



**PREVENTIVE MAINTENANCE OF LYOPHILIZER**

|   |                        |
|---|------------------------|
| <b>Department:</b> Quality Assurance                        | <b>SOP No.:</b>        |
| <b>Title:</b> SOP for Preventive Maintenance of Lyophilizer | <b>Effective Date:</b> |
| <b>Supersedes:</b> Nil                                      | <b>Review Date:</b>    |

**1.0 Revision History:**

| Rev. No. | Details of changes | Reason for change |
|----------|--------------------|-------------------|
| 00       | NIL                | NEW SOP           |

**2.0 Objective:**

**2.1** The Objective of this SOP is to describe the procedure for preventive maintenance of Lyophilizer.

**3.0 Scope:**

**3.1** This SOP is applicable for preventive maintenance of Lyophilizer installed in Injection.

**4.0 Responsibility:**

**4.1 The Maintenance Operator shall be responsible:**

**4.1.1** To carry out preventive maintenance of equipment.

**4.1.2** To report any deviation and/or deficiency observed during preventive maintenance.

**4.1.3** To maintain the record of all checks.

**4.2 The Maintenance Engineer shall be responsible:**

**4.2.1** To get the preventive maintenance done as per annual maintenance planner.

**4.2.2** To check the preventive maintenance activity is carried out and deviations and/or deficiencies are complied as per requirement.

**4.3 The Production Representative shall be responsible:**

**4.3.1** To keep the respective area and equipment ready for preventive maintenance.

**4.3.2** To verify that preventive maintenance is carried out.



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**5.0 Accountability:**

Head –Engineering Services

**6.0 Procedure:**

**6.1 Caution:**

**6.1.1** Before carrying out preventive maintenance, switch `off` the mains, remove fuses and display the `Under Maintenance` board.

**6.2 Monthly Preventive Maintenance Activities:**

**6.2.1** Clean shelves chamber door gasket by IPA and inspect it for cuts, abrasion or any surface damage, replace it, if required.

**6.2.2** Check stoppering hydraulic system for leakages if found rectify it.

**6.2.3** Check scale formation of all tubes thoroughly, if not remove by brushing then descale with Sulfuric acidic solution.

**6.2.4** Clean all tubes by applying soft water jet.

**6.2.5** Clean product condenser door gasket by IPA and inspect it for cuts, abrasion or any surface damage, replace it if required.

**6.2.6** Open water-ring vacuum pump and clean rotor and spacer plate.

**6.2.7** Lubricate bearing with grease and assemble motor and fit along with water-ring vacuum pump.

**6.2.8** Check all triclover gaskets for cuts, abrasion and any surface damage replace it if required.

**6.2.9** Fill new vacuum oil Teresstic-32 up to the require level and fit drain plug to the position. if require.

**6.2.10** Open the panel board & remove the dust from main panel by air blower.

**6.2.11** Open the contactor and clean the contacts with Carbon Tetra Chloride and refit properly.

**6.2.12** Check earthlings, tighten it properly.

**6.2.13** Take a running trial and check for any abnormal noise and vibrations. Rectify it, if required.

**6.2.14** Maintain the record of all checks in checklist. (Annexure-I).

**7.0 Annexure:**

**Annexure-1:** Monthly Preventive Maintenance Checklist for Lyophilizer.



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**8.0 References (S):**

NIL

**9.0 Glossary**

SOP : Standard Operating procedure

No : Number

QA : Quality Assurance



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**ANNEXURE-I**

|                        |                  |               |
|------------------------|------------------|---------------|
| <b>EQUIPMENT CODE:</b> | <b>LOCATION:</b> | <b>MONTH:</b> |
|------------------------|------------------|---------------|

| S.No. | DESCRIPTION   | OBSERVATIONS/ REMARKS |
|-------|---|-----------------------|
| 1.    | Clean shelves chamber door gasket by IPA and inspect it for cuts, abrasion or any surface damage, replace it, if required.  |                       |
| 2.    | Check stoppering hydraulic system for leakages if found rectify it.   |                       |
| 3.    | Check scale formation of all tubes thoroughly, if not remove by brushing Then descale with sulfuric acidic solution.        |                       |
| 4.    | Clean all tubes by applying soft water jet.   |                       |
| 5.    | Clean product condenser door gasket by IPA and inspect it for cuts, abrasion or any surface damage, replace it if required. |                       |
| 6.    | Open water-ring vacuum pump and clean rotor and spacer plate.   |                       |
| 7.    | Lubricate bearing with grease and assemble motor and fit along with water-ring vacuum pump.                                 |                       |
| 8.    | Check all triclover gaskets for cuts, abrasion and any surface damage replace it if required.                               |                       |
| 9.    | Fill new vacuum oil Teresstic-32 up to the require level and fit drain plug to the position. if require.                    |                       |
| 10.   | Open the panel board & remove the dust from main panel by air blower.   |                       |
| 11.   | Open the contactor and clean the contacts with Carbon Tetra Chloride and refit properly.                                    |                       |
| 12.   | Check earthlings, tighten it properly.  |                       |
| 13.   | Take a running trial and check for any abnormal noise and vibrations. Rectify it, if required.                              |                       |

|  |  |                     |  |
|--|--|---------------------|--|
| <b>Done by:</b><br><b>(Operator)</b>       |  | <b>Done on:</b>     |  |
| <b>Checked by:</b><br><b>(Engineer)</b>    |  | <b>Next due on:</b> |  |
| <b>Verified by: (Concerned Department)</b> |  |                     |  |

**FREQUENCY:** Monthly Preventive Maintenance

**CAUTION:** Before carrying out preventive maintenance, switch off the mains, remove fuse and display the under maintenance board.