

# Standard Operating Procedure

## Title: Creation of Certificate of Analysis

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- 2.1.1. Certificates of Manufacture can be issued for finished good and raw material goods, both chemicals and components.
- 2.1.2. Certificates of Manufacture contains the following information:
  - Product Code No.
  - Process Order No.
  - Date of Manufacture (Finished goods and chemicals only)
  - Expiry Date
  - Regulatory statement (If applicable)
  - Date of Release
  - Authorised Person signature.
- 2.2. Why do we produce Certificate of Manufacture?
  - 2.2.1. Certificates of Manufacture are produced for product that is sold to third party contract manufacturers where a Certificate of Analysis are not authorised to be issued for components.
- 2.3. Who is responsible for creating Certificate of Manufacture?
  - 2.3.1. The Laboratory is responsible for generating and issuing all Certificates of Manufacture. Only the designated Authorised Person can sign the Certificates of Manufacture.
  - 2.3.2. Only the authorised Laboratory delegate is to create Certificates of Manufacture.
- 2.4. How are Certificates of Manufacture created?
  - 2.4.1. Certificates of Manufacture are created using a template.
3. Creating Certificate of Analysis for Goods Sold
  - 3.1. See Flowchart – Manual Creation of Certificate of Analysis in [Appendix C](#).
  - 3.2. Collect the Certificate of Analysis template and the corresponding finished product specification and test report (TEM-060) for the specific product code and check if the specification number on the template matches with that of finished Product Specification and Test Report for that material code. Copy the correct C of A template onto an official letter head. The C of A template can not be changed at any occasion as it is prepared based on the regulatory requirements where the goods are to be marketed.
  - 3.3. Only Blue felt tip pen is to be used on Certificate of Analysis.
  - 3.4. Ensure all results conform to the specifications, e.g. If the specification is stated as 'Positive' then the conforming result must be recorded as 'Positive', if the specification is stated as 'Sterile' then the conforming result must be recorded as 'Sterile', write all numerical values with units.
  - 3.5. If the specification is different on the template to the Material code, write the Material code in pencil above the specification number. This will aid Distribution Department in issuing the Certificate of Analysis.