KOVERA LABS

CERTIFICATE OF ANALYSIS

REPORT # KVR-2026-49613A-S896

Client(s): ZC LABS **Certified:** 10/24/2026

This Certificate of Analysis certifies that the sample listed herein was tested by Kovera Labs using validated analytical methods and was found to meet the stated specifications at the time of analysis.

SAMPLE INFORMATION

Product	KPV	**Form**	Lyophilized Powder
Batch	ZC-KPV-261012	**Labeled Qty**	10 mg
Cap Color	Black	**Crimp Color**	Silver

TEST RESULTS

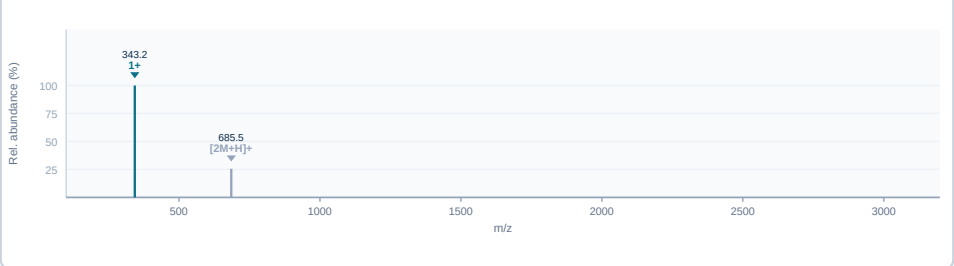
	REFERENCE STANDARD	RESULT
Batch Avg Purity	(>98%)	99.817% ✓
Batch Avg Net Content	(~10mg)	10.16 mg ✓
Identity Confirmation (LC-MS)	(KPV)	KPV ✓
Endotoxin Safety Screen	(≤0.5 EU/mL)	PASS ✓
Fentanyl Presence Analysis	(Not Detected)	Not Detected ✓
Rapid Sterility Screening	(No Growth)	No Growth ✓
Heavy Metal Screening	(Negative)	Negative ✓

BATCH CONFORMITY RESULTS

Vial	Purity (%)	Net Content (mg)
Vial 1	99.842	10.21
Vial 2	99.793	10.11
Batch Average	**99.817%**	**10.16 mg**

MASS SPECTRUM

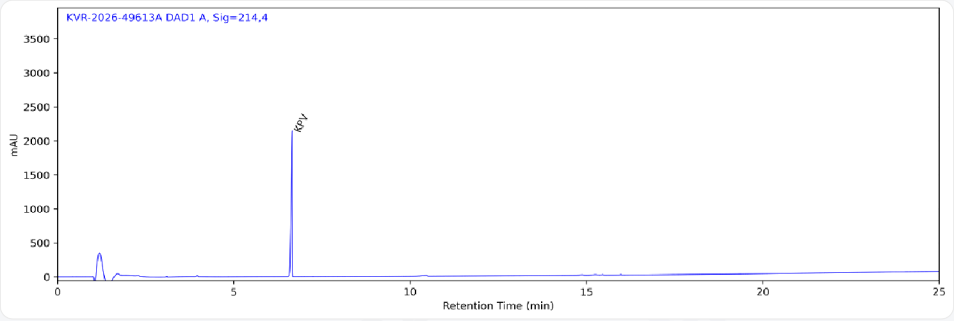
ESI + mode, MS1 centroid Charge states confirmed **1**



Each coloured stick is a confirmed charge state of the compound(s) above, drawn at the intensity measured for that ion. Height is relative to the strongest confirmed ion and is not proportional to concentration; content is reported in the Test Results above. The 1 grey stick(s) are the same compound's own in-source fragment and multimer ions, labelled by species: they are produced from the analyte in the ion source and are not separate substances in the vial.

CHROMATOGRAM

Method: RP-HPLC | Column: C18 | Detection: DAD @ 214 nm



Lemar Arghandiwal
Lab Director

koveralabs.com/verify

Report#: KVR-2026-49613A-S896
Access Code: JOM4VR6

KOVERA LABS

BACTERIAL ENDOTOXIN ANALYSIS

(Kinetic Chromogenic LAL, USP <85>)

Report Number: **KVR-2026-49613A-S896**

CLIENT & SAMPLE INFORMATION

Client	ZC LABS	**Certified Date**	10/24/2026
Product Name	KPV	**Strength**	10 mg
Lot / Batch	ZC-KPV-261012	**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	Kinetic Turbidimetric	**Detection λ**	660 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	< 0.07 EU/mL
Acceptance Limit	≤ 0.5 EU/mL
Sample CV (%)	3.7%
Spike CV (%)	4.5%
Spike Recovery (%)	90%
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

REVIEWED BY

Lemar Arghandiwal

Lab Director

CLIENT & SAMPLE INFORMATION

Client	ZC LABS	**Certified Date**	October 24, 2026
Product Name	KPV	**Strength**	10 mg
Lot / Batch	ZC-KPV-261012	**Condition**	Lyophilized

ICP-MS metals analysis performed using EPA-referenced methods; results evaluated against internal acceptance criteria.

TEST METHODOLOGY

Test Performed	Elemental Impurities Analysis	**Instrument**	ICP-MS
Sample Prep	HNO_3 / H_2O_2 matrix	**Calibration**	Multi-element standard curve
Internal Std	Sc, Ge, In, Bi	**Material Type**	Raw Material (Research Use)

ELEMENTAL IMPURITIES RESULTS

Element	Result (ppm)	Acceptance Limit (ppm)	Status
Pb Lead	< 0.5	≤ 10	PASS
As Arsenic	< 0.15	≤ 1.5	PASS
Cd Cadmium	< 0.05	≤ 0.5	PASS
Hg Mercury	< 0.3	≤ 3	PASS

METHOD SUITABILITY (SPIKE RECOVERY)

Element	Spike Level	Recovery	Criteria
Pb Lead	5 ppm	98%	70–150%
As Arsenic	0.75 ppm	102%	70–150%
Cd Cadmium	0.25 ppm	95%	70–150%
Hg Mercury	1.5 ppm	91%	70–150%

Spike recovery confirms method suitability for the sample matrix.

INTERPRETATION

Elemental impurities were determined using ICP-MS with EPA-referenced analytical methods. All tested elements (Pb, As, Cd, Hg) are below the stated acceptance limits. Spike recovery values fall within acceptable ranges, confirming method suitability. The sample meets the stated acceptance criteria for elemental impurities.

QUALITY CONTROL

Method Blank: Pass **CCV:** Pass **Duplicate RPD:** < 20%

AUTHORIZATION

REVIEWED BY
Lemar Arghandiwal
Lab Director

KOVERA LABS

RAPID STERILITY SCREEN

Report Number: **KVR-2026-49613A-S896**

CLIENT & SAMPLE INFORMATION

Client	ZC LABS	**Sample Name**	KPV
Lot Number	ZC-KPV-261012	**Sample Matrix**	Lyophilized Powder
Date Received	10/23/2026	**Certified Date**	10/25/2026

TEST METHODOLOGY

RAPID STERILITY SCREENING METHOD

Sample is reconstituted and incubated in growth media under controlled conditions. Cultures are monitored for microbial growth over the incubation period. This rapid screening method provides preliminary sterility assessment and is suitable for quality control purposes. For regulatory compliance, full compendial sterility testing may be required.

TEST RESULTS

TEST PARAMETER	SPECIFICATION	RESULT	STATUS
Bacteria (Aerobic/Anaerobic)	No Growth	**No Growth**	PASS
Fungi / Yeast	Not Detected	**Not Detected**	PASS

TEST METHOD	INCUBATION PERIOD	TEMPERATURE
Rapid Sterility	**2 days**	**30-35C**

FINAL DETERMINATION

STERILITY SCREEN RESULT

SAMPLE PASSES STERILITY SCREEN

No microbial growth detected during incubation period