The CoA Review Checklist

Ten steps, in order: steps 1 to 3 establish what you are looking at, 4 to 7 do the comparisons, 8 to 10 test whether the document can be trusted as a document. The full procedure with failure modes: pharmatrust.tech/resources/how-to-check-a-certificate-of-analysis

1. **Tie the certificate to the goods.**
   Material name, grade and batch number match the container label and the order. ICH Q7 11.40 to 11.41

2. **Identify the issuer.**
   Original manufacturer, or a repacker, agent or broker? A re-issued certificate names the testing laboratory and attaches the original. ICH Q7 11.43 to 11.44

3. **Establish the governing standard.**
   Monograph, supplier specification or your agreed specification: pin down the claim before reading anything else.

4. **Check the test list is complete**
   against the claimed standard. A claimed monograph with tests missing is a gap in the claim. ICH Q7 11.42

5. **Compare printed limits against the claimed standard's limits.**
   A looser printed limit means every pass on that row was judged against a weaker promise.

6. **Read the results against the printed limits.**
   Quantitative tests need numbers with units; "complies" belongs only to qualitative tests. ICH Q7 11.42

7. **Check arithmetic and internal consistency.**
   Impurities against their total, assay against its neighbours, repeated values that must agree.

8. **Check methods.**
   Each test names its method; unstated methods make monograph comparisons meaningless.

9. **Check the dates.**
   Manufacturing, release, retest or expiry: present, unambiguous, mutually consistent, and consistent with today's date if the material is about to be used.

10. **Check authorisation.**
    A dated signature from the issuer's quality unit, with the issuer's name and contact details in the text, not only in a logo. ICH Q7 11.43

When checking the document is not enough. At least one specific identity test per batch stays with the recipient under 21 CFR 211.84(d), EU GMP Chapter 5 (5.35) and ICH Q7 (7.30), and reduced testing must be earned through documented supplier evaluation and periodic full analyses. A document check cannot prove a document genuine; where stakes or doubts are high, the answer is a laboratory.

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