



SCAN TO VERIFY

PASS — ALL SPECIFICATIONS MET

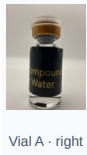
7 of 7 layers complete

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

 Vial A: as received & analyzed	Brand	Vault compounds Llc	Product	Bacteriostatic Water for Injection, USP (0.9% benzyl alcohol added)
	Lot / Batch	BACWAT-3ML-2609-JYZ	Label Claim	3 mL
	Matrix	solution	Sample Count	1
	Vial Size	3mL	Cap Color	Clear
	Crimp Color	Bronze	Contents Color	Clear/Translucent
	Seal Intact	Yes	Condition	sealed, intact
	Received	Oct 8, 2026 PT	Sampling	client submitted

MORE VIEWS OF VIAL A



Vial A - right



CERTIFICATE OF ANALYSIS · DX DILUENT & SOLVENT PANEL

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

AX-2026-4274-68K8

Bacteriostatic Water for Injection, USP (0.9% benzyl alcohol added) ·
Lot BACWAT-3ML-2609-JYZ
Issued Oct 15, 2026 PT · v1
Verify: 0DD9-9B0C-BB08



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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 6.47 min, reference standard 6.48 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%	99.75% 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	0.874676 % w/v · 97.1862% 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 4.75	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 6.47 min, reference standard 6.48 min retention time corresponds to the reference standard run on the same sequence	PASS
Result	analyte 6.47 min, reference standard 6.48 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>)	99.75% GC area% (largest single impurity 0.15%, total impurities 0.25%) at least 99.25% by GC area normalisation, largest single impurity at or below 0.3%, total impurities at or below 0.5%	PASS
Result	99.75% 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		



3	Benzyl Alcohol Content		0.874676 % w/v · 97.1862% of the 0.9% w/v label claim		PASS
	Benzyl alcohol preservative content by GC-FID (USP <341>)		80-120% of the frozen label claim; stored percentage must equal measured content / declared content × 100; USP <341> system suitability and traceability required		
	Result		0.874676 % w/v; 97.1862% 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		Target DNA not detected		PASS
	Rapid Microbial DNA Screen (qPCR target panel)		Rapid PCR screen		
	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		0.21 EU/mL		PASS	
	Bacterial endotoxin, USP <85> (kinetic chromogenic LAL)		< 0.5 EU/mL (USP <85>)			
Result		0.21 EU/mL	Acceptance	< 0.5 EU/mL (USP <85>)		
Source container		A				

6	Heavy Metals		All below limits		PASS		
	ICP-MS (USP 232/233)		ICH Q3D(R2) Table A.2.2, parenteral route				
	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 4.75		PASS	
	pH (USP <791>) + Submitted-container visual appearance and visible-particle screen		pH within 4.50 - 7.00			
Result		pH 4.75	Acceptance	pH within 4.50 - 7.00		
Source container		A				



SCAN TO VERIFY

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

ed25519:6fd2edeb9d4add3403393f73...

Technical Reviewer

Michael Niles

Reviewer Signature

ed25519:03112b94746e9f645ae68e79...

Laboratory Director

Daniel Brennan

Director Signature

ed25519:b0df67c69986a9804897eb36...

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Seal: ed25519:62e13b6903e2eb40f2fff638ed7ce45ed5716f09...

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