



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Autoclave Cum Bung Processor

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

To lay down a procedure for Operation and Cleaning of Autoclave Cum Bung Processor

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Autoclave Cum Bung Processor of production area in Dry Powder Injectable Section.

3.0 RESPONSIBILITY:

Operating Person – Production

4.0 ACCOUNTABILITY:

Head – Production.

5.0 ABBREVIATIONS:

DPI	Dry Powder Injection
IPA	Iso Propyl Alcohol
ID	No. Identification Number
Pvt.	Private
LOD	Loss on Drying
LAF	Laminar Air Flow
Ltd.	Limited
MMI	Man Machine Interface
Min.	Minutes
Nos.	Numbers
PLC	Programmable Logic Control
Prod.	Production
QA	Quality Assurance
QC	Quality Control
RPTS	Repeats
SS	Stainless Steel
SOP	Standard Operating Procedure
SLS	Sodium Lauryl Sulphate
Sec.	Seconds
Temp.	Temperature
W/V	Weight by Volume
WFI	Water for Injection

6.0 PROCEDURE:

6.1 Check Points:

6.1.1 Check availability of soft water for vacuum pump.



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6.1.2 Compressed air supply is available at appropriate utility location (6.0 to 8.0 kg/cm²).

6.1.3 Check Purified water and WFI supply.

6.1.4 Check Pure Steam supply is of 1.2 kg /cm² to 3.0 kg / cm² (Approx.)

6.1.5 For user privileges refer SOP.

6.1.6 Refer Annexure-VII for alarm management details.

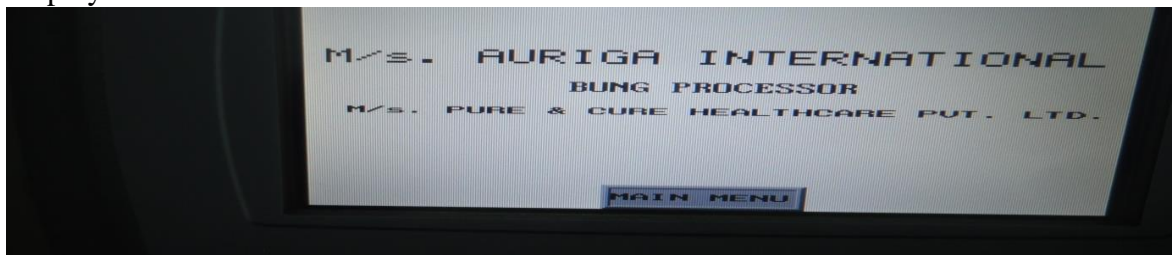
6.1.7 Interpretation of Bowie dick test paper shall be performed as per point no. 6.8

6.1.8 Interpretation of strip chart graph shall be performed as per point no. 6.10

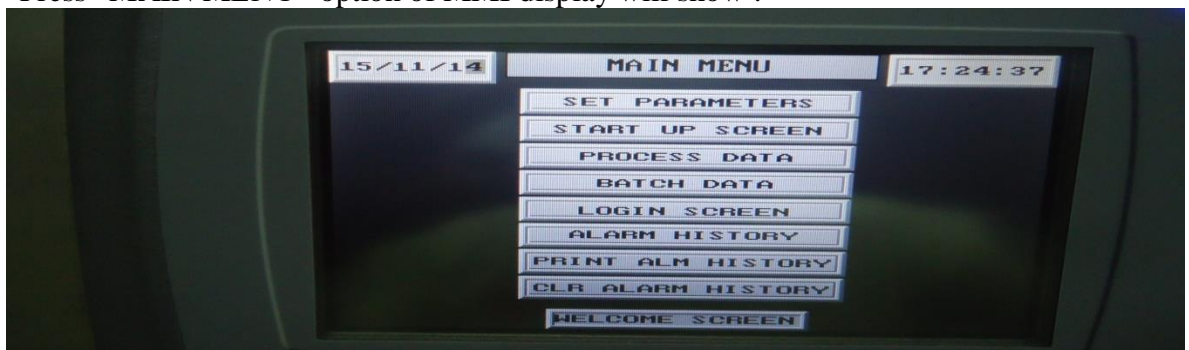
6.2 Operation:

6.2.1 Switch “ON” the Main power supply of Machine and printer machine simultaneously.

6.2.2 Display will show on MMI screen:



6.2.3 Press “MAIN MENU” option of MMI display will show :



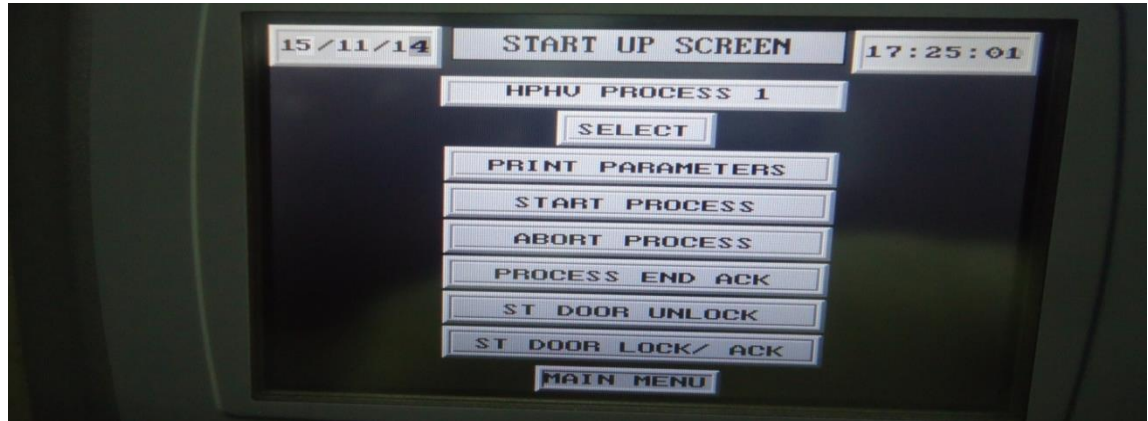
6.2.4 Select the Process “START UP” and the MMI screen will Show :



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6.2.5 Press the Printer parameters.

6.2.6 Start the cycle with their respective Process Data.

6.3 Sterilization (Auto Mode):

6.3.1 Load the object which is to be sterilized in the chamber of Autoclave Cum Bung processor unit as per load pattern.

6.3.2 Push the button for closing the door provided on Panel board.

6.3.3 Check the proper utility required for select cycle.

6.3.4 If all utility are satisfactory start the cycle.

6.3.5 After completion of cycle the screen will display 'PROCESS END'.

6.3.6 Wait for desired pressure decrease to open the door.

6.3.7 After completion of particular cycle open the Aseptic Area side door by pressing open switch on panel.

6.3.8 *Note:* If strip chart recorder graph does not come with any reason in that case cycle shall be verified and accepted with temperature mapping print.

6.4 Bung Process Cycle (Auto):

6.4.1 Set parameter for Bung Processor-I and check the parameter **Annexure VI**.

6.4.2 Check the above parameter and press "START" key to start the process.

6.4.3 Process will start from Detergent wash, Purified water wash, WFI wash and Silicon wash followed by Sterilization and Drying process.

6.4.4 Give the sample of water for wash water analysis after WFI wash with intimation slip to QA as per **Annexure-III**.



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6.4.5 On completion of Bung Cycle in Auto Mode send the dried Rubber Plug sample for loss on drying analysis to QC with intimation slip as per **Annexure-IV**.

6.5 Bung Process (Manual):

6.5.1 Operation:

6.5.1.1 Switch "ON" the PLC.

6.5.1.2 Load the required quantity of Bungs in Bung trolley as per Load Pattern.

6.5.1.3 Load the trolley in Bung Processor chamber and ensure of the proper fitting of trolley.

6.5.1.4 Close the door of Bung Processor by pressing door close button provided on the panel.

6.5.1.5 Ensure that all required utility are available.

6.5.1.6 Start the cycle "Bung Processing".

6.5.1.7 Switch "ON" the rotating motor during whole cycle.

6.5.2 Detergent Wash:

6.5.2.1 Pour 1.0 % w/v of SLS solution in the cup provided in machine.

6.5.2.2 Fill the purified water in the chamber and start the detergent filling.

6.5.2.3 Open Air Vent valve, main valve, recirculation valve, side pocket drain & Purified Water IN valve. Recirculation pump will be start afterwards.

6.5.2.4 On completion of detergent dosing continue the recirculation with fluidization for 10 minutes.

6.5.2.5 Close the air valve and wait for 3 minutes for Stabilization.

6.5.2.6 Continue the overflow of purified water for 10 minutes by opening the valve of Purified Water IN and Compressed air IN after Stabilization.

6.5.2.7 Drain the water from chamber by opening the drain valve.

6.5.2.8 Continue the side washes to remove dust or particles which are still remaining on the Bungs or sides the chamber for 3 minutes.

6.5.2.9 Drain the chamber water for 5 minutes.

6.5.3 Purified Water Wash:

6.5.3.1 After detergent wash start the PW filling in chamber.



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- 6.5.3.2 Start the recirculation pump and fluidization with continue motion of rotating cage for 10 minutes.
- 6.5.3.3 On completion of above step close the air valve and wait for 5 minutes for the stabilization.
- 6.5.3.4 After stabilization overflow the purified water for 10 minutes.
- 6.5.3.5 Stop overflowing of purified water and open the drain valve.
- 6.5.3.6 Now start the machine wash for 3 minutes with Purified water by opening the purified water IN valve.
- 6.5.3.7 Drain the chamber water for 5 minutes.
- 6.5.4 **WFI Wash:**
 - 6.5.4.1 Open WFI valve and steam to jacket valve continuously.
 - 6.5.4.2 After vacuum of the chamber, WFI filling will take place.
 - 6.5.4.3 PLC will check the desired temperature of WFI, if it is less than settable temperature steam valve will be "ON".
 - 6.5.4.4 On achieving desired temperature, Stabilization will be started up for 5 minutes.
 - 6.5.4.5 On completion of above step drain will take place. After that side wash take place to remove dust or particles which are still remaining on Bung and sides the chamber.
 - 6.5.4.6 Give the sample of water for wash water analysis with intimation slip to QA as per **Annexure-III**.
- 6.5.5 **Silicon Wash:**
 - 6.5.5.1 Fill the required quantity of silicon solution or silicon oil in the cup provided with machine.
 - 6.5.5.2 Open the Silicon dosing pump for "SILICON IN" in the chamber for 1 minute.
 - 6.5.5.3 Fill WFI up to high level, PLC will check desired temperature of water.
 - 6.5.5.4 If water temperature is less than settable temperature steam will start to chamber for achieving desired temperature.
 - 6.5.5.5 On achieving desired temperature motion of rotating cage will start and Silicon Soaking will start for 10 minutes.
 - 6.5.5.6 On completion of above step drain will take place. After that side wash take place to remove dust or particles which are still remaining on Bung and sides the chamber.
- 6.5.6 On completion of Silicon wash start sterilization as per Auto Mode procedure.



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6.5.7 On completion of sterilization, dry the Bungs by applying vacuum, at that time rotating cage will continuously rotate.

6.5.8 On completion of Bung Cycle in Manual Mode send the dried Rubber Plug sample for loss on drying analysis to QC with intimation slip as per **Annexure-IV**

6.5.9 After Completion of Operation, Clean the machine.

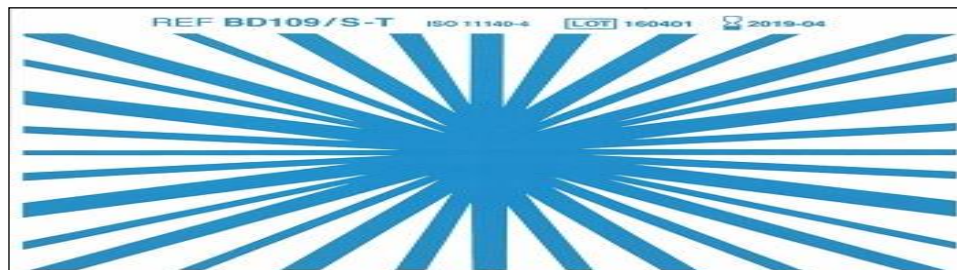
6.6 Record the Operation and cleaning detail in “**Machine Utilization Record**” as per SOP.

6.7 Vacuum leak test should be performing on daily basis, prior to start any batch processing & record the observation in “**Vacuum Leak Test Record**” as per **Annexure-I**.

6.8 Bowie Dick test should be performing on weekly basis, prior to start any batch processing & record the observation in “**Bowie Dick Test Record**” as per **Annexure-II**.

6.8.1 The color of Bowie-Dick Test Indicator should show a **Uniform Color change** from **Sky Blue to Black after process exposure** (Refer photographs as under).

6.8.2 Representation of Bowie Dick kit before sterilization, shown as under.



6.8.1.1 Representation of Bowie Dick kit after sterilization, shown as under.



6.8.1.2 Fill data as per applicable on the back side Bowie Dick kit paper and put tick mark or cross mark to conclude the result and then sign off Bowie Dick kit paper.

6.8.1.3 Remark: No change/ Non-Uniform Change and or Air Entrapment (bubble) Spot on the Test Pack indicates inadequate air removal from the sterilization chamber, Hence need to investigate by QMS tool.



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If vendor of Bowie Dick test kit is changed, then parameters shall be decided on the basis of vendor recommendations and COA.

Note: Sterilized items should be used within 24 hours from the time of their sterilization.

6.9 Load Pattern of Autoclave Cum Bung Processor is given below for reference:

6.9.1 Minimum Garment Load (Load Pattern No.....):

Load Details:

- 05 Set inner garment (05 inner, 05 lower, 10 booties, 05 cap)
- 05 Set secondary garment (05 head gear, 05 boiler suit, 10 booties, 05 goggles)

Load Configuration: Follow the Annexure – Pictorial Representation of Validated Load Pattern - I.

6.9.1.1 Unloading Procedure for Garments:

- Unload the sterile garments in closed SS container under LAF.
- Transfer the sterile garments to Aseptic area Entry air lock-2 in Dynamic Garment Storage Cabinet through mobile LAF.

6.9.2 Maximum Garment Load (.....):

Load Details:

- 20 Set Inner Garments (20 Nos. Inner, 20 Nos. Lower, 20 Nos. Cap & 40 Nos. Booties)
- 20 Set Secondary Garments (20 Nos. Head Gear, 20 Nos. Boiler, 20 Nos. Google & 40 Nos. Booties)

Load Configuration: Follow the Annexure – Pictorial Representation of Validated Load Pattern - II.

6.9.2.1 Unloading Procedure for Garments:

- Unload the sterile garments in closed SS container under LAF.
- Transfer the sterile garments to Aseptic area Entry air lock-2 in Dynamic Garment Storage Cabinet through mobile LAF.

6.9.3 Accessories Load (Load Pattern No.):

Load Details:

- Bung Box (05 Nos.)
- Bung UN loader (01 No.)
- S.S. Waste Bin (02 Nos.)
- Bucket (05 Nos.)
- SS Container with lid (01 Nos.)



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Load Configuration: Follow the Annexure – Pictorial Representation of Validated Load Pattern - III.

6.9.4 Manufacturing Blender Load (Load Pattern No. –):

Load Details-

- Blender (01 Piece)
- Gasket (02 Nos.)
- Aluminum Foil (02 meter)
- SS Container (01 No.)
- SS Scoop (01 No.)
- Mopping Pad (02 Nos.)

Load Configuration: Follow the Annexure – Pictorial Representation of Validated Load Pattern - IV.

6.9.5 Mixed Load (Load Pattern No.):

Load Details

Load Details	
Sterile Garments Set With Goggle	20 Nos.
Inner Garment Set	20 Nos.
Mopping Pads	10 Nos.
Powder Hopper	01 Nos.
Port Wheel	01 Nos.
Piston, Piston Lock, Filter Tip	24 Nos.
Bung Container	01 Nos.
Pressure Vessel	01 Nos.
Bung Hopper and Chute	01 Nos.
Side Guard with power felt	02 Nos.
Filtration Assembly	01 Nos.
Forceps	06 Nos.
Forceps Sanitizer	02 Nos.
Nitrogen Filter Housing	01 Nos.
Silicone Tube	02 Nos.
SS Scoops	02 Nos.
SS Spoon	02 Nos.
SS Large Spoon	02 Nos.
Ln Key	02 Nos.
Aluminum Foil	01 meter
Aluminum tape	01 meter
Autoclable Tape	01 meter
Clean Room Pen	01 Nos.
Autoclave IPA Bottle	04 Nos.
Bio Barrier Paper	02 Nos.
Capsule Filter	03 Nos.



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Autoclavable Paper	06 Nos.
Vent Filter	02 Nos.
MOP Head with stand	02 Nos.
Clean room marker	01 Nos.
Container Sealer	01 Nos.
Aluminum Seal	02 Nos.

Load Configuration: Follow the Annexure – Pictorial Representation of Validated Load Pattern - V.

6.9.5.1 Unloading Procedure for Sterilized Items:

- Unload the Sterilized Items under LAF.
- Transfer the Sterilized Items to their aseptic working place through mobile LAF.

6.9.6 Flip of Seal Load (Load Pattern No.):

Load Details:

- Minimum Load: 2500 Seals. (02 Nos. Perforated Box) Flip of Seals per container (Approx. 1250)
- Maximum Load: 55000 Seals (11 Nos. Perforated Box) Flip of Seals per container (Approx. 5000)

Load configuration: Follow the Annexure – Pictorial Representation of Validated Load Pattern – VI & VII.

6.9.7 Bung Load (Load Pattern No.):

Load Details:

- Minimum Load: 2500 Bungs (01 Cassette)
- Maximum Load: 55000 Bungs (16 Cassette) per cassette 3450 Bungs approx.

Load Configuration: Follow the Annexure – Pictorial Representation of Validated Load Pattern – VIII & IX.

Procedure for Bung Loading in cassette trolley:

- Take out bung cassette from cassette trolley.
- Take the packet of Rubber Bung from Dynamic pass box.
- Cut the packet with the help of scissors/paper cutter under LAF & load in bung cassette, load these cassettes in Bung Trolley & lock it in cassette trolley.
- Repeat this procedure for entire batch.
- After completion of bung loading in cassettes, load the cassette trolley in autoclave cum bung processor machine.
- Close the door of autoclave & start the procedure



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Image 1



Image 2

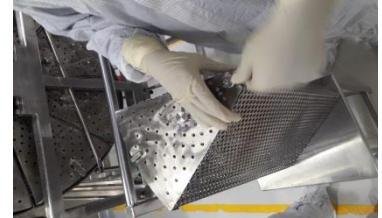
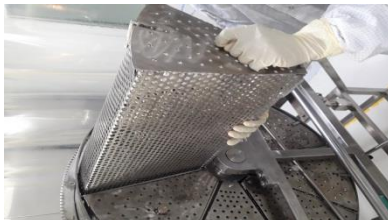


Image 3



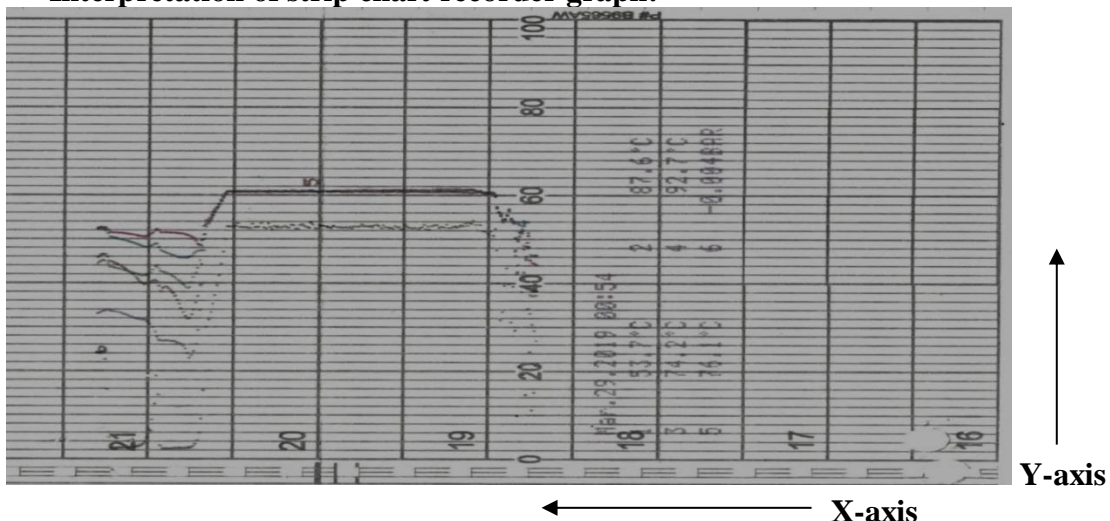
6.9.8 Media Load (Load Pattern No.):

Load Details:

- 02 Nos. Pressure Vessel containing 50 Liters Media each.

Load Configuration: Follow the Annexure – Pictorial Representation of Validated Load Pattern - X.

6.10 Interpretation of strip chart recorder graph:



“X” Axis Interpretation.	- Time scale : One large Div. = 10 min (chart recorder speed 60 mm/min)
“Y” Axis Interpretation	- Temperature and pressure is displayed on Y axis (Left to right) - Temperature scale is from 0°C to 200°C (Left to right) , 1 Div. = 4°C - Pressure & vacuum scale is from -1 to + 3 Bar (Left to right) For pressure scale 12.5 Div. = 1 Bar and 1 small Div. = 0.08 Bar



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6.11 Cleaning of Autoclave Cum Bung Processor:

- 6.11.1 Wipe off outside body of the Autoclave cum Bung processor with wet sponge.
- 6.11.2 Wipe off all the pipe connections.
- 6.11.3 Take out drain cover screen, Scrub it thoroughly using nylon brush and 0.1% SLS Solution Wash it with Purified water thoroughly.
- 6.11.4 Clean the chamber and door with 0.1% SLS solution using lint free duster, hot water and Nylon Brush. Wash thoroughly with Purified Water followed by final rinse with WFI.
- 6.11.5 Wash the trolleys and shelves also with 0.1% SLS solution and then with Purified water.
- 6.11.6 Finally rinse it with WFI.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Vacuum Leak Test Record	
Annexure-II	Bowie Dick Test Record	
Annexure-III	Sample Intimation Slip (Rinse/Swab Test)	
Annexure-IV	Sample Intimation Slip (LOD of Rubber Plug)	
Annexure-V	Pictorial Representation Of Validated Load Pattern	
Annexure-VI	Details of Set Parameter	
Annexure-VII	Alarm Management Details and action plan	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- 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 – III SAMPLE INTIMATION SLIP (RINSE/SWAB TEST)

From: Production	To: Quality Assurance
Initiated By: Production _____	Date & Time: _____
Intimation Received By:(QA) _____	Date & Time: _____

Equipment Details (To be filled by Production)

Name of Equipment/Bung Details		Equipment	
Previous Product		Batch No.	
Equipment to be Used for		Batch No.	

Contact Parts/Bung to be sampled:

- | | |
|----------|----------|
| 1. _____ | 3. _____ |
| 2. _____ | 4. _____ |
| 5. _____ | 6. _____ |
| 7. _____ | 8. _____ |

Sampling Details (To be filled by Quality Control)

Type of Sampling: Rinse/Swab Test _____
Sample Collected by: _____
Date/Time _____
A.R. No.: _____
The Rinse/Swab sample complies/does not comply the standard specification, the equipment can be used/not to be used for further process.
Analyzed by _____
Name _____
Sign.& Date _____
Manager-QC Sign & Date

If sample does not comply (To be filled by Quality Assurance)

Remark _____	Head-QA
Name _____	Sign & Date
Sign & Date _____	



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ANNEXURE – IV SAMPLE INTIMATION SLIP (LOD OF RUBBER PLUG)

From: Production	To: Quality Assurance
	A.R. No. _____
Initiated By: Production _____	Date & Time: _____
Intimation Received By:(QA) _____	Date & Time: _____
Product Details (To be filled by Production)	
Product Name	Equipment
Batch No.	Batch Size
Mfg. Date	Exp. Date
Sampling Details (To be filled by Quality Assurance)	
Sampled by (QA): _____	
Date of sampling: _____	
Quantity Sampled (gm./Nos.): _____	
Analysis Details (To be filled by Quality Control)	
A.R. No. _____	
LOD: _____	(Limit: _____)
Remarks (by QC): The sample complies/does not comply as per IP/BP/USP/IH specification.	
Analyzed by Sign & Date	Manager-QC Sign & Date



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ANNEXURE – V

PICTORIAL REPRESENTATION OF VALIDATED LOAD PATTERN

Load Pattern No	Pictorial Representation of Validated Load Pattern.	Load Configuration	No. of Articles
I		GARMENT MINIMUM LOAD (HPHV PROCESS 1)	
		5 Set Inner Garments (5 Nos. Inner, 5 Nos. Lower, 5 Nos. Cap & 10 Nos. Booties)	5 Nos.
		5 Set Secondary Garments (5 Nos. Head Gear, 5 Nos. Boiler, 5 Nos. Google & 10 Nos. Booties)	5 Nos.
II		GARMENT MAXIMUM LOAD. (HPHV PROCESS 1).	
		20 Set Inner Garments (20 Nos. Inner, 20 Nos. Lower, 20 Nos. Cap & 40 Nos. Booties)	20Nos.
		20 Set Secondary Garments (20 Nos. Head Gear, 20 Nos. Boiler, 20 Nos. Google & 40 Nos. Booties).	20Nos.
III		ACCESSORIES LOAD (HPHV PROCESS 1)	
		Bung Box	05 Nos.
		Bung Unloader	01 Nos.
		SS Waste Bin	02 Nos.
		Bucket	05 Nos.
		SS Container with lid	01 Nos
IV		BLENDER LOAD (HPHV Process 1)	
		Blender	01 Nos.
		Gasket	02 Nos.
		Aluminum Foil	02Meter
		SS Container	01 Nos.
		SS Scoop	01 Nos.



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Load Pattern No	Pictorial Representation of Validated Load Pattern.	Load Configuration	No. of Articles
		Mopping Pad	02 Nos
V		MIXED LOAD (HPHV PROCESS 1)	
		Sterile Garments Set With Goggle	20 Nos.
		Inner Garment Set	20 Nos.
		Mopping Pads	10 Nos.
		Powder Hopper	01 Nos.
		Port Wheel	01 Nos.
		Piston, Piston Lock, Filter Tip	24 Nos.
		Bung Container	01 Nos.
		Pressure Vessel	01 Nos.
		Bung Hopper and Chute	01 Nos.
		Side Guard with power felt	02 Nos.
		Filtration Assembly	01 Nos.
		Forceps	06 Nos.
		Forceps Sanitizer	02 Nos.
		Nitrogen Filter Housing	01 Nos.
		Silicone Tube	02 Nos.
		SS Scoops	02 Nos.
		SS Spoon	02 Nos.
		SS Large Spoon	02 Nos.
		Ln Key	02 Nos.
		Aluminum Foil	01 meter
		Aluminum tape	01 meter
		Autoclable Tape	01 meter
		Clean Room Pen	01 Nos.
		Autoclave IPA Bottle	04 Nos.
		Bio Barrier Paper	02 Nos.
		Capsule Filter	03 Nos.
Autoclavable Paper	06 Nos.		
Vent Filter	02 Nos.		
MOP Head with stand	02 Nos.		
Clean room marker	01 Nos.		
Container Sealer	01 Nos.		
Aluminum Seal	02 Nos.		
VI		FLIP OFF SEAL MINIMUM LOAD (HPHV Process 1)	



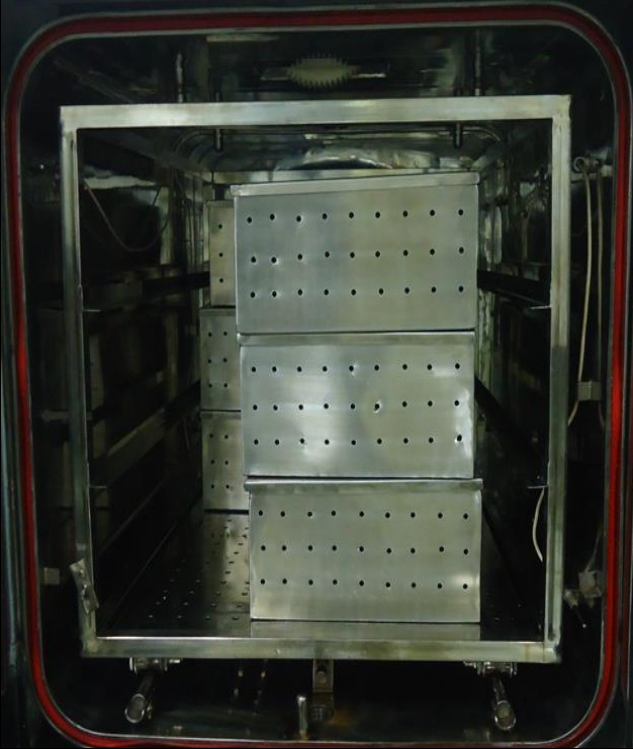


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Load Pattern No	Pictorial Representation of Validated Load Pattern.	Load Configuration	No. of Articles
		Flip off Seals	2500 Nos.
VII		FLIP OFF SEAL MAXIMUM LOAD (HPHV Process 1)	
		Flip off Seals	55000 Nos.
VIII		HPHV PROCESS 2 BUNG MINIMUM LOAD	
		Load the bungs	2500 Bungs)
IX		BUNG MAXIMUM LOAD HPHV PROCESS 2	




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Load Pattern No	Pictorial Representation of Validated Load Pattern.	Load Configuration	No. of Articles
		Load the bungs	55000 Bungs
X		MEDIA LOAD (STANDARD PROCESS) Pressure Vessel containing 50 Liters Media each.	02 Nos.



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ANNEXURE – VI DETAILS OF SET PARAMETER

S No.	Parameter	Set parameter VLT	Set Parameter Bowie Dick	Set Parameter Standard Process 1	Set Parameter HPHV Process 1	Bung Process 1
1.	WASH I					
A.	MACHINE WASH					3 Min.
B.	DETERGENT IN					1 Min.
C.	FLUIDIZATION					10 Min.
D.	STABILIZATION					5 Min.
E.	PURIFIED WATER OVER FLOW					10 Min.
F.	DRAIN					5 Min.
G.	MACHINE WASH					3 Min.
H.	DRAIN					5 Min.
I.	NO. OF RPTS					1 No.
2.	WASH II					
A.	FLUIDIZATION					10 Min.
B.	STABILIZATION					5 Min.
C.	PURIFIED WATER OVER FLOW					10 Min.
D.	DRAIN					5 Min.
E.	MACHINE WASH					3 Min.
F.	DRAIN					5 Min.
G.	NO. OF RPTS					1 No.
3.	WASH III					
A.	STABILIZATION					5 Min.
B.	DRAIN					5 Min.
C.	MACHINE WASH					3 Min.
D.	DRAIN					5 Min.
E.	NO. OF RPTS					1 No.
4.	SILICONIZATION					
A.	SILICON IN					1 Min.
B.	SILICON SOAKING					10 Min.
C.	DRAIN					5 Min.
D.	MACHINE WASH					3 Min.
E.	DRAIN					5 Min.
F.	NO. OF RPTS					1 No.



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5.	STER. SEL. (1/0)					1
6.	PRE VACUUM	-0.600 BAR	-0.500 BAR	0.000 BAR	-0.500 BAR	-0.500 BAR
7.	DELAY BEFORE HOLD	5MIN				
8.	VACCUM HOLD TIME	10MIN				
9.	ACCEPTABLE LEAKAGE	0.013 BAR				
10.	PRE PRESSURE		0.500 BAR	0.000 BAR	0.500 BAR	0.500 BAR
11.	NO. OF PRE PULSES		3 NOS	0 NOS.	3 NOS	3 NOS
12.	HEAT UP 1		110.0 °C	110.0°C	110.0 °C	110.0 °C
13.	HEAT UP HOLD 1		5 MIN	3 MIN	5 MIN	5 MIN
14.	HEAT UP 2		115.0 °C	115.0 °C	115.0 °C	115.0 °C
15.	HEAT UP HOLD 2		3 MIN	2 MIN	3 MIN	3 MIN
16.	HEAT UP 3		119.0 °C	118.0 °C	119.0 °C	119.0 °C
17.	HEAT UP HOLD 3		2 MIN	1 MIN	2 MIN	2 MIN
18.	HEAT UP CONTROL BAND		0.2 °C	0.3 °C	0.2 °C	0.2 °C
19.	SMALL VOLUME SP		120.0°C	120.0°C	120.0°C	120.0°C
20.	STER. HOLD TEMP		121.4°C	121.4°C	121.4°C	121.4°C
21.	STER. HOLD TIME		660 SEC.	20 MIN	30 MIN	30 MIN
22.	TEMP. CANTROL BAND		0.3 °C	0.3 °C	0.3 °C	0.3 °C
23.	OVERSHOOT TEMP.		124.0°C	124.0°C	124.0°C	124.0°C
24.	STER. STOP TEMP.		120.0°C	120.0°C	120.0°C	120.0°C
25.	STER. RESET TEMP.		119.5°C	119.5°C	119.5°C	119.5°C
26.	POST VAC. START PRESS.				0.200BAR	0.200BAR
27.	POST VACUUM				-0.600BAR	-0.600BAR
28.	VACCUM HOLD TIME				10MIN.	20MIN.
29.	POST PRESS				-0.100BAR	-0.100BAR
30.	NO. OF POST PULSES				3NOS	3 NOS
31.	PROCESS END PRESSURE	-0.030 BAR	0.040 BAR	0.050 BAR	-0.050 BAR	-0.050 BAR
32.	EXHAUST ON		5 SEC.	5 SEC.	5 SEC.	5 SEC.
33.	EXHAUST OFF		50SEC.	50 SEC.	50 SEC.	50 SEC.
34.	CHAMBER WATER TEMP.					30.0 °C
35.	BASKET DRIVE ON					120 SEC.
36.	BASKET DRIVE OFF					60 SEC.



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ANNEXURE – VII

ALARM MANAGEMENT DETAILS AND ACTION PLAN

S.No.	ALARM	REASON	ACTION PLAN	ALARM TYPE	IMPACT
1.	Emergency Stop	Emergency switch in pressed condition	Release the emergency switch to continue the process cycle	Non critical	No impact
2.	Compressed air pressure low	Compressed air valve closed/ compressed air line is leaking	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact
3.	Door –II gasket vacuum problem	Vacuum pump operation problem/ pneumatic valve not working.	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact
4.	Door open temperature problem	If temperature not fall down below door open temperature	Inform the engineering dept. for rectification	Non critical	No impact
5.	Chamber pressure overshoot	Drain line chocked	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact
6.	Pre- Heating problem	Pure steam is not available/ pneumatic valve at chamber inlet not working	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact
7.	Pure steam pressure low	Pure steam is not available/ pneumatic valve at chamber inlet not working	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact
8.	Sterilization temperature overshoot	Drain line chocked condensate in pure steam supply	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact
		Sensor faulty. Fault in pressure transmitter.		Non critical	No impact
9.	Sterilization temperature low	Non availability of pure steam/power tripping	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact



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10.	Water level problem	Water level sensor not working/ drain line chocked.	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact
11.	PW pressure low	Non availability of purified water	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact
12.	WFI pressure low	Non availability of WFI	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact
13.	Soft water pressure low	Non availability of soft water	Inform the engineering dept. for rectification and run the cycle after rectification	Non critical	No impact
14.	VLT failure	Due to system leakage	Immediately inform to engineering department to check chamber leakage and after rectification; VLT cycle shall be run again to check chamber leakage. If VLT cycle failed in repeat cycle; same shall be handled with incident.	Critical	Impact to be assessed on batches filled between last passed VLT cycle and the failed cycle.
15.	Bowie- dick test failure	Presence of air pocket Improper pre vacuum pulses	Immediately inform to engineering department for rectification; Bowie- dick cycle shall be run again. If Bowie- Dick cycle failed in repeat cycle; same shall be handled with incident.	Critical	Impact to be assessed on batches filled between last passed Bowie- Dick cycle and the failed cycle.
16.	Chamber pressure high/ pressure release problem	Door gasket leakage	Inform the engineering dept. for rectification and run the cycle after rectification	Critical	Impact on previous batches.