teknova:

Certificate of Analysis
GMP Manufactured

Product Name: **WFI Quality Water, 200 L, Sterile-Filtered.**

Part Number:	20143
Lot Number:	20143######
Date Manufactured:	DD-MMM-YYYY
Expiration Date	MM-YYYY

Appearance:	Clear and colorless
Method of Sterilization:	0.1µm Sterile filtration
Storage Conditions:	Room Temperature, 15°C-25°C

Batch Release Test	Specification	Result
Bioburden	≤10 CFU/ 100mL	
Conductivity (USP <645>)	Pass	
Endotoxin (USP<85>)	< 0.25EU/mL	
pH	Pass	
Sterility (USP <71>)	No Growth	
Total Organic Carbon (TOC) (USP <643>)	≤8000ppb	

Water System Testing*	Specification	Result
Ammonium	≤ 0.2 ppm	
Calcium and Magnesium	Passes EP test for Sterilized Water for Injection	
Chlorides	Passes EP test for Sterilized Water for Injection	
Density	Pass	
DNase[†]	Pass	
EP Nitrates	≤ 0.2 ppm	
Mycoplasma (USP <63>)	None Detected	
Osmolality	Pass	
Oxidizable Substance	Passes EP test for Sterilized Water for Injection	
Particulate Matter (USP <788>)	≥10µm: ≤25/mL ≥25µm: ≤ 3/mL	
Protease[‡]	Pass	
RNase[††]	Pass	
Sulfates	Passes EP test for Sterilized Water for Injection	
Total Organic Carbon (TOC) (USP <643>)	≤ 500 ppb	

Water System Testing* : The above tests are conducted against the Water System on a routine basis.
DNase[†]: Assessed with quantitative bacterial DNase fluorescence detection using DNaseAlert assay.
Protease[‡]: Assessed with quantitative bacterial protease fluorescence detection using Pierce assay.
RNase[††]: Assessed with quantitative bacterial RNase fluorescence detection using RNase Alert assay.

Conformance Statement: This is to certify that this product conforms to the specifications above. This product is GMP manufactured in compliance with Teknova's Quality Management System certified to ISO 13485. This product is tested in accordance with documented quality procedures and approved as a result of meeting the required specification.

Date QC Released:

Released By:

<u>Title of Releaser</u>