



STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Preventive maintenance Programme	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 PURPOSE:

To define a procedure to carry out preventive maintenance of equipments/instruments.

2.0 SCOPE:

2.1 This procedure applies to for all the equipments/instruments and utility equipments covered under Preventive Maintenance schedule at

3.0 REFERENCE(S) & ATTACHMENTS:

3.1 References

3.1.1 SOP "Status Labeling".

3.2 Attachments

3.2.1 Attachment –I : Preventive Maintenance schedule.

3.2.2 Attachment-II : Preventive maintenance check list.

3.2.3 Attachment-III : Index of Preventive maintenance check list.

3.2.4 Attachment-IV : Equipment /Instrument history card.

4.0 DEFINITION & ABBREVIATION(S):

4.1 Definition

4.1.1 Preventive Maintenance

Preventive maintenance is planned maintenance activity aimed at prevention of breakdowns and failures of equipments /instruments.

4.2 Abbreviations

4.2.1 CAPA: Corrective and Preventive Action

4.2.2 HVAC: Heating, Ventilation, and Air conditioning

4.2.3 QA: Quality Assurance

5.0 RESPONSIBILITY:

5.1 Corporate Quality Assurance

5.1.1 To ensure implementation of the procedure.

5.2 Concerned department:

5.2.1 To handover the equipment's /instruments for preventive maintenance as per schedule.

5.2.2 To check the performance for proper working after preventive maintenance.



STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Preventive maintenance Programme	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.3 Engineering department

- 5.3.1 To prepare preventive maintenance schedule and checklist.
- 5.3.2 To intimate the monthly preventive maintenance schedule to concerned department.
- 5.3.3 To carry out the preventive maintenance as per schedule.
- 5.3.4 To maintain preventive maintenance records.

5.4 Quality Assurance

- 5.4.1 To ensure that preventive maintenance is carried out as per defined procedure.
- 5.4.2 To ensure that preventive maintenance documents are maintained.

5.5 QA Head

- 5.5.1 To ensure the implementation of defined procedure.

5.6 Plant Head

- 5.6.1 To ensure the implementation of defined procedure.

6.0 Distribution:

- I. Quality Assurance
- II. Quality Control
- III. Production
- IV. Ware house
- V. Engineering
- VI. Environment, Health and safety



STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Preventive maintenance Programme	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

7.0 PROCEDURE:

- 7.1 Preventive maintenance schedule shall be prepared in the month of December every year in consultation with concerned department as per Attachment-I.
- 7.2 Equipment's/ instruments which require outside expertise or agency for preventive maintenance shall also be covered under the annual preventive maintenance schedule.
- 7.3 Engineering department shall plan and prepare a preventive maintenance checklist of each equipment/ instrument or when a new equipment / instrument are installed in the plant as per Attachment- II.
- 7.3.1 Preventive maintenance checklist shall be prepared based on maintenance manual/manufacturer recommendation / experience.
- 7.3.2 Preventive maintenance checklist shall have a unique number. The Preventive maintenance checklist number shall be **PM/LC/NNN/RR**,
Where,
PM shall be Preventive Maintenance.
LC shall be Location code in two alphabetical digits.
NNN shall be serial number of the checklist i.e. 001, 002, 003.....n
RR shall be revision number of the checklist.
First preventive Maintenance checklist number shall be **PM/LC/001/00**.
- 7.3.3 Each checklist shall be approved by engineering head.
- 7.3.4 List of Preventive maintenance checklist shall be maintained as per Attachment–III.
- 7.4 Preventive maintenance shall cover inspection, repair, preservation and replacement of the parts as required.
- 7.5 Engineering department shall ensure that right quality of consumables e.g. oils, greases, minor change parts are available.
- 7.6 Engineering department shall label as “Under Preventive Maintenance” on the scheduled date as per SOP titled “Status Labeling”.
- 7.7 Preventive maintenance shall be carried out as per the preventive maintenance checklist and mention the activity against the check list point of preventive maintenance of that equipment / instrument.
Note: In case of any change/ modifications/ part replacements done during the preventive maintenance, the same shall also be recorded in equipment/ instrument history card and QA shall be informed for impact analysis study.
- 7.8 After completing the preventive maintenance, engineer shall ask to concern person of concerned department to take machine trial.



STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Preventive maintenance Programme	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 7.8.1 If the machine status is satisfactory, handover the machine to the concern department. In case of utility and HVAC equipment, performance shall be verified by responsible engineer.
- 7.8.2 If the machine status is not satisfactory engineering department shall take appropriate corrective action.
- 7.8.3 In case of any major part to be replaced, which may affect the machine performance it shall take place through a planned modification system procedure.
- 7.9 The record of the preventive maintenance shall be maintained in “Equipment/Instrument History Card” (Attachment–IV).
- 7.10 The tolerances of preventive maintenance shall be as under:
 - Monthly ± 3 days**
 - Quarterly ± 7 days**
 - Half yearly ± 15 days**
 - Yearly ± 30 days**
- 7.10.1 In case if the machine is not available for preventive maintenance due to any reason beyond the tolerance period an incident for the same shall be raised and handled as per incident SOP.

8.0 REVISION HISTORY:

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Preventive maintenance Programme	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Attachment-II

PREVENTIVE MAINTENANCE CHECKLIST

DEPARTMENT-ENGINEERING

Check List No.:		Make	
Equipment / Instrument Name		Type/Model	
Location		Frequency of P.M.	
Equipment/ Instrument ID No.		Year	

S.No.	Check Points	Actual Date			
		Observation			
1					
2					
3					
4					
5					
6					

Other Observations-					

Done by (Sign./date)				
Checked by (Sign./date)				

Prepared By (Sign /Date)	Checked by (Sign/ Date)	Approved By (Sign/Date)

Format No.



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Preventive maintenance Programme	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Attachment-III

INDEX OF PREVENTIVE MAINTENANCE CHECK LIST

DEPARTMENT - ENGINEERING

Sr. No.	Check List Titles	Check list No	Effective date	Remarks	Sign. Eng. Head
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					

Prepared By (Sign /Date)	Checked by (Sign/ Date)	Approved By (Sign/Date)

Format No.....

Format No.....



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Preventive maintenance Programme	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Attachment- IV

EQUIPMENT/INSTRUMENT HISTORY CARD

Equipment/ Instrument Name :		Code No. :	
Location/Block :		Make :	
Department :		Type/ Model:	
SOP No. :		Capacity :	

S.No.	Type of maintenance (Breakdown/ Preventive)	Equipment/ Instrument taken for maintenance		Equipment/ Instrument given after maintenance		Done by	Checked by	Remarks
		Date	Time	Date	Time			

Format No.....

Format No.....