Axiom
ANALYTICS

CERTIFICATE OF ANALYSIS · DX DILUENT & SOLVENT PANEL

Axiom Analytics Laboratories
2108 N St Ste N, Sacramento, CA 95816 US

AX-2026-1283-TK58

Bacteriostatic Water for Injection, USP (0.9% benzyl alcohol added) · Lot T-BAC-0093
Issued Oct 17, 2026 PT · v1
Verify: E8D4-3EA7-082A

SCAN TO VERIFY

PASS — ALL SPECIFICATIONS MET

7 of 7 layers complete

L1	L2	L3	L4	L5	L6	L7
Identity	Chromatographic & Carrier Purity	Declared Content	Sterility	Endotoxin	Heavy Metals	Physicochemical Properties

Sample & Vial Validation



Vial A: as received & analyzed

MORE VIEWS OF VIAL A



Vial A · right

Brand	**Research Vault Group**	Product	**Bacteriostatic Water for Injection, USP (0.9% benzyl alcohol added)**
Lot / Batch	**T-BAC-0093**	Label Claim	**10 mL**
Matrix	**solution**	Sample Count	**1**
Vial Size	**10mL**	Cap Color	**Black**
Crimp Color	**Silver / Aluminum**	Contents Color	**Clear/Translucent**
Seal Intact	**Yes**	Condition	**sealed, intact**
Received	**Oct 13, 2026 PT**	Sampling	**client submitted**

Results relate only to the item or portion tested. Unless sampling was performed or witnessed by Axiom Analytics, the laboratory does not attest that the submitted sample represents the wider lot or batch. A PASS designation means only that the reported result met the specification shown. It does not establish safety, efficacy, regulatory approval, legality, or suitability for human or animal use.

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Test Results

Test	Specification	Result	
Identity · GC-FID verified compendial	retention time corresponds to the reference standard run on the same sequence	analyte 6.61 min, reference standard 6.59 min	PASS
Purity · GC-FID verified compendial	at least 99.25% by GC area normalisation, largest single impurity at or below 0.3%, total impurities at or below 0.5%	99.88% GC area% (largest single impurity 0.15%, total impurities 0.25%)	PASS
Benzyl Alcohol Content verified compendial	80-120% of the frozen label claim; stored percentage must equal measured content / declared content × 100; USP <341> system suitability and traceability required	0.950705 % w/v · 105.6339% of the 0.9% w/v label claim	PASS
Sterility · Rapid PCR research screen	Rapid PCR screen	Target DNA not detected	PASS
Endotoxin verified compendial	< 0.5 EU/mL (USP <85>)	0.21 EU/mL	PASS
Heavy Metals research screen	ICH Q3D(R2) Table A.2.2, parenteral route	All below limits	PASS
pH research screen	pH within 4.50 - 7.00	pH 6.3	PASS
Visual Appearance research screen	colorless; clear; free from visible particles	colorless; clear; no visible particles observed	PASS

Layer Results

1 Identity · GC-FID

GC-FID identity vs reference standard (USP <621>)

analyte 6.61 min, reference standard 6.59 min — PASS
retention time corresponds to the reference standard run on the same sequence

Result	**analyte 6.61 min, reference standard 6.59 min**	Acceptance	**retention time corresponds to the reference standard run on the same sequence**

2 Purity · GC-FID

GC-FID chromatographic purity, area% (USP <621>)

99.88% GC area% (largest single impurity 0.15%, total impurities 0.25%) — PASS
at least 99.25% by GC area normalisation, largest single impurity at or below 0.3%, total impurities at or below 0.5%

Result	**99.88% GC area% (largest single impurity 0.15%, total impurities 0.25%)**	Acceptance	**at least 99.25% by GC area normalisation, largest single impurity at or below 0.3%, total impurities at or below 0.5%**
Criterion source	**Axiom Analytics SPEC-PURITY-001, Revision 1, effective 2026-08-31**		

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3 Benzyl Alcohol Content

Benzyl alcohol preservative content by GC-FID (USP <341>)

0.950705 % w/v · 105.6339% of the 0.9% w/v label claim
80-120% of the frozen label claim; stored percentage must equal measured content / declared content × 100; USP <341> system suitability and traceability required

PASS

Result	**0.950705 % w/v; 105.6339% of the 0.9% w/v label claim**	Acceptance	**80-120% of the frozen label claim; stored percentage must equal measured content / declared content × 100; USP <341> system suitability and traceability required**

4 Sterility · Rapid PCR

Rapid Microbial DNA Screen (qPCR target panel)

Target DNA not detected
Rapid PCR screen

PASS

Result	**Target DNA not detected**	Acceptance	**Rapid PCR screen**
Units	**qualitative DNA target call**	Reporting threshold	**Pan-bacterial VIC Ct 34; Pan-fungal FAM Ct 33**

5 Endotoxin

Bacterial endotoxin, USP <85> (kinetic chromogenic LAL)

0.21 EU/mL
< 0.5 EU/mL (USP <85>)

PASS

Result	**0.21 EU/mL**	Acceptance	**< 0.5 EU/mL (USP <85>)**
Source container	**A**		

6 Heavy Metals

ICP-MS (USP 232/233)

All below limits
ICH Q3D(R2) Table A.2.2, parenteral route

PASS

Result	**All below limits**	Acceptance	**ICH Q3D(R2) Table A.2.2, parenteral route**
Source container	**A**		

Element	Specification	Result	Status
Lead (Pb)	≤ 0.5 ppm (µg/g)	Not Detected	PASS
Arsenic (As)	≤ 1.5 ppm (µg/g)	Not Detected	PASS
Cadmium (Cd)	≤ 0.2 ppm (µg/g)	Not Detected	PASS
Mercury (Hg)	≤ 0.3 ppm (µg/g)	Not Detected	PASS
Cobalt (Co)	≤ 0.5 ppm (µg/g)	Not Detected	PASS
Vanadium (V)	≤ 1 ppm (µg/g)	Not Detected	PASS
Nickel (Ni)	≤ 2 ppm (µg/g)	Not Detected	PASS

7 pH

pH (USP <791>) + Submitted-container visual appearance and visible-particle screen

pH 6.3
pH within 4.50 - 7.00

PASS

Result	**pH 6.3**	Acceptance	**pH within 4.50 - 7.00**
Source container	**A**		

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7 Visual Appearance

pH (USP <791>) + Submitted-container visual appearance and visible-particle screen

colorless; clear; no visible particles observed
colorless; clear; free from visible particles

PASS

Result	**colorless; clear; no visible particles observed**	Acceptance	**colorless; clear; free from visible particles**
Source container	**A**		

Reporting Scope & Limitations

`[Sterility · Rapid PCR]` DNA-target research screen only. It detects microbial DNA from viable and non-viable organisms alike, and is neither viable-CFU enumeration under USP <61> nor a batch sterility determination under USP <71>.

Digital Signatures

Analyst	**Alana Reeves**	Analyst Signature	**ed25519:902cc8fc9902ea142ecb4828...**
Technical Reviewer	**Michael Niles**	Reviewer Signature	**ed25519:ac9e83c0a67ca9a790a0ad24...**
Laboratory Director	**Daniel Brennan**	Director Signature	**ed25519:09ffb65ad0ff73550788dc4d...**

Where physical instrument analysis is performed, it takes place within Axiom Analytics' laboratory network, allocated at Axiom's discretion based on method, capacity, and order volume. Axiom Analytics performs sample accession, chain of custody, analytical oversight, and data review, and issues and is responsible for this certificate. Where analysis is subcontracted, the method is performed within the partner laboratory's published ISO/IEC 17025 scope of accreditation for that method, not merely at a laboratory holding ISO/IEC 17025 accreditation. Axiom Analytics does not itself currently hold ISO/IEC 17025 accreditation. The method-validation status of each reported result is identified beside that result. Partner laboratory identities are not disclosed: where samples are analyzed under double-blind conditions, they are identified only by an internal lot ID.

Each signature is an ed25519 signature over the SHA-384 hash of this report. Scan the QR on the letterhead or verify independently at https://axiomanalyticslab.com/verify/AX-2026-1283-TK58.

CRYPTOGRAPHICALLY SEALED (ed25519 + SHA-384)

SHA-384: 5836f1d5d652be2053585caeeaf110ae77c7bde2e211cb58f5f2df156b696349...

Seal: ed25519:5fc3f1506e84cc66e5bfe806566d66ce16643ce0...

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