 Discovery Labs	<b>STANDARD OPERATING PROCEDURE</b>			
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<b>TITLE: CALIBRATION OF EQUIPMENT</b>				

### 1.0 PURPOSE:

To provide a policy for performing the calibration of equipment and instruments used in the testing and manufacturing process.

### 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 Production, Maintenance, Stores and QualityControl departments to establish a calibration programme to 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


### 4.0 DEFINITIONS:

**Calibration:** The set of operations that established under specified conditions, the relationship between values indicating by an instrument or system for measuring, recording and controlling of the values represented by a material measure, and the corresponding known values of a reference standard.

### 5.0 PROCEDURE:

5.1 Annual calibration schedule shall be prepared for all manufacturing area related equipment / instruments by MT dept. & analytical related by QC dept. and shall be approved by Quality Assurance in the month of December of every year.copies shall be distributed to concern departments and the concerned HOD shall ensure that all the equipment / instruments are calibrated as per the schedule. Any new equipment /

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	G. Swapna	Ch. Mahendar Reddy
Department	Quality Assurance	Quality Assurance	Quality Assurance

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instrument is received, the calibration schedule shall be prepared for the new equipment / instrument in the form of annexure format to the annual schedule in 1<sup>st</sup> week of subsequent month and it shall be approved by QA. All these inclusions shall be updated in the annual schedule at the end of year for the next year annual schedule.

5.2 The head of each department shall ensure that every new equipment / instrument is qualified (DQ/IQ/OQ/PQ) before its first use and included in the Master Equipment / Instrument record which gives a clear description and unique identification.

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

5.3.1 Equipment / Instrument number.

5.3.2 Equipment / Instrument description.

5.3.3 Manufacturer, model and serial number.

5.3.4 Calibration Interval.

5.3.5 Calibration SOP reference.


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

5.4 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.

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

5.5.1 **Calibration schedule:** The schedule for calibration of the equipment shall be provided, depending on the nature of the activity for which they are used.

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Sign & Date			
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5.5.1.1 The following allowed variation (number of days) shall be followed by Quality control while carrying out calibration

Allowed variation for weekly calibration is  $\pm 1$  day

Allowed variation for monthly calibration is  $\pm 3$  days

Allowed variation for quarterly calibration is  $\pm 3$  days

Allowed variation for Half-Yearly calibration is  $\pm 7$  days

Allowed variation for Yearly calibration is  $\pm 15$  days

5.5.1.2 The following allowed variation (number of days) shall be followed by Maintenance while carrying out calibration.

Allowed variation for weekly calibration is  $\pm 1$  day

Allowed variation for monthly calibration is  $\pm 3$  days

Allowed variation for quarterly calibration is  $\pm 3$  days

Allowed variation for Half-Yearly calibration is  $\pm 7$  days

Preventive maintenance for major equipments  $\pm 7$  Days

Allowed variation for Yearly calibration is  $\pm 15$  days


5.5.2 **Calibration Method:** To provide the step by step procedure to be carried out in the calibration procedure of the equipment.

5.5.3 **Acceptance criteria:** Limits for acceptance of the calibration performed shall be fixed based on the National / International standard.

5.5.4 **Steps to be initiated in case of failure of the equipment in calibration:**

5.5.4.1 If equipment / instrument that affect the quality of the product being produced or analyzed, either directly or indirectly, could

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not be calibrated, a note shall be issued to the Quality Assurance department in the “Deviation”, providing all the details of failure in the form of internal communication.

5.5.4.2 The concerned department to which the equipment belongs shall be informed by the Quality Assurance department to raise a Deviation and initiate an investigation for the causes that lead to the out of calibration.

5.5.4.3 A Deviation report shall be raised and subsequent investigation shall be carried out and these details shall be documented as per the SOP-“Deviation-Corrective Action and Preventive Action”.


5.5.4.4 A maintenance job order shall be issued to maintenance department for the required repairs of the equipment.

5.5.4.5 The Maintenance department shall place stand-by pre-calibrated equipment and take the existing equipment for repair.

5.5.4.6 In case of equipment, which fails in calibration, the concerned departments shall call service engineer for repairing the same equipment. The data pertaining to previous batches manufactured / analyzed (from the last calibration date onwards) using the equipment / instrument shall be reviewed and the review shall be documented.

5.5.4.7 An “UNDER MAINTENANCE” tag should be attached to the equipment / instrument in a highly visible manner.

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5.5.4.8 Instrument / equipment shall be repaired or replaced with a new unit and calibrated according to the concerned calibration SOP prior to placing it back in service.

5.5.4.9 Based on the out of calibration result investigation details, the performance of the previous batches since previous calibration shall be reviewed and justified. The review details shall be documented.


5.5.4.10 The Quality Assurance department shall be notified regarding the removal of the “UNDER MAINTENANCE” status together with the information whether the equipment / instrument returned to operation is repaired or a new unit.

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

5.5.5.1 The purpose of defining standard 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.


5.5.5.2 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.

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- 5.6 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.
- 5.7 A calibration tag shall be filled and attached to all calibrated equipment / instruments and containing the following information.
- 5.7.1 Equipment / Instrument ID number.
  - 5.7.2 Date of calibration ( Date/ Month/ Year )
  - 5.7.3 Signature of person performing the calibration.
  - 5.7.4 Next calibration date (Due date/month/year
- 5.8 It is the responsibility of the concerned department personnel to review the equipment 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, not over due or out of service and it is also the responsibility for maintaining the schedule up-to-date in a neat and presentable manner.
- 5.9 Whenever the operation of any instrument is questioned, calibration verification shall be performed by the Maintenance / Quality Control departments.
- 5.10 If the calibration of any equipment is not possible to perform, the equipment shall be sent to an outside agency for calibration.
- 5.11 A copy of calibration procedure shall be procured from the outside agency and it shall be reviewed by Maintenance / Quality Control personnel 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.

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5.12 The Maintenance / Quality Control department shall be responsible to assure that the calibrations done on-site and by outside agencies comply with the requirements of this procedure.

5.13 Upon getting the calibration certificates from the outside agency, those certificates shall be handed over to Quality Assurance for their review. Quality Assurance shall review the calibration certificates, put QA 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.

#### **5.0 FORMATS / ANNEXURE(S):**

Nil

#### **6.0 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

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	G. Swapna	Ch. Mahendar Reddy
Department	Quality Assurance	Quality Assurance	Quality Assurance

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