TITLE: CALIBRATION POLICY

1.0 PURPOSE:

To lay down a procedure for calibration of equipments/ instruments that are used for control, weighing, measuring, monitoring and testing for assuring the quality of product.

2.0 SCOPE:

The procedure applies to all the equipment and instruments used at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 It is the responsibility of the relevant user department to establish a calibration program for all the equipment being used in the manufacturing process and analysis.

3.2 It is the responsibility of the relevant department HODs to ensure that all equipment/instruments are calibrated according to their specific schedule and that the details are documented.

3.3 It is the responsibility of Quality assurance department to review the calibration certificates, received from external labs.

4.0 DEFINITIONS:

4.1 **Calibration:** The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.

4.2 **Performance check:** Verifying the acceptable performance of instrument for its intended use. This shall be applied to:

4.2.1 Instrument where check is required each time it is used or scheduled to occur at regular intervals.

4.2.2 Instruments, where frequency and checks are designed to minimize the impact due to calibration failure. In such cases, the verification checks can be more frequent and less intensive in nature as compared to calibration.

4.3 **Out of Calibration:** Equipment/Instrument is in working condition but it has drifted outside its accuracy specification and beyond the permitted limits i.e. it has been in error to an unacceptable degree.

4.4 **Out of Order:** The Equipment/Instrument found not in working condition i.e. faulty condition.

5.0 PROCEDURE:

5.1 Annual calibration schedule shall be prepared for all manufacturing area related equipment / instruments by Engineering Department and analytical related by QC personnel

5.2 The schedules shall be approved by Quality Assurance in the month of December of every year.

5.3 Controlled copies shall be distributed to concern departments and the concerned HOD shall ensure that all the equipment / instruments are calibrated as per the schedule.

5.4 Any new equipment / instrument is received, the calibration schedule shall be prepared for the new equipment / instrument in the form of annexure format to the annual schedule once the equipment / instrument qualification is completed.

5.5 All these inclusions shall be updated in the annual schedule at the end of year for the next year annual schedule.

5.6 The head of each department shall ensure that every new equipment / instrument is qualified before its use and included in the Master Equipment / Instrument record which gives a clear description and unique identification.

5.7 The Master Equipment / Instrument record should include but not limited to , the following:

5.7.1 Equipment / Instrument number.

5.7.2 Equipment / Instrument description.

5.7.3 Manufacturer, model and serial number.

5.7.4 Calibration Interval.

5.7.5 Signature and dates from the department head for approval of the document.

5.8 Before including the new equipment / instrument, a calibration procedure shall be developed by the concerned departments to explain in detail the steps to be followed in performing calibration.

5.9 The Engineering / Quality Control departments shall develop a calibration procedure. The procedure shall provide the following details:

5.10 The procedure for calibration shall explain in detail the steps to be followed in performing calibration and shall include, but not limited to, the following:

5.10.1 **Methodology:** Methodology shall describe the step by step procedure including the conditions where the calibration to be carried out.

5.10.2 **Calibration frequency:** The frequency of calibration for each equipment/ instrument shall be fixed depending on the robustness of the equipment/ instrument, the operating parameters to be measured and the criticality of the operation.

5.10.3 In general the number of days allowed to calibrate the instrument against the schedule date, until if instrument wise specific requirements are not established;
Allowed variation for weekly calibration is $\pm$1 day
Allowed variation for monthly calibration is $\pm$ 3 days

Allowed variation for quarterly calibration is ± 5 days

Allowed variation for Half-Yearly calibration is ± 7days

Allowed variation for Yearly calibration is ± 15 days

5.10.4 **Acceptance criteria:** Limits for acceptance of the calibration performed shall be fixed based on the user requirements.

5.11 **Calibration procedure:**

5.11.1 Engineering / QC representative shall identify the equipment/ instruments for calibration as per schedule and shall give prior information to the user for clearance to perform calibration.

5.11.2 Before calibration, the master equipment/ instrument which is used for calibration shall be verified for its validity of calibration

5.11.3 After getting the clearance from user, calibrate the identified equipments/ instruments by following respective approved procedure for calibration through either in-house facility or external agency service.

5.11.4 If process is being carried out in the respective equipment, spare instrument shall be arranged on the equipment to continue the usage of equipment. Once the calibration of respective instrument is completed the same shall be replaced.

5.11.5 After the completion of every calibration, an equipment / instrument calibration record/ form shall be filled by the person performing the calibration with all the information required.

5.11.6 Calibration tag shall be filled and attached to all calibrated equipment / instruments and containing the following information.

Equipment / Instrument ID number.

Date of calibration (Date/ Month/ Year)

Signature of person performing the calibration.

Next calibration date (Due date/month/year

5.11.7 It is the responsibility of the concerned department personnel to review the calibration labels attached to the equipment / instrument and calibration schedule periodically to make sure that the equipment / instrument being operated in the department are currently under calibration.

5.11.8 If instrument calibration is to done at External agency, the same shall be given prior communicated to qualified lab, which internally after receiving certificates QC/Engineering department with review and certify the documents received.

5.12 **Steps to be taken when equipment/ instrument is found to be out of calibration:**

5.12.1 In case of equipment/ instrument which fails in calibration, the Engineering / QC shall initiate steps to repair / replace the equipment/ instrument and an "OUT OF CALIBRATION" status shall be displayed on the equipment / instrument.

5.12.2 Deviation Report shall be raised by user / Engineering / QC, investigation shall be carried out and details of investigation shall be documented.

5.12.3 The data pertaining to immediate previous batches manufactured / tested using the equipment/ instrument shall be assessed for impact and if required investigation shall be extended to other batches manufactured / tested since the last valid calibration date. The same shall be documented.

5.12.4 The equipment/ instrument shall be repaired or replaced with a new equipment/ instrument which is qualified/ calibrated prior to placing it back in service.

5.13 **Steps to be taken when equipment/ instrument is found to be out of schedule:**

5.13.1 If calibration is not performed within the scheduled due date, deviation Report shall be raised by user, investigation shall be carried out and details of investigation shall be documented.

5.14 **Steps to be taken when equipment/ instrument is found to be out of order:**

5.14.1 A maintenance job order, if applicable, shall be issued by User department to ESD for the required repairs of the equipment/ instrument and an "UNDER MAINTENANCE" status shall be displayed on the equipment / instrument.

5.14.2 QC shall initiate steps to repair / replace the equipment/ instrument and these details shall be documented.

5.14.3 The equipment/ instrument shall be repaired or replaced with a new equipment/ instrument which is qualified/ calibrated according to the relevant SOPs prior to placing it back in service.

5.14.4 Damaged equipments/ instruments (E.g.: breakage of glass) shall be identified and replaced or repaired.

5.15 **Definition of standards, references or any other equipment to be used during calibration:**

5.15.1 The purpose of having standard instrument or having a reference during calibration is to have a check as to whether the instrument is able to perform its function as compared to the standard and to make the necessary amendments or changes as required, to make the instrument suitable.

5.15.2 The standard shall be calibrated and rectified on a schedule basis or as required by each piece of equipment and only by the manufacturer of the equipment or by the standards calibration laboratories.

5.16 Whenever the operation of any instrument is questioned, calibration verification shall be performed by the Maintenance / Quality Control departments, the same shall be documented

5.17 If the calibration of any equipment is not possible to perform, the equipment shall be sent to an outside agency for calibration.

5.18 A copy of calibration procedure shall be procured from the outside agency and it shall be reviewed and to ensure that the standards. In the absence of a written calibration procedure, a certification signed by the outside agency specifying method used will be acceptable.

5.19 Upon getting the calibration certificates from the outside agency, those certificates shall be reviewed and put seal on the certificate and sign it. Issue a calibration tag along with a copy of certificate to the concerned department to make it available at equipment / instrument area.

6.0 FORMATS / ANNEXURE(S):

Nil

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.07.2009	New SOP " Calibration of Equipment" is introduced across all the intermediates manufacturing facilities of Discovery.	--
01	15.06.2014	Revised as per current SOP & more clear and clarity.	--
02	01.01.2018	SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/ 17037
03	01.07.2019	The procedure to handle out of calibration is elaborated and title changed to calibration policy	CCF/GEN/ 19013
04		SOP has been revised by including the section 5.11.8.	CCF/GEN/ 21008

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	R. Pallavi	B. Naresh	N. Sreedhar
Department	Quality Assurance	Quality Assurance	Quality