

# Certificate of Analysis

## Water, USP/EP Purified

**Lot Number:** 1404G22

**Product Number:** 9190

**Date Packaged:** APR 11, 2024

**Expiration Date:** APR 2025

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	Passed
Ammonia (NH <sub>3</sub> )	max 0.3 ppm	<= 0.00026 ppm
Ammonium (NH <sub>4</sub> )	max 0.2 ppm	<= 0.000275 ppm
Appearance	Clear, colorless liquid	Passed
Calcium (Ca)	max 0.5 ppm	<= 0.00002 ppm
Carbon Dioxide (CO <sub>2</sub> )	To Pass Test	Passed
Chloride (Cl)	max 0.5 ppm	<= 0.00012 ppm
Conductivity at 25°C	max 1 µS/cm	0.05634 µS/cm
Endotoxins (Chromogenic determination)	max 0.25 EU/mL	<= 0.0005 EU/mL
Heavy Metals (as Pb)	max 0.1 ppm	<= 0.01 ppm
Magnesium (Mg)	max 0.5 ppm	<= 0.00002 ppm
Microbial Count (at time of manufacture)	max 100 CFU/mL	< 1 CFU/mL
Nitrate (NO <sub>3</sub> )	max 0.2 ppm	< 0.00002 ppm
Organic Carbon (TOC)	max 0.50 ppm	0.01 ppm
Oxidizable Substances (Permanganate Retention)	To Pass Test	Passed
pH at 25°C (Method: SQCP027, SQCP033)	5.0-7.0	6.4
Residue after evaporation (Non-Volatile Matter)	max 0.001 %	0 %
Sulfate (SO <sub>4</sub> )	max 0.5 ppm	< 0.00005 ppm

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)
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9190-5HP

20 L Ropak™

12 months

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



Heidi J Green (04/11/2024)

Operations Manager

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

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