

# Standard Operating Procedure

## Title: Finished Goods – Laboratory Testing & Documentation

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- 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 from 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.