Annex 4

Model certificate of analysis

It has been recommended in various forums that the World Health Organization (WHO) should establish a model certificate of analysis (CoA) for use by quality control laboratories (QCLs) and in trade in starting materials and finished pharmaceutical products (FPPs). The model for such a certificate was first published in 2002 (*1*) and the current model is shown in Appendix 1. The items included are based on *WHO good practices for pharmaceutical quality control laboratories* (*2*) and *WHO good manufacturing practices for pharmaceutical products* (*3*). In addition, requirements of the International Standard ISO/IEC 17025 (*4*) and recommendations of the International Pharmaceutical Excipients Council (*5*) have been taken into account. Any specific legal requirements existing in the country of issue or importation should also be considered when issuing the certificate. This guidance is essentially designed for QCLs not related to manufacturers since the QCLs of manufacturers may have some of the information listed below in other quality system documents and therefore not necessarily included in the CoA.

The format and organization of the information on the CoA is at the issuing laboratory's discretion. The CoA can be printed on letterhead with the logo of the issuing laboratory.

According to *WHO good practices for pharmaceutical quality control laboratories* (*2*) the CoA lists tests performed on a particular sample with the results obtained and the acceptance criteria applied, followed by an indication of whether or not the sample complies with the specification. A CoA is usually prepared for each batch of a substance or product and should include the following information:

- the name and address of the laboratory issuing the CoA;
- the identification number of the CoA and on each page an identification, the page number and the total number of pages to ensure that every page is recognized as a part of the certificate;
- the name, address and contact person representing the originator of the request for analysis;
- the number assigned to the sample by the laboratory during registration upon receipt;
- the date on which the sample was received in the laboratory and the quantity of sample (number of units or packages);

- the name, description (for example, active ingredient, dosage form, strength, package size in the case of FPPs; grade in the case of starting materials; type and material of the primary packaging), batch number (used by the original manufacturer and repacker or trader) of the sample for which the certificate is issued, the expiry date (or retest date, where applicable) and date of manufacture (if available);
- the name and address of the original manufacturer; in addition, if supplied by repackers or traders, the certificate should show the name and address of the repacker or trader;
- specifications for testing and a reference to the test procedure(s) used, including the acceptance criteria (limits);
- the results of all tests performed on the sample for which the certificate is issued (in numerical form, where applicable) and a comparison with the established acceptance criteria (limits); results of tests performed by subcontractors should be identified as such;
- any comments, observations or information on specific test conditions, where these are necessary for the interpretation of the results;
- a conclusion as to whether or not the sample was found to be within the limits of the specification;
- the date and signature of the head of the laboratory or other authorized person approving the certificate.

If the sampling plan and procedures used by the laboratory or other bodies are relevant to the validity or interpretation of the results, they should be referenced in the CoA.

Where relevant to the validity or application of the results, or if required by a customer, a statement on the estimated uncertainty of measurement should be included. However, it should be borne in mind that pharmacopoeial content limits are set taking into account the uncertainty of measurement and the production capability, and acceptance criteria for an analytical result should be predefined. Under currently applicable rules, neither the pharmacopoeias nor the medicines regulatory authorities require the value found to be expressed with its associated expanded uncertainty for compliance testing.

In the case of testing under contract, a customer may also request other information to be specified in the CoA.

If appropriate, the CoA may include a photograph(s) of the packaging and/or product tested.

If new certificates are issued by or on behalf of repackers or traders, these certificates should show the name and address of the laboratory that performed

the tests and the name and address of the original manufacturer. A copy of the CoA generated by the original manufacturer should be attached.

When the certificate is used in trade it may also include a statement of the expected conditions for shipping, packaging, storage and distribution, deviation from which would invalidate the certificate.

QCLs with accreditation to the International Standard ISO/IEC 17025 should include in the CoA a reference to the accreditation, if related to the specific analysis.

References

1. Model certificate of analysis. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-sixth report. Geneva: World Health Organization; 2002: Annex 10 (WHO Technical Report Series, No. 902).
2. Good practices for pharmaceutical quality control laboratories. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-fourth report. Geneva: World Health Organization; 2010: Annex 1 (WHO Technical Report Series, No. 957).
3. WHO good manufacturing practices for pharmaceutical products. Geneva: World Health Organization (http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/, accessed 29 December 2017).
4. General requirements for the competence of testing and calibration laboratories. Geneva: International Organization for Standardization; 2005 (ISO/IEC 17025:2005).
5. Certificate of analysis guide for pharmaceutical excipients. Brussels: International Pharmaceutical Excipients Council; 2013 (http://ipec-europe.org/UPLOADS/CoA-guide-2013.pdf, accessed 29 December 2017).

Appendix 1

Model certificate of analysis for starting materials and finished pharmaceutical products

This model is intended to serve as an example and not to be prescriptive.

Header:
Logo of the laboratory or company issuing the certificate (if applicable)
Identification no. of the CoA *page X of Y*

Name and address of the laboratory issuing the CoA: _____

_____

Identification no. of the CoA: _____

Name, address and contact person representing the originator of the request for analysis: _____

_____

Registration no. of the sample: _____

Date received: _____ Quantity received: _____

Name of the product (International Nonproprietary Name (INN), brand name, etc.): _____

_____

Dosage form, strength, package size (if applicable): _____

_____

Type and material of the primary packaging: _____

_____

Batch number: _____

Date of manufacture (if available): _____

Expiry date/retest date: _____

Name and address of the original manufacturer: _____

_____

Phone: _____ Email: _____

Name and address of the repacker and/or trader (if applicable): _____

_____

_____

Phone: _____ Email: _____

Specifications for testing: _____

Test	Method reference[1]	Acceptance criteria	Result[2,3]	Compliance statement

Additional information, if requested by the customer:

Comments:

Conclusion on compliance of the sample with the specifications:

Name of the head of laboratory or person authorized to approve the certificate:

Phone: _____ Email: _____

Signature:

Date:

[1] Reference to a pharmacopoeia or technique.

[2] Results in numerical form, whenever applicable.

[3] Results of tests performed by subcontractors should be identified as such.