

Certificate of Analysis

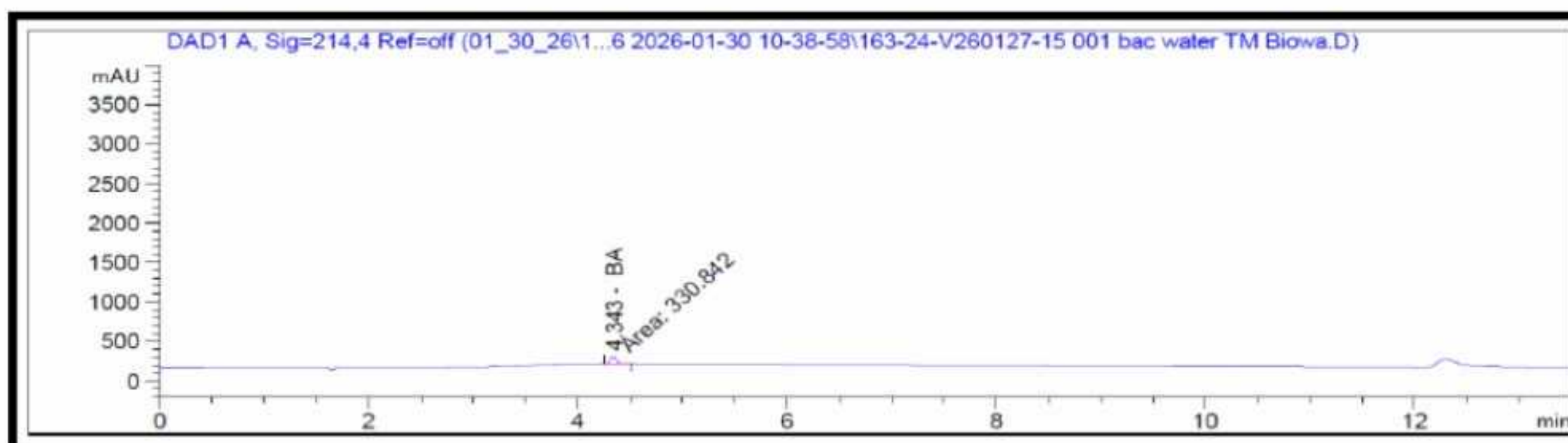
Report To:
TM BLOWATER, INC

Compound: Bacteriostatic Water
Amount: 10ml
Laboratory ID: BTUS060226-1
Date Reported: 02-5-2026 Lot
Number: 26227-b11 Batch
Number: 02



Analysis	Method	Result	Acceptable Range (unit)
Benzyl Alcohol Content	HPLC-UV/VIS	0.9%	0.72%-1.08%
pH	USP <791>	6.66	4.0-7.0
Endotoxins	LAL	53.1	EU/mL
Total Dis. Solids (TDS)	SM 2540C	≤ 1.3	μS/cm
Conductivity	SM 2510B	9.23	uS/cm

Pass/Fail according to US Pharmacopeia <1231> limits.



Product Identification

- **Product Name:** Water for Injection (WFI)
- **Grade:** USP / EP / JP Compliant
- **Intended Use:** Pharmaceutical / Biotech Manufacturing
- **Dosage Form:** Aqueous Solution
- **Route of Administration:** Parenteral (as component)
- **Storage Conditions:** 20–25°C, protect from contamination
- **Shelf Life:** 24 months from date of manufacture (validated) ☐ 40 °C / 75% RH 1 month

Batch Information

- **Product Code:** TMB-WFI-STD-2026
- **Lot / Batch Number:** 26227-b11
- **Manufacturing Date:** 02-01-2026
- **Expiry / Retest Date:** 02-05-2026
- **Quantity Released:** N/A
- **Manufacturing Site:** New Orleans Louisiana
- **Container / Closure:** 02-06-2026

Composition

- **Water Content:** 99.1%
- **Additives / Preservatives:** 0.9%
- **Source:** Purified Water / ROx2 WFI **USP <1231> is guidance, not a pass/fail monograph.**
Enforceable limits come from chapters like **USP <645> (Conductivity)**, **USP <643> (TOC)**, **USP <71> (Sterility)**, and **USP <85> (Endotoxins)**.

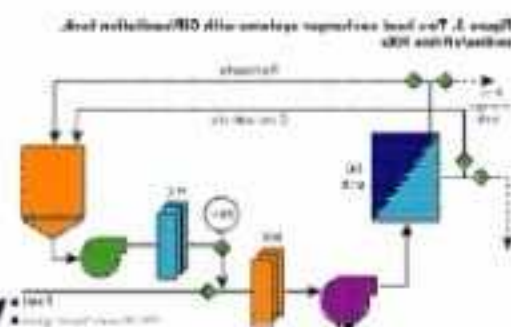
Analytical Results (20 Parameters)

#	Test Parameter	Specification (USP/EP)	Method	Result	Status
1	Appearance	Clear, colorless	Visual	C/C	Pass
2	Odor	Odorless	Organoleptic	Od	Pass
3	pH (25°C)	5.0 – 7.0	USP <791>	6.21	Pass
4	Conductivity (25°C)	≤ 1.3 µS/cm	USP <645>	13µS/cm	Pass
5	Resistivity (25°C)	≥ 0.77 MΩ·cm	USP <645>	N/A	N/A
6	Total Organic Carbon (TOC)	≤ 500 ppb	USP <643>	388	Pass

#	Test Parameter	Specification (USP/EP)	Method	Result	Status
7	Total Dissolved Solids (TDS)	≤ 10 ppm	Gravimetric	≤7ppm	Pass
8	Turbidity	≤ 1.0 NTU	USP <855>	.67	Pass
9	Particulate Matter	Meets USP requirements	USP <788>	N/A	N/T
10	Bacterial Endotoxins	≤ 0.25 EU/mL	USP <85> (LAL)	0.10–0.25	Pass
11	Sterility	No growth	USP <71>	N/A	N/T
12	Bioburden	≤ 10 CFU/100 mL	USP <61>	N/A	N/T
13	Nitrates	≤ 0.2 ppm	USP <353>	ND ₃ .13	Pass
14	Chlorides	≤ 0.5 ppm	USP <221>	0.0	Pass
15	Sulfates	≤ 0.5 ppm	USP <221>	N/A	N/T
16	Ammonia	≤ 0.2 ppm	USP <261>	0.0	Pass
17	Calcium & Magnesium	≤ 1.0 ppm	ICP-OES	.8	Pass
18	Heavy Metals (as Pb)	≤ 0.1 ppm	USP <232>/<233>	≤0.1ppm	Pass
19	Silicates	≤ 1.0 ppm	Spectrophotometric	N/T	Pass
20	Oxidizable Substances	Pass	USP <401>	0.0	Pass

Microbiological Summary

- **Sample Location:** Final loop return / point of use
- **Loop Temperature:** ≥ 80°C (hot loop) ☐ / Ambient ☒ 20–25 °C
- **Sanitization Method:** Thermal ☒ ☐ Ozone ☐ Chemical ☐



- **Frequency:** ☐ ☒ ☐

Compliance Statement

This lot of **Water for Injection (WFI)** was produced, sampled, tested, and released in accordance with **USP <1231>**, **USP <645>**, **USP <643>**, **USP <71>**, **USP <85>**, and applicable **cGMP (21 CFR Parts 210 & 211)** requirements. Third party verification by Vanguard Laboratories returned results 02/05/2026 with Pass.

Final Disposition

- ☒ **PASS – RELEASED**
☐ **FAIL – Rejected**
☐ **HOLD – Investigation Required**

Authorization

Reviewed By (QA): Brian Lakin Date: 02-05-2026
 Authorized Release: [Signature] Date: 02-06-2026

Biotech. US, Inc.

Address: 1309 Coffeen Ave, Sheridan, WY 82801

Vanguard Laboratory

Vanguard Labors 2635 Parkmont Ln Olympia, WA 98502

Email: bio.us.director@outlook.com

Notes (Important)

- This COA is WFI-correct (0.9% preservative, no bacteriostatic claims).
- If this WFI feeds aseptic filling, retain USP sterility closed loop system.
- If used as bulk process water, sterility may be removed but endotoxin must remain.

Composition

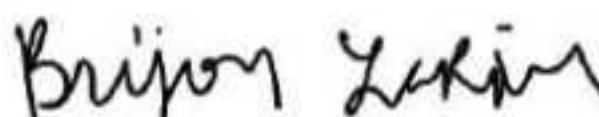
- **Water Content:** 100.0%
- **Additives / Preservatives:** None
- **Source:** Purified Water further processed by distillation or equivalent membrane process per USP <1231>

Notes (Important)

Please consult A2LA Certificate #6377.01.11 for a list of accredited tests. Samples were received in acceptable condition. The result(s) in this report relate only to the portion of the sample(s) tested. All analyses were performed consistent with the B.US Quality Management System. B.US and its staff performed sample selection process. However, third-party Vanguard Labs did not observe or participate in the sample selection process and cannot confirm the authenticity of the sample or its representativeness of the associated lot/batch.



Report By: Brijon LaRive, Laboratory Director



Approved by: Patrick LaRive PHD. CEO/ President

