



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Maintenance of laboratory instruments	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down procedure for Maintenance of Laboratory Instruments.

2.0 SCOPE:

This SOP is applicable to Chemical lab.

3.0 RESPONSIBILITY - Execution - Executive QC
Checking - Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 MAINTENANCE PROCEDURE

- 5.1.1 If malfunction or any problem found in instrument analyst shall fill the break down maintenance slip (Annexure -I) inform to Manager QC or Designee for the same and keep label of 'UNDER MAINTENANCE /NOT TO BE USED' (Annexure-II) with initial and date.
- 5.1.2 'UNDER MAINTENANCE /NOT TO BE USED' Annexure-II shall be pasted at the instrument.
- 5.1.3 Manager QC shall instruct to analyst to analyst for the make entry in "Instrument usage log " for "Under Maintenance" in "remark" column.
- 5.1.4 Analyst shall also make entry in "INSTRUMENT HISTORY CARD"(Annexure-III) for "Sr No." "Date of under maintenance", Type of maintenance".
- 5.1.5 Analyst shall fill the "Date" "From"(Name of dept.), "Equipment /Instrument", "Location" (Location of Instrument /equipment installed), "Nature of problem", "Special precautions to be taken", "Equipment given for maintenance", "Date", "Time" "Intimated By/date/time"(initial of analyst),columns in(Annexure-I) in duplicate and hand over to Manager QC or Designee.
- 5.1.6 Manager QC or Designee shall verify the filled matter and put initial/date /time/ and send it to Engineering Dept.
- 5.1.7 Head Engineering or Designee shall put initial/date /time/ in "Received By" column and keep one copy with him and remaining will be return to QC Dept.
- 5.1.8 If required , Manager QC or Designee inform to service engineer (Manufacturer) for the rectification.
- 5.1.9 Service engineer (Manufacturer) shall issue a service report duly sign after rectification.



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Maintenance of laboratory instruments	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.1.10 After rectification of instrument Manager QC or Designee shall insure the working of instrument and instruct analyst to check the calibration (if applicable) as per specified procedure.

5.1.11 After satisfactory calibration, analyst shall submit the data for checking and for approval.

5.1.12 Analyst shall make entry in a in "INSTUMENT HISTORY CARD" FOR "part if replace" (if required), "Rectified by /Date"(Initial or name of manufacturer ,who rectified the instrument)", "Calibrated by /Date" "Checked by/Date", "Remark".

5.1.13 Manager QC or Designee shall instruct analyst to remove the "UNDER MAINTENANCE /NOT TO BE USE" label and usage of instrument can be started.

5.2 Preventative Maintenance Procedure

5.2.1 Analyst shall prepare the Preventative Maintenance schedule for the coming year at the end of current year for major instrument in consultation with Manager Quality Control.

5.2.2 Frequency of Preventative Maintenance for instrument shall be every 6-month.

5.2.3 Preventative Maintenance shall carry out within ± 1 month of the scheduled date.

5.2.4 After completion of preventative Maintenance, analyst shall put initial/date and verify by Manager QC or Designee in schedule.

5.2.5 On the scheduled date the analyst shall labeled as 'UNDER Preventative Maintenance'(Annexure-IV) on respective instrument.

5.2.6 Analyst shall procure required spare parts (if required to change) in advance for the preventative Maintenance.

5.2.7 Analyst shall carry out Preventative Maintenance as per the work description (As per attached with SOP) for respective instrument.

5.2.8 Analyst shall reconnected electrical supply after completion of the preventive maintenance.

5.2.9 Analyst shall make entry in "PREVENTATIVE MAINTENANCE HISTORY CARD" for "Sr. no.", "Work Description", Actual Work Carried Out"(Shall make "4" in 6 month or in 12 month column if work carry out satisfactory), "Due date", "Date of Preventative Maintenance Carry Out", "Done By / Date". If found any abnormalities than make entry in "Remark"column and inform to Manager QC.

5.2.10 Analyst shall give the "PREVENTATIVE MAINTENANCE HISTORY CARD" to Manager QC for the checking.



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Maintenance of laboratory instruments	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.2.11 Analyst shall calibrate the instrument if required and make the necessary entry in respective calibration log.
- 5.2.12 After preventative Maintenance of instrument Manager QC or Designee shall ensure the working of instrument.
- 5.2.13 Manager QC or Designee shall put the initial and date in “PREVENTATIVE MAINTENANCE HISTORY CARD” in checked by/Date” column and instruct analyst to remove the “UNDER PREVENTIVE MAINTENANCE” label and usage of instrument can be started.

5.3 Relocation of instrument

- 5.3.1 In case of instrument relocate fill the “INSRUMENT HISTORY CARD”

6.0 SAFETY & PRECAUTIONS:

Not Applicable

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded From & date

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

Not Applicable

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QC : Quality Control



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control

SOP No.:

Title: Maintenance of laboratory instruments

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Annexure – I: Break Down Maintenance Intimation Slip

Annexure –II: Status Label: “Under Maintenance /Not To Be Used”

Annexure – III: Preventive Maintenance History Card

Annexure –IV: Status Label: “Under Preventive Maintenance ”



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Maintenance of laboratory instruments	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE – I

BREAK DOWN MAINTENANCE INTIMATION SLIP

To :
Date :
From :

Equipment/Instrument :
Location :
Nature of Problem :

Special Precaution to be taken :

Equipment given for the Maintenance

Date :
Time :
Intimated By : Date : Time:
Department Head :
Received By : Date : Time:

Maintenance Report

From : Engineering
Reason for break down :
Corrective action taken :

Equipment handover at : Date : Time:
Checked By Head : Date : Time:
Received By : Date : Time:
Engg. Dept. Initiator Book Copy



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Maintenance of laboratory instruments	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE – II

STATUS LABEL: “UNDER MAINTENANCE /NOT TO BE USED”

UNDER MAINTENANCE / NOT TO BE USED

DATE :

SIGN:



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Maintenance of laboratory instruments	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE – IV

STATUS LABEL: “UNDER PREVENTIVE MAINTENANCE ”

UNDER PREVENTIVE MAINTENANCE

DATE :

SIGN: