manager. Master Document Change Control Form (**Form-365**) is generated by the Laboratory Technician to correct the error.

3.2. Control Methods to be used for Finished Goods, Trial and Stability testing, is established by Technical Service, QA and Laboratory teams as a part of master documents.

3.3. Finished Good testing: Control Method to be used is noted on the Finished Product Specification and Test Report.
Trial and Stability testing: Control Method is noted on the card or Protocol.

4. Pre-Testing

4.1. Note any unusual sample characteristics of the Finished Goods, Trial or Stability samples.

4.2. Determine the type and sequence of tests to be performed.

4.3. For each test, utilise the appropriate personal protective equipment.

4.4. Set up the test equipment and ensure that it is within calibration. If not, calibrate the equipment prior to use (see SOP **LAB-010**).

Do not use an instrument that is out of calibration to perform a test.

4.5. Alert the Laboratory manager immediately if an instrument is failing its calibration. The authorised laboratory technician arranges the service/repair of the equipment. See **SOP LAB-010.**

5. Reagents Used in Testing

5.1. Reagent solutions are made up according to the Finished Product Specification-Test Report and the corresponding Test methods.

5.2. When a reagent solution requires standardisation, duplicate standardisations are performed according to the method. Duplicate results should not differ by more than 2%.

5.3. Reagent solutions used must be within the expiry date.

5.4. See **SOP LAB-035** for the preparation and storage of reagent solutions.

5.5. See **SOP LAB-040** for the disposal of Reagent waste.

6. Standards Used in Testing

6.1. When a standard solution is prepared, the information and calculations relating to the standard must be recorded in the workbook. See **SOP LAB-025** on correct data entry into the workbook.

6.2. See **SOP LAB-035** for the preparation and storage of Standard solutions.

6.3. Refer to **SOP LAB-020** for the use and storage of Primary and Secondary Standards.

UNLABELLED CHEMICALS are a SAFETY HAZARD to others and ARE NOT PERMITTED.

7. Sample testing

9.3. Results not within specification follow **SOP LAB-055.** and record all details of the investigation on **Form-305**.

10. Documentation of Results

A workbook is a legal document. All data is to be neat and legible. Scribbles, liquid paper and pencil are not permitted. Calculations are to be clearly shown. Any mistakes in a workbook or a Results Recording Sheet when corrected are crossed out neatly, initialled and dated. See **SOP LAB-025.**

10.1. A numbered workbook including numbered pages is required to document/log all testing information, including out of specification investigation results.

10.2. Information required in a workbook.
Finished Goods Name and Code Number, Batch Production Number, control method number/s, testing date and all raw testing data, e.g. weights, volume.
The information regarding the standard used in the testing should be written down, for example, Batch Number or Lab. Batch Number, expiry date and assay.

10.3. All calculations and measurements are to be entered into the Analyst's workbook.

10.4. Tests, e.g. Identity and Limit tests, can be directly entered onto the FG Specification and Test Report, Stability Card or Trial Card. Terms such as "negative", "positive", "conforms" should be used to describe limit and identity tests. All entries on FG Specification and Test Report, Trial Card or Stability Card are to be signed and dated.

10.5. FTIR, UV/VIS, Particle Counters and Polarimeter etc results generated by a computer printout are attached to the FG Specification and Test Report. The computer printout of the standardisation of solutions on the UV/VIS and Polarimeter are attached to the analyst's workbook.

10.6. A Finished Goods Trend card **(Form-260)** is assigned for each single finished Product. Laboratory staff has to fill up the test results accordingly form the workbooks and sign the card

10.7. The FG Specification and Test Report is then filed in the appropriate work file.

11. QA Inspection Sheet

11.1. After a finished product is tested according to corresponding "Finished Product Specification and Test Report" (**TEM-160**) the selective test results are to be entered into part B of "QA Inspection sheet" (**Form-565**). Authorised laboratory analyst should enter the results from the analyst work book and the completed Finished Product Test Report **(TEM-160)**. The Inspection sheet has to be transferred to QA for final release of the Batch.

12. Microbiological Testing

Microbiological testing is required for various Finished goods.

Check the FG Specification and Test Report and if "MICRO STATUS" is required, send the required sample to in house or contract micro laboratories. Document the micro results on to the FG Specification and Test Report and on the trend card writing the contract laboratory reference no.

13. Completed FG Specification and Test Report

13.1. Completed FG Specification and Test Report are filed in the appropriate work file.

