

GLP-1 Supplement Batch Record Audit Checklist

Self-Assessment for Berberine, Chromium & Metabolic Support Manufacturers

GLP-1 adjacent supplements are one of the most watched categories in the FDA's current enforcement environment. Audit your documentation practices against the standard an inspector or retail buyer would expect — before they do.

■ Incoming Raw Material Documentation

- Every incoming lot has a formal receiving record with supplier name, lot number, and date.
Whiteboard notes, emails, and informal logs do not meet GMP receiving record standards.
- COA attached to the receiving record for each lot — not filed separately.
- For botanical ingredients: COA shows actual assay value, not just "conforms to spec".
Actual assay value is needed to calculate quantity adjustments for potency compliance.
- Incoming lot approved (or rejected) before use in production — documented disposition.

■ Potency Tracking and Quantity Adjustment

- For each botanical ingredient lot: actual assay value recorded at receiving.
- Batch quantity calculated based on actual assay value, not nominal.
If label claims 500mg berberine and lot is 95.2% purity, quantity must be adjusted accordingly.
- Quantity adjustment calculation documented in the batch record.
- Adjusted quantity verified by a second operator before blending begins.
- Finished product tested to confirm potency within spec — results linked to batch number.

■ Batch Record Completeness — Run This on Your Last 5 Batches

- Batch record exists for every production run.
If you cannot produce a complete batch record for every run in the last 12 months, you have a gap.
- Batch record shows actual quantities weighed — not just the formula quantities.
- Lot number of each ingredient recorded in the batch record.
- Operator identity recorded for each production step.
- Second operator verification recorded for critical steps (weighing, blending completion).
- Actual yield calculated and compared to theoretical yield.

- Batch record completed and reviewed before the next production run begins.

■ Lot Traceability Self-Test

- Pick any finished goods lot from the last 6 months. Can you identify every raw material lot used within 5 minutes?

If no, your traceability documentation has a critical gap.

- Pick any raw material lot. Can you identify every finished goods lot that used it within 5 minutes?

This is the recall direction question. If no, a recall would require pulling all inventory.

- For each finished goods lot: is the test result retrievable by batch number?

■ Deviation and Out-of-Spec Documentation

- Any production run with a yield deviation >5% has a written deviation record.

- Any finished product test result out of spec has a written investigation record.

Investigation must include: root cause, disposition decision, and corrective action.

- Corrective actions from deviations are documented and followed up.

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