

Standard Operating Procedure

Title: Raw Materials - Laboratory Testing and Documentation

- 2.2. An entry is made into the Raw Material Register form (**Form-255**) as soon as the samples arrived into the laboratory.

3. Pre-Testing

- 3.1. Raw Materials are tested to the FI/FO (First in/First out) principle or urgency unless specifically requested as a priority.

Information regarding the Raw Material is documented on the sample container, Goods Receipt Slip and Raw Material Specification and Test Report sheet. The Raw Material is assigned an unique Laboratory batch number which will be same in the containers and GRS slip.

- 3.2. Controlled Test methods for Raw Material Specifications-Test Report for chemicals are located in the Raw Material filing cabinets and are filed alphabetically.

Controlled Test methods for Packaging Material Specifications-Test Report are filed in Material Code Number order on the packaging material shelves.

Note: Any Raw Material Specification found to contain an error should be brought to the attention of the Laboratory Manager immediately.

To correctly verify the Raw Material against the Raw Material Specification-Test Report:

3.2.1. **Sample verification:**

Check the code number, name, batch number on the sample container is identical to the information contained on the Specification-Test Report. Check the Code number, Name, Supplier, Manufacturer and manufacturer's lot number matches with GRS supplied and the Specification report.

3.2.2. **Specification report and Test Methods verification:**

Check the test method number for the specific tests listed on the Specification report matches with that of test methods. Check that the quantity required for testing in the Raw Material Specifications matches the quantity sampled.

- 3.3. Raw Materials with Manufacturer's Batch Number that have been previously received, require reduced testing according to the Raw Material Specification.

- 3.4. Raw Materials qualifying for extension of expiry date also require reduced testing according to Raw Material Specification (see **SOP LAB-005**).

- 3.5. To check if a chemical Raw Material has been previously received check Laboratory Raw Material Register Log (**Form-255**).

4. Documentation of Results

A workbook is a legal document and should be treated with care. All results should be entered in the manner specified in SOP LAB-025.

- 4.1. A numbered workbook including numbered pages is required to document/log all testing information, including repeats and how the problem was solved for the repeat testing to become an acceptable results.
- 4.2. It is not required to write all the testing steps or methods in the workbook, only those steps that require measurements that affect a calculated result.
- 4.3. Tests, e.g. Identity and Limit tests can be directly entered onto the Specification-Test report. Terms such as "negative", "positive" and "conforms" should be used to describe Limit and Identity tests. All entries on the Specification-Test report should be signed and dated.

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5.3.2. When a reagent solution requires standardisation, this should be done in duplicate according to the compendia method, the duplicate results should not differ by more than 2%.

5.3.3. The reagent solutions should be stored in appropriate containers (glass/plastic bottles) and labelled legibly with information as to name of reagent, strength and or factor, date of preparation or standardisation, storage conditions, expiry date, the initials of the person preparing the reagent and reference to the source of raw data.

5.3.4. See **SOP LAB-035** for information on the use and storage of analytical reagents.

5.4. Standards used in testing

5.4.1. When a standard solution has been made up accurately, the information regarding the standard should be recorded in the workbook.

5.4.2. The standard solutions should be stored in appropriate containers and labelled legibly with information including the name, date prepared, storage conditions, expiry date and the initials of the person who prepared the standard.

5.4.3. See **SOP LAB-020** for information on the use and storage of Primary and Secondary Standards.

Unlabelled chemicals are a safety hazard to others and does not comply to GLP.

5.5. It is essential that work areas are clean and tidy at the end of the day.

5.6. Equipment is to be left in a clean condition and ready for the next user.

6. Out-Of-Specification Results

The procedure for dealing with Out of Specification (OOS) results is detailed in **SOP LAB-055 using Form-310**.

7. Microbiological Testing

Microbiological testing is required for various Raw Materials.

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

8. Completed Raw Material Specification Sheet

Completed Raw Material Specification sheets are placed in the "Raw Materials for Passing" tray for release by the Laboratory Manager or delegate.

9. Release of Raw Materials

9.1. The Laboratory Manager or delegate checks the completed Raw Material Specification and Test report against the standard Release Specification, workbook entries, proof of testings and the trend card (**Form-265**) before releasing the batch.

9.2. The Laboratory Team Specialist or delegate assigns a **RELEASE** or **CONDITIONAL RELEASE** or **REJECT** status to the Raw Material. The Raw Material Specification-Test report and the Trend card is signed and dated.