

QA standard operating procedure

Release criteria, lot-locking, and deviation handling for every shipped vial.

Each lot is released by a designated analyst who reviews the identity, purity, endotoxin, and visual records against the predefined release specification. The reviewer is independent of the analyst who performed the underlying assays.

A lot is locked when the reviewer signs the release record. From that point the lot identifier, the analyst name, the release date, and the underlying instrument files are immutable and reproducible from cold storage.

Deviations — out-of-specification results, equipment qualification failures, or chain-of-custody breaks — block release. A documented investigation establishes root cause before any subsequent release decision.

All released CoAs are archived alongside the underlying chromatogram and assay records for the full retention period required by the governing jurisdiction.

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