



AquaPurST

Lot Specific Certificate of Analysis, Irradiation, Sterility, and Bacterial Endotoxins Testing

Product: AquaPur ST, meets USP specifications for Sterile Purified Water

Description: Decon # 8904 (1 Gallon 4/cs)

Lot # 791065 with an expiration date of April 2022 has been manufactured in April 2020 and sterilized within the following parameters.

Certificate of Analysis

DATE: April 2020

USP Water Conductivity	≤ 1.3 umhos/cm*	Pass
USP <645>		

USP Total Organic Carbon	< 0.5 PPM	Pass
USP <643>		

*At the time of manufacturing

Endotoxin Testing:

Date: 06/17/2020

USP Method

Test Result

Current Method

<0.25 EU/mL

Bacterial Endotoxin Test

(Non-Pyrogenic)

Irradiation Details:

Date: 05/23/2020

Specified Dose (kGy)

Delivered Dose (kGy)

Min: 15.0 Max: 50.0

Min: 18.1 Max: 42.2

Sterility Testing:

Date: 06/26/2020

USP Method

Test

Test Result

USP Current Method

Filter Membrane
(14 day incubation)

Pass

C of A and Irradiation results were provided by the manufacturing and irradiation facilities. Sterility and bacterial endotoxin testing results were provided by an accredited independent testing lab. Details on file at Decon Labs and are available upon request.

Reviewed and Approved by:

Date: June 2020

Karen Wend

Manager, Quality and Technical Services

COA template revised 10/26/2016: Addition of Statements: Method of preparation and meets USP specifications for Sterile Purified Water. Clarification of Conductivity Specification.

BSE/TSE Statement: There are no materials of animal origin in the raw materials or in the process aides used to manufacture any Decon products.

AquaPur ST is prepared by deionization, reverse osmosis, UV treatment, ultrafiltration, and gamma irradiation.

Not for Parenteral use, not for injection, wound irrigation or infusion, not for dialysis.