BATCH TEST LABORATORIES LIMITED

Independent Analytical Testing & Quality Verification

BATCH TEST PROCESS FLOW

Lifecycle & Decision Model — Version 2.0

This document describes the end-to-end quality verification lifecycle at **Batch Test Laboratories Limited**. It reflects our **'Investigate First'** philosophy: when an atypical observation is made, we consult the supplier for technical context *before* classifying anything as a failure. This ensures fairness, transparency, and educational value for our customers.

PHASE 1: RECEIPT & IN-HOUSE VERIFICATION

STEP 1 — BATCH RECEIPT

Product arrives sealed. Check packaging integrity, documentation match, and seal condition.

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STEP 2 — IN-HOUSE PHYSICAL CHECKS

Vial integrity • Seal security • Vacuum/suction test • Powder appearance • Reconstitution clarity • Mixing behaviour

DECISION POINT: ANOMALY DETECTED?

If **all checks pass** with no atypical observations, proceed directly to Phase 2 (Third-Party Testing). If **any observation deviates** from expected norms — no suction, unexpected colour, clumping, etc. — the batch is flagged for **Anomaly Resolution**.

PATH A — ALL CLEAR	PATH B — ANOMALY EXPLAINED	PATH C — ANOMALY FAIL
All checks PASS. Proceed to Janoshik testing.	Supplier provides technical explanation. Status = EXPLAINED.	No satisfactory explanation. Status = FAIL. Batch rejected.

PHASE 2: ANOMALY RESOLUTION (If Applicable)

When an anomaly is noted, Batch Test Labs contacts the supplier with specific observations. We request technical explanation covering: production process, equipment used, chemical rationale, and intended stability profile.

OBSERVATION	SUPPLIER QUERY	ASSESSMENT
Document exactly what was seen: 'No suction', 'Dark blue layer', etc.	Send detailed questions to supplier. Request technical context.	Evaluate response. Does it align with known chemistry? Is it plausible?

Outcome: If the explanation is accepted, the check receives status **EXPLAINED** (green, same visual weight as PASS). If the explanation is insufficient or contradictory, the check receives status **FAIL** (red). All supplier responses are published verbatim in the Verification Report for full transparency.

PHASE 3: INDEPENDENT THIRD-PARTY TESTING

All batches — regardless of in-house check results — are subject to random spot-testing by independent laboratories. Our primary partner is **Janoshik** for HPLC and MS verification. This is **mandatory** before any batch receives a full Certificate of Analysis (COA).

JANOSHIK SPOT TEST

PHASE 4: DOCUMENT ISSUANCE

The document type issued depends on the batch status and third-party test completion:

STATUS	DOCUMENT ISSUED	MEANING
Pending	Verification Report (Amber)	In-house checks complete. Third-party results pending.
Explained	Verification Report (Amber)	Anomaly noted, supplier explanation accepted. Third-party still pending.
Complete	Certificate of Analysis (Green)	In-house checks passed + third-party HPLC/MS confirmed.
Fail	No document issued	Batch rejected. Not offered for sale.

KEY PRINCIPLES

1. Investigate First — Never classify an observation as FAIL until the supplier has been given opportunity to explain. Fairness and accuracy matter.

2. Publish Everything — All supplier responses are included verbatim in Verification Reports. Transparency builds trust.

3. Third-Party Validates — Only independent HPLC/MS results can confirm identity and purity. In-house checks are physical/observational only.

4. Learn & Update — Each anomaly resolution becomes part of our knowledge base. Future batches of the same product benefit from prior learnings.

CASE STUDY: GHK-CU (CU50-20260726-01)

This batch demonstrates the 'Investigate First' model in action:

Observation	No vacuum suction on needle puncture. Dark blue surface layer on lyophilised cake.
Initial Reaction	Could have been classified as FAIL (no suction + atypical appearance).
Action Taken	Contacted supplier for technical explanation before classification.
Supplier Response	GHK-Cu sealed on non-vacuum capping machine (hygroscopic nature). Dark blue layer = copper peptide concentration at freeze-drying surface. Intentional residual moisture for stability.
Assessment	Explanation consistent with GHK-Cu chemistry (copper-chelated peptide, known stability profile). Accepted.
Final Status	EXPLAINED (green). Verification Report issued. Janoshik HPLC/MS pending for final confirmation.

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This process flow is a living document. As Batch Test Labs acquires in-house HPLC and MS capabilities, Phase 1 will expand to include analytical testing. The 'Investigate First' principle remains core to our quality ethos.

Issued by: Quality Assurance Department
Email: info@batchtestlabs.co.uk
Company: Batch Test Laboratories Limited
Website: www.batchtestlabs.co.uk