STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Calibration Policy	**Effective Date:**
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1.0 OBJECTIVE:

To lay down a Procedure for Calibration Policy.

2.0 SCOPE:

This SOP is Applicable for all the Equipment/Instrument handled and maintained at ……...

3.0 RESPONSIBILITY:

Officer/Executive QA

4.0 ACCOUNTABILITY:

Head QA

5.0 DEFINITION:

Calibration: The set of operation that establish, under specified condition, the relationship between value indicated by instrument or system for measuring (for example ,weight ,temperature and pH) recording or controlling ,or the vale represented by a material measure, and the corresponding known value of a reference standard limit of accepentace of the results of measuring should be established . Always remember any reference standard in always used in calibration.

6.0 PROCEDURE:

6.1 PRECAUTIONS:

6.1.1 Do not use non calibrated Equipment/Instrument.

6.2 EQUIPMENT - CALIBRATION & MAINTENANCE:

6.2.1 Manufacturing equipment shall be qualified for intended services and it shall be assigned a unique Tag No. as its identity QA team shall be responsible for assigning the specific Tag No., maintenance record and the list.

6.2.2 QC/QA department shall perform the qualification of analytical instrument/equipments installed in the laboratory. QC/QA department shall assign tag no. independently & maintain the record.

6.2.3 Calibration of engineering/utility equipment/ instrument shall be done by engineering department. Engineering department shall also be responsible for assigning tag no. and calibration of measuring gauges and timers attached with the equipment or area.

6.2.4 Each and every equipments shall have SOP for it's operation as well as calibration along with precautions to be followed.

6.2.5 Calibration record of equipments shall be maintained by the user department. The record shall contain the following:

- Reference SOP
- Calibration Record
- Acceptance Criteria

6.2.6 Maintenance record of equipment shall be maintained separately.

6.2.7 Calibration & qualification of equipment, apparatus, gauges and recording devices shall be done at defined frequency. However, when equipment is in operation and/or for any other reasons calibration could not be done at due period, a permissible deviation shall be follows:

Calibration Frequency	Permissible Deviation
Daily	No Deviation
Monthly	± 2 Day
Quarterly	± 3 Day
Half Yearly	± 15 Day
Yearly	± 30 Day

6.2.8 Due to any reason, if calibration due date exceeds the above – mentioned permissible deviation, the delay in calibration shall be authorized by Head QA under deviation.

6.2.9 When the instrument is not in use, due to no activity in the area, daily calibration of equipment (e.g. Weighing balances, pH meter etc.) is not necessary. In the calibration record no activity shall be mentioned. However prior to start up of the activity, equipment shall be calibrated.

6.2.10 Calibration Tag as per Format, Titled **"CALIBRATED"** in SOP, shall be tagged on all equipment. The tag shall contain information like Eq. ID No. , date of calibration, due date of calibration, signature of calibrating person. Specimen of calibration tag is mentioned below:

6.2.11 Calibration Planner (For Internal & external), as per **Annexure-I**, Titled **"Calibration Planner (For Internal & external)"** shall be maintained for all the Instruments/Equipments.

6.2.12 When any new Instruments/Equipments shall be introduced in the facility, addendum of the Master Calibration Planner for Instruments/Equipments shall be prepared after calibration for the Instruments/Equipments as Annexure-II. This addendum planner of new Instruments/Equipments shall be incorporate in next year Master Calibration Planner for Instruments/Equipments.

6.3 EXTERNAL CERTIFICATION OF WEIGHTS & MEASURING DEVICES:

6.3.1 Weights and measuring devices (viz. reference weights, thermometers load cell, balance and other measuring gauges) shall be calibrated by external laboratory having National Traceable Reference e.g. NPL (National Physical Lab) and NABL (National Accreditation Board Ltd.) for Calibrated Weights and Measuring Devices.

6.3.2 The calibration shall be done with respect to operating range of In House calibration.

6.3.3 Such external laboratory shall issue the calibration certificate for each calibrated device. On receipt of any calibration certificate, QA personnel shall review the report for accuracy and correctness for acceptability of the data.

6.3.4 If the report complies, a stamp having details i.e. Reviewed by Signature & Date.

6.3.5 If the report doesn't comply as per the defined acceptance criteria, further corrective action shall be taken accordingly.

6.3.6 QA department shall review the report randomly during internal audit and put their signature on the same.

6.3.7 If such calibration could not be arranged in time, the re-calibration of the same shall be done within a period of next 3 months. During this extended period, calibration of weight and measuring devices is considered valid.

6.3.8 Daily Verification of balance is carried out only for self – verification. If balance is not in use, self calibration on daily basis shall not be done. During this period, shifting of balances to other place of work is not allowed, for use of balance should be verify.

6.3.9 If master thermometers are send for calibration, during the period, internally calibrated thermometers shall be used for calibration of another thermometers (if required).

6.3.10 Data in various instruments shall be recorded as per the data recording system programmed by instrument/equipment manufacturer.

6.3.11 During Out of Calibration (OOC) or Breakdown or Malfunctioning the particular instrument is identified by a label stating as per Format**,** Titled **"STATUS LABELING"** in SOP.

6.3.12 If the equipment is not having recording devices, the readings/observations shall be recorded from display and data shall be checked online by second person for its correctness in record.

6.3.13 When any equipment is out of order:

- The concerned service engineer shall be informed.
- A standby arrangement shall be made if available.
- If the standby arrangement is available, the same may be used after calibration.
- If standby arrangement is not available, samples shall be sent to other department/external approved laboratory.

6.3.14 For routine servicing and maintenance, either annual service contract or service arrangement is made with instrument's manufacturer/authorized service agent. Frequency of servicing shall be followed as per the contract. An equipment/instrument history card of all critical & major equipment is maintained by the user department. A service report is also maintained separately.

6.4 HANDLING OF STANDARD CALIBRATED WEIGHTS :

6.4.1 On receipt of calibrated standard weights, it shall be kept in respective specified area.

6.4.2 The analytical standard weight box up to 2gm is kept properly in secured place. These are maintained in original box.

6.4.3 All the another standard brass weights are stored in plastic/stainless steel box.

6.4.4 All standard calibrated weights (cast iron) used in stores & production department are kept on pallets/trolley. These weights are covered with polybag so as to prevent due contamination. Specified box on calibration certificate, including date of calibration and due date of calibration shall be displayed either on or on the box.

6.4.5 Handling of analytical weights (up to 200 gm) shall carefully using specified forceps to be done by using plastic tip forceps.

7.0 ABBREVIATIONS:

SOP	Standard Operation Procedure
Sr. No.	Serial Number
Ltd.	Limited
No.	Number
QA	Quality Assurance
QC	Quality Control
gm	Gram
OOC	Out of Calibration
NABL	National Accreditation Board Limited
NPL	National Physical Lab
ID	Identification

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure– I	Calibration Planner (For Internal & External)	
Annexure – II	Calibration Frequency of Instruments	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Engineering Department.

10.0 REFERENCE:

- SOP, Titled **"Status Labeling".**

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11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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ANNEXURE-I

CALIBRATION PLANNER (FOR INTERNAL & EXTERNAL)

Year: **Frequency:**

S. No.	Name of Equipment / Instrument	Equipment / Instrument ID No.	Location	Done Date	Due Date	Done Date	Due Date

Remarks:

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ANNEXURE-II

CALIBRATION FREQUENCY OF INSTRUEMNTS

S.No.	Components	Calibration Frequency
1.	Vacuum Gauge	1 Year
2.	Pressure Gauge	1 Year
3.	Magnehelic Gauge	1 Year
4.	Compound Gauge	1 Year
5.	Temperature Sensors	1 Year
6.	Ampere Meter	1 Year
7.	Volt Meter	1 Year
8.	Temperature Gauges	1 Year
9.	Digital Temperature Hygrometer	1 Year
10.	Digital Temperature Controller	1 Year
11.	PID Controller	1 Year
12.	Digital Temperature Recorder	1 Year
13.	Digital Temperature Indicator	1 Year
14.	Glass Thermometer	1 Year
15.	Digital Timer	1 Year
16.	Humidity Indicator with Sensors	1 Year
17.	Hour Meter	1 Year
18.	pH sensors with indicator	1 Year
19.	Temperature Data Logger	1 Year
20.	Flow Meter	1 Year
21.	Lux Meter	1 Year
22.	Anemometer	1 Year
23.	Aerosol Photometer	1 Year
24.	Air borne particle counter	1 Year
25.	Weights	1 Year
26.	Liquid Borne Particle Counter	1 Year
27.	USB Data logger	1 Year
28.	Microbiological Air Sampler	1 Year
29.	Digital Vernier Caliper	1 Year

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S.No.	Components	Calibration Frequency
30.	Stainless Steel Scale	1 Year
31.	Screw Gauge	1 Year
32.	Filter Integrity Tester	1 Year
33.	Conductivity Sensor	1 Year
34.	Weighing Balance	1 Year
35.	Digital Thermometer	1 Year
36.	Infrared Thermometer	1 Year
37.	Clean Room Monitor	1 Year