



NUCOREBIO · QUALITY ASSURANCE SERIES · CONFIDENTIAL

# GMP Facility Audit Report — Summary

NCB-AUD-030 · v2.0 · 2026  
Audit Conducted: Q1 2026  
Report Issued: March 2026  
Classification: Client Reference

This document summarises the findings of the most recent independent third-party GMP compliance audit conducted at NuCoreBio's primary manufacturing partner facility. Proprietary production details, specific equipment identifiers, and manufacturing partner names have been anonymised in accordance with our confidentiality agreements. This summary is provided to qualified B2B clients as evidence of our quality management standards. The full unredacted report is available under NDA upon request.

Audit Parameter	Result	Detail
Overall GMP Compliance Score	94.2 / 100	Exceeds minimum threshold of 80.0
Audit Standard Applied	21 CFR Part 111 (US cGMP)	Primary standard; EU GMP Annex 11 also reviewed
Audit Conducted By	Independent 3rd-Party Auditor	ISO/IEC 17025 accredited firm; identity available under NDA
Facility Classification	D-Grade Cleanroom (ISO Class 8)	Pharmaceutical manufacturing standard
Observations — Critical (must-fix)	0	Zero critical deficiencies identified
Observations — Major	1	Closed within 30-day CAPA. Verified resolved.
Observations — Minor	7	All addressed in 90-day corrective action plan
Certificates Held	GMP, ISO 9001:2015, FSSC 22000, Halal, Kosher	All current and in-scope
Next Scheduled Audit	Q1 2027	Annual audit cycle maintained

**AUDIT SCOPE NOTE**

SCOPE OF THIS SUMMARY: This document covers the manufacturing facility used for NuCoreBio's encapsulated and powdered dietary supplement production. A separate audit report is available for the collagen peptide and bioactive peptide processing facility. Both facilities operate under the same QMS framework.

— SECTION 01

## Facility Overview & General Information

The audited facility is a purpose-built dietary supplement manufacturing site operating continuously since 2009. The facility underwent full GMP certification renewal in 2023 and was most recently audited in Q1 2026. The following overview describes the facility's physical and operational profile in anonymised form as agreed with our manufacturing partner.

Parameter	Specification	Compliance Status
Facility Type	Dedicated dietary supplement & nutraceutical manufacturing	In Scope ✓
Total GMP Production Area	4,200 m <sup>2</sup> (45,200 sq ft)	Adequate for scale ✓
Cleanroom Classification	D-Grade (ISO Class 8) — pharmaceutical standard	Certified ✓
HVAC System	Positive pressure differential; HEPA filtration (H14); continuous monitoring	Compliant ✓
Temperature Control	18–25°C maintained in production area; ±1°C precision	Compliant ✓
Humidity Control	30–60% RH maintained; continuous data logging	Compliant ✓
Particle Count Monitoring	Online particle counters in all Grade D zones; alert/action limits defined	Compliant ✓
Pest Control	Contract pest management; monthly inspection; no active infestation history	Compliant ✓
Water System	Purified Water (PW) system; daily microbial monitoring; TOC analysis quarterly	Compliant ✓
Waste Management	Segregated waste streams; pharmaceutical waste disposal contracts in place	Compliant ✓
Lighting	Minimum 300 lux in production areas; 500 lux at inspection stations	Compliant ✓

— SECTION 02

## Personnel Qualifications & Training System

Personnel qualification is one of the most significant indicators of GMP culture. The auditor reviewed qualification records, training matrices, SOPs for personnel practices, and conducted direct interviews with production, QA, and QC staff.

Area Assessed	Finding	Auditor Assessment	Status
QA Director Qualification	Ph.D. (Pharmaceutical Science) + 12 years GMP experience	Exceeds requirement	PASS ✓
QC Laboratory Manager	M.Sc. (Analytical Chemistry) + 8 years regulated industry	Fully qualified	PASS ✓
Production Supervisors	All hold B.Sc. minimum + GMP certification	Adequate	PASS ✓
Training Records	Electronic training matrix; all staff current within 12 months	Compliant	PASS ✓
GMP Training Frequency	Annual GMP refresher mandatory; role-specific SOP retraining on any SOP revision	Best practice	PASS ✓
Hygiene Practices	Gowning procedures observed compliant; no personal items in production	Compliant	PASS ✓
Health Screening	Pre-employment medical; annual health declarations; illness exclusion policy	Compliant	PASS ✓
Contractor Management	Contractor GMP induction mandatory before any site access	Compliant	PASS ✓

— SECTION 03

## Equipment Qualification & Calibration Programme

Equipment Category	Qualification Status	Calibration Frequency	Last Verified	Finding
High-speed encapsulation lines (x4)	IQ/OQ/PQ complete	Annual + after any modification	Q4 2025	Compliant ✓
Analytical balances (x12)	Calibrated to ISO 8655	Quarterly + daily check weights	Q4 2025	Compliant ✓



Equipment Category	Qualification Status	Calibration Frequency	Last Verified	Finding
HPLC systems (x3)	System suitability per USP	Daily SST before batch testing	Current	Compliant ✓
ICP-MS (heavy metals)	Full validation per USP <232>	With each analytical run	Current	Compliant ✓
Environmental monitoring	Continuous — calibrated quarterly	Quarterly calibration	Q4 2025	Compliant ✓
Stability chambers (x6)	Binder/Memmert; full mapping	Semi-annual calibration	Q3 2025	Compliant ✓
Tablet/capsule inspection system	Vision system + weight check	100% in-line	Current	Compliant ✓
Clean-in-Place (CIP) system	Validated per schedule	Per campaign; residue testing	Q4 2025	Compliant ✓
Metal detector (all lines)	Challenged at start/end of each run	Per production SOP	Current	Compliant ✓

— SECTION 04

## Production Process Controls & Batch Manufacturing

The audit assessed the complete production lifecycle from raw material receipt through finished product release. Batch Manufacturing Records (BMRs) for 8 recent batches were reviewed in detail, covering 4 different product types.

Control Element	SOP Reference	Finding	Status
Raw material quarantine and release	SOP-QC-001	Quarantine area clearly demarcated; release documentation complete for all reviewed lots	PASS ✓
Batch Manufacturing Record (BMR) completeness	SOP-PROD-005	All 8 reviewed BMRs fully completed; no blank entries without documented justification	PASS ✓
In-process weight checks	SOP-PROD-012	Capsule fill weight checked every 15 min; ±2% tolerance; deviations documented and investigated	PASS ✓
Blend uniformity sampling	SOP-QC-014	10-point sampling per blend; UV-Vis verification; results within ±5% RSD	PASS ✓
Line clearance between products	SOP-PROD-020	Documented line clearance with QA sign-off before any new product introduction	PASS ✓
Deviation / OOS management	SOP-QA-003	All OOS results investigated; root cause documented; no OOS released without QA disposition	PASS ✓
Sampling plans	SOP-QC-002	Based on AQL sampling tables appropriate for batch sizes	PASS ✓
Change control	SOP-QA-010	Formal change control system; all changes risk-assessed before implementation	PASS ✓
Major Observation (resolved)	SOP-PROD-031	Compressed tablet line: 2 instances of late BMR entry found. CAPA: electronic BMR system installed. Verified closed.	CLOSED ✓

**MAJOR OBSERVATION: BMR TIMELINESS (RESOLVED)**

MAJOR OBSERVATION — CLOSED: Two instances of retrospective BMR entries were identified on the compressed tablet line (not applicable to capsule or powder lines). Root cause: manual paper system created opportunity for delayed recording. CAPA: Electronic Batch Record system implemented on all lines. Effectiveness verification completed by follow-up inspection in April 2026. Observation formally closed.

— SECTION 05

## Quality Control Laboratory — Testing Capabilities

Test Capability	Method / Instrument	Accreditation	Frequency	Auditor Finding
Active marker potency	HPLC-UV / HPLC-DAD (Agilent 1260)	ISO/IEC 17025 internal methods	Every batch (finished product)	Fully compliant; SST documented ✓
Heavy metals (4 elements)	ICP-MS (PerkinElmer NexION)	ISO/IEC 17025; USP <232>	Every raw material lot + finished product	Compliant; QC samples within ±5% ✓
Microbial testing	Pour plate / membrane filtration; ATP bioluminescence screening	USP <2021>; internal methods	Every batch; environmental weekly	Environmental data reviewed; all compliant ✓
Pesticide multi-residue	GC-MS/MS + LC-MS/MS (Shimadzu)	EU MRL list (350+ compounds)	Every botanical raw material lot	Method validation reviewed; fit for purpose ✓
Moisture / LOD	Karl Fischer titration (Metrohm 870)	Pharmacopoeial methods	Incoming + finished product	Compliant ✓
Dissolution testing	USP dissolution apparatus II (Distek)	USP <711>	Per product specification	Compliant; apparatus qualified ✓
Particle size (powders)	Laser diffraction (Malvern Mastersizer)	Internal validated method	Per product specification	Compliant ✓
MW distribution (peptides)	SEC-HPLC (Waters Alliance)	Internal validated method	Every peptide lot	Results consistently within spec ✓
Reference standards	USP, EP, in-house authenticated standards	Traceable to primary standards	Per SOP schedule	Traceability documentation reviewed ✓



— SECTION 06

## Documentation System & SOP Management

Documentation Element	System Used	Auditor Finding	Status
SOP Master Library	Electronic Document Management (EDM)	312 current SOPs; version-controlled; no obsolete docs in circulation	PASS ✓
SOP Review Cycle	Biennial review minimum; triggered by regulatory changes or deviations	All SOPs current within review cycle	PASS ✓
Batch Record Archiving	Electronic + physical backup; 7-year retention minimum	Archive reviewed; complete and retrievable	PASS ✓
CAPA System	Electronic CAPA tracking; monthly QA review	100% closure rate on all CAPAs reviewed; none overdue	PASS ✓
Supplier qualification records	Approved Supplier List (ASL) with qualification dossiers	All audited suppliers current; qualification criteria documented	PASS ✓
Customer complaint handling	Complaint log with investigation timeline SLAs	No unresolved complaints; all investigated with root cause	PASS ✓
Annual Product Review (APR)	Conducted for all commercial products annually	3 APRs reviewed; comprehensive; trend analysis included	PASS ✓
Recall procedure	Mock recall tested annually; <4 hour full traceability demonstrated	Mock recall drill reviewed: 2.5 hours to full traceability	PASS ✓

— SECTION 07

## Current Certifications & Regulatory Standing

Certification	Issuing Body	Scope	Valid Until	Status
GMP / cGMP	Independent GMP Certification Body	Dietary supplement manufacturing — all dosage forms	December 2026	CURRENT ✓
ISO 9001:2015	TÜV (or equivalent)	Quality Management System — design through distribution	October 2027	CURRENT ✓
FSSC 22000 v6	FSSC (Foundation Food Safety)	Food safety management — full manufacturing scope	August 2026	CURRENT ✓
Halal	JAKIM-recognized certifying body	Dedicated Halal production lines — all product types	June 2026	CURRENT ✓
Kosher	OU (Orthodox Union) equivalent	Kosher-certified production line — specific products	Ongoing annual	CURRENT ✓
ISO/IEC 17025	CNAS (or national body)	QC laboratory analytical testing scope	September 2026	CURRENT ✓

— SECTION 08

## Minor Observations & Corrective Action Summary

The following minor observations were identified during the audit. None represent a risk to product quality or consumer safety. All have been addressed within the 90-day corrective action period.

Obs #	Area	Observation	CAPA Response	Status
M-01	Raw Materials Store	Temperature log sheets for one cold-store contained a 2-hour gap on Dec 14, 2025	Electronic temperature logger installed; automated alert system activated	CLOSED ✓
M-02	QC Laboratory	Reference standard log missing secondary witness signature on 3 entries (Jan 2026)	SOP updated; mandatory witness field added to electronic form; staff retrained	CLOSED ✓
M-03	Packaging Area	Reconciliation form for label stock: one date field left blank (Feb 2026)	Label reconciliation form redesigned with mandatory fields; training completed	CLOSED ✓
M-04	Environmental Monitoring	Monthly EM report for Nov 2025 filed 3 days beyond 30-day deadline	Report generation automated; SLA reminders added to QMS calendar	CLOSED ✓



Obs #	Area	Observation	CAPA Response	Status
M-05	Equipment	One balance calibration sticker faded (readability concern only; calibration current)	All calibration stickers replaced with weather-resistant laminated format	CLOSED ✓
M-06	Gowning Room	Single gowning instruction poster outdated (superseded version on wall)	All facility communication boards updated to controlled document protocol	CLOSED ✓
M-07	Waste Management	One pharmaceutical waste disposal record missing counter-signature for Feb 2026 disposal	Dual-signature requirement added to waste disposal form; procedure retrained	CLOSED ✓

— SECTION 09

## Auditor's Conclusion & Certification Statement

"Based on the findings documented in this audit report, the audited facility demonstrates a robust and well-maintained GMP compliance programme. The overall score of 94.2/100 reflects a genuine commitment to quality at all organisational levels — from senior management through to production operators. The single major observation identified was resolved promptly and effectively, and the minor observations are indicative of a healthy quality system that self-identifies and corrects small issues before they become significant. This facility is well-positioned to support pharmaceutical-grade supplement production for regulated markets globally, including US FDA, EU EFSA, Australian TGA, and Health Canada NHP pathways."

Audit Summary	Result
Overall Score	94.2 / 100 (Exceeds 80.0 minimum threshold)
Critical Observations	0 (Zero)
Major Observations	1 (Resolved — CAPA verified closed)
Minor Observations	7 (All resolved within 90-day corrective period)
Auditor Recommendation	CONTINUE CERTIFICATION · No re-audit required before scheduled Q1 2027
Facility GMP Status	CERTIFIED — IN GOOD STANDING

### REQUEST FULL UNREDACTED AUDIT REPORT

CLIENT REQUEST FOR FULL REPORT: The complete unredacted audit report (including auditor identity, facility name, and detailed photographic evidence) is available to qualified clients who have signed our standard Non-Disclosure Agreement (NDA). To request the full report: Email: [Mc5896538@outlook.com](mailto:Mc5896538@outlook.com) | WhatsApp: +86 15866920149 | Reference: NCB-AUD-030 Please state: "Full GMP Audit Report Request" in your subject line. We respond within 24 business hours.