



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Filling, Dropper Fixing & Screw Capping Machine

SOP No.:		Department:	Production	
		Effective Date:		
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1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of filling, Dropper Fixing & Screw Capping Machine.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Filling, Dropper Fixing & Screw Capping Machine (Make: Techline) in the Production Department.

3.0 RESPONSIBILITY:

Operating Person: Production

4.0 ACCOUNTABILITY:

Head- Production

5.0 ABBREVIATIONS:

LAF	Laminar Air Flow
No.	Number
Ltd	Limited
QA	Quality Assurance
Pvt.	Private
M/C	Machine
w.r.t.	With respect To
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 PRECAUTIONS:

- 6.1.1 Ensure that proper electric supply & earthing are provided to the machine.
- 6.1.2 Avoid filling the hopper to its full capacity.
- 6.1.3 Use silicone tubing as per the category of the product.
- 6.1.4 Ensure that availability of required utility like electricity, compressed air and Nitrogen gas.
- 6.1.5 Open the valve of compressed air, nitrogen gas & check the pressure on pressure gauge.
- 6.1.6 Remove the cover of the particle counter probe. Ensure that particle counter is ON condition throughout the process.
- 6.1.7 Sanitize your hands before every intervention in Grade "A" of during assembling of machine parts.
- 6.1.8 Ensure the proper pneumatic connection of machine before start the assembling of the machine parts.



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6.1.9 Ensure the proper connection of silicon tubing and proper alignment of filling needles during initial machine setting, before start the filling operation

6.1.10 In case if power supply tripping / power failure due to any unforeseen reason , filling Machine will auto stopped then Re start filling machine after power resumption to avoid jerk to the vibrating strip and also prevent the unexpected breakdown

6.2 Critical Control Parameters of Suspension Products During Filling Process:

6.2.1 Ensure the UPS Supply connection to filling tank required for stirrer operation before transfer the suspension from holding tank to filling tank.

6.2.2 Ensure the audio visual alarm system is in working condition if stirrer stopped.

6.2.3 Ensure the RPM of filling tank stirrer is set as per the suitability.

6.2.4 Filling tank stirrer should be start after completely dipping of tank stirrer by suspension.

6.2.5 Ensure the RPM of re-circulation pump as per the suitability.

6.2.6 Ensure the continuation of filling process without any stoppages.

6.2.7 Ensure the 10 strokes of filling machine have been discarded after breakdown/stoppage in running filling process and 11th stroke has been send to QC for assay analysis and separate the lot after breakdown.

6.3 Machine Parts Assembling and Setting:

6.3.1 Ensure that the filling and screw capping machine LAF is ON with desired limit before assembling of machine parts.

6.3.2 Dacron bag/Tyvek bag of the machine parts should be removed when they are transferred under filling LAF.

6.3.3 Transfer all the sterilized machine parts like Hopper, manifold, Connector, Filling needle, Purging needle and Silicon tubes from cooling zone to filling room through mobile LAF.



Transfer all the sterilized machine parts from cooling zone to filling room through mobile LAF



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6.3.4 Assembling of Orientator Hopper:

6.3.4.1 Open the acrylic door of filling machine. Place the Orientator hopper just near to filling machine. Open the zip of decron bag and push the hopper towards class 100. Touch the outer surface of hopper to avoid any contamination on inner side of hopper. Place the hopper at its position.

6.3.4.2 Sanitize the hands and scissor with IPA 70 % solution. Cut the tyvek bag with scissor and pick out the bolt of with sterile forcep. Tight this bolt with sanitized key. After this also sanitize the area where bolt is tightened.

6.3.4.3 Cut the tyvek bag and pick out the vial dispensing chute and assemble at its position.

6.3.5 Assembling of Dropper fixing Hopper:

6.3.5.1 Open the acrylic door of dropper fixing unit of filling and dropper machine. Place the Dropper hopper just near to dropper fixing unit, open the zip of decron bag and push the hopper towards class 100. Touch the outer surface of hopper to avoid any contamination on inner side of hopper. Place the hopper at its position.

6.3.5.2 Sanitize the hands and scissor with IPA 70 % solution. Cut the tyvek bag with scissor and pick out the bolt of with sterile forcep. Tight this bolt with sanitized key. After this also sanitize the area where bolt is tightened.

6.3.5.3 Cut the tyvek bag and take out the dropper chute & dropper pressing assembly and assemble at its position.

6.3.6 Assembling of Capping Hopper:

6.3.6.1 Open the acrylic door of capping unit. Place the capping hopper just near to capping machine, open the zip of decron bag and push the hopper towards class 100. Touch the outer surface of hopper to avoid any contamination on inner side of hopper. Place the hopper at its position.

6.3.6.2 Sanitize the hands and scissor with IPA 70 % solution. Cut the tyvek bag with scissor and pick out the bolt with sterile forcep. Tight this bolt with sanitized key. After this also sanitize the area where bolt is tightened.

6.3.6.3 Cut the tyvek bag and take out the Capping chute & Capping head assembly and assemble at its position.

6.3.7 In mobile LAF connect the silicon tubing with inlet of manifold & SS connector. Open the acrylic door of filling machine and assemble at its position.

6.3.8 The bio-barrier paper of each open end of tube, nozzles or manifold should be removed only at the time of connecting to each other. Other end of tube should be kept closed with bio-barrier paper till it is required for further connections. Follow this procedure for all connections.



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- 6.3.9** Assemble the filling needle at its position and check its alignment.
- 6.3.10** Connect the silicon tubing with manifold & purging needle. Assemble the purging needle at its position. Check the alignment of the entire purging needle.
- 6.3.11** Connect the Silicon tubing with manifold to product line of filling vessel.
- 6.3.12** Connect the Silicon tubing for Nitrogen to the filling vessel.
- 6.3.13** Place the SS scissors, forceps & SS jug at its position.
- 6.3.14** Adjust the transferring star wheel for smooth run of vials on conveyer.
- 6.3.15** Adjust the vibrator bowl for flowing freely from the vibratory bowl feeder to the dispenser by rotating the knob.
- 6.3.16** Adjust the height of chute as per vial by rotating the knob and inlet & outlet star wheel. Adjust the filling needle at proper height w.r.t. vial size in the filling machine nozzle mounting bracket.
- 6.3.17** Adjust the Torque and height of the dropper pressing head w.r.t. vial size.
- 6.3.18** Adjust the Torque and height setting of the Capping Head.
- 6.3.19** During assembling and machine setting sanitize the hands with filtered 70 % IPA solution after frequent interval.
- 6.3.20** Now start the machine by inching switch and check the volume as per specification.
- 6.3.21** Take a trial run of complete machine operation for smooth run before starting the solution supply in the filling line.
- 6.3.22** Open the solution valve of the tank and let the solution pass in the tube up to the nozzle by removing the trapped air in the tubes.
- 6.3.23** Before starting the filling activity, let the QA and QC person to withdraw the initial samples of the filling process as per the sampling SOP.

6.4 Machine Operation:

- 6.4.1** Switch "ON" the power supply of M/C & check status of PLC. It should be as:



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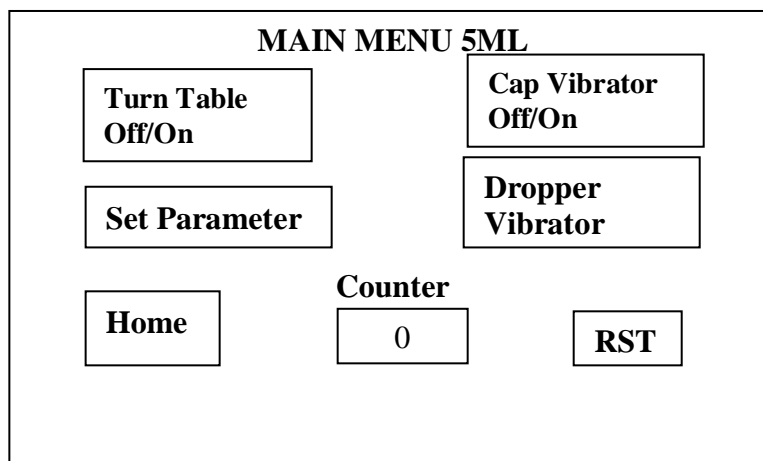
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TECHLINE INDUSTRIES
A/105-107 Bharat Industrial Estate
Off Lake Road, Near Hind Rectifier
Bhandup (W) Mumbai -400078
Phone: 022 25962384
FILLING LINE –CFL 120

MENU

6.4.2 Touch the menu that screen will be disappearing as is:





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6.4.3 Touch the set parameter than screen will be disappearing as is:



6.4.4 Touch the star image than screen will be disappearing as is:

ENTER PASSWORD				
E.SC	7	8	9	←
Delta	4	5	6	
+/-	1	2	3	
	0	-	ENTER	

6.4.5 Put the password which is providing for the same & touch enter key than screen will be disappearing as is:



6.4.6 Touch arrow key than screen will be disappearing as is:

		△	<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">Load</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">Send</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">Save</div> <div style="border: 1px solid black; padding: 2px;">↩</div>
3 ML		▽	
		▽	



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6.4.7 Set the pack of vial which is required then touch load key screen will be disappearing as is:

6.4.7.1 FOR CFL 120:

5 ML		△	Load
Valve-1	0.6	▽	Send
Valve-2	0.6		Save
Valve-3	0.6		
Valve-4	0.625		
Valve-5	0.6		
Valve-6	0.65		

6.4.7.2 FOR CFL 200:

5 ML		△	Load
Valve-1	0.6	▽	Send
Valve-2	0.6		Save
Valve-3	0.6		
Valve-4	0.625		
Valve-5	0.6		
Valve-6	0.65		
Valve-7	0.6		
Valve-8	0.6		
Valve-9	0.65		
Valve-10	0.6		
Valve-11	0.65		
Valve-12	0.65		
Nitrogen Valve	1.5		

6.4.8 On the step PLC display valve 1, 2, 3, 4, 5, 6 (For CFL 120) & 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 (For CFL 200) this is filling nozzles. By these valves adjust volume of vial in their specification.

6.4.9 After volume adjustment touch save key and then touch send key. After touching save & send key touch arrow key than screen will be disappearing as is.



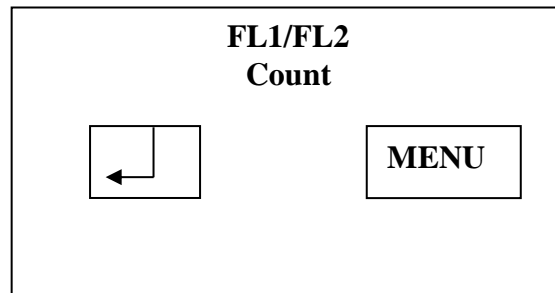
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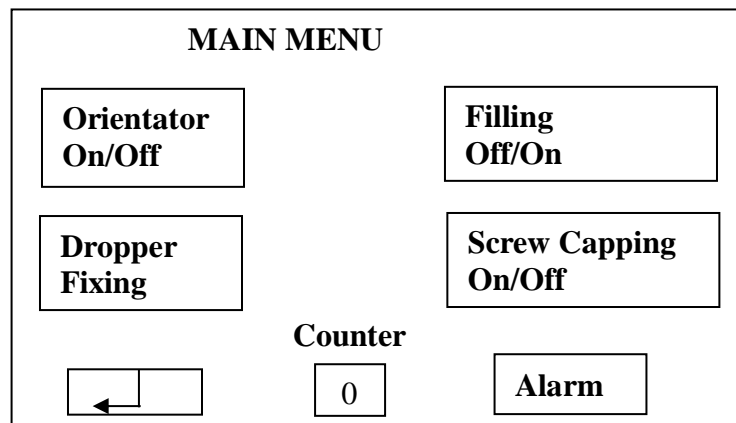
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- 6.4.10 Touch menu key than screen will be disappearing as is the step 6.2.5.
- 6.4.11 Touch the turn table key in main menu than start turn table for operation.
- 6.4.12 Touch cap vibrator key than start vibrator for operation.
- 6.4.13 Touch cap vibrator key than start cap vibrator for operation.
- 6.4.14 Touch arrow key for next operation.
- 6.4.15 Start the turn table and conveyor:



- 6.4.16 Start the Orientator operation by touching Orientator key.
- 6.4.17 Before touching the filling key press inch button which is provided in the front of machine for setting of vial, N₂ gas Nozzles pre & post and filling Nozzles.
- 6.4.18 Check volume of 1 to 6 (In case of CFL 120) & 1 to 12 Vials (In case of CFL 200) according to the pack size then to go to step no.6.2.11 and adjust the volume.
- 6.4.19 Start the filling operation by touching dropper fixing key.
- 6.4.20 Start dropper fixing operation by touching dropper fixing key.
- 6.4.21 Start screw capping operation by touching screw capping key.
- 6.4.22 Operate the filling machine within validated speed.



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Validated speed is as:

Minimum speed- 40%

Optimum speed- 70 %

Maximum speed- 90%.

6.5 Challenge Test During the Filling Operation:

Perform below mentioned challenge test initially before start the filling machine, after every breaks down/breaks and towards end of operation.

6.5.1 No Vial No fill: Pick one vial from feeding track by using sterile forcep. Solution should not dispensed from filling nozzle.

6.5.2 Low infeed of dropper in chute: Check the machine operation at lower level of dropper in the chute. Machine should be stopped

6.5.3 Vial without dropper: Pass one vial without dropper in front of this sensor. Capping Machine should be stopped.

6.5.4 Low infeed of cap in chute: Check the machine operation at lower level of cap in the chute. Machine should be stopped.

6.5.5 Empty vial detection and rejection: Pass one empty vial in front of this sensor. Machine automatically detect and reject to the empty vials. This is applicable for CFL-200 MC.

6.6 Sensor Control Detail:

6.6.1 Sensor Control detail In Three piece Filling, dropper fixing and screw capping machine (CFL-120):

Sensor	Functional role of Sensor
Sensor – I	Intermittently sensing the flow of bottles and switching off when infeed track of turn table becomes full.
Sensor- II	Intermittently sensing the flow of bottles and switching ON the dosing station of solution.
Sensor- III	Intermittently sensing the flow of bottles and switching off the flow of solution in case of No vial at filling nozzle. (No vial No fill)
Sensor- IV	Intermittently sensing the flow of bottles and switching off the dosing station when turn table of filling becomes full. (FL-TT Full)
Sensor –V	Intermittently sensing the flow of bottles and switching off the dropper station when there is no flow of bottles for more than 2 seconds. (DF-No Bottle)
Sensor- VI	Intermittently sensing the flow of dropper and switching off when there is



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Sensor	Functional role of Sensor
	no dropper in the chute for more than 5 seconds. (Chute-No Dropper) Alarm is also generated as Chute-No Dropper.
Sensor -VII	Intermittently sensing the flow of bottle and switching off the dropper station when any one bottle stays there for more than 2 seconds. (DF-Over load)
Sensor-VIII	Intermittently sensing the dropper and immediately stop the capping unit,if there is no dropper on the bottle for more than 2 seconds. (No Dropper on bottle)
Sensor -IX	Intermittently sensing the flow of cap and switching off when there is no cap in the chute for more than 2 seconds. (Chute-No Cap) Alarm is also generated as Chute-No Cap.
Sensor- X	Intermittently sensing the bottle and counting them.

6.6.2 Sensor Control detail In Three piece Filling, dropper fixing and screw capping machine (CFL-200):

Sensor	Functional role of Sensor
Sensor-I	Intermittently sensing the flow of bottles and switching off when infeed track of turn table becomes full. (TT-Full)
Sensor-II	Intermittently sensing the flow of bottles and switching off over flow of vials in Chute. (2 Sensors are for two track)-Chute Over flow
Sensor-III	Intermittently sensing the flow of bottles and switching off the flow of solution in case of No vial at filling nozzle. (No vial No fill)
Sensor-IV	Intermittently sensing the flow of bottles and switching off when turn table of filling becomes full. (FL-TT Full)
Sensor-V	Intermittently sensing the flow of bottles and switching off when there is no flow of bottles for more than 2 seconds. (DF-No Bottle)
Sensor-V	Intermittently sensing the flow of dropper and switching off when there is no dropper in the chute for more than 5 seconds. (Chute-No Dropper) Alarm is also generated as Chute-No Dropper.
Sensor-VI	Intermittently sensing the flow of bottle and switching off when any one bottle stays there for more than 2 seconds. (DF-Over load)



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Sensor	Functional role of Sensor
Sensor-VII	Intermittently sensing the flow of cap and switching off when there is no cap in the chute for more than 2 seconds. (Chute-No Cap) Alarm is also generated as Chute-No Cap.
Sensor-VIII	These are two sensor DS-1 & DS-2. DS-1 Intermittently sensing the bottles at the same time DS-2 senses droppers. If DS-2 misses sense, immediately stop the capping unit. (No Dropper on bottle)
Sensor-IX	Intermittently sensing the bottle and switching off if there is no flow of bottle for than 2 seconds. Screw capping unit is stopped. (SC-No Bottle)
Sensor-X	Intermittently sensing the bottle and switching on Ejector solenoid coil if there is no fluid in the bottle. It rejects vial without any fluid. (Ejector Sensor)

6.7 ALARM ACKNOWLEDGEMENT :

S.No.	Reason of alarm	Alarm acknowledgement	Action
1.	Low pressure of Compressed air	No compressed air	Filling machine stopped
2.	Low pressure of Compressed air	Low Nitrogen pressure	Filling machine stopped
3.	Low infeed of dropper in chute	No dropper	Filling machine stopped
4.	Low infeed of cap in chute	No Cap	Filling machine stopped

6.8 Compressed Air and Nitrogen Pressure Setting:

- 6.8.1 Set the compressed air pressure at 6.0 kg/cm² and cut off pressure at 5.0 kg/cm² from the Pressure regulator provided with machine. Below the pressure 5.0 kg/cm² of Compressed air Filling machine is stopped.
- 6.8.2 Set Nitrogen pressure at 2.0 kg/cm² from the regulator provided in the machine.
- 6.8.3 Set Nitrogen pressure in between 0.3 to 0.5 kg/cm² at pre and post purging.

6.9 Procedure to Perform the Intervention:

- 6.9.1 When any intervention is to be performed under grade A. ensure that the filled vials should be removed from filling track to avoid any contamination.
- 6.9.2 During transfer of Vial/Dropper/Cap from bench type LAF to respective hopper, sanitize the pack with IPA 70 % solution then place on the surface of machine. Sanitize the SS scissor, cut the poly bag and pour into respective hopper slowly slowly.



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- 6.9.3** During assembling of sterilized machine parts in grade A sanitize the hands before to perform each intervention.
- 6.9.4** During removal of stucked/jammed vials in the chute ensure the filled vials available in the filling track should be removed before to perform this intervention.
- 6.9.5** During removal of stucked/jammed dropper in the chute ensure the filled vials available in the filling track should be removed before to perform this intervention.
- 6.9.6** During tea break, lunch break and shift change over remove all the filled and sealed vials from the filling and capping track.
- 6.9.7** During filling if any minor or major breakdown occurs then after performance such intervention replace the hand glove and sanitize with IPA 70 % before start the filling operation.

6.10 Machine Parts Dismantling and Machine Cleaning:

- 6.10.1** Switch off the machine after completion of filling operation.
- 6.10.2** Collect the remaining vials, dropper and cap and transfer from filling room to outer area through scrap pass out dynamic pass box.
- 6.10.3** Dismantle the machine parts and transfer into unit preparation for cleaning.
- 6.10.4** Clean the machine with WFI by using lint free mop. First clean the acrylic door & then machine surface and SS panel.
- 6.10.5** Sanitize the machine with lint mop soaked with scheduled disinfectant solution. First sanitize the acrylic door & then machine surface and SS panel.
- 6.10.6** Sanitize the machine with lint mop soaked with IPA 70 % solution. First sanitize the acrylic door & then machine surface and SS panel.
- 6.10.7** Dry the acrylic door, machine surface and SS panel with dry lint free mop.
- 6.10.8** Record the operation details in "Machine Utilization record" as per Format.
- 6.10.9** After cleaning and sanitization of machine, perform the cleaning and sanitization the area as per SOP.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Challenge test record during filling operation	
Annexure-II	Assembling of Orientator Hopper	
Annexure-III	Assembling of Dropper Fixing Hopper	
Annexure-IV	Assembling of Capping Hopper	

ENCLOSURES: SOP Training Record.



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8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Production (I-Block)
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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ANNEXURE-I

CHALLENGE TEST RECORD DURING FILLING OPERATION

Date	Product Name	Batch No.	Monitoring ↓	Type of Challenge test					Nitrogen pressure in filling tank (Kg/cm ²)	Done By (Prod.)	Checked By (Prod.)	Verified By (IPQA)
				No Vial No fill	Low infeed of dropper in chute	Vial without dropper	Low infeed of cap in chute	Empty vial detection and rejection				
			Time									
			Observation (OK/ Not OK)									
			Time									
			Observation (OK/ Not OK)									

Remark: Give the reason if observation is Not OK: _____



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ANNEXURE-II ASSEMBLING OF ORIENTATOR HOPPER



Place the Orientator hopper just near to filling machine



Open the zip of decron bag and push the hopper towards class 100



Place the hopper at its position.



Do not touch outer surface of Orientator



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Sanitize the hands with IPA 70%



Sanitize the scissor with IPA 70%



Pick out bolt with sterile forcep Tight this bolt with sanitized key



After this also sanitize the area where bolt is tightened.



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Cut the tyvek bag using sterilized scissor.



Pick out the vial dispensing chute and assemble at its position.



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ANNEXURE-III ASSEMBLING OF DROPPER FIXING HOPPER



Open the zip of decron bag and push the hopper towards class 100



Place the hopper at its position.



Place the Dropper hopper at its position.



Open the zip of bag under LAF



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Sanitize the hands with IPA 70%



Cut the poly bags and load the dropper in hopper



Cut the tyvek bag with scissor and pick out the bolt with sterile forceps



After this also sanitize the area where bolt is tightened.



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Cut the tyvek bag and take out the dropper chute & pressing assembly



Assemble dropper chute & pressing assembly at its position.



Check the setting of dropper chute



Assemble the dropper finger setting



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ANNEXURE IV ASSEMBLING OF CAPPING HOPPER



Open the zip of decron bag and push the capping hopper towards class 100



Touch the outer surface of capping hopper to avoid any contamination



Sanitize hands and scissor with IPA 70 %. Cut the tyvek bag with scissor and pick out the bolt with sterile forceps



Tight this bolt with sanitized key



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Sanitize the area with IPA 70% where bolt is tightened.



Cut the tyvek bag using sterilized scissor



Take out the capping chute



Assemble the Capping chute



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Check the Capping head assembly at its position.



In mobile LAF connect the silicon tubing with inlet of manifold & SS connector



Open the acrylic door of filling machine and assemble at its position.



Assemble the filling needle at its position and check its alignment.



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Connect the silicon tubing with manifold & purging needle



Assemble the purging needle at its position



Connect the Silicon tubing with manifold to product line of filling vessel.





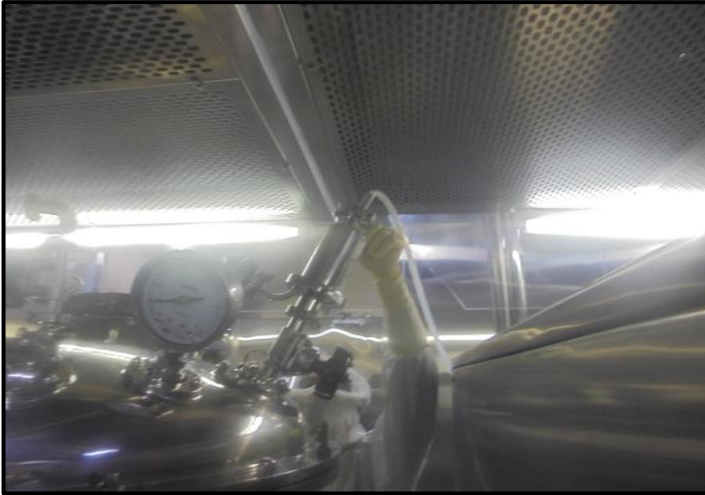
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Connect the Silicon tubing for Nitrogen to the filling vessel.



Cut the tyvek bag and keep SS scissors at its position



Cut the tyvek bag keep forceps at its position



Cut and remove the tyvek bag Keep jug at its position