

Certificate of Analysis (COA) Review Checklist

A certificate of analysis review starts with a specific document and a specific item. This checklist helps you record what the supplied pages actually show, where each finding appears, and which connections still need evidence. Use one worksheet per report and item pairing. The fields are intentionally blank: no laboratory, lot, test result, or conclusion has been supplied or verified by this toolkit. It is an administrative reading aid for non-clinical research documentation.

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Review reference

Review date and recorder's actual role

Item or catalog reference under review

Reason for the document review

1. Preserve the document you reviewed

Start with the issuer's file as received. Record the route by which it arrived, the date you obtained it, and the identifiers printed inside it. A download date describes your copy; it does not establish when the report was issued. A readable copy or transcription can help review, but keep it labeled separately from the original. If a page is missing, cropped, or unreadable, identify that gap before summarizing the report.

- ☐ Record the original filename, source location, and date received.
- ☐ Compare the displayed page count with the pages actually available.
- ☐ Transcribe the report number, issue date, and revision exactly as printed.
- ☐ Label any transcription or edited reading copy and retain the original.

Original filename and saved location

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Source URL or correspondence reference

Date received

Issuer / report number / printed issue date / revision

Pages available / stated page count

Missing or unreadable pages and affected entries

2. Record the item-to-report connection

Keep the catalog reference, supplier lot, laboratory sample identifier, and report number in separate fields. Compare the report's sample description with the item record rather than relying on the shared product name. A bulk sample and a packaged item need a documented connection if that relationship matters to the review. Preserve mismatches verbatim. FDA Q7 section 11.4 illustrates batch identification in API certificates; it is pharmaceutical manufacturing guidance, not a rule establishing the status of a research supplier.

- ☐ Record the supplier lot and laboratory sample identifier separately.
- ☐ Locate the report's sample description and the item description used for comparison.
- ☐ Identify any supporting record connecting the sample to the supplier lot and item.
- ☐ Leave a missing mapping unresolved rather than repairing an identifier by assumption.

Item description and source location

Supplier lot exactly as shown / source location

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Laboratory sample identifier / report page

Report sample description / report page

Mapping evidence filename or correspondence reference

Exact mismatch or missing connection

3. Make one entry for each reported test

Repeat this block for each test relevant to the documented review question. Keep the test name, method reference, result wording, stated basis, acceptance criterion if supplied, and page location together. Copy qualifications such as not reported or below a stated limit without converting them into a different finding. Do not add a test merely because another report includes it. NIST's SRM definitions distinguish certified and non-certified property information for NIST materials; those categories cannot be assigned to an ordinary COA by this worksheet.

- ☐ Copy each relevant test name and its method reference from the report.
- ☐ Preserve the reported result wording, units or basis, and any qualifier without recalculation.
- ☐ Identify whether an acceptance criterion is actually stated and where it appears.
- ☐ Record a missing test result as not located, rather than as a passing or failing result.

Test name / report page or table

Method reference as printed

Result exactly as reported

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Reported units or basis / qualification or footnote

Stated acceptance criterion and source, if present

What this entry addresses in the review question

What this entry leaves unresolved

4. Keep origin and version questions specific

A visible laboratory name or signature is information to investigate, not confirmation of authorship. Record an independently located issuer contact route and any response about this exact report number and revision. Keep report-origin confirmation separate from interpretation of results. If no response is available, preserve that status. If a replacement arrives, retain both files and the issuer's explanation; a newer filename alone does not establish that the earlier document was superseded.

- ☐ Record how the independent issuer contact route was located.
- ☐ Identify the exact report number and revision addressed by any response.
- ☐ Record only the parts of origin or version status the issuer explicitly confirmed.
- ☐ Preserve earlier files and link any replacement to its written explanation.

Independent issuer contact source and date checked

Question prepared / report identifier addressed

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Date requested / response reference, if any

Exact scope of issuer response

Version relationship supported by the response

Unanswered origin or version question

5. Log the gap and the evidence needed

Describe each open issue in terms that another reader can check: an absent page, conflicting lot code, unexplained result basis, or unconfirmed revision. Name the evidence that would answer that question. A missing document is a documentation gap; it is not proof of a defective material or a fabricated report. When a clarification arrives, append its date and location without rewriting the initial observation. Repeat this block for separate issues.

- ☐ State the exact field or passage that creates the question.
- ☐ Specify the document or explanation needed to resolve it.
- ☐ Assign a follow-up owner and a target review date without inventing a response.
- ☐ Close an issue only with a recorded evidence reference and a dated explanation.

Issue reference and date recorded

Observed gap / original report location

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Requested evidence or clarification

Follow-up owner / target review date

Response reference and date, if received

Still open or resolved / evidence supporting that status

6. Finish with a bounded document finding

Choose a status for the document review: not started, in progress, incomplete with listed gaps, or complete for the stated review question. Complete means the named administrative checks have evidence, not that the material is approved or every reported result has been independently reproduced. State which files and fields you examined. Keep supplier statements attributed, and distinguish document matches from laboratory conclusions. There is no automatic quality score or supplier ranking.

- ☐ Identify the exact review question and the records examined.
- ☐ List completed checks alongside their supporting locations.
- ☐ Carry all unresolved questions into the final note.
- ☐ Date the finding and identify the recorder by their actual role.

Document-review status selected by recorder

Checks completed and supporting references

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Unresolved questions and follow-up references

Bounded finding in the recorder's own words

Recorded by / actual role / date

7. Professional-review limitation

This checklist cannot authenticate a laboratory report, validate an analytical method, establish accreditation, or determine a material's fitness for a project. Where a decision depends on those questions, the responsible organization should obtain review by a qualified analytical or quality professional with access to the underlying records. FDA and NIST links explain their own document contexts; they do not certify Fit Club Elite, its suppliers, or any product. Completing the worksheet supplies no independent laboratory evidence.

- ☐ Keep any professional review separate from the administrative checklist.
- ☐ Record a reviewer's actual role and the evidence they considered.
- ☐ Leave conclusions outside the reviewed evidence unmade.

Question requiring professional review, if any

Responsible reviewer / actual role

Review record reference and date, if available

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Source references

FDA: Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, section 11.4

<https://www.fda.gov/media/71518/download>

NIST: SRM Definitions

<https://www.nist.gov/srm/srm-definitions>

A completed checklist is not proof of identity, purity, sterility, safety, legal compliance, or project suitability. Keep missing information visible; obtain qualified review for consequential decisions.