



PRODUCT IDENTITY

Brand **PEPKITS**  
Product Name **CJC with DAC (GHRH Analog (DAC))**  
Cat. No. **TWA-CJCD-5**  
Specification **5mg / vial**  
CAS Number **863288-34-0**  
Mol. Formula **C<sub>165</sub>H<sub>269</sub>N<sub>47</sub>O<sub>46</sub>**  
Mol. Weight **3647.39 Da**

BATCH INFORMATION

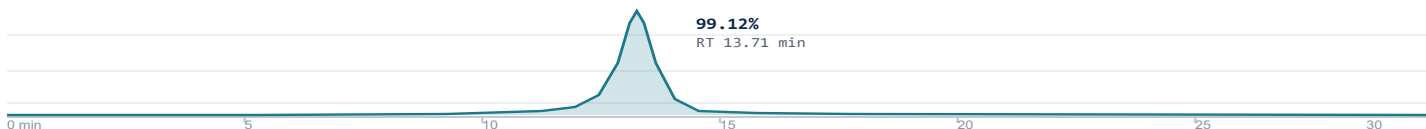
Batch Number **TWA-26-PKITS48**  
Manufacture Date **2026-03-26**  
Test Date **2026-04-07**  
Expiry Date **2028-03-26**  
Sample Weight **43.0 mg**  
Analyst **Dr. J. Bergmann**

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 — CJC WITH DAC — BATCH TWA-26-PKITS48



SYSTEM SUITABILITY

USP <621>

| PARAMETER              | ACCEPTANCE | RESULT | STATUS |
|------------------------|------------|--------|--------|
| Theoretical Plates (N) | ≥ 2000     | 14,931 | PASS   |
| Tailing Factor (T)     | ≤ 2.0      | 1.02   | PASS   |
| RSD (n=6 injections)   | ≤ 1.0%     | 0.41%  | PASS   |
| Resolution (Rs)        | ≥ 2.0      | 12.2   | PASS   |

**PURITY RESULT: 99.12% — CONFORMS to specification ≥ 98.0%**  
RP-HPLC, UV 220 nm. Largest single impurity 0.04%, total impurities 0.70%.

PURITY & IDENTITY RESULTS

| TEST PARAMETER          | SPECIFICATION             | RESULT   | STATUS |
|-------------------------|---------------------------|----------|--------|
| Appearance              | White lyophilized powder  | Conforms | PASS   |
| RP-HPLC Purity          | ≥ 98.0%                   | 99.12%   | PASS   |
| Largest Single Impurity | ≤ 0.50%                   | 0.04%    | PASS   |
| Total Impurities        | ≤ 2.0%                    | 0.70%    | PASS   |
| MALDI-TOF (m/z)         | [M+H] <sup>+</sup> ± 2 Da | 3648.39  | PASS   |
| Potentiometric Assay    | 98.0–102.0%               | 99.6%    | PASS   |
| Karl Fischer (Moisture) | ≤ 5.0%                    | 4.0%     | PASS   |
| pH (1mg/mL aq.)         | 4.0–8.0                   | 4.9      | PASS   |
| Solubility              | BAC water, sterile water  | Conforms | PASS   |

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AN-3941

**Dr. M. Sullivan**

QC Reviewer  
QR-8792

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QA Director  
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Test Date **2026-04-07**

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 100.0%, method blank < LOD.

ELEMENTAL IMPURITIES

ICH Q3D(R2)

| ELEMENT        | ICH CLASS | PDE ORAL (MG/G) | RESULT (MG/G) | STATUS |
|----------------|-----------|-----------------|---------------|--------|
| Arsenic (As)   | 1         | ≤ 15            | 0.184         | PASS   |
| Cadmium (Cd)   | 1         | ≤ 5             | 0.077         | PASS   |
| Mercury (Hg)   | 1         | ≤ 30            | 0.222         | PASS   |
| Lead (Pb)      | 1         | ≤ 5             | 0.274         | PASS   |
| Cobalt (Co)    | 2A        | ≤ 50            | 1.314         | PASS   |
| Vanadium (V)   | 2A        | ≤ 100           | 0.573         | PASS   |
| Nickel (Ni)    | 2A        | ≤ 200           | 7.321         | PASS   |
| Silver (Ag)    | 2B        | ≤ 150           | 0.126         | PASS   |
| Gold (Au)      | 2B        | ≤ 100           | < LOD         | PASS   |
| Palladium (Pd) | 2B        | ≤ 100           | 0.961         | PASS   |
| Copper (Cu)    | 3         | ≤ 3000          | 4.54          | PASS   |
| Iron (Fe)      | 3         | ≤ 1300          | 25.94         | PASS   |
| Zinc (Zn)      | 3         | ≤ 13000         | 23.12         | PASS   |
| Chromium (Cr)  | 3         | ≤ 11000         | 4.926         | PASS   |
| Manganese (Mn) | 3         | ≤ 2500          | 9.459         | PASS   |

METHOD VALIDATION

| PARAMETER                | ACCEPTANCE | RESULT | STATUS |
|--------------------------|------------|--------|--------|
| Spike Recovery (Class 1) | 85–115%    | 95.3%  | PASS   |
| Repeatability RSD (n=6)  | ≤ 5.0%     | 1.11%  | PASS   |
| CRM Recovery             | 90–110%    | 100.0% | PASS   |
| Method Blank             | < LOD      | < LOD  | PASS   |

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Cat. No. **TWA-CJCD-5**  
Batch No. **TWA-26-PKITS48**  
Sample Vol. **1.7 mL**

METHOD

Standard **USP <71> / EP 2.6.1**  
Technique **Membrane Filtration (0.45 µm)**  
Environment **ISO Class 5 Laminar Flow**  
Test Date **2026-04-07**  
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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Test Date **2026-04-07**

**METHOD**

Standard **USP <85> / EP 2.6.14 / ChP 2020**  
Technique **Kinetic Fluorimetric (rFC)**  
Reagent **Lonza PyroGene™ Recombinant Factor C**  
Reagent Lot **L2860 (Exp: 2026-10)**  
λ (sensitivity) **0.03 EU/mL**

**SYSTEM SUITABILITY**

| PARAMETER                                 | ACCEPTANCE     | RESULT        | STATUS |
|-------------------------------------------|----------------|---------------|--------|
| Correlation Coefficient (r <sup>2</sup> ) | ≥ 0.980        | 0.9892        | PASS   |
| Slope                                     | -2.10 to -2.50 | -2.445        | PASS   |
| PPC Recovery                              | 50–200%        | 172.6%        | PASS   |
| Negative Control                          | < 0.03 EU/mL   | < 0.004 EU/mL | PASS   |

**ENDOTOXIN: 0.033 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-PKITS48 | 0.026         | 0.033         | 0.033        | ≤ 0.50 | PASS   |

**VERIFY ONLINE:** Look up this batch at [tidewateranalytical.com/verify](https://tidewateranalytical.com/verify) using code **TWA-26-PKITS48**

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](mailto:cs@tidewateranalytical.com).

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