TITLE: PROCEDURE FOR MAINTENANCE AND USAGE OF ANALYTICAL INSTRUMENTS / EQUIPMENTS

1.0 PURPOSE:

To lay down a procedure for Maintenance of Analytical Instruments / Equipments

2.0 SCOPE:

This SOP is applicable for the instruments used in Quality Control Department at Discovery Intermediates Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 Analyst-QC shall be responsible to follow this SOP.

3.2 Head-QC/Designee shall be responsible for ensuring implementation of this SOP.

3.3 Head-QA/Designee shall be responsible for monitoring overall compliance of this SOP.

4.0 DEFINITIONS:

4.1 **Break Down Maintenance:**

Maintenance activity that is carried out to repair the Instruments/equipments which are under break down.

4.2 **Calibration:**

Operation establishing the relation between quantity values provided by measurement standards and the corresponding indications of a measuring system, carried out under specified conditions and including evaluation of measurement uncertainty.

5.0 PROCEDURE:

5.1 **Breakdown / Maintenance:**

5.1.1 If any Instrument/Equipment breakdown occurs during the calibration or during the routine analysis or displays any ‘Error Message’ then immediately the analyst shall inform to Head-QC/designee.

5.1.2 Head-QC/designee shall verify the Instrument/Equipment and perform primary inspection and instruct the analyst to enter the details in its respective ‘Instrument history card’.

5.1.3 Head-QC/designee shall inform to concerned service engineer to resolve the problem. Mean while the Equipment/Instrument shall be switched off and labeled with "Under Maintenance Label" (Current version of the format no: QC048-FM084) at a prominent location or at the control switch ensuring adequate visibility.

5.1.4 Note: The Breakdown Instrument/Equipment should not be used until rectification.

5.1.5 If the defect is related to Electrical department, the work order shall be raised and send to the engineering department. The concerned person shall rectify the defect.

5.1.6 If the defect is not rectified by internal personnel, call the service engineer. Service engineer shall rectify it and enter the details in Instrument History card (Current version of the format no: QC048-FM080)

5.1.7 If any parts of the instrument are replaced then the same shall be entered in the 'Instrument History Card' of the respective instrument and also in the service report and collect the service report duly signed by the service engineer after completion of the maintenance.

5.1.8 If the source for the breakdown has any influence on the analysis of previous samples, then the same shall be informed to QA. The extent of the problem and consequences shall be investigated by QA.

5.1.9 On successful completion of the maintenance work the "Under Maintenance Label" shall be removed and the 'Instrument History card' shall be updated and the performance check/calibration shall be done (if necessary). After successful completion of the calibration the instrument/equipment shall be used for regular analysis.

5.1.10 For all the critical instruments (Ref Annexure-1) used in the quality control laboratory, Preventive Maintenance shall be done as per the schedule by internal or external personnel.

5.1.11 If any Instrument/Equipment gets breakdown frequently then review the possible causes and if trend noticed, then initiate preventive maintenance to avoid the breakdowns.

5.2 **Calibration / Performance Verification :**

5.2.1 Head-QC or his designee and Head-QA or his designee shall decide the need and extent of calibration required for the Instrument/Equipment and same shall be addressed in standard operating procedure.

5.2.2 The decision regarding calibration of one kind of equipments may be assumed to be valid for other similar Instruments/Equipments arriving later, which shall be used within the same usage range.

5.2.3 A standard operating procedure shall be prepared for calibration of Instruments/Equipments along with acceptance criteria, frequency/schedule and required standards.

5.2.4 A complete Calibration shall be performed as mentioned in respective Instrument / Equipment SOP and shall be recorded in respective raw data formats.

5.2.5 Standards and apparatus used for calibration of critical instruments shall be calibrated by qualified external legal calibration agency and shall be stored in a safe and secure place.

5.2.6 After completion of the calibration, the calibration raw data and reports (if any) shall be get checked and approved by Head-QC or his designee respectively.

5.2.7 After approval of the document, affix the calibration status label on the respective Instrument/Equipment.

5.2.8 The following tolerance limits shall be followed for the calibration of Instruments/ Equipments based on the frequency of calibration.

Frequency	Tolerance
Once in a year	± 10 days
Once in Six months	± 07 days
Once in Three months	± 04 days
Once in a Month	± 02 days
Daily	Perform the calibration daily

5.2.9 Do not use any Instruments / Equipment or its component beyond the date of validity of Calibration.

5.2.10 If any Instruments/Equipments are to be relocated within the laboratory / plant premises, perform the calibration only after executing 'Change Control' as per "Change control" SOP.

5.2.11 Calibration shall be performed after relocation for the sensitive and critical Instruments/Equipments. The necessity and the extent of calibration upon relocation shall be decided by the user department in consultation with Quality Assurance and if required with engineering and IT departments.

5.2.12 Calibration records should be reviewed regularly to evaluate the effectiveness for each instrument/equipment.

5.2.13 Prepare a 'Master calibration schedule' based on the frequency of each instrument as per the current version of the format number QC048-FM083.

5.2.14 If any new Instrument/Equipment is received, that can be updated.

5.2.15 Ensure that the schedule of all Instruments/Equipment and the apparatus which shall be calibrated by approved 'External agency' is available with concerned department.

5.2.16 The equipment/instrument vendor or vendor authorized service agency or authorized government legal agency shall be considered as approved external agency to perform calibration.

5.2.17 Ensure that the Calibration is carried out by the external agency as per the schedule. Ensure the standards/apparatus used during calibration are within the calibration due date.

5.2.18 Head-QC/designee shall verify and duly sign on the calibration reports given by the external agency.

5.2.19 If the Calibration fails, then do not use the Instruments/Equipment for analysis. Initiate CAPA as per the Corrective and preventive action SOP and the calibration failure shall be investigated.

5.2.20 The impact of calibration failure on previously tested samples using that Equipment/Instrument shall be investigated.

5.2.21 Perform Calibration of all parameters after service provided by relevant service providers.

5.2.22 Whenever the entire QC lab closed for one or two days in the case of public holiday or in any cases, calibrate the instruments (Daily calibrated instruments) immediate next working day of the lab.

5.2.23 Tag/affix the 'Calibration Label' (Current version of the format no: QC048-FM081) to instrument after completion of the calibration / performance check.

5.2.24 Display the 'Calibration Label' (Current version of the format no: QC048-FM082) on the instrument. Replace the previous 'Calibration Label' with existing new label.

5.2.25 Annual maintenance contract (AMC) for all critical instruments in Quality Control lab shall be maintained and service engineers shall perform their respective preventive maintenance.

5.2.26 The details of preventive maintenance including replaced parts if any shall be entered in the 'Instrument History Card' of the respective instrument and also in the service report.

5.2.27 Head-QC/designee shall do final review, approve the service report given by the service person and shall be filed.

5.3 **Recording of Instrument Usage Log**:

5.3.1 Quality Control analyst shall record Equipment /Instrument Usage Log as per the QC048-FM086 for all the Quality Control Equipment/Instrument.

5.3.2 At the time of usage of Analytical Balance Analyst shall enter all the details in Analytical Balance usage log as per QC048-FM087.

5.3.3 At the time of usage of HPLC/GC Analyst shall enter all the details in usage log as per QC048-FM088.

5.3.4 Based on the requirement Analyst will choose the Equipment /Instrument for analysis.

5.3.5 Enter in remarks any break downs, etc.

5.3.6 Yearly once change the usage logbooks.

6.0 FORMATS / ANNEXURE(S):

6.1 Instrument History Card : QC048-FM080

6.2 Calibration Label : QC048-FM081

6.3 Master Calibration Schedule : QC048-FM083

6.4 Under Maintenance Label : QC048-FM084

6.5 Instrument Usage Log book : QC048-FM086

6.6 Balance usage log book : QC048-FM087

6.7 HPLC/GC Usage Log : QC048-FM088

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	01.01.2017	New SOP introduced.	--