

WATER QUALITY STANDARDS

(A) American Society for Testing and Materials (ASTM) D1193-91

Standard specification for Reagent Grade Water				
	Type 1 *	Type 2 **	Type 3 ***	Type 4
Electrical Conductivity Max. ($\mu\text{S}/\text{cm}$ @ 25°C)	0.056	1.0	0.25	5.0
Electrical Resistivity Min. ($\text{M}\Omega\text{-cm}$ @ 25°C)	18.0	1.0	4.0	0.2
pH @ 25°C	-	-	-	5.0-8.0
TOC max. $\mu\text{g}/\text{l}$	100	50	200	no limit
Sodium max. $\mu\text{g}/\text{l}$	1	5	10	50
Silica max. $\mu\text{g}/\text{l}$	3	3	500	no limit
Chloride max. $\mu\text{g}/\text{l}$	1	5	10	50

* Requires the use of a 0.2 μm membrane filter.

** Prepared by distillation.

*** Requires the use of a 0.45 μm membrane filter.

When bacterial levels need to be controlled, reagent grade types should be further classified as follows:

	Type A	Type B	Type C
Total Bacteria Count max. CFU/100ml	1	10	1000
Endotoxin max. EU/ml	0.03	0.25	-

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(B) National Committee for Clinical Laboratory Standards (NCCLS) - 1988

	Type I	Type II	Type III
Bacteria (CFU/ml)	< 10	> 1000	N/A
pH	N/A	N/A	5.0-8.0
Resistivity (MΩ-cm @ 25°C)	> 10 *	> 1	> 0.1
SiO₂ (mg/l)	< 0.05	< 0.1	< 1
Total Solids (mg/l)	0.1	1	5
Total Oxidisable Organic Carbon (mg/l)	< 0.05	< 0.2	< 1

Type I water must be free of particulate matter larger than 0.2 μ m.

* Resistivity of Type I must be measured in-line.

N/A = not applicable.

Type I

Test methods requiring minimal interference and maximum precision and accuracy, i.e. atomic absorption and flame emission spectrometry, enzymatic procedures sensitive to trace metals, electro-phoretic procedures, high sensitivity chromatographic procedures, buffer solutions, preparation of standard solutions.

Type II

General laboratory testing other than above and glasswashing.

Type III

Glassware washing, preliminary rinsing of glassware and feedwater for producing higher grade water.

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(C) College of American Pathologists (CAP) - 1988

Suggested minimum specifications

	Type I	Type II	Type III
Resistivity (MΩ.cm @ 25°C)			
a. In-line	10.0	-	-
b. Effluent (as used)	-	2.0	0.1
Silicate (mg/l at SiO₂)	0.05	0.1	1.0
pH	N/A	N/A	5.0-8.0
Microbiological Content	10	1000	N/A

Particulate matter - Type I water should be free of particles (< 500 particles/litre) greater than 0.2 μ m.

Suggested water quality uses:

Type I: Tissue or cell culture, ultra-micro analysis, critical analytical procedures, standard preparations.

Type II: Most routine laboratory methods, immunology, haematology and other areas.

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(D) Water Quality Standards for Haemodialysis

Category	Substance	Symbol	AAMI max. level (Also recommended by the RA) *	From EC ** Pharmacopoeia
1	Aluminium	Al	0.01 ppm	0.01 ppm
1	Copper	Cu	0.1 ppm	♦
1	Fluoride	F	0.2 ppm	0.2 ppm
1	Nitrates	NO ₃	2 ppm	2 ppm
1	Sulphate	SO ₄	100 ppm	50 ppm
1	Zinc	Zn	0.1 ppm	0.1 ppm
1	Chloramines		0.1 ppm	
1	Free Chlorine	CL ₂	0.5 ppm	
1	Total Available Chlorine			0.1 ppm
2	Calcium	Ca	2 ppm	2 ppm
2	Magnesium	Mg	4 ppm	2 ppm
2	Potassium	K	8 ppm	2 ppm
2	Sodium	Na	70 ppm	50 ppm
2	Chlorides	Cl		50 ppm
3	Arsenic	As	0.005 ppm	♦
3	Barium	Ba	0.1 ppm	♦
3	Cadmium	Cd	0.001 ppm	♦
3	Chromium	Cr	0.01 ppm	♦
3	Lead	Pb	0.005 ppm	♦
3	Mercury	Hg	0.002 ppm	0.001 ppm
3	Selenium	Se	0.01 ppm	
3	Silver	Ag	0.005 ppm	♦
	pH			6-8 pH
	Oxidisable Substances			nil
	Ammonium			0.2 ppm
	Heavy Metals			0.1 ppm
	Microbial Contamination		TVC < 200 per ml	TVC < 100 per ml
	Endotoxins		10.0 EU/ml	< 0.25 EU/ml

Categories 1 Toxic substances described in Dialysis literature.

2 Non-toxic substances included in dialysis fluid.

3 Substances described as toxic in Drinking Water literature.

* From a draft document by the Standards Subcommittee of the Renal Association.

** From 'Water for diluting concentrated haemodialysis solutions' Annex to the European Pharmacopoeia Fasciculé 16. (Adopted by the Council of Europe).

♦ Included in the global limit for Heavy Metals

AAMI The Association for the Advancement of Medical Instrumentation (USA) 1981

RA The Renal Association
EC European Community 1992
01.01.95

Date: