PepDirekt | Field Audit Intelligence Report

#2026-04-CN

Audit Nature: Supply Chain Compliance Verification
Phase I: Documentary Forensic & Site Integration

■ CAUTION

Restricted Trust / Under Intensive Verification

Subject	Tirzepatide & Retatrutide — Batch Validation (Mandated by US Clinical Client)
Location	East China Bio-cluster | Nanjing / Suzhou Regions, Jiangsu Province
Issued	April 27, 2026
Classification	PUBLIC (Redacted) — Vendor Identity & Full Lot Numbers Withheld

I. AUDIT CONTEXT

Acting on behalf of our US clinical partners, the **PepDirekt** audit team is currently executing a physical verification mission within the Jiangsu pharmaceutical manufacturing corridor. The primary objective is to authenticate the clinical-grade integrity of specific peptide batches and ensure total physical traceability from the point of origin.

Two batches are under review: **Tirzepatide (Lot: JT-202***)** and **Retatrutide (Lot: JT-218***)**, both supplied by a Tier-1 Chinese peptide manufacturer. Standard COA documentation was submitted by the vendor prior to facility entry. Our compliance team conducted a forensic cross-check before on-site inspection.

Vendor-Submitted COA Data (Pre-Audit Snapshot)

Batch / Product	HPLC Purity	Peptide Content	Moisture	Na Salt	Qty	Mfg. Date
Tirzepatide JT-202***	99.68% (Spec: ≥99.0%)	94.94% (Spec: ≥85.0%)	3.9%	0.85%	50 g	2025-10-23
Retatrutide JT-218***	99.57% (Spec: ≥99.0%)	95.40% (Spec: ≥85.0%)	3.7%	0.59%	1,150 g	2025-09-16

II. FORENSIC FINDINGS — Document Analysis & Logical Discrepancies

While the surface data claims compliance, our analysis has identified the following **Critical Risk Indicators** prior to facility entry:

P0 CRITICAL ALERT | Finding 1 of 3 — **DATA INTEGRITY MISMATCH**

During a **pixel-level review** of the Tirzepatide COA report, a significant discrepancy was identified between the cover lot number and the HPLC chromatogram metadata:

- **Cover Page (COA):** Lot No. **JT-202*****
- **HPLC Sample Info Page:** Lot No. **JT-185*****

These two batch identifiers are entirely different — the discrepancy spans thousands of lot sequence units, suggesting the chromatogram data originates from a *different production batch*.

Auditor's Inference: *In supply chain auditing, such inconsistencies typically signal 'Template Recycling' — the analytical data submitted may not have been generated from the specific batch currently offered for sale. This finding has triggered our* ***SOP-001 (Anomaly Correction Protocol)****.*

TECHNICAL GAP | Finding 2 of 3 **ABSENCE OF RAW METADATA**

The vendor provides only **static PDF documentation** with no access to source instrument files. PepDirekt has issued a formal demand for the original **.lcd / .org raw metadata files** generated directly by the HPLC/MS chromatography workstations (SHIMADZU Inertsil ODS-SP, 4.6×250mm, 5µm).

Without raw metadata, the following cannot be independently verified:

- Original acquisition timestamps
- Manual peak integration records
- Instrument audit trail sequences

Auditor's Inference: *Without verifying original timestamps and manual integration logs,* ***PepDirekt cannot certify the finality or authenticity of the reported purity levels.*** *The HPLC data field is hereby classified as Unverified Pending Metadata Disclosure.*

QUALITY OBSERVATION | Finding 3 of 3 **PEPTIDE CONTENT VARIANCE**

Forensic analysis of both COA reports reveals that while nominal HPLC purity values are high (99.68% and 99.57%), the **actual Peptide Content** figures are approaching the lower compliance boundary:

- Tirzepatide Peptide Content: **94.94%** (Minimum Spec: ≥85.0%)
- Retatrutide Peptide Content: **95.40%** (Minimum Spec: ≥85.0%)

While still within specification, the delta between HPLC purity and peptide content implies significant non-peptide mass (moisture, salts, excipients) at approximately 4–6%.

Auditor's Inference: *This indicates a potential* ***~5% dosage variance*** *during clinical compounding formulation. This risk has been escalated to the client's procurement risk profile. Reconstitution protocols must account for actual peptide content, not nominal purity.*

III. ONGOING FIELD ACTIONS

1 **Unannounced Compliance Walkthrough**

The audit team is scheduled to enter the Nanjing manufacturing facility (Building E6) next week to directly inspect the **Audit Trail** logs of all HPLC/MS laboratory equipment in use for these batches.

2 **Randomized Blind Sampling**

For the batches in question, PepDirekt has mandated immediate **Batch Retention** by the vendor. Our team will execute on-site randomized sampling under direct observation, with samples hand-delivered by designated personnel to our partner independent laboratory for parallel confirmation testing.

3 **Capital Protection Recommendation**

Pending a legally satisfactory explanation for the identified batch mismatches, PepDirekt has formally advised the client to maintain **Escrow Status**. No funds are to be released to the vendor until all discrepancies are resolved and independently verified.

IV. AUDITOR'S STATEMENT

> ***"A PDF report is a claim, not a guarantee. PepDirekt's value lies in deconstructing 'perfect' documentation to find the ground truth. The batch mismatch identified in this mission — JT-202*** on the cover versus JT-185*** embedded in the HPLC metadata — underscores the absolute necessity of forensic oversight at the point of origin."***

— **Lead Auditor, PepDirekt** | East China Audit Mission | April 2026