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## Certificate of Analysis

Water, USP / EP / JP Purified

Lot Number: 2404H98 Product Number: R9189000

Date Packaged: APR 23, 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>9</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      | $0.027~\mathrm{ppm}$ |
| 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        |

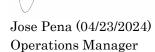
| Specification  | Reference      |
|----------------|----------------|
| Water R        | EP (1095500)   |
| Purified Water | EP (1997:0008) |
| Purified Water | JP (N/A)       |
| Purified Water | USP (N/A)      |

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.

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| Part Number   | Size / Package Type      | Shelf Life (Unopened Container) |
|---------------|--------------------------|---------------------------------|
| R9189000-20E1 | 20 L Ronak <sup>TM</sup> | 12 months                       |

Recommended Storage:  $15^{\circ}\text{C}$  -  $30^{\circ}\text{C}$  ( $59^{\circ}\text{F}$  -  $86^{\circ}\text{F}$ )



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