

## Standard Operating Procedure

### Title: Laboratory In-Process and Finished Product Quality Control

5.3.2 Obtain the specific product folder, which contains the Finished Product Specifications and Test Methods.

5.3.3 Enter the following sample information into the blank Product Test Record Form:

Product Name  
Specifications Reference Number  
Date  
Batch / Lot Number  
Product Type (e.g. Blend, Bulk and Finished Goods)  
Test to be performed  
Reference  
Test Frequency  
Specification of the test.

**Note:** The Laboratory Manager or designee should be consulted to clarify if full testing is required for this lot or whether the lot is part of the reduced testing program.

5.3.3.1 A Product Test Record Sheet must be generated upon testing a blend sample.

5.3.4 Carry out the test by the test method listed in the Finished Product Specifications and Test Methods, document the testing in the Laboratory workbook as per standard procedure. Complete, sign and date all documentation as per Good Documentation Practices. On completion the laboratory analyst should perform the followings:

5.3.4.1 Open the product specific files and enter the sample lot number and the results into the required worksheets. The trend graphs should be updated with the new results entry.

5.3.4.2 Check the results entered in the corresponding trend graphs are within both the Upper Control Limit and Lower Control Limit. If not, proceed as per section 5.3.8.

**Note:** There should be a few charts ready for use for individual and average test results; e.g. Active Assay Chart, Dissolution Chart and Moisture Chart.

5.3.5 Complete the Product Test Record form by entering the results, the Laboratory Workbook reference and test completion date in the corresponding section in the Product Test Record form, sign and date the entries.

5.3.6 Ensure the test results conform to the Finished Product Specifications, if not, proceed as per section 5.3.8.

5.3.7 The Laboratory Analyst should report the results with the same number of decimal places as the specifications (unless specified in the reporting criteria from the method).

5.3.8 The Laboratory Analyst must report any result that is out of specification, out of trend or any deviations from the testing to the Laboratory Manager or designee.

5.3.8.1 If the test result is out of either Upper Control Limit or Lower Control Limit, but within the Finished Product specifications, the Laboratory Analyst must note the out-of-trend result in the workbook.