BACTERIAL ENDOTOXIN ANALYSIS

(Kinetic Chromogenic LAL, USP <85>)

Sample ID: **KVR-2026-C4F2CB**

CLIENT & SAMPLE INFORMATION

Client	Mile High Compounds	Analysis Date	03/20/2026
Product Name	Bacteriostatic Water	Strength	N/A
Lot / Batch	BAC-030-MH-02	Condition	Lyophilized

This Certificate of Analysis certifies that the sample listed herein was tested for bacterial endotoxin using a kinetic chromogenic LAL assay in accordance with USP <85> Bacterial Endotoxins Test.

TEST METHODOLOGY

Test Performed	Quantitative Bacterial Endotoxin Test	Compendial Ref	USP <85>
Assay Type	Chromogenic (Kinetic)	Detection λ	405 nm
Detection Range	0.01 – 1.0 EU/mL	Endotoxin Std	E. coli O111:B4
Dilution Vol	2.0 mL	Matrix	LAL Reagent Water

QUANTITATIVE RESULTS

Parameter	Result
Endotoxin Level	< 0.04 EU/mL
Acceptance Limit	≤ 0.5 EU/mL
Sample CV (%)	3.7%
Spike CV (%)	3.3%
Spike Recovery (%)	82%
Final Determination	PASS

CONTROLS

Control	Expected	Observed	Status
Positive Control	Detectable	As expected	Pass
Negative Control	No signal	As expected	Pass

INTERPRETATION

Endotoxin content was quantitatively determined using a kinetic chromogenic LAL assay in accordance with USP <85>. Result reported as below quantitation threshold. The measured endotoxin level meets the specified acceptance criteria. The sample passes the endotoxin limit test.

AUTHORIZATION

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