

# Product Specification

## Water, USP/EP Purified

**Lot Number:** SAMPLE

**Product Number:** 9190

**Date Packaged:** N/A

**Expiration Date:** N/A

This product is manufactured by a continuous process that has been validated under cGMP to produce high purity Water meeting, as a minimum, the specifications below at time of packaging. The analysis results are from the most recent scheduled monitoring. (Consult RICCA CHEMICAL COMPANY Technical Reference Document TRD04 for information regarding quantitative interpretations of USP and EP limit tests.)

This product has a low microbial count, but is not filled in a sterile area or into sterilized containers. Therefore, this water is not sterile and should not be used for injection or parenteral solution preparation.

Per USP <1231>, "It is the user's responsibility to ensure fitness for use of this packaged article when used in manufacturing, clinical, or analytical applications where the pure bulk form of the water is indicated."

### Contains

H<sub>2</sub>O CAS No. 7732-18-5 MW 18.02

Test	Specification	Result
Acidity or Alkalinity	To Pass Test	N/A
Ammonia (NH <sub>3</sub> )	max 0.3 ppm	N/A
Ammonium (NH <sub>4</sub> )	max 0.2 ppm	N/A
Appearance	Clear, colorless liquid	N/A
Calcium (Ca)	max 0.5 ppm	N/A
Carbon Dioxide (CO <sub>2</sub> )	To Pass Test	N/A
Chloride (Cl)	max 0.5 ppm	N/A
Conductivity at 25°C	max 1 µS/cm	N/A
Endotoxins (Chromogenic determination)	max 0.25 EU/mL	N/A
Heavy Metals (as Pb)	max 0.1 ppm	N/A
Magnesium (Mg)	max 0.5 ppm	N/A
Microbial Count (at time of manufacture)	max 100 CFU/mL	N/A
Nitrate (NO <sub>3</sub> )	max 0.2 ppm	N/A
Organic Carbon (TOC)	max 0.50 ppm	N/A
Oxidizable Substances (Permanganate Retention)	To Pass Test	N/A
pH at 25°C	5.0-7.0	N/A
Residue after evaporation (Non-Volatile Matter)	max 0.001 %	N/A
Sulfate (SO <sub>4</sub> )	max 0.5 ppm	N/A

Specification	Reference
Purified Water	EP (2009:0008)
Water R	EP (1095500)
Purified Water	USP (N/A)

This water is specially purified by conventional water softening, prefiltration, activated carbon organic adsorption, reverse osmosis, mixed bed triple deionization, ultraviolet light irradiation, and 0.2 micron membrane filtration. Consult RICCA CHEMICAL COMPANY Technical Reference Document TRD02 (for lot numbers starting with 1) or TRD03 (for lot numbers starting with 2) for details of the water purification process.

Part Number	Size / Package Type	Shelf Life (Unopened Container)
9190-2.5	10 L Cubitainer®	12 months
9190-5HP	20 L Ropak™	12 months

9190-5	20 L Cubitainer®	12 months
9190-1	4 L natural poly	12 months
9190-1G	4 L amber glass	12 months
9190-1CT	4 L Cubitainer®	12 months

**Recommended Storage:** 15°C - 30°C (59°F - 86°F)

This Certificate of Analysis is designed to comply with ISO Guide 31 "Reference Materials -- Contents of Certificates and Labels."