SOP: LFA 00072
Procedure to establish the capability of analyst to perform the analysis accurately

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1 Objective

Applicable to the analyst and the ability to perform the analysis with accuracy

2 Scope

Applicable to the analyst and the ability to perform the analysis with accuracy

3 Responsibility

By Quality Control Officer

4 Accountability

Quality Control Manager

5 Procedure

5.1. The QA Manager shall identify the samples with known analytical values.

5.2. The QA Manager will document the sample?s analytical values along with the acceptable limits, code no. and AR nos. in a register, which is maintained for such purpose.

5.3. As per sample requirement, all the coded samples will be kept in sealed vials at $2 - 8°C$.

5.4. The coded sample as well as any information pertinent to the analysis will be disclosed to the analyst.

5.5. Materials that are already approved by the QA lab or by the Supplier test report (authentic/authorized testing agency) will be used as testing material for routine validation exercise.

5.6. The analyst will validate by doing one or more of the following:

- Assay
- Identification by IR spectrophotometer
- Melting point
- Moisture content

5.7. Validation will include using one or more of the following methods of analysis

- HPLC
- IR Spectrophotometer
- KF Analysis
- Melting Point analysis
- Titrimetry
- UV Spectrophotometer

5.8. The results are then compared with the cGLP compliance, and with the expected values.

5.9. Materials that are subjected to the quality monograph will be provided to the analyst.

5.10. No repeat test is allowed to the analyst.

5.11. The ability of the analyst to perform the test is considered as satisfactory if the results are within the acceptable limits.

5.12. The analyst will be re-evaluated after two years.

5.13. Information about strip charts, chromatograms, calculation and manager?s comments should be filed under the analyst training files.

5.14. A new analyst will be evaluated within one year of joining the company.

5.15. After the test is completed, the QC Officer will check the result and file the record.

5.16. QA Officer will give his recommendation to the QA Manager.

5.17. QA Manager will review the report and decide which analyst will undergo routine analysis. If an analyst failed the test, he/she will undergo training for testing equipment and testing procedure.

5.18. The result provided by the analyst will be crosschecked with previous documents, including checking for any similarities of the results.

5.19. If the material is new and has not been tested before by an approved analyst of the company, the supplier report will be considered as an acceptable reference for the validation test. If the analyst failed to qualify the test, as per the vendor, another approved analyst will check and do a repeat test.

5.20. If there are three or more analysts who are under evaluation, percentage Relative Standard Deviation will be used to interpret the result. The percentage RSD should not be more than 1%.

5.21. The result of the analyst should not differ by defined acceptance criteria to the actual test report of the material.

6 Abbreviations

SOP Standard Operating Procedure

QC Quality Control

GLP Good Laboratory Practice