	STANDARD OPERATING PROCEDURE			
Discovery Labs	SOP No.:	SOP-ED-010-04	Effective Date:	17.08.2017
	Supersedes :	SOP-ED-010-03	Next Review Date:	16.08.2020
	Department:	Engineering	Page:	1 of 4

TITLE: MAINTENANCE PROCEDURE AND SCHEDULE FOR ALL EQIPMENT AND INSTRUMENTS

1.0 PURPOSE:

To define maintenance procedure and schedule for all equipment and instruments used for plant process.

2.0 SCOPE:

This procedure is covers maintenance of all equipments used in manufacturing facility at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 Technician and Electrician:

Is the responsible to follow the safety precautions during maintenance works.

3.2 Engineer:

Is responsible to prepare the procedure, schedule and to monitor the activity.

3.3 Engineering Head:

Is the overall responsibility for whole activity

3.4 User Department:

It is the user department responsibility to release the equipment for breakdown maintenance or preventive maintenance based on annual preventive maintenance schedule.

It is the user department responsibility to release the instruments for calibration, based on Annual calibration schedule.

4.0 DEFINITIONS: NIL.

5.0 PROCEDURE :

5.1 Maintenance of equipments:

5.1.1 It shall be ensured that the equipments used in the process perform as per design through appropriate maintenance.

5.1.2 Equipments not performing as per design shall not be used without rectification.

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5.1.3   Servicing and repair of equipments shall be carried out as per written procedures by trained technicians.

5.1.4   After any major repairs, it shall be ensured that the equipment confirms to current specifications.

5.1.5   Request for breakdown maintenance shall be made by the production in charge in the 'Job Order' ED010-FM001

5.1.6   The production in-charge shall make sure that the equipment is safe for handling over and also protect the process material if any from cross contamination.

5.2   Preventive maintenance of equipment:

5.2.1   To meet the production schedule in time preventive maintenance is essential for any equipment to run smoothly without inherent failures.

5.2.2   All equipments used in the process shall be subjected to preventive maintenance at a defined frequency.

5.2.3   A separate list of equipments requiring preventive maintenance at the above mentioned frequencies shall be documented and describing the list of checks to carry out at a define frequency for each equipment.

5.2.4   The items to be serviced for individual equipment of the preventive maintenance shall be documented and servicing shall be carried out as per written procedures.

5.2.5   A preventive maintenance schedule shall be prepared for annual frequency for every year (Annual plan) and the maintenance carried out shall be recorded.

5.2.6   Schedule shall be prepared based on the equipment maintenance requirement and supplier specification.

5.2.7   Preventive maintenance checklist shall be prepared separately for all equipments.

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5.2.8   Head of the maintenance and production department shall approve preventive maintenance schedule.

5.2.9   Preventive maintenance schedule shall be as per the formats ED010-FM006 and ED010-FM044

5.2.10   ED010-FM006 and ED010-FM044 shall be prepared once in a year and a copy shall be issued to production department.

5.2.11   During preventive maintenance, safety and cleaning procedure must be followed.

5.2.12   Preventive maintenance schedule shall be prepared and implemented within 30 days from the date of completion of equipment qualification of a particular equipment.

5.2.13   Records of preventive maintenance shall be made in the preventive maintenance record for equipments.

5.2.14   Preventive maintenance program can be performed with relaxation of ± 7 days to the Scheduled date.

5.3   **Calibration of Instruments:**

5.3.1   Calibration schedule plan shall be prepared as per ED010-FM039 once in a year

5.3.2   Acceptance criteria for calibration of all instruments $\pm$ 7 days from the due date for in house calibration and external calibration.

5.4   While doing calibration Job order ED010-FM001 to be raised by user department for repairs and replacement of instruments with spare.

5.5   While doing preventive or Breakdown maintenance Job order ED010-FM001 to be raised by user department for repairs and rectifications.

6.0   FORMATS / ANNEXURE(S):

6.1   Job order   :   ED010-FM001

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6.2	Preventive maintenance schedule for all equipments	:	ED010-FM006
6.3	Equipment History Record	:	ED010-FM011
6.4	Calibration schedule for all instruments	:	ED010-FM039

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.	Remarks
00	01.08.2009	New SOP	---	---
01	17.07.2014	All process equipments maintenance procedure is revised.	---	---
02	10.09.2014	1) Title name Changed 2) Calibration of Instruments explained in the procedure	---	---
03	01.01.2017	1. SOP format changed in line with SOP-QA-001-04 2. Form "Calibration schedule for all instruments" ED010-FM039 included	ED-CRF-006/16	---
04	17.08.2017	1. SOP format changed in line with SOP-QA-001-05.	CCF/GEN/17007	--

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