



TEMPLATE FOR CERTIFICATE OF ANALYSIS

The items included are based on good practices for national pharmaceutical control laboratories and good manufacturing practices (GMP) for pharmaceutical products¹. The certificate lists the results and includes a final evaluation and the conclusions of the examination of one or more samples.

In accordance with GMP, the certificate can be used in lieu of testing by the manufacturer (except for the identification tests as a minimum requirement), provided that the reliability of the supplier's analysis is established by the periodic validation of the test results by appropriate means and, if feasible, by on-site audits of the supplier's capabilities. Certificates must be originals (not copies or duplicates) or their authenticity must otherwise be assured, i.e. they must be issued by the supplier of the material concerned (manufacturer, broker, etc.), or based on the analytical worksheet of the laboratory testing the sample(s).

The certificate should include:

1. The name and address of the laboratory performing the tests.
2. The serial/document number of the certificate of analysis.
3. The name, description (i.e. grade, quantity received, type of container) and number (used by the original manufacturer and re-packer/trader) of the batch for which the certificate is issued, the date of manufacture, and the expiry date (or retest date).
4. The date on which the batch/sample for which the certificate is issued was received.
5. A reference to the test procedure used, including the acceptance criteria (limits).
6. The results of all tests performed on the batch for which the certificate is issued (in numerical form, where applicable) and a comparison with the established acceptance criteria (limits).
7. Any additional test results obtained on samples from the batch as part of a periodic statistically based testing programme.
8. A statement indicating whether the results were found to comply with the requirements.
9. The date(s) on which the test(s) was (were) performed.
10. The signature of the head of the laboratory or an authorized person.
11. The name, address, and telephone and fax numbers of the original manufacturer. If supplied by re-packers or traders, the certificate should show the name, address, and telephone and fax numbers of the re-packer/trader and a reference to the original manufacturer.
12. A statement of the expected conditions of shipping, packaging, storage and distribution, deviation from which would invalidate the certificate.
13. A copy of the certificate generated by the original manufacturer, if the sample is supplied by a re-packer or trader.

¹ Good manufacturing practices for pharmaceutical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report. Geneva, World Health Organization, 1992, Annex 1 (WHO Technical Report Series, No. 823).

APPENDIX 1

Model certificate of analysis for active pharmaceutical ingredients, excipients and medicinal products

Registration number of sample or certificate:

Name and address of laboratory testing the sample:

Sample information

Name of product (INN, brand name(s), etc.):

Dosage form (if applicable):

Marketing authorization number (if applicable):

Description (appearance of container and contents):

Batch number(s):

Required storage conditions²:

Date received: _____ Date of manufacture: _____

Expiry date (for medicinal products) or retest date (for starting materials or excipients):

Name and address of original manufacturer:

Telephone: _____ Fax: _____

Name and address of re-packer and/or trader (if applicable):

Telephone: _____ Fax: _____

Test procedure (reference to test procedure) (if applicable)	Result (numerical result) (if applicable) ³	Acceptance criteria (limits)
2A. Tests performed on samples from batch for which certificate is issued		
B. Tests performed as part of periodic statistically based testing programme		

² Statement of expected conditions of shipping, packaging, storage and distribution, deviation from which could render the certificate invalid.

³ Indicate if the results were obtained from periodic statistically based testing.

Conclusions:

Compliance with acceptance criteria: YES NO

Date test performed/finalized: _____

Name and address of head of laboratory/authorized person:

Telephone: _____ Fax: _____

Signature: _____

