



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Preventive Maintenance of Lyophilizer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

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 describe the procedure for preventive maintenance of Lyophilizer.

3.0 Scope

3.1 This SOP is applicable for preventive maintenance of Lyophilizer installed in G-Block Injection of _____

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.



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- 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

8.0 References (S)

NIL

9.0 Glossary

SOP : Standard Operating procedure

No : Number

QA : Quality Assurance



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ANNEXURE I

Monthly Preventive Maintenance Checklist for Lyophilizer

EQUIPMENT CODE:	LOCATION:	MONTH:
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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.	



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Done by: (Operator)		Done on:	
Checked by: (Engineer)		Next due on:	
Verified by: (Concerned Department)			

FREQUENCY :- MONTHLY PREVENTIVE MAINTENANCE

CAUTION : BEFORE CARRYING OUT PREVENTIVE MAINTENANCE, SWITCH OFF THE MAINS, REMOVE FUSE AND DISPLAY THE UNDER MAINTENANCE BOARD.