Customer:
BacWaterMax

EA Sample ID: 26EA1013-042
Sample Name: Reconstitution Solution 5ml
Sample Type: Liquid
Batch/Lot: BW26830

Date Received:
10/14/2026
Date Completed:
10/30/2026

ETHOS ANALYTICS

CERTIFICATE OF ANALYSIS

Summary of Results

Analysis Type	Method	Date Tested	Status
Benzyl Alcohol	HPLC	10/15/2026	Complete
Bacterial Endotoxins	USP <85>	10/19/2026	Complete
Traditional Sterility	USP <71>	10/30/2026	Complete
Fentanyl	USP <2251>	10/15/2026	Complete
Residual Solvents	USP <467>	10/19/2026	Complete
Heavy Metals	ICP-MS	10/17/2026	Pass
Microbiological	Petrifilm/qPCR	10/18/2026	Pass



Label Claim Profile

Analyte	Result	Specification	LOD
Benzyl Alcohol	Vial 1 = 0.95%	0.9%	0.01%
Benzyl Alcohol	Vial 2 = 0.96%	0.9%	0.01%
Average	0.96%	0.9%	N/A
Identity of the analyte was confirmed by retention time concordance with a certified reference standard, per USP <621>.			
Bacterial Endotoxins (Gel-Clot: 1:10 Dilution)	<1.25 EU/ml	<5 EU/ml	λ = 0.125 EU/mL
Traditional 14-Day USP <71> Sterility	Pass = No Microbial Growth	No Microbial Growth	N/A
Fentanyl (2 Vials)	Vials 1,2 = Not Detected	<LOD	10ppm
Container Closure Integrity (Dye Ingress) USP <1207>	No dye ingress observed	No dye ingress	N/A
pH (USP <791>)	6.7	Report Only	N/A
Acetone	<LOD	<5000ppm	500ppm
Acetonitrile	<LOD	<410ppm	50ppm
Benzene	<LOD	<2ppm	0.1ppm
Chloroform	<LOD	<60ppm	5ppm
Cyclohexane	<LOD	<3880ppm	50ppm
Methanol	<LOD	<3000ppm	50ppm
DMF (N,N-Dimethylformamide)	<LOD	<880ppm	50ppm
Dichloromethane (Methylene Chloride)	<LOD	<600ppm	50ppm
Diethyl Ether (Ethyl Ether)	<LOD	<5000ppm	500ppm
Isopropanol (2-Propanol)	<LOD	<5000ppm	500ppm
Hexanes	<LOD	<290ppm	5ppm
Ethanol	<LOD	<5000ppm	500ppm
THF (Tetrahydrofuran)	<LOD	<720ppm	50ppm
TFA (Trifluoroacetic acid)	<LOD	Report Only	50ppm

NOTES: Two vials were independently tested to evaluate batch consistency and vial-to-vial variability.

LOD = LIMIT OF DETECTION; LOQ = LIMIT OF QUANTIFICATION

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Noel Samsum
Laboratory Director
30-Oct-2026

The sample analyzed was inspected and is free from visual mold, mildew, and foreign matter. The testing procedures, equipment calibration, and maintenance are all in accordance with ISO/IEC 17025:2017 standards. The presented report is only applicable to the sample specified above and may not be applied to any similar or identical products. Reports are prohibited from being reproduced with alterations of any kind.

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Heavy Metal Analysis (USP <233>)

Analyte	Result (mcg/ml)	LOQ (ppm)	LOD (ppm)	Limit (mcg/ml)	Pass/Fail
Arsenic	**<LOQ**	0.010	0.005	0.5	Pass
Cadmium	**<LOQ**	0.010	0.005	0.1	Pass
Lead	**<LOQ**	0.010	0.005	0.5	Pass
Mercury	**<LOQ**	0.010	0.005	0.1	Pass

Microbiological Analysis (USP <61>, USP <62>)

Microbe	Result	Limit	Pass/Fail
Total Aerobic Plate	**<10 CFU/g**	<100 CFU/g	Pass
Coliform	**<10 CFU/g**	<10 CFU/g	Pass
Bile-Tolerant Gram-Negative Bacteria	**<10 CFU/g**	<10 CFU/g	Pass
Yeast and Mold	**<10 CFU/g**	<10 CFU/g	Pass
Escherichia Coli	**Negative/1g**	Negative/1g	Pass
Salmonella	**Negative/1g**	Negative/1g	Pass
Staphylococcus Aureus	**Negative/1g**	Negative/1g	Pass

NOTES:

CFU = Colony Forming Unit
NS = Not Specified
NT = Not Tested

LOQ = Limit of Quantification
LOD = Limit of Detection

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