biomedical Grade Water (D5196)	
Electrical Resistivity (Megohm-cm)	
measured at production point (no air)	10.0
measured at storage tank (with air)	1.0
TOC (ug/L)	20.0
Heterotrophic Bacteria Count	<10/1000 mL
Endotoxin (EU/mL)	<0.03
Volatile Chlorinated Hydrocarbon (ug/L)	5.0
Arsenic (ug/L)	0.1
Cadmium (ug/L)	0.1
Chromium (ug/L)	1.0
Cobalt (ug/L)	1.0
Copper (ug/L)	1.0
Fluoride (ug/L)	1.0
Iron (ug/L)	1.0
Lead (ug/L)	1.0
Nickel (ug/L)	0.1
Potassium (ug/L)	2.0
Silica (Total) (ug/L)	6.0
Sodium (ug/L)	0.5
Titanium (ug/L)	1.0
Zinc (ug/L)	0.5
Acetate (ug/L)	3.0
Ammonia (ug/L)	1.0
Chloride (ug/L)	1.0
Chloroform (ug/L)	6.0
Formate (ug/L)	2.0
Nitrate (ug/L)	1.0
Phosphate	1.0
Phthalates (ug/L)	0.1
Sulfide (ug/L)	1.0
Sulfate (ug/L)	1.0

- Design per D5196 Sect. 4.5: The distribution outlets or faucets must be of non-contaminating design and materials. Particular care must be given to the valve seat and joint construction. The outlet must be protected from biological contamination particularly when the use is only occasional. Ultraviolet (UV), chemical, or heat sterilization should be considered.

## WATER PURIFICATION STANDARDS

Pharmacopeia Grade Water			
	USP 24 - Purified	EP - Purified	USP 24 -WFI*
Conductivity (MicroSiemens)	<1.3 uS/cm at 25 C	<4.3 uS/cm at 20 C	<1.3 uS/cm at 25 C
Bacteria	< 100 CFU/ml	<100 CFU/ml	<100 CFU/L
Endotoxin(EU)	-	<0.25 EU/ml	<0.25 EU/ml
TOC	< 500 ug/L	< 500 ug/L	< 500 ug/L
Nitrates	-	<0.2 ppm	-
Heavy Metals	-	<0.1 ppm	-

\* - Prepared by distillation or reverse osmosis

Dialysis Grade Water		
	AAMI	European Pharmacopeia
Calcium (mg/L)	2 (0.2 mEq/L)	2 (0.05mmol/l)
Magnesium (mg/L)	4 (0.3 mEq/L)	2 (0.08 mmol/l)
Potassium (mg/L)	8 (0.2 mEq/L)	2 (0.08 mmol/l)
Sodium (mg/L)	70 (3.0 mEq/L)	50 (2.2mmol/l)
Antimony (mg/L)	0.006	0.006
Arsenic (mg/L)	0.005	0.005
Barium (mg/L)	0.1	0.1
Beryllium (mg/L)	0.0004	0.0004
Cadmium (mg/L)	0.001	0.001
Chromium (mg/L)	0.014	0.014
Lead (mg/L)	0.005	0.005
Mercury (mg/L)	0.0002	0.0002
Selenium (mg/L)	0.09	0.09
Silver (mg/L)	0.005	0.005
Aluminum (mg/L)	0.01	0.01
Chloramines (mg/L)	0.1	0.1
Free chlorine (mg/L)	0.5	0.5
Copper (mg/L)	0.1	0.1
Fluoride (mg/L)	0.2	0.2
Nitrate (as N) (mg/L)	2	2
Sulfate (mg/L)	100	100
Thallium (mg/L)	0.002	0.002
Zinc (mg/L)	0.1	0.1
Total Viable Microbial Counts	<200/ml	*
Endotoxin	<2 EU/ml	+
Resistivity (Deionization only)	> 1 Megohm-cm at 25 C	> 1 Megohm-cm at 25 C

	Regular Water	Ultrapure Water	Sterile Water
* - Total Viable Microbial Counts	<100 CFU/ml	<0.1 CFU/ml	<0.000001 CFU/ml
+ - Endotoxin	<0.25 EU/ml	<0.03 EU/ml	<0.03 EU/ml

# WATER PURIFICATION STANDARDS

ASTM Electronics and Semiconductor Grade Water (D5127-99)						
	Type E-1	Type E-1.1	Type E-1.2	Type E-2	Type E-3	Type E-4
Linewidth (microns)	1.0-0.5	0.5-0.25	0.25-0.18	5.0-1.0	>5.0	-
Resistivity, 25 C	18.2	18.2	18.2	17.5	12	0.5
Endotoxin (EU/ml)	0.03	0.03	0.03	0.25	-	-
TOC (ug/L)	5	2	1	50	300	1000
Dissolved Oxygen (ug/L)	1	1	1	-	-	-
Residue after evaporation	1	0.5	0.1	-	-	-
SEM Particles/L (micron range)						
0.1-0.2	1000	1000	200	-	-	-
0.2-0.5	500	500	100	3000	-	-
0.5-1	50	50	1	-	10000	-
10	-	-	-	-	-	100000
On-line particles/L (micron range)						
0.05-0.1	500	500	100	-	-	-
0.1-0.2	300	300	50	-	-	-
0.2-0.3	50	50	20	-	-	-
0.3-0.5	20	20	10	-	-	-
>0.5	4	4	1	-	-	-
Bacteria /100mL						
100 mL Sample	1	1	1	-	-	-
1 L Sample	1	1	0.1	10	10000	100000
Total Silica (ug/L)	3	0.5	0.5	10	50	1000
Dissolved Silica (ug/L)	1	0.1	0.05	-	-	-
Ammonium (ug/L)	0.1	0.1	0.05	-	-	-
Bromide (ug/L)	0.1	0.05	0.02	-	-	-
Chloride (ug/L)	0.1	0.05	0.02	1	10	1000
Fluoride (ug/L)	0.1	0.05	0.03	-	-	-
Nitrate (ug/L)	0.1	0.05	0.02	1	5	500
Nitrite (ug/L)	0.1	0.05	0.02	-	-	-
Phosphate (ug/L)	0.1	0.05	0.02	1	5	500
Sulfate (ug/L)	0.1	0.05	0.02	1	5	500
Aluminum (ug/L)	0.05	0.02	0.005	-	-	-
Barium (ug/L)	0.05	0.02	0.001	-	-	-
Boron (ug/L)	0.05	0.02	0.005	-	-	-
Calcium (ug/L)	0.05	0.02	0.002	-	-	-
Chromium (ug/L)	0.05	0.02	0.002	-	-	-
Copper (ug/L)	0.05	0.02	0.002	1	2	500
Iron (ug/L)	0.05	0.02	0.002	-	-	-
Lead (ug/L)	0.05	0.02	0.005	-	-	-
Lithium (ug/L)	0.05	0.02	0.003	-	-	-
Magnesium (ug/L)	0.05	0.02	0.002	-	-	-
Manganese (ug/L)	0.05	0.02	0.002	-	-	-
Nickel (ug/L)	0.05	0.02	0.002	1	2	500
Potassium (ug/L)	0.05	0.02	0.005	2	5	500
Sodium (ug/L)	0.05	0.02	0.005	1	5	1000
Strontium (ug/L)	0.05	0.02	0.001	-	-	-
Zinc (ug/L)	0.05	0.02	0.002	1	5	500

CAP- College of American Pathologist  
 NCCLS - National Committee for Clinical Laboratory Standards  
 ASTM - American Society for Testing and Materials  
 AAMI - Association for the Advancement of Medical Instrumentation  
 USP - United States Pharmacopeia  
 WFI - Water for Injection