Should you have any comments on the attached text, please send these to: Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms, World Health Organization, 1211 Geneva 27, Switzerland; email: kopps@who.int; fax: (+41 22) 791 4730; and to Mrs Xenia Finnerty (finnertyk@who.int), by 15 July 2017.

Working documents are sent out electronically and they will also be placed on the Medicines website for comment. If you do not already receive directly our draft guidelines please let us have your email address (to bonnyw@who.int) and we will add it to our electronic mailing list.
**SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/16.687:**

**MODEL CERTIFICATE OF ANALYSIS**

<table>
<thead>
<tr>
<th>Task</th>
<th>Date</th>
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<tbody>
<tr>
<td>Suggestion to revise the <em>Model certificate of analysis</em> (published as Annex 10 in the WHO Technical Report Series, No. 902), 2002 during the <em>Joint meeting on regulatory guidance for multisource products with the medicines quality assurance group and the prequalification of medicines team - assessment group</em> held in Copenhagen, taking care of the new trends and international developments</td>
<td>8–9 July 2016</td>
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<tr>
<td>Drafting of a revised text based on the suggestions made during the above meeting by Dr J. Sabartova, Czech Republic</td>
<td>August–September 2016</td>
</tr>
<tr>
<td>Presentation to the fifty-first meeting of the WHO Expert Committee for the Specifications of Pharmaceutical Preparations (ECSPP), recommendation to continue revising process</td>
<td>17–21 October 2016</td>
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<tr>
<td>Circulation for comments</td>
<td>November 2016</td>
</tr>
<tr>
<td>Compilation of comments received</td>
<td>February 2017</td>
</tr>
<tr>
<td>Discussion of feedback received during an informal consultation</td>
<td>2–4 May 2017</td>
</tr>
<tr>
<td>Circulation for comments</td>
<td>June 2017</td>
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<tr>
<td>Compilation of comments received</td>
<td>August–September 2017</td>
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<tr>
<td>Presentation to fifty-second meeting of the WHO ECSPP</td>
<td>October 2017</td>
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<td>Any follow-up action, as needed</td>
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Model certificate of analysis

It has been recommended in various fora that the World Health Organization (WHO) should establish a model certificate of analysis (CoA) for use by quality control laboratories and in trade in starting materials and finished pharmaceutical products (FPPs). A model of such a certificate is shown in Appendix 1. The items included are based on WHO good practices for pharmaceutical quality control laboratories (1) and WHO good manufacturing practices for pharmaceutical products (2). In addition, requirements of the International Standard ISO/IEC 17025 (3) and recommendations of the International Pharmaceutical Excipients Council (4) have been taken into account. If any specific legal requirements exist in the country of issue or importation they should be considered when issuing the certificate. Quality control laboratories of a manufacturer 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 headed paper with a logo of the issuing laboratory can be used.

According to WHO good practices for pharmaceutical quality control laboratories (1) CoA lists test procedures applied to a particular sample with the results obtained and the acceptance criteria applied, and indicates 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 total number of pages in order to ensure that the page is recognized as a part of the certificate;
– the name, address and contact person of the originator of the request for analysis;
– the number assigned to the sample by the laboratory during registration at receipt;
– the date on which the sample was received in the laboratory and the sample quantity (number of units/packages);
– the name, description (e.g. 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/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;

1 This was previously published as Annex 10 in the WHO Technical Report Series, No. 902, 2002.
any comments, observations, or information on specific test conditions should be included, where 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.

In the case that 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 born 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 presently 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 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, name and address of the original manufacturer and 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 of shipping, packaging, storage and distribution, deviation from which would invalidate the certificate.
References


Appendix 1

Model certificate of analysis for starting materials and finished pharmaceutical products

Name and address of the laboratory issuing the CoA: _________________________________
_____________________________________________________________________________
Identification no. of the CoA: ______________________________________________________
Name, address and contact person of the originator of the request for analysis: __________
_____________________________________________________________________________
Registration no. of the sample: _____________________________________________________
Date received: ___________________ Quantity received: _____________________________
Name of the product (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: ________________________________________________

<table>
<thead>
<tr>
<th>Test</th>
<th>Method reference&lt;sup&gt;2&lt;/sup&gt;</th>
<th>Acceptance criteria</th>
<th>Result&lt;sup&gt;3, 4&lt;/sup&gt;</th>
<th>Compliance statement</th>
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Additional information, if requested by the customer:

Comments:

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<sup>2</sup> Reference to a pharmacopoeia or technique.

<sup>3</sup> Results in numerical form, whenever applicable.

<sup>4</sup> Results of tests performed by subcontractors should be identified as such.
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

***