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Annex 10
Model certificate of analysis

It has been recommended in various fora that WHO should establish a model certificate of analysis for use in trade in starting materials and by manufacturers of pharmaceutical substances, excipients and medicinal products. A model of such a certificate is shown in Appendix 1. The items included are based on good practices for national pharmaceutical control laboratories and good manufacturing practices (GMP) for pharmaceutical products (*1*). 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). For further details, see Annex 3.

The certificate should include:

- The name and address of the laboratory performing the tests.
- The registration number of the certificate of analysis.
- The name, description (i.e. grade, quantity received, type of container) and number (used by the original manufacturer and repacker/trader) of the batch for which the certificate is issued, the date of manufacture, and the expiry date (or retest date).
- The date on which the batch for which the certificate is issued was received.
- A reference to the test procedure used, including the acceptance criteria (limits).
- 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).

- Any additional test results obtained on samples from the batch as part of a periodic statistically based testing programme.
- A statement indicating whether the results were found to comply with the requirements.
- The date(s) on which the test(s) was (were) performed.
- The signature of the head of the laboratory or an authorized person.
- The name, address, and telephone and fax numbers of the original manufacturer. If supplied by repackers or traders, the certificate should show the name, address, and telephone and fax numbers of the repacker/trader and a reference to the original manufacturer.
- A statement of the expected conditions of shipping, packaging, storage and distribution, deviation from which would invalidate the certificate.
- A copy of the certificate generated by the original manufacturer, if the sample is supplied by a repacker or trader.

Reference

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 conditions:[1] _____

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 repacker and/or trader (if applicable):

Telephone: Fax:

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

Conclusions:

Compliance with acceptance criteria: yes☐ no☐

Date test performed/finalized:

Name and address of head of laboratory/authorized person:

Telephone: Fax:

Signature:

Explanatory notes

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

[2] Indicate if the results were obtained from periodic statistically based testing.