

ENGINEERING DEPARTMENT

**Title:** Plant Equipment Preventive Maintenance

| SOP No.:               | Revision No.:  | 00      |
|------------------------|----------------|---------|
| <b>Effective Date:</b> | Supersedes No. | Nil     |
| Review Date:           | Page No.       | 1 of 12 |

#### 1.0 OBJECTIVE:

To lay down a procedure for planned preventive maintenance of equipments/machines.

### 2.0 SCOPE:

This SOP is applicable to planned preventive maintenance of Equipments /Machines.

#### 3.0 **RESPONSIBILITY:**

Operating Person: Engineering Operating Person: User Department

### 4.0 ACCOUNTABILITY:

Head - Engineering

### **5.0 ABBREVIATIONS:**

HOD Head of Department

HVAC Heating Ventilation and Air Conditioning

Ltd. Limited
No. Number
Pvt. Private

QA Quality Assurance QC Quality Control

SOP Standard Operating Procedure

### 6.0 PROCEDURE:

- **6.1** Schedule for planned preventive maintenance shall be made for each category as below:
  - **6.1.1 Equipment/machine:** All process equipments/ machines used for batch processing & QC equipments in the facility.
  - **6.1.2 HVAC:** All equipments related to HVAC system which are used in the facility.
  - **6.1.3** Water Systems: All equipments of water systems.
  - **6.1.4 Utility: -** All equipments of utilities.
  - **6.1.5** All equipments shall be covered in yearly schedule of planned preventive maintenance.
  - **6.1.6** Separate schedule shall be made for Water System, Production, and Utility & HVAC equipments/machines.
- Officer/Executive (Engineering) shall prepare a preventive maintenance schedule of equipment's/ machines for next calendar year as per **Annexure I. "Yearly Schedule for Planned Preventive Maintenance"** at a frequency of preventive maintenance, which shall be appropriate as per recommendations of manufacturer/user/engineering department. Yearly schedule for planned preventive maintenance shall be prepared in the last month of every year or whenever required.



#### ENGINEERING DEPARTMENT

**Title:** Plant Equipment Preventive Maintenance

| SOP No.:        | Revision No.:  | 00      |
|-----------------|----------------|---------|
| Effective Date: | Supersedes No. | Nil     |
| Review Date:    | Page No.       | 2 of 12 |

- 6.3 Annexure-I shall be referred as standard specimen for yearly schedule for planned preventive maintenance.
- Preventive maintenance of AHU's of HVAC system is scheduled, such that respective manufacturing facility/ room equipment/ machine are also planned on same date wherever applicable. Engineering department will ensure simultaneous preventive maintenance as mentioned above. This is to ensure intended purpose of preventive maintenance.
- Equipments/ machines shall be scheduled for preventive maintenance for frequency of 01 month & 03 months as may seem appropriate with respect to duty/criticality of such equipment/machine.
- 6.6 The first Schedule Planner of the year shall have a Revision No. 00. This planner shall be revised to the next revision no. every year, while incorporating all the addendums (Annexure VI "Addendum Planer for Planned Preventive Maintenance for New Equipments/ Machines").
- 6.7 Monthly planned preventive maintenance schedule (Annexure-II) shall be derived from yearly schedule of planned preventive maintenance (Annexure-I) to intimate user department.
- 6.8 Check-list for preventive maintenance of equipment/machine shall be prepared as per **Annexure –IV** "**Template of Checklist**". Template of Checklist denotes name of equipment/machine for preventive maintenance.
- 6.9 Check-list for preventive maintenance of equipment/machine shall be updated as and when required to serve intended purpose.
- 6.10 Annexure IV "Template of Checklist" shall be referred as standard specimen of preventive maintenance check-list.
- 6.11 List of preventive maintenance checklist shall be maintained and updated in Annexure V "List of Preventive maintenance checklist".
- Annexure -V "List of Preventive maintenance checklist" shall be revised in the last month of every year while incorporating all the addendum (Annexure-VII).
- 6.13 Preventive Maintenance checklist shall have the document no as PM/NNN-RR, where PM stand for preventive maintenance, NNN stand for document no starting from 001 and RR stand for revision no.
- Addition of new equipment shall be done by addendum as per annexure -VI "Addendum Planner for Planned Preventive Maintenance for New Equipment". Addendum shall be a schedule for planned preventive maintenance of new equipments/machines. New check-list shall be made for new equipment/machine. If required, check-list shall be prepared as per Annexure VII "Addendum for Addition & Revision of Checklist".
- 6.15 If any equipment/machines in operation, if removed from use shall be indicated in remark column of yearly schedule for planned preventive maintenance. QMS tool of change control shall be implemented to omit such equipment/machine from preventive maintenance schedule.
- **QMS** tool of change control shall be implemented for transfer of equipment/machine from one location to another. Change control no. shall be given to such equipment/machine for further reference of preventive maintenance in the record book.



ENGINEERING DEPARTMENT

**Title:** Plant Equipment Preventive Maintenance

| SOP No.:        | Revision No.:  | 00      |
|-----------------|----------------|---------|
| Effective Date: | Supersedes No. | Nil     |
| Review Date:    | Page No.       | 3 of 12 |

- After approval of Head QA, Officer/Executive QA shall issue the controlled copy of yearly schedule for planned preventive maintenance to engineering department.
- 6.18 On receiving control copy of yearly schedule of preventive maintenance (Annexure –I) from Head QA, Engineering officer/ Executive/ Manager /Sr. Manager shall prepare monthly planned preventive maintenance schedule(Annexure-II) to intimate user department during last week of each month. This is to facilitate each user department to release the respective equipment/machine on schedule date with tolerance of ±3 days. In-turn user department shall fill-up annexure- II and submit to engineering department. Engineering department accordingly will plan & carry out preventive maintenance.
- 6.19 Total productive maintenance (TPM) is applicable & implemented with this new yearly schedule of planned preventive maintenance. Accordingly each equipment/machine shall be released/handed over to engineering department for maximum time period of 08 hrs., which may be extended as per requirement, to finally serve intended purpose.
- **6.20** Equipment/machine operator shall be part/team member for the whole time period of preventive maintenance.
- 6.21 User department shall handover the equipment/ machine in clean condition/ free from product traces to engineering department.
- 6.22 Preventive maintenance shall be carried out as per prescribed check-list, which shall be equipment/machine specific.
- 6.23 Engineering officer/Executive/Manager will ensure that right tool &tackles & consumable are employed in carrying out preventive maintenance activity.
- **6.24** Engineering officer/Executive/Manager will obtain appropriate safety permit as per **SOP** as and when required.
- Major change in the configuration of equipment/machine, shall be carried out through change control procedure and same shall be mentioned under remark column of respective checklist.
- **6.26** Equipment/machine operator with user supervision team will ensure the completeness of preventive maintenance, as per requirement.
- 6.27 After completion of preventive maintenance activity, user shall log the detail of preventive maintenance in their log card/book to maintain records.
- 6.28 After completion of preventive maintenance, affix duly filled & signed prescribed "TAG" of preventive maintenance on respective equipment as per SOP Title- "STATUS LABEING".
- **6.29** Engineering officer/Executive/Manager along with equipment /machine operator and supervisor, will check performance and efficacy of preventive maintenance and pursue any further action to eliminate flaws/errors.
- **6.30** Check Before Starting Preventive Maintenance:
  - **6.30.1** Inform to user department about Start of preventive maintenance. Ensure that equipment machine operator is available as a part of engineering team.



#### ENGINEERING DEPARTMENT

**Title:** Plant Equipment Preventive Maintenance

| SOP No.:               | Revision No.: | 00      |
|------------------------|---------------|---------|
| <b>Effective Date:</b> | Supersedes No | . Nil   |
| Review Date:           | Page No.      | 4 of 12 |

- **6.30.2** Check and ensure that necessary tool& tackles and consumable etc. are available.
- **6.30.3** Engineering department personnel shall ensure that equipment/machine is isolated from electrical mains.
- **6.30.4** Display of status board indicating equipment/machine under preventive maintenance. Display board remains till completion of work.
- 6.31 After completing the preventive maintenance activity of equipment/machine take a trial of equipment and check for any abnormality.
  - **6.31.1** Abnormal Level of the machine/equipment.
  - **6.31.2** Any loose or broken part of Metallic/Non Metallic part of the machine/equipment.
  - **6.31.3** Any loose wires/ carbon deposited/ dusty electrical connection.
- 6.32 If any abnormality is found after completing preventive maintenance then record the same in remark column of checklist. Corrective action shall be made after consult with seniors.
- 6.33 If any point is observed during preventive maintenance then same shall be written in observed column of respective preventive maintenance checklist.
- 6.34 After successfully completion of preventive maintenance activity, engineering officer/executive handover the equipment to user department.
- **6.35** User department shall clean the Area/Machines/Equipments/HVAC's after preventive maintenance or breakdown.

### **6.36** Frequency for Preventive Maintenance defined as below:

| S.No. | Section Name         | Frequency of Preventive |
|-------|----------------------|-------------------------|
|       |                      | Maintenance             |
| 1.    | HARDGEL              | QUARTERLY $\pm$ 07 DAYS |
| 2.    | COMPRESSION          | MONTHLY $\pm$ 03 DAYS   |
| 3.    | GRANULATION          | QUARTERLY ± 07 DAYS     |
| 4.    | COATING              | QUARTERLY $\pm$ 07 DAYS |
| 5.    | PACKING              | QUARTERLY ± 07 DAYS     |
| 6.    | SOFTGEL              | QUARTERLY $\pm$ 07 DAYS |
| 7.    | AMPOULE              | QUARTERLY $\pm$ 07 DAYS |
| 8.    | DRY POWDER INJECTION | QUARTERLY $\pm$ 07 DAYS |
| 9.    | FFS                  | QUARTERLY $\pm$ 07 DAYS |
| 10.   | THREE PIECE          | QUARTERLY $\pm$ 07 DAYS |
| 11.   | OINTMENT & LIQUID    | QUARTERLY $\pm$ 07 DAYS |
| 12.   | HVAC EQUIPMENT       | QUARTERLY $\pm$ 07 DAYS |
| 13.   | AIR COMPRESSOR       | QUARTERLY $\pm$ 07 DAYS |
| 14.   | NITROGEN PLANT       | QUARTERLY $\pm$ 07 DAYS |
| 15.   | DIESEL GENERATOR     | QUARTERLY $\pm$ 07 DAYS |
| 16.   | TRANSFORMER          | QUARTERLY $\pm$ 07 DAYS |



ENGINEERING DEPARTMENT

**Title:** Plant Equipment Preventive Maintenance

| SOP No.:               | Revision No.:  | 00      |
|------------------------|----------------|---------|
| <b>Effective Date:</b> | Supersedes No. | Nil     |
| Review Date:           | Page No.       | 5 of 12 |

| S.No. | Section Name            | Frequency of Preventive<br>Maintenance |
|-------|-------------------------|--|
| 17.   | CHILLER & COOLING TOWER | QUARTERLY ± 07 DAYS                    |
| 18.   | WATER SYSTEM            | MONTHLY ± 07 DAYS                      |
| 19.   | QUALITY CONTROL         | QUARTERLY ± 07 DAYS                    |
|       | QUALITI CONTROL         | HALF YEARLY ± 15 DAYS                  |
| 20.   | LARGE VOLUME PARENTAL   | QUARTERLY ± 07 DAYS                    |
| 21.   | WAREHOUSE               | QUARTERLY ± 07 DAYS                    |

- **6.36.1** Actual preventive maintenance date may be pre-ponded or post-ponded within tolerance. Next date of preventive maintenance shall be as per schedule date.
- 6.37 Frequency of preventive maintenance for water system equipment & Compression section equipment's shall be considered with variation of monthly  $\pm$  7 days. This is being specific for water system & its use in manufacturing facility.
- 6.38 Frequency of preventive maintenance for QC equipment shall be considered with variation of 3 months  $\pm$  7 days & 6 monthly  $\pm$  15 days as may seem appropriate with respect to duty/criticality of such equipment/machine. This is being specific for QC equipment's.
- **6.39** In case of failure of planned preventive maintenance scheduled date and tolerance period.
  - **6.39.1** User department will take deviation and approved by QA department. Engineering department will carry out preventive maintenance of such equipment/machine as per new date as mentioned in deviation. In this case, next due date shall remain as per schedule.

#### 7.0 ANNEXURES:

| ANNEXURE No.  | TITLE OF ANNEXURE   | FORMAT No. |  |  |  |  |
|---|---|------------|--|--|--|--|
| Annexure - I  | Annexure - I Yearly Schedule for Planned Preventive Maintenance               |            |  |  |  |  |
| Annexure - II Monthly Planned Preventive Maintenance Schedule |   |            |  |  |  |  |
| Annexure – III  | Annexure – III Template of Checklist  |            |  |  |  |  |
| Annexure - IV   | Annexure - IV List of preventive maintenance Checklist                        |            |  |  |  |  |
| Annexure – V  | Addendum Planer for Planned Preventive Maintenance for New Equipment/ Machine |            |  |  |  |  |
| Annexure – VI   | Addendum for Addition & Revision of Checklist                                 |            |  |  |  |  |

**ENCLOSURES:** SOP Training Record

### **8.0 DISTRIBUTION:**

Controlled Copy No. 01 Quality Assurance
 Controlled Copy No. 02 Engineering
 Master Copy Quality Assurance

### 9.0 REFERENCES:

Not Applicable.



Title: Plant Equipment Preventive Maintenance

| SOP No.:               | Revision No.:  | 00      |  |  |  |  |  |
|------------------------|----------------|---------|--|--|--|--|--|
| <b>Effective Date:</b> | Supersedes No. | Nil     |  |  |  |  |  |
| Review Date:           | Page No.       | 6 of 12 |  |  |  |  |  |

### 10.0 REVISION HISTORY:

### **CHANGE HISTORY LOG**

| Revision No. | Change<br>Control No. | Details of Changes | Reason for<br>Change | Effective Date | Updated<br>By |
|--------------|-----------------------|--------------------|----------------------|----------------|---------------|
|              |                       |                    |                      |                |               |



| Title: Plant Equipment Preventive Maintenance |  |                |         |  |  |  |  |
|---|--|----------------|---------|--|--|--|--|
| SOP No.:                                      |  | Revision No.:  | 00      |  |  |  |  |
| <b>Effective Date:</b>                        |  | Supersedes No. | Nil     |  |  |  |  |
| <b>Review Date:</b>                           |  | Page No.       | 7 of 12 |  |  |  |  |

### ANNEXURE - I

#### YEARLY SCHEDULE FOR PLANNED PREVENTIVE MAINTENANCE

YEAR: REVISION No.: BLOCK: SCHEDULE FOR: Preventive Maintenance EFFECTIVE DATE: AREA:

| S.<br>No | Equipment<br>. Name | Equipment<br>ID | Equipment<br>Location | Planning & Execution | Frequency | January | February | March | April | May | June | July | August | September | October | November | December |
|----------|---------------------|-----------------|-----------------------|----------------------|-----------|---------|----------|-------|-------|-----|------|------|--------|-----------|---------|----------|----------|
|          |                     |                 |                       | P                    | Q/M       |         |          |       |       |     |      |      |        |           |         |          |          |
|          |                     |                 |                       | A                    | Q/M       |         |          |       |       |     |      |      |        |           |         |          |          |
|          |                     |                 |                       | P                    |           |         |          |       |       |     |      |      |        |           |         |          |          |
|          |                     |                 |                       | A                    | Q/M       |         |          |       |       |     |      |      |        |           |         |          |          |

Note: P – Planned Date & A – Actual Done Date, Q- Quarterly & M – Monthly Remarks for deviation/ omittance etc.

Prepared By Officer / Executive Engineering Head Engineering User Department Head QA

Sign Date Name



| SOP No.:               | Revision No.:  | 00      |  |  |  |  |
|------------------------|----------------|---------|--|--|--|--|
| <b>Effective Date:</b> | Supersedes No. | Nil     |  |  |  |  |
| Review Date:           | Page No.       | 8 of 12 |  |  |  |  |

### ANNEXURE – II

### MONTHLY PLANNED PREVENTIVE MAINTENANCE SCHEDULE

### **MONTH & YEAR:**

| S.  | Machine/<br>Equipment | Location | Intimation | Scheduled | Prepared<br>by<br>(Engg.) | release               | User<br>dept.  | Actual<br>Done | Review By (Sign & Date) |      |
|-----|-----------------------|----------|------------|-----------|---------------------------|-----------------------|----------------|----------------|-------------------------|------|
| No. | ID                    |          | Date       | on        | Sign &<br>Date            | date by<br>user dept. | Sign &<br>Date | On             | QA                      | Engg |
|     |                       |          |            |           |                           |                       |                |                |                         |      |
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**Checklist No:** 

Remark (If any):

Done By (Engg):

Sign& Date

# PHARMA DEVILS ENGINEERING DEPARTMENT

Title: Plant Equipment Preventive Maintenance

| SOP No.:        | Revision I | <b>No.:</b> 00 |  |
|-----------------|------------|----------------|--|
| Effective Date: | Supersede  | es No. Nil     |  |
| Review Date:    | Page No.   | 9 of 12        |  |

### ANNEXURE – IV TEMPLATE OF CHECKLIST

| Equipm     | nent ID:  |               |  |  |  |  |
|------------|---|---------------|--|--|--|--|
| Freque     | ncy:  | ue Date:      |  |  |  |  |
| Done D     | ate:  | ext Due Date: |  |  |  |  |
| S.No.      | Equipment Check Point   | Observation   |  |  |  |  |
| 1.         | Checks before starting preventive maintenance :   |               |  |  |  |  |
| a)         |   |               |  |  |  |  |
| <b>b</b> ) | b) Take the necessary tools, spares, waste cotton and lubricants to respective area.  |               |  |  |  |  |
| c)         | Switch "OFF" the power supply of "Equipment Name" from main panel. Display "Under Preventive Maintenance" label until work completed. |               |  |  |  |  |
| 2.         |   |               |  |  |  |  |
| 3.         |   |               |  |  |  |  |
| 4.         |   |               |  |  |  |  |
| 5.         |   |               |  |  |  |  |
| 6.         |   |               |  |  |  |  |
| After C    | ompleting Preventive Maintenance activity check these point:  |               |  |  |  |  |
| 1.0        | Abnormal Level of the machine/equipment.  |               |  |  |  |  |
| 2.0        | Any loose or broken part of Metallic/ Non Metallic part of the machine/equipment.   |               |  |  |  |  |
| 3.0        | Any loose wires/ carbon deposited/ dusty electrical connection.   |               |  |  |  |  |
| Observ     | ed Point  |               |  |  |  |  |
| 1.         |   |               |  |  |  |  |
| 2.         |   |               |  |  |  |  |
| 3.         |   |               |  |  |  |  |

**Review By (Engg. Section Head):** 

Sign & Date



Year:

**Prepared By** 

**Engineering** 

Officer/Executive

## PHARMA DEVILS

ENGINEERING DEPARTMENT

| Title: Plant Equipment Preventive Maintenance |  |                      |          |  |  |
|---|--|----------------------|----------|--|--|
| SOP No.:                                      |  | <b>Revision No.:</b> | 00       |  |  |
| <b>Effective Date:</b>                        |  | Supersedes No.       | Nil      |  |  |
| <b>Review Date:</b>                           |  | Page No.             | 10 of 12 |  |  |

### ANNEXURE – V

### LIST OF PREVENTIVE MAINTENANCE CHECKLIST

**Effective Date:** 

**Approved By** 

**Quality Assurance** 

Manager

**Revision No.:** 

| S.No.  | Title     | Checklist No. |
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| Remark | (If any): |               |

**Checked By** 

Engineering

**Operating Manager** 



| SOP No.:               | Revision No.:  | 00       |
|------------------------|----------------|----------|
| <b>Effective Date:</b> | Supersedes No. | Nil      |
| <b>Review Date:</b>    | Page No.       | 11 of 12 |

### ANNEXURE – VI

### ADDENDUM PLANNER FOR PLANNED PREVENTIVE MAINTENANCE FOR NEW EQUIPMENT

Year:
Block:

| S.No. | <b>Equipment Name</b> | Equipment ID: | Location | Reference<br>Change Control No. | Due On | Done On | Next Due<br>On | Next Done<br>on | Remark |
|-------|-----------------------|---------------|----------|---------------------------------|--------|---------|----------------|-----------------|--------|
| 1.    |                       |               |          |                                 |        |         |                |                 |        |
| 2.    |                       |               |          |                                 |        |         |                |                 |        |
| 3.    |                       |               |          |                                 |        |         |                |                 |        |
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Prepared By (Sign & Date) Officer/Executive Engineering Reviewed By (Sign & Date) Operating Manager Engineering Approved By (Sign & Date) Manager Quality Assurance



| Title: Plant Equipment Preventive Maintenance |  |                      |          |  |  |
|---|--|----------------------|----------|--|--|
| SOP No.:                                      |  | <b>Revision No.:</b> | 00       |  |  |
| <b>Effective Date:</b>                        |  | Supersedes No.       | Nil      |  |  |
| Review Date:                                  |  | Page No.             | 12 of 12 |  |  |

### ANNEXURE – VII ADDENDUM FOR ADDITION & REVISION OF CHECKLIST

| S.  | Date | Checklist | <b>Change Control</b> |      | Detail of Change | Revised       | Done By     | Reviewed By<br>Sign & Date |
|-----|------|-----------|-----------------------|------|------------------|---------------|-------------|----------------------------|
| No. | Date | No.       | No.                   | Name | Detail of Change | Checklist No. | Sign & Date | Sign & Date                |
|     |      |           |                       |      |                  |               |             |                            |
|     |      |           |                       |      |                  |               |             |                            |
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