

Standard Operating Procedure

Title: Creation of Certificate of Analysis

- The generic name of the active ingredient (s) should be used
- Numerical values and/or limits should be written with the corresponding units
- For identification: reference should be made to the 'Approved test(s)'
- Numerical results should apply whenever the specification is numerical (units are optional if stated under specification)
- For semi-quantitative tests, results would be reported as 'less than x units' or within a given interval
- For impurities, numerical result should be reported if applicable '< detection limit (numerical + units)' should be reported
- Non numerical results should be reported as required e.g. complies, approved or conforms
- Date of release
- GMP statement and conclusion, if required
- Full signature of Authorised Person.

1.1.4. Additional general requirements:

- Title: Certificate of Analysis.
- Information on the site generating the Certificate of Analysis e.g. printing the Certificate of Analysis on company letterhead.
- The Certificate of Analysis should be in English.

1.2. Why produce Certificates of Analysis?

- 1.2.1. Every batch that is manufactured and sold must have a Certificate of Analysis which gives the assurance of conformity and product quality or to accompany the product for customs clearance.

1.3. Who is responsible for creating Certificate of Analysis?

- 1.3.1. The Laboratory is responsible for generating and issuing all Certificates of Analysis and the Authorised Person (see SOP **QMS-070**) is the signatory.

- 1.3.2. Only the authorised Laboratory delegates are to create Certificate of Analysis.

1.4. How are Certificates of Analysis created?

Certificate of Analysis are manually created based on a standard template system or from another manufacturer's Certificate of Analysis. See **Form-320** for a standard template of Certificate of Analysis.

1.5. When are Certificates of Analysis to be generated?

- 1.5.1. Certificate of Analysis is created for all manufactured goods once they have been released. Once completed and signed, are directly issued through Distribution Department.

2. What are 'Certificates of Manufacture'?

2.1. Certificates of Manufacture are:

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- 3.6. Any change to the Certificate of Analysis must be proceeded through Technical Department change control procedure as written in the SOP **QMS-030**.
 - 3.7. Once a Certificate of Analysis has been created, write the country and date as it was completed on the Finished Product Specification and Test Report (**TEM-060**) for the batch
 - 3.8. If the batch is a rework batch, refer to the original test report for results. There is no need to generate another Certificate of Analysis if it has already been issued (from the original test report).
 - 3.9. Once all Certificates of Analysis are completed, give to the Authorised Person to sign. This will then be forwarded to the Distribution Department.
 - 3.10. Any incorrect Certificate of Analysis is to be destroyed by shredding or depositing in the Security Paper Waste bin.
 - 3.11. File the Finished Product Specification and Test Report and the C of A template to their original cabinets.
 - 3.12. A Certificate of Analysis is usually only issued once per batch. If a request is made for a batch that has previously had a Certificate of Analysis or a Certificate of Manufacture generated and issued for/to the same country/Third Party Contractor, inform the relevant department and do not reissue the Certificate of Analysis or Certificate of Manufacture unless another original is absolutely necessary.

4. C of A or C of M for Raw Materials

- 4.1. All requested components are to have a Certificate of Manufacture issued.
- 4.2. All requested Raw Materials are to have either a Certificate of Analysis or a Certificate of Manufacture depending on where the Certificate of Analysis or Certificate of Manufacture is being sent.
- 4.3. If a Certificate of Analysis will be issued and the product was manufactured by a Third Party Contractor, there should be a manufacturer's Certificate of Analysis attached. In this instance, photocopy the manufacturer's Certificate of Analysis and stamp with the Raw Material Stamp as follows. Fill out the appropriate details and give to the Authorised Person for signing.
- 4.4. Example of the Raw Material Stamp:

Product Batch No.	
Expiry Date / Retest Date	
Authorised Person	
Date of Release	