**Certificate of Analysis (COA) – Template**

*For use with Benchling data sources (Registry, Results, Inventory, Workflows, Notebook, Attachments)*

**Instructions for the LLM (high-level):**

* Populate fields only where data exist; omit unused sections without placeholders.
* Prefer structured Benchling objects and include their IDs/URLs (Registry entity, Inventory lot, Results table, Workflow run, Notebook entry, Attachment).
* For each test, include units, method/SOP, specification (acceptance criteria), actual result, and PASS/FAIL derived from comparison.
* Include provenance: timestamps, analyst, instrument model/serial, and software version when available.
* Surface any deviations/OOS/change controls and their impact assessment; record in the Deviations section.

# 1) Header / Cover

* Company name & address
* Document title (Certificate of Analysis / Certificate of Testing)
* Product name & description
* Catalog/Part number (if applicable)
* Batch/Lot number
* Print date / COA version
* Intended use label (e.g., Research Use Only)

*Header fields (example table):*

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Company | Document Title | Product Name | Catalog/Part No. | Batch/Lot No. | COA Version | Print Date | Intended Use |
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# 2) Product & Batch Metadata

* Description & formulation/buffer
* Concentration / Fill volume / Unit size
* Storage conditions & stability / retest date
* Container/closure system
* Manufacturing site and date(s) of manufacture

*Batch metadata (example table):*

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Description | Formulation/Buffer | Concentration | Fill/Unit Size | Storage | Retest/Expiry | Container/Closure | Manufacture Date(s) | Manufacturing Site |
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# 3) Specifications & Results

*Record one line per test. Use category to group (e.g., Formulated Bulk, Drug Product, Raw Material, Safety Panel).*

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Category | Test | Method/SOP or Pharmacopeia | Specification (with unit) | Result (with unit) | PASS/FAIL | Sample/Replicate ID | Instrument/Software | Attachments/URL | Notes |
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# 4) Optional Panels

* Adventitious agent/virology panel (e.g., HIV/HTLV/CMV/EBV, etc.)
* Microbiology (bioburden, sterility, mycoplasma), CCIT
* Identity (e.g., RAPD, sequencing), purity (e.g., SDS-PAGE, HPLC), potency/assay-specific endpoints

*Panel layout (example table):*

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| --- | --- | --- | --- | --- | --- | --- |
| Panel | Analyte/Endpoint | Method | Specification | Result | PASS/FAIL | Notes/Links |
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# 5) Visual Evidence (optional)

* Attach images such as SDS-PAGE gels, chromatograms, size distribution plots
* Include caption and link to the raw file in Benchling Attachments

*Image Caption Placeholder:*

|  |  |  |
| --- | --- | --- |
| Figure ID | Caption | Attachment Link/ID |
|  |  |  |
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# 6) Deviations / OOS / Change Controls

* List relevant records with IDs, brief description, and impact on release decision

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| --- | --- | --- | --- | --- | --- |
| Record ID | Type (Deviation/OOS/CC) | Description | Impact Assessment | Disposition/Justification | Link/URL |
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# 7) Disposition

* Final decision (Pass/Fail) for the lot/batch
* Reference to release criteria and any conditional release notes

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| --- | --- | --- | --- |
| Disposition | Justification/Notes | Released By (Name) | Date |
|  |  |  |  |

# 8) Approvals / Signatures

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| --- | --- | --- |
| QC Reviewer (Print/Sign/Date) | QA Reviewer (Print/Sign/Date) | Additional Approver(s) |
|  |  |  |
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# 9) Version / Change History

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| --- | --- | --- |
| Version | Description of Changes | Effective Date |
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# 10) References

* SOPs or methods referenced (numbers/versions)
* Pharmacopoeial chapters (e.g., USP <701>, <467>, EP 2.6.7)
* External documents (e.g., vendor COAs)

# 11) Footer / Disclaimers

* Intended use (e.g., Research Use Only / Not for human or veterinary use)
* Storage and handling advisories (e.g., do not vortex LNPs; avoid freeze-thaw)

# Guidance for finding accurate, relevant data and which section(s) they relate to:

* Registry → product entity and lot fields (name, catalog/part no., lot, formulation, storage, intended use).
* Inventory → lot quantities, container/closure, retest/expiry, storage location.
* Notebook/Workflow → batch record entry for manufacture date/time, equipment used.
* Results → one row per test: method/SOP, spec, result, unit, analyst, instrument, sample ID; derive PASS/FAIL from spec.
* Attachments → link evidence (reports, images) to tests and figures.
* External COAs → if provided as PDFs, ingest key fields (lot, product, tests, results) and attach the file; cite Third-Party Source in References.