



PRODUCT IDENTITY

Brand **PEPKITS**
Product Name **AOD-9604 (Anti-Obesity Fragment)**
Cat. No. **TWA-AOD-5**
Specification **5mg / vial**
CAS Number **127279-01-2**
Mol. Formula **C₇₈H₁₂₃N₂₃O₂₃S**
Mol. Weight **1815.10 Da**

BATCH INFORMATION

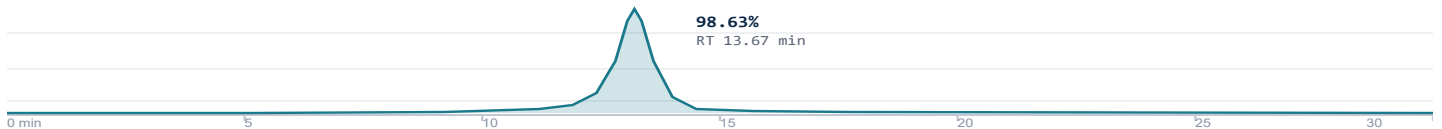
Batch Number **TWA-26-PKITS03**
Manufacture Date **2026-04-05**
Test Date **2026-04-16**
Expiry Date **2028-04-05**
Sample Weight **41.1 mg**
Analyst **Dr. J. Bergmann**

ANALYTICAL METHOD

RP-HPLC

Instrument **Agilent 1260 Infinity II (S/N: SN346156)**
Column **Phenomenex Luna C18(2) 250×4.6mm 5µm (Lot: PH32148)**
Mobile Phase A / B **0.1% TFA in Water · 0.1% TFA in Acetonitrile (HPLC Grade)**
Gradient **5% B → 70% B over 30 min, 1.0 mL/min**
Detection **UV @ 220 nm (primary), 280 nm (secondary)**
Column Temp / Injection **40°C · 10 µL · 35 min run time**

HPLC CHROMATOGRAM — UV 220 NM — AOD-9604 — BATCH TWA-26-PKITS03



SYSTEM SUITABILITY

USP <621>

PARAMETER	ACCEPTANCE	RESULT	STATUS
Theoretical Plates (N)	≥ 2000	13,079	PASS
Tailing Factor (T)	≤ 2.0	0.97	PASS
RSD (n=6 injections)	≤ 1.0%	0.33%	PASS
Resolution (Rs)	≥ 2.0	13.0	PASS

PURITY RESULT: 98.63% — CONFORMS to specification ≥ 98.0%

RP-HPLC, UV 220 nm. Largest single impurity 0.07%, total impurities 0.43%.

PURITY & IDENTITY RESULTS

TEST PARAMETER	SPECIFICATION	RESULT	STATUS
Appearance	White lyophilized powder	Conforms	PASS
RP-HPLC Purity	≥ 98.0%	98.63%	PASS
Largest Single Impurity	≤ 0.50%	0.07%	PASS
Total Impurities	≤ 2.0%	0.43%	PASS
ESI-MS (m/z)	[M+H] ⁺ ± 2 Da	1816.10	PASS
Potentiometric Assay	98.0–102.0%	99.7%	PASS
Karl Fischer (Moisture)	≤ 5.0%	1.8%	PASS
pH (1mg/mL aq.)	4.0–8.0	7.2	PASS
Solubility	BAC water, sterile water	Conforms	PASS

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QC Reviewer
QR-7970

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QA Director
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Test Date **2026-04-16**

INSTRUMENT & METHOD

Instrument **Thermo iCAP RQ ICP-MS**
S/N **SN594227**
Digestion **Microwave (CEM MARS 6)**
Mode **He collision (KED)**
Standard **ICH Q3D(R2) / USP <232>**

ALL 15 ELEMENTS CONFORM to ICH Q3D(R2) Oral Permitted Daily Exposure limits

No element exceeded specification. CRM recovery 102.8%, method blank < LOD.

ELEMENTAL IMPURITIES

ICH Q3D(R2)

ELEMENT	ICH CLASS	PDE ORAL (MG/G)	RESULT (MG/G)	STATUS
Arsenic (As)	1	≤ 15	0.218	PASS
Cadmium (Cd)	1	≤ 5	0.047	PASS
Mercury (Hg)	1	≤ 30	0.199	PASS
Lead (Pb)	1	≤ 5	0.366	PASS
Cobalt (Co)	2A	≤ 50	1.412	PASS
Vanadium (V)	2A	≤ 100	0.825	PASS
Nickel (Ni)	2A	≤ 200	8.142	PASS
Silver (Ag)	2B	≤ 150	0.058	PASS
Gold (Au)	2B	≤ 100	< LOD	PASS
Palladium (Pd)	2B	≤ 100	0.850	PASS
Copper (Cu)	3	≤ 3000	5.17	PASS
Iron (Fe)	3	≤ 1300	22.73	PASS
Zinc (Zn)	3	≤ 13000	17.46	PASS
Chromium (Cr)	3	≤ 11000	3.879	PASS
Manganese (Mn)	3	≤ 2500	11.736	PASS

METHOD VALIDATION

PARAMETER	ACCEPTANCE	RESULT	STATUS
Spike Recovery (Class 1)	85–115%	93.5%	PASS
Repeatability RSD (n=6)	≤ 5.0%	1.25%	PASS
CRM Recovery	90–110%	102.8%	PASS
Method Blank	< LOD	< LOD	PASS

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Cat. No. **TWA-AOD-5**
Batch No. **TWA-26-PKITS03**
Sample Vol. **1.1 mL**

METHOD

Standard **USP <71> / EP 2.6.1**
Technique **Membrane Filtration (0.45 µm)**
Environment **ISO Class 5 Laminar Flow**
Test Date **2026-04-16**
Incubation **14 days (30–35°C / 20–25°C)**

GROWTH PROMOTION TEST (POSITIVE CONTROLS)

ORGANISM	ATCC	MEDIUM	DAY 7	DAY 14	STATUS
<i>Staphylococcus aureus</i>	6538	TSB	Growth	Growth	PASS
<i>Bacillus subtilis</i>	6633	TSB	Growth	Growth	PASS
<i>Clostridium sporogenes</i>	19404	FTM	Growth	Growth	PASS
<i>Candida albicans</i>	10231	SDA	Growth	Growth	PASS
<i>Aspergillus brasiliensis</i>	16404	SDA	Growth	Growth	PASS

STERILITY: PASSES USP <71> — No microbial or fungal growth at Day 7 or Day 14

All replicates clear under aerobic, anaerobic, and fungal/yeast media at both inspection intervals.

STERILITY RESULTS

TEST	MEDIUM	DAY 7	DAY 14	STATUS
Aerobic Growth	TSB	Clear	Clear	PASS
Anaerobic Growth	FTM	Clear	Clear	PASS
Fungi / Yeasts	SDA	Clear	Clear	PASS

MICROBIAL LIMITS

USP <61> / <62>

TEST	LIMIT	RESULT	STATUS
TAMC (Aerobic count)	≤ 100 CFU/g	< 10 CFU/g	PASS
TYMC (Yeast/Mold)	≤ 10 CFU/g	< 10 CFU/g	PASS
<i>E. coli</i>	Absent	Not Detected	PASS
<i>Salmonella</i>	Absent	Not Detected	PASS
<i>S. aureus</i>	Absent	Not Detected	PASS
<i>P. aeruginosa</i>	Absent	Not Detected	PASS

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Batch No. **TWA-26-PKITS03**
Test Date **2026-04-16**

METHOD

Standard **USP <85> / EP 2.6.14 / ChP 2020**
Technique **Kinetic Fluorimetric (rFC)**
Reagent **Lonza PyroGene™ Recombinant Factor C**
Reagent Lot **L2303 (Exp: 2026-09)**
 λ (sensitivity) **0.03 EU/mL**

SYSTEM SUITABILITY

PARAMETER	ACCEPTANCE	RESULT	STATUS
Correlation Coefficient (r^2)	≥ 0.980	0.9856	PASS
Slope	-2.10 to -2.50	-2.425	PASS
PPC Recovery	50–200%	112.8%	PASS
Negative Control	< 0.03 EU/mL	< 0.005 EU/mL	PASS

ENDOTOXIN: 0.058 EU/mg — PASSES limit of ≤ 0.50 EU/mg
Mean of two replicates. PPC recovery within USP <85> acceptance range.

SAMPLE RESULTS

SAMPLE	REP 1 (EU/MG)	REP 2 (EU/MG)	MEAN (EU/MG)	LIMIT	STATUS
TWA-26-PKITS03	0.066	0.049	0.058	≤ 0.50	PASS

VERIFY ONLINE: Look up this batch at tidewateranalytical.com/verify using code **TWA-26-PKITS03**

This Certificate of Analysis is issued by Tidewater Analytical, an independent contract analytical laboratory operating under cGMP-aligned procedures. Testing was performed on a representative sample of the referenced batch; results apply to the sample as received and are not transferable to other lots. Retain sample stored at 2–8°C for 5 years from test date. For questions: cs@tidewateranalytical.com.

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