

# Standard Operating Procedure

## Title: Raw Materials - Laboratory Testing and Documentation

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- 4.4. All calculations are to be entered into the Technician's workbook and the Specification-Test report.
  - 4.5. **Information required in a workbook:**  
Raw Material name and Material Number, Lab. batch number, testing date and all raw testing data, e.g. weights, volume.  
The information regarding the standard used in the testing should be written down, e.g. Batch Number, Expiry Date and assay.
  - 4.6. See **SOP QMS-020**. All data is to be neat and legible. There are to be **no scribbles, no liquid paper** and **all** calculations are to be clearly shown. **Pencil is not to be used**. Any mistake should be crossed out neatly, dated and initialled. Corrections on the Specification-Test report are to be initialled and dated.
  - 4.7. All results, which are generated by a computer printout, (e.g. UV/VIS, FTIR, Polarimeter etc), should be attached to the Specification-Test report.
  - 4.1. A raw material trend card (**Form-265**) is assigned for each single raw material. Laboratory staff has to fill up the test results accordingly from the workbooks and sign the card.

### 5. Testing of Raw Materials

There are associated authorised SOPs, Raw Material Control Methods and Packaging test methods and Instrument manuals that must be used to test raw materials and components.

#### 5.1. Testing that requires the use of instruments

- 5.1.1. The Technician needs to ensure that the instrument has been calibrated according to the calibration schedule.
- 5.1.2. If the instrument is within calibration, testing can proceed. If the instrument has not been calibrated, the calibration must take place according to the appropriate SOP.
- 5.1.3. If the instrument is out of calibration, alert the Laboratory manager so that the appropriate steps can be taken. Do not use the instrument to perform the test.

#### 5.2. Packaging Material - Approval Against Supplier Certificate of Analysis or Conformance

- 5.2.1. For these approved packaging materials the Manufacturer's Certificate of Analysis or Conformance is accepted as a basis for approval of the material in Production. The Certificate must clearly identify the respective delivery. These packaging materials are identified as requiring Certificates of Analysis on the Packaging Material specification-Test Report.
- 5.2.2. If historically, a component has been accepted without testing and there have not been any major recurring complaints about the component, this component can continue to be accepted against the Certificate of Analysis or Conformance. If problems occur with the component it is at the discretion of the Laboratory Manager to reinstate full testing of the material.

#### 5.3. Reagents used in testing

- 5.3.1. Reagent solutions should be made up according to the Raw Material Specification-Test Report and Test methods.