

# Certificate of Analysis

## Water, USP / EP / JP Purified

**Lot Number:** 2404F24

**Product Number:** R9189000

**Date Packaged:** APR 12, 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, EP, and JP 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	To Pass Test	Passed
Alkalinity	To Pass Test	Passed
Ammonia (NH <sub>3</sub> )	max 0.05 ppm	0.00011 ppm
Appearance	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 0.1 ppm	0.00017 ppm
Conductivity at 25°C	max 1 µS/cm	0.055 µS/cm
Endotoxins (Chromogenic determination)	max 0.25 EU/mL	< 0.01 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	3 CFU/mL
Nitrate (NO <sub>3</sub> )	max 1 ppb	< 0.02 ppb
Nitrogen (as Nitrite) (NO <sub>2</sub> -N)	max 1 ppb	< 0.02 ppb
Organic Carbon (TOC)	max 0.5 ppm	0.027 ppm
Oxidizable Substances (Permanganate Retention)	To Pass Test	Passed
pH at 25°C (Method: SQCP027, SQCP033)	5.0-7.0	6.3
Residue after evaporation (Non-Volatile Matter)	max 0.001 %	0.0004 %
Sulfate (SO <sub>4</sub> )	max 0.5 ppm	< 0.00005 ppm

Specification	Reference
Water R	EP (1095500)
Purified Water	EP (1997:0008)
Purified Water	JP (N/A)
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)
-------------	---------------------	---------------------------------

R9189000-20E1

20 L Ropak™

12 months

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



Jose Pena (04/12/2024)

Operations Manager

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

This test report shall not be reproduced, except in full, without the written approval of Ricca Chemical Company.