

Certificate of Analysis

Water, USP/EP Purified

Lot Number: 1404H30

Product Number: 9190

Date Packaged: APR 16, 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

 H₂O CAS No. 7732-18-5 MW 18.02

| Test | Specification | Result |
|---|-------------------------|-------------|
| Acidity or Alkalinity | To Pass Test | Passed |
| Ammonia (NH ₃) | max 0.3 ppm | 0.00002 ppm |
| Ammonium (NH ₄) | max 0.2 ppm | 0.00002 ppm |
| Appearance | Clear, colorless liquid | Passed |
| Calcium (Ca) | max 0.5 ppm | 0.00002 ppm |
| Carbon Dioxide (CO ₂) | To Pass Test | Passed |
| Chloride (Cl) | max 0.5 ppm | 0.00004 ppm |
| Conductivity at 25°C | max 1 µS/cm | 0.056 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 | < 1 CFU/mL |
| Nitrate (NO ₃) | 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 | 6.5 |
| Residue after evaporation (Non-Volatile Matter) | max 0.001 % | 0.001 % |
| Sulfate (SO ₄) | 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) |
|-------------|---------------------|---------------------------------|
|-------------|---------------------|---------------------------------|

| | | |
|--------|------------------|-----------|
| 9190-1 | 4 L natural poly | 12 months |
|--------|------------------|-----------|

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



Heidi J Green (04/16/2024)
Operations Manager

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