

PRODUCT SPECIFICATIONS SHEET
WORLD/GMP GRADE
PURIFIED WATER

Meets USP/EP/JP Monographs
0.22 micron filtered

With USP<232>, EMA and ICH Q3D Test Results

Catalog No: 232WORLD -Size Code*

Recommended Retest Date: Eighteen Months from the Date of Manufacture

55 gallon Poly Drums

Manufactured in compliance with cGMP

TEST	MONO- GRAPH	SPECIFICATION	TYPICAL RESULT
Appearance	EP	Clear colorless liquid	Pass
Total Organic Carbon ¹	USP/EP	<0.50 mg C/L	<0.05 mg C/L
Water Conductivity ¹	USP/EP	NMT 1.3 µS/cm at 25C	<0.1 µS/cm
Nitrates	EP	0.2 ppm max	<0.2 ppm
Acidity or Alkalinity Purity 1 - Acidity or Alkalinity	EP JP	Acidity-No blue color develops Alkalinity- yellow/orange color develops - not red	Pass
Chlorides Purity 2 - Chloride	EP JP	No change occurs	Pass
Sulfates Purity 3 - Sulfate	EP JP	No change occurs	Pass
Purity 4 - Nitrogen from Nitrate	JP	No yellow color develops	Pass
Purity 5 - Nitrogen from Nitrite	JP	No pale red color develops	Pass
Ammonium Purity 6 - Ammonium	EP JP	NMT 0.2 ppm NMT 0.05 mg/L	<0.2 ppm <0.05 mg/L
Heavy Metals Purity 7 - Heavy Metals	EP JP	0.1 ppm max No change occurs	<0.1 ppm Pass
Purity 8 - Potassium Permanganate- Reducing Substances	JP	The red color does not disappear	Pass
Residue on Evaporation Purity 9 - Residue on Evaporation	EP JP	NMT 0.001% NMT 1.0 mg	<0.001% <1.0 mg
Oxidisable Substances	EP	The solution remains faintly pink	Pass
Calcium and Magnesium	EP	A pure blue color is produced	Pass
Microbial Contamination (TAMC)	EP	≤10 ² CFU/mL (200 CFU/mL)	≤ 10 CFU/mL
Microbial Limits	USP	≤100 CFU/mL	≤10 CFU/mL
Microbiological Monitoring	EP	≤100 CFU/mL	≤10 CFU/mL

¹ Meets stated value at the time of manufacture.

Not intended for use as a sterile or potable product or in the manufacture of dialysis solutions.

Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients¹

Reported in µg/g (ppm)

Element	Class	Oral Concentration µg/g	Parenteral Concentration µg/g	Inhalation Concentration µg/g	TYPICAL RESULT (in µg/g) (ppm)
Cd (Cadmium)	1	0.5	0.2	0.2	0.00
Pb (Lead)	1	0.5	0.5	0.5	0.00
As (Arsenic)	1	1.5	1.5	0.2	0.00
Hg (Mercury)	1	3	0.3	0.1	0.00
Co (Cobalt)	2A	5	0.5	0.3	0.00
V (Vanadium)	2A	10	1	0.1	0.00
Ni (Nickel)	2A	20	2	0.5	0.00
Tl (Thallium)	2B	0.8	0.8	0.8	0.00
Au (Gold)	2B	10	10	0.1	0.00
Pd (Palladium)	2B	10	1	0.1	0.00
Ir (Iridium)	2B	10	1	0.1	0.00
Os (Osmium)	2B	10	1	0.1	0.00
Rh (Rhodium)	2B	10	1	0.1	0.00
Ru (Ruthenium)	2B	10	1	0.1	0.00
Se (Selenium)	2B	15	8	13	0.00
Ag (Silver)	2B	15	1	0.7	0.00
Pt (Platinum)	2B	10	1	0.1	0.00
Li (Lithium)	3	55	25	2.5	0.00
Sb (Antimony)	3	120	9	2	0.00
Ba (Barium)	3	140	70	30	0.00
Mo (Molybdenum)	3	300	150	1	0.00
Cu (Copper)	3	300	30	3	0.00
Sn (Tin)	3	600	60	6	0.00
Cr (Chromium)	3	1100	110	0.3	0.00

¹Includes all requirements for ICH Q3D-Step 4 version, EMA (EP) 5.2 and USP <232> and <233> General Chapters.

Form: Water, USP/EP/JP Rev 2.2, 06/16, KAD

This product is for further commercial manufacturing, laboratory or research use, and may be used as an excipient or a process solvent for pharmaceutical purposes. It is not intended for use as an active ingredient in drug manufacturing nor as a medical device or disinfectant. Appropriate/legal use of this product is the responsibility of the user.