



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Lube Transfer Pump	Effective Date:
Supersedes: Nil	Review Date:
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Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down the procedure for Cleaning and operation of Lube transfer pump.

2.0 SCOPE:

2.1 This procedure is applicable for Cleaning and operation of Lube transfer pump in Liquid orals.

3.0 RESPONSIBILITY:

3.1 Technical associate Production - For Execution

3.2 Officer/ Executive Production Department- for verification and implementation of SOP

3.3 Head Production Department- shall ensure compliance of the SOP.

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 Cleaning

After completion of batch, affix "TO BE CLEANED" label and during cleaning affix "UNDER CLEANING" label, dully checked by production officer as per reference SOP No. ("Status labeling").If next product is the same as previous product (campaign production), follow batch-to-batch change over procedure. If next product is different from previous product, follow product-to-product change over procedure.

5.1.1 Batch-to-Batch change over procedure (Type A):

Follow the cleaning procedure from 5.1.1.1 to 5.1.1.16 (If the holding tank is empty) and follow the cleaning procedure from 5.1.1.17 to 5.1.1.27(If the holding tank is not empty).

5.1.1.1 **If the holding tank is empty:** After completion of the batch, Collect the remaining liquid of previous batch from the transfer lines by opening the triclover clamps situated at lowest points into the SS container and add sufficient quantity of purified water into it and drain the liquid.



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- 5.1.1.2 Switch OFF the electric supply from tank's panel board and switch ON the electric panel of lube transfer pump.
- 5.1.1.3 Wash the inner surface of tank with purified water by connecting purified water to spray ball for five minutes and open outlet valves of tank and run the lube pump to circulate the water from transfer pipes to the tank.
- 5.1.1.4 Connect the drain pipe to the valve situated at the joint of transfer pipe of tank to the lube pump and put the other end of drain pipe to the drain opening.
- 5.1.1.5 Open the valve and drain the water completely and close the valve.
- 5.1.1.6 Clean the opening point of the holding tank with the help of purified water and nylon brush.
- 5.1.1.7 Again wash the inner surface of tank with purified water through spray ball for another 10 minutes or till there are no visible traces of product and continue the water circulation through lube pump from both the connected pipe line.
- 5.1.1.8 Open the valve (connected to drain pipe) and drain the water completely, Close the outlet valves after complete water is drained out and put dummy on the outlet valve by dismantle the S.S connection pipe.
- 5.1.1.9 After circulation of water through S.S liquid transfer pipe, dismantle the silicon pipe, clamp, fan plate, gasket & S.S. liquid transfer pipe (between Lube pump, holding tank and filling & sealing machine).
- 5.1.1.10 Transfer the silicon pipe, clamp, fan plate, gasket & S.S. liquid transfer pipe into the wash area. Clean the Gasket, clamp, silicon pipe, fan plate and S.S liquid transfer pipe with the help of purified water and nylon brush.
- 5.1.1.11 After cleaning and drying reassemble the fan plate of lube pump and put a dummy on the opening.
- 5.1.1.12 Clean and dry the Gasket, clamp, silicon pipe & S.S. liquid transfer pipe with help of lint free duster and compressed air and ensure proper drying and intactness of Gasket, clamp & S.S. liquid transfer pipe.
- 5.1.1.13 Store the gasket and clamp in a closed dry container. Store the S.S. liquid transfer pipe in a virgin polybag by covering both opening and end mouth with aluminum foil/ Shrink wrap (If the product is not scheduled with in the day).
- 5.1.1.14 Store the Silicon pipe in inverted position in change part room. Cover the both opening and end mouth of Silicon pipe with aluminum foil/ Shrink wrap.



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- 5.1.1.15 Put 'CLEANED' status label having Equipment ID/Area, Previous product, Previous Batch No., Done by, Checked by Production officer finally checked by Quality Assurance (QA) as per reference SOP ("Status labeling").
- 5.1.1.16 Record the details of operation of Lube pump in equipment usage log sheet as per reference SOP ("Making entries in equipment usage and cleaning log sheet").
- 5.1.1.17 **If the holding tank is not empty(Cleaning required in between the batch due to any stoppage for a day):** Before start of cleaning, Collect the remaining amount of liquid from filling machine and SS transfer pipeline (from the lowest point) in S.S container with the help of SS jug and transfer the collected liquid into the holding tank.
- 5.1.1.18 Close the valve No. 22 for Holding Tank-I, valve No. 28 for Holding Tank- II, put a dummy after valve no. 22, valve no. 24 for Holding Tank-I and valve No. 28, valve no. 30 for Holding Tank- II. Disconnect the S.S transfer line associated with the holding tank for circulation and transfer to the wash area for cleaning, put dummy on the opening. Open the valve No. 23 for Holding Tank-I, valve No. 29 for Holding Tank-II.
- 5.1.1.19 Attach the silicon pipe from purified water supply and inlet of the lube transfer pump. Start purified water supply from the lube pump inlet and drain this water from filling machine tank's bottom valve, piston and valve No.24(For Holding Tank-I),valve No. 30 (For Holding Tank- II) of SS transfer line before holding tanks at slow speed for 5 minutes.
- 5.1.1.20 After circulation of water through S.S liquid transfer pipe, dismantle the silicon pipe, clamp, fan plate, gasket & S.S. liquid transfer pipe (between Lube pump, holding tank and filling & sealing machine).
- 5.1.1.21 Transfer the silicon pipe, clamp, fan plate, gasket & S.S. liquid transfer pipe into the wash area. Clean the Gasket, clamp, silicon pipe, fan plate and S.S liquid transfer pipe with the help of purified water and nylon brush.
- 5.1.1.22 After cleaning and drying reassemble the fan plate of lube pump and put a dummy on the opening.
- 5.1.1.23 Clean and dry the Gasket, clamp, silicon pipe & S.S. liquid transfer pipe with help of lint free duster and compressed air and ensure proper drying and intactness of Gasket, clamp & S.S. liquid transfer pipe.
- 5.1.1.24 Store the gasket and clamp in a closed dry container. Store the S.S. liquid transfer pipe in a virgin polybag by covering both opening and end mouth with aluminum foil/ Shrink wrap (If the product is not scheduled with in the day).



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- 5.1.1.25 Store the Silicon pipe in inverted position in change part room. Cover the both opening and end mouth of S.S. liquid transfer pipe with aluminum foil/ Shrink wrap.
- 5.1.1.26 Put 'CLEANED' status label having Equipment ID/Area, Previous product, Previous Batch No., Done by, Checked by Production officer finally checked by Quality Assurance (QA) as per reference SOP ("Status labeling").
- 5.1.1.27 Record the details of operation of Lube pump in equipment usage log sheet as per reference SOP ("Making entries in equipment usage and cleaning log sheet").
- 5.1.2 **Product-to-product change over procedure (Type B):** This procedure is applicable if -there is a change in product, if the batches have been processed for 7 consecutive days, if the equipment is taken for maintenance during processing and maintenance work continues for more than 24 hrs or maintenance work involves any part, which comes in direct contact with product, If the equipment is not used within 72 Hrs, after type "A" Cleaning and If the equipment not used within 240Hrs(10 Days), after type "B" cleaning.
- 5.1.2.1 Clean the lube pump as per process of type "A" cleaning of Holding tank (reference SOP ("Cleaning and operation of 3000 ltrs holding tank"))
- 5.1.2.2 Switch 'ON' the pump and pass the hot purified water as per type 'B' cleaning of holding Tank (reference SOP ("cleaning and operation of 3000 liters holding tank")).
- 5.1.2.3 After circulation, follow the procedure from 5.1.1.20 to 5.1.1.27.
- 5.1.2.4 Finally rinse the pump with 10 liter of purified water.
- 5.1.2.5 Inform the QA to collect swab/rinse water sample if required and drain the water completely.
- 5.1.2.6 After collecting rinse (if required), dismantle the fan plate, transfer to wash area for cleaning. Clean with the fan plate with sufficient amount of purified water and dry with compressed air.
- 5.1.2.8 After cleaning and drying reassemble the fan plate of lube pump and put a dummy on the opening.
- 5.1.2.9 Mop the equipment with dry lint free cloth from outside.
- 5.1.2.10 Put 'CLEANED' status label having Equipment ID/Area, Previous product, Previous Batch No., Done by, Checked by Production officer finally checked by Quality Assurance (QA) as per reference SOP ("Status labeling").
- 5.1.2.11 Record the details of operation of Lube pump in equipment usage log sheet and check the cleaning activity as per Annexure I ("Cleaning checklist of lube transfer pump").
- 5.2 **Set up and operation**
- 5.2.1 Ensure that Lube pump is cleaned.



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- 5.2.2 After line clearance from Q. A. put "EQUIPMENT STATUS" label on the machine.
- 5.2.3 Attach the pump to inlet and outlet S.S lines which transfer material from holding tank to bottle filling machine.
- 5.2.4 Fill purified water into the cooling pot.
- 5.2.5 Open the outlet valve of holding tank, line valve.
- 5.2.6 Start the lube pump from main switch to start filling.
- 5.2.7 OFF the lube pump from main on completion of the operation.
- 5.2.8 Affix "TO BE CLEANED" label on the equipment.
- 5.2.9 Record the details of operation of Lube pump in equipment usage log sheet as per Reference SOP ("Making entries in equipment usage and cleaning log sheet").

5.3 NOTE

- 5.3.1 Ensure water level in COOLING pot before start the lube pump
- 5.3.2 Ensure air pressure in the unit is NLT 3.0 Kg/cm².
- 5.3.3 Change the purified water of the cooling pot every day.
- 5.3.4 If the holding tank is not empty and lube pump cleaning crossed 72Hrs: Clean the lube pump by connecting purified water supply to the inlet through silicon pipe for 5 min and drain the water by connecting the drain pipe to its outlet. Dismantle the silicon pipe, fan plate and transfer to wash area for cleaning and drying. Mop the lube pump from outside with lint free duster and reassemble the fan plate.
After Cleaning, Put 'CLEANED' status label having Equipment ID/Area, Previous product, Previous Batch No., Done by, Checked by Production officer finally checked by Quality Assurance (QA) as per reference SOP ("Status labeling").

6.0 ABBREVIATION (S):

- 6.1 SOP. : Standard Operating Procedure.
- 6.2 No. : Number
- 6.3 NA : Not applicable
- 6.4 S.S : Stainless steel.
- 6.5 Q.A. : Quality Assurance.

7.0 REFERENCE (S):

- 7.1 SOP No.: Status labeling.
- 7.2 SOP No.: Making entries in equipment usage and cleaning log sheet.



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7.3 SOP No.: Cleaning and operation of holding tank.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Cleaning checklist of lube transfer pump		Logbook

9.0 DISTRIBUTION:

9.1 **Master copy** : Quality Assurance

9.2 **Controlled copy (s)** : Production department (01), Quality Assurance (01)

9.3 **Reference copy (s)** : Production department (01)

10.0 REVISION HISTORY:

S.No.	Revision no.	Change control no.	Reason (s) for revision	Details of revision	Effective date
01	00	NA	New SOP	NA	



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ANNEXURE I

CLEANING CHECKLIST OF LUBE TRANSFER PUMP

Name of the Equipment: Lube Transfer Pump

Equipment I.D. No. :

Previous product:

Batch No. :

Date :

S.No.	Activity	Activity Performed
1.	Wash the lube pump through purified water by connecting purified water through holding tank for five minutes and drain the water.	
2.	Again wash the lube pump through purified water by connecting purified water through holding tank for five minutes or till there are no visible traces of product and drain the water.	
3.	Dismantle the clamp, fan plate, gasket, and S.S connection pipe and clean with sufficient quantity of purified water.	
4.	Reassemble the dismantle parts.	
5.	Switch 'ON' the pump pass hot purified water through holding tank and drain the water.	
6.	Dismantle the SS connection pipe from the holding tank.	
7.	Mop the equipment with dry lint free cloth from outside.	

Checked By (Production)
Sign/Date

Verified By (QA)
Sign/Date

Note: Put '√' mark if activity performed and put 'X' if activity not performed.