



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Sparkler Filter Press	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 Sparkler Filter Press.

2.0 SCOPE:

2.1 This procedure is applicable for Cleaning and Operation of Sparkler Filter Press in Liquid department.

3.0 RESPONSIBILITY:

3.1 Technical associate Production: Cleaning and operation of sparkler filter press.

3.2 Officer / Executive Production: For checking

3.3 Head Production: shall ensure compliance and implementation 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, checked by production officer as per reference SOP (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 Cleaning Type "A" procedure (batch-to-batch change over procedure):

5.1.1.1 Switch off the electric supply and disconnect the plug of filter press.

5.1.1.2 Close outlet valve of tank and disconnect the outlet connection of tank (inlet Connection of filter press).

5.1.1.3 First release the pressure from filter press assembly with the help of air knob or by opening the outlet valve of pressure vessel.

5.1.1.4 Collect the remaining amount of liquid of filter press assembly in a SS container and discard it.



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- 5.1.1.5 Dismantle the pipe line associated with the filter press, pull and transfer the filter press and pipe line to the wash area.
- 5.1.1.6 Open the filter press assembly by loosening the locking bolts of the pressure vessel with a spanner and remove the lid.
- 5.1.1.7 Open the bolt fixed at the center of the filter plates and take out the plates assembly.
- 5.1.1.8 Open all the bolts one by one with a spanner.
- 5.1.1.9 Separate the plates and non-woven filter pads, S.S. Sieve plate and spacers.
- 5.1.1.10 Remove the filter pads and discard them.
- 5.1.1.11 Wash the entire parts of sparkler filter press (chamber, lid, filter sieve, filter plates, pipe lines and trolley tray) with purified water to remove the syrup solution and scrub with the help of lint free cloth and nylon brush.
- 5.1.1.12 Open the valves and clean them. Scrub the difficult to clean areas thoroughly.
- 5.1.1.13 Finally Wash the entire parts of sparkler filter press with sufficient amount of purified water and allow them to dry.
- 5.1.1.14 Finally reassemble the sparkler filter press without the filter pads.
- 5.1.1.15 After completion of cleaning activity, affix "CLEANED" label dully filled and signed on the machine as per reference SOP ("Status labeling").
- 5.1.1.16 Record the cleaning details in equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").
- 5.1.2 Cleaning Type "B" (Product-to-product change over procedure):**
- 5.1.2.1 This procedure is applicable if -There is a change in product or during campaign production if the batches have been processed for 7 consecutive days or 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, after cleaning type "A" if equipment is not used within 72 Hrs, after cleaning type "B" if equipment is not used within 240 Hrs.
- 5.1.2.2 Follow the process of Cleaning Type "A" procedure (batch-to-batch change over procedure) from point No. 5.1.1.1 to 5.1.1.13.
- 5.1.2.3 Finally mop the entire parts with 70% IPA solution and reassemble the entire parts without filter pads.
- 5.1.2.4 Transfer the sparkler filter press into the manufacturing area.



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- 5.1.2.5 Finally rinse the Sparkler filter press with 10 liter of purified water Inform the QA to collect swab/rinse water sample (if required).
- 5.1.2.6 Dismantle all part and allow them to dry, after drying reassembles the filter press without the filter pads.
- 5.1.2.7 After completion of cleaning activity, affix "CLEANED" label dully filled and signed on the machine as per reference SOP ("Status labeling").
- 5.1.2.8 Record the cleaning details in equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet") and check the cleaning activity as per Annexure II(Cleaning checklist of sparkler filter press).
- 5.1.3 Cleaning Type "A" (for cartridge filter assembly)**
- 5.1.3.1 Switch off the electric supply and disconnect the plug of filter press.
- 5.1.3.2 Close outlet valve of tank and disconnect the outlet connection of tank (inlet connection of filter press).
- 5.1.3.3 First release the pressure from cartridge filter assembly by opening of air knob screw which is situated on top of cartridge filter assembly.
- 5.1.3.4 Collect the remaining amount of liquid if present in the cartridge filter assembly in a SS container and discard it.
- 5.1.3.5 Remove the cartridge filter assembly from outlet valve no.20 by opening the clamp and pipe line associated with the assembly.
- 5.1.3.6 Transfer the uncleaned cartridge filter assembly and pipe line to the wash area along with filter press assembly.
- 5.1.3.7 Open the cartridge filter assembly by opening the clamp and remove the cartridge filter and discard the cartridge filter.
- 5.1.3.8 Open the filter press assembly by loosening the locking bolts of the pressure vessel with a spanner and remove the lid.
- 5.1.3.9 Open the bolt fixed at the center of the filter plates and take out the plates assembly.
- 5.1.3.10 Separate the plates, S.S. Sieve plate and spacers.
- 5.1.3.11 Wash the entire parts of sparkler filter press (chamber, lid, filter sieve, filter plates, pipe lines and trolley tray), cartridge filter assembly parts and and pipe line with purified water to remove the syrup solution and scrub with the help of lint free cloth and nylon brush.
- 5.1.3.12 Open the valves and clean them. Scrub the difficult to clean areas thoroughly.
- 5.1.3.13 Finally wash the parts with sufficient amount of purified water and allow them to dry.



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5.1.3.14 Reassemble the cartridge filter assembly without the cartridge filter and pipe line associated with the filter press only If cartridge filter assembly is required in next product. And if Cartridge filter assembly is not required in next product then dismantle the cartridge filter assembly, put a dummy on valve no. 20 and transfer the cartridge filter assembly to the clean equipment room, affix “CLEANED” status label duly checked and verified by both Production and Quality Assurance as per reference SOP (“Status labeling”). Shrink wrap or insert cartridge filter assembly in virgin polybag for storage.

5.1.3.15 After completion of cleaning activity, affix “CLEANED” status label on the equipment dully filled and signed on the machine as per reference SOP (“Status labeling”).

5.1.3.16 Record the cleaning details in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.1.4 Cleaning Type “B” (for cartridge filter assembly)

5.1.4.1 Follow the process of Cleaning type “A” (for cartridge filter assembly) from point No. 5.1.3.1 to 5.1.3.11.

5.1.4.2 Finally mop the entire parts with 70% IPA solution and reassemble the entire parts without cartridge filter.

5.1.4.3 Transfer the sparkler filter press into the manufacturing area.

5.1.4.4 Finally rinse the Sparkler filter press with 10 liter of purified water Inform the Q.A. to collect swab/rinse water sample (if required).

5.1.4.5 After rinsing activity, Dismantle all part and allow them to dry, after drying reassembles the sparkler filter press with /without cartridge filter assembly.

If Cartridge filter assembly is not required; dismantle the cartridge filter assembly, put a dummy on valve no. 20 and transfer the cartridge filter assembly to the spare room, affix “CLEANED” status label duly checked and verified by both Production and Quality Assurance as per reference SOP (“Status labeling”). Shrink wrap or insert cartridge filter assembly in virgin polybag for storage.

5.1.4.6 After completion of cleaning activity, affix “CLEANED” status label on the equipment dully filled and signed on the machine as per reference SOP (“Status labeling”).

5.1.4.5 Record the cleaning details in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”) and check the cleaning activity as per Annexure II (“Cleaning checklist of sparkler filter press”).

5.2 Machine set up and operation through filter pad:



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5.2.1 The filter press consists of the following parts:

- ◆ Scavenger plate
- ◆ Screen plates
- ◆ Interlocking cups
- ◆ Filter plate
- ◆ Central tie rod
- ◆ Filter pads

5.2.2 Ensure that filter press and attached SS lines are cleaned.

5.2.3 After line clearance from QA, put the "EQUIPMENT STATUS" label dully filled and signed on the machine as per SOP ("Status labeling").

5.2.4 Ensure that the diameter of filter press connected lines should equal or more than the diameter of filter press connections.

5.2.5 Set the cartridge bottom gasket properly.

5.2.6 Set the scavenger plate on the cartridge bottom gasket.

5.2.7 Set screen plates, filter pad, interlocking cup and filter plate respectively on Scavenger plate one by one in correct order and position.

5.2.8 Fit the top ring properly.

5.2.9 Tighten the side tie rods and central tie rods and put a dummy at valve no. 20 or close the Valve.

5.2.10 Connect the outlet valve of the tank to inlet valve of filter press by SS lines.

5.2.11 Connect the outlet valve of the filter press to inlet valve of storage tank / mixing tank by SS lines.

5.2.12 Open the outlet valve of manufacturing tank and inlet valve of filter press.

5.2.13 Initially keep outlet valve of filter press closed and recirculation valve open.

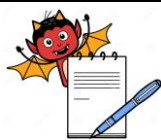
5.2.14 Switch on the power supply and start the filter press Pump.

5.2.15 Keep open the air vent initially. Close the air vent valve at the moment liquid start flowing out from the air vent.

5.2.16 Check the clarity of filtered solution in Sight flow indicator (SFI).

5.2.17 In case of presence of particle, fibers etc. reset the filtration assembly of frames and plates.

5.2.18 Continuously monitor the pressure gauge reading. It should not exceeding 2.0 Kg/cm² in case of excessive pressure built up, reset the filter assembly.



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5.2.19 After completion of Filtration activity, affix “TO BE CLEANED” label dully filled and signed on the machine as per reference SOP (“Status labeling”).

5.2.20 Record the details of machine operation in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.3 Machine set up and operation through cartridge filter

5.3.1 Set up of cartridge filter.

5.3.1.1 Ensure that filter press and attached SS lines are cleaned.

5.3.1.2 Connect the cartridge filter assembly to outlet valve no. 20.

5.3.1.3 Connect the outlet valve of the tank to inlet valve of filter press by SS process lines.

5.3.1.4 Connect the outlet valve of cartridge filter assembly point to the inlet point of Holding tank / mixing tank with SS process line.

5.3.1.5 Connect the outlet point of process line to the inlet valve no.18 of holding tank.

5.3.1.6 Open the outlet valve of manufacturing tank and inlet valve of cartridge filter assembly which contain cartridge filter.

5.3.1.7 Switch on the power supply and start the filter press Pump.

5.3.1.8 Continuously monitor the pressure gauge reading. It should not exceeding 2.0 Kg/cm² in case of excessive pressure built up, reset the cartridge filter assembly.

5.3.1.9 After completion of Filtration activity, affix “TO BE CLEANED” label dully filled and signed on the machine as per reference SOP (“Status labeling”).

5.3.1.10 Record the details of machine operation in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

NOTE: Record the Filter pad and Cartridge filter usage detail as per Annexure-I and records are maintained separately for Filter pad, Cartridge filter and cartridge filter (Make – MDI).

6.0 ABBREVIATION (S):

6.1 SOP: Standard Operating Procedure

6.2 No. : Number

6.3 SS : stainless steel

7.0 REFERENCE(S):

7.1 SOP: Status labeling

7.2 SOP: Making entries in equipment usage and cleaning log sheet



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8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure - I	Cartridge filter / filter pad usage record		Log Book
Annexure - II	Cleaning checklist of sparkler filter press		Log Book

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.	Version No.	Change Control No.	Reason(s) for revision	Details of revision	Effective Date
01	00	NA	New SOP	NA	NA



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ANNEXURE II

CLEANING CHECKLIST OF SPARKLER FILTER PRESS

Equipment Name: Sparkler filter press

Equipment ID: EQI/N2/SPF/___

Previous product:

Batch No.:

Date:

S.No.	Activity	Activity Performed
1.	Open the filter press assembly by loosening the locking bolts of the pressure vessel with a spanner and remove the lid.	
2.	Open the bolt fixed at the center of the filter plates and take out the plates assembly.	
3.	Open all the bolts one by one with a spanner.	
4.	Separate the plates and non-woven filter pads, S.S. Sieve plate and spacers.	
5.	Remove the filter pads and discard them.	
6.	Wash the parts with purified water to remove the syrup solution and scrub with lint free cloth and nylon brush.	
7.	Wash the parts with purified water (chamber, lid, filter sieve, filter plates, pipe lines and trolley tray) with the help of lint free cloth and nylon-brush. Open the valves and clean them. Scrub the difficult to clean areas thoroughly.	
8.	Finally wash the parts with sufficient amount of purified water and allow them to dry.	
9.	Finally mop the entire parts with 70% IPA solution and reassemble the entire parts without filter pads.	

After every use (for cartridge filter assembly)

1.	Remove the cartridge filter assembly from outlet valve no. 20 by opening the clamp and pipe line associated with the assembly.	
2.	Transfer the uncleaned cartridge filter assembly and pipe line to the wash area.	
3.	Open the cartridge filter assembly by opening the clamp and remove the cartridge filter and discard them.	
4.	Wash the cartridge filter assembly parts with purified water to remove the syrup solution and scrub with lint free cloth and nylon brush.	
5.	Finally wash the parts with sufficient amount of purified water and allow them to dry.	
6.	Finally mop the assembly with 70% IPA solution and Reassemble the cartridge filter assembly without the cartridge filter and pipe line associated with the filter press.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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