

Certificate of Analysis

**Water, USP Purified
STERILE Filtered, WFI Quality****Lot Number:** 9311473**Product Number:** R9192000**Date Packaged:** NOV 01, 2023**Expiration Date:** NOV 2024

This product was filtered through a 0.22-micron sterile filter and added to the packaging in a certified ISO Class 7 clean room through a closed system. The packaging used for the containment of this product is sterilized by gamma irradiation prior to use. This water also meets USP requirements for Purified Water, Sterile.

Test results labeled (Bulk Water) are from the monthly water system quality analysis. Other test results are for the packaged product. The conductivity of the packaged product is measured in line without temperature compensation and meets the requirements of USP <645> Stage I (max. 1.3 µS/cm at 25°C).

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."

Prior to performing TOC testing, it is recommended to flush the spigot with at least 1L of the sterile filtered water.

Contains**H₂O** CAS No. 7732-18-5 MW 18.02

Test	Specification	Result
Bacterial Endotoxin - USP <85>	< 0.2500 EU/mL	< 0.0100 EU/mL
Conductivity (Bulk Water) at 25°C - USP <645>	max 1.300 µS/cm	0.800 µS/cm
Conductivity (Packaged Water) - USP <645>	Meets Requirements	0.600 µS/cm
Conductivity Measurement Temperature (Packaged Water)	Actual Value Reported	25.0 °C
Sterility USP <71>: No Growth	No Growth	No Growth
Total Organic Carbon (Bulk Water) - USP <643>	max 500 ppb	30 ppb
Total Organic Carbon (Packaged Water) - USP <643>	max 500 ppb	29 ppb

This USP Purified Water, Sterile Filtered is prepared by reverse osmosis and sterile filtration. No antimicrobial or other substance has been added. This water is not intended for direct parenteral administration; it is for use in research and manufacturing.

Part Number	Size / Package Type	Shelf Life (Unopened Container)
R9192000-20S	20 L Poly Bag in Box	12 months

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



Heidi J Green (11/01/2023)

Operations Manager

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

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