



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of High Pressure High Vacuum Autoclave

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

To lay down a procedure for Operation and Cleaning of High Pressure High Vacuum Autoclave.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of High Pressure High Vacuum Autoclave, ID No.- **PC/IB/HPV-002**, Make: **Machin Fabrik**, Capacity: **675 liter** Production Area of Ampoule section.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

HPHV	High Pressure High Vacuum
Ltd.	Limited
No.	Number
QA	Quality Assurance
RPM	Rotation per Minute
SOP	Standard Operating Procedure
VLT	Vacuum Leak Test

6.0 PROCEDURE:

6.1 EQUIPMENT DESCRIPTION :

- 6.1.1** The autoclave is a horizontal, HPHV, double door, rectangular type steam sterilizer with vertical sliding double door.
- 6.1.2** The sterilization chamber is made up of SS sheet, which is welded with U-profile SS jacket.
- 6.1.3** The sterilization chamber is providing with two vertical sliding doors, which are also made up of SS reinforced with support structure.
- 6.1.4** Both doors will be opens with pneumatic cylinder.
- 6.1.5** Both the doors having interlocking system, which prevent opening of both door at the same time.
- 6.1.6** Compound gauges are located on both the side.
- 6.1.7** Sterilization chamber of autoclave is insulated with glass wool, which helps in reducing the heat loss to the environment and ensuring uniform distribution of temperature inside the chamber.



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6.1.8 Autoclave has control panel, Vacuum pump, pressure gauges, five internal probes for temperature monitoring and control (Four inside the chamber, one in drain), pressure transducer for chamber pressure monitoring and recording, steam generator as the part of machine.

Equipment	HPHV Steam Sterilizer
Id Number
Make	Machin Fabrik
Sr. No.
Chamber size	750 (w) x 750 (h) x 1200 (d) mm
Chamber volume	675 liters
Working pressure	up to 2.2 kg/cm ² (g)
Working temperature	Up to 134 ⁰ c
MOC Chamber	SS 316L
MOC jacket	SS 304

6.2 EQUIPMENT DETAILS:

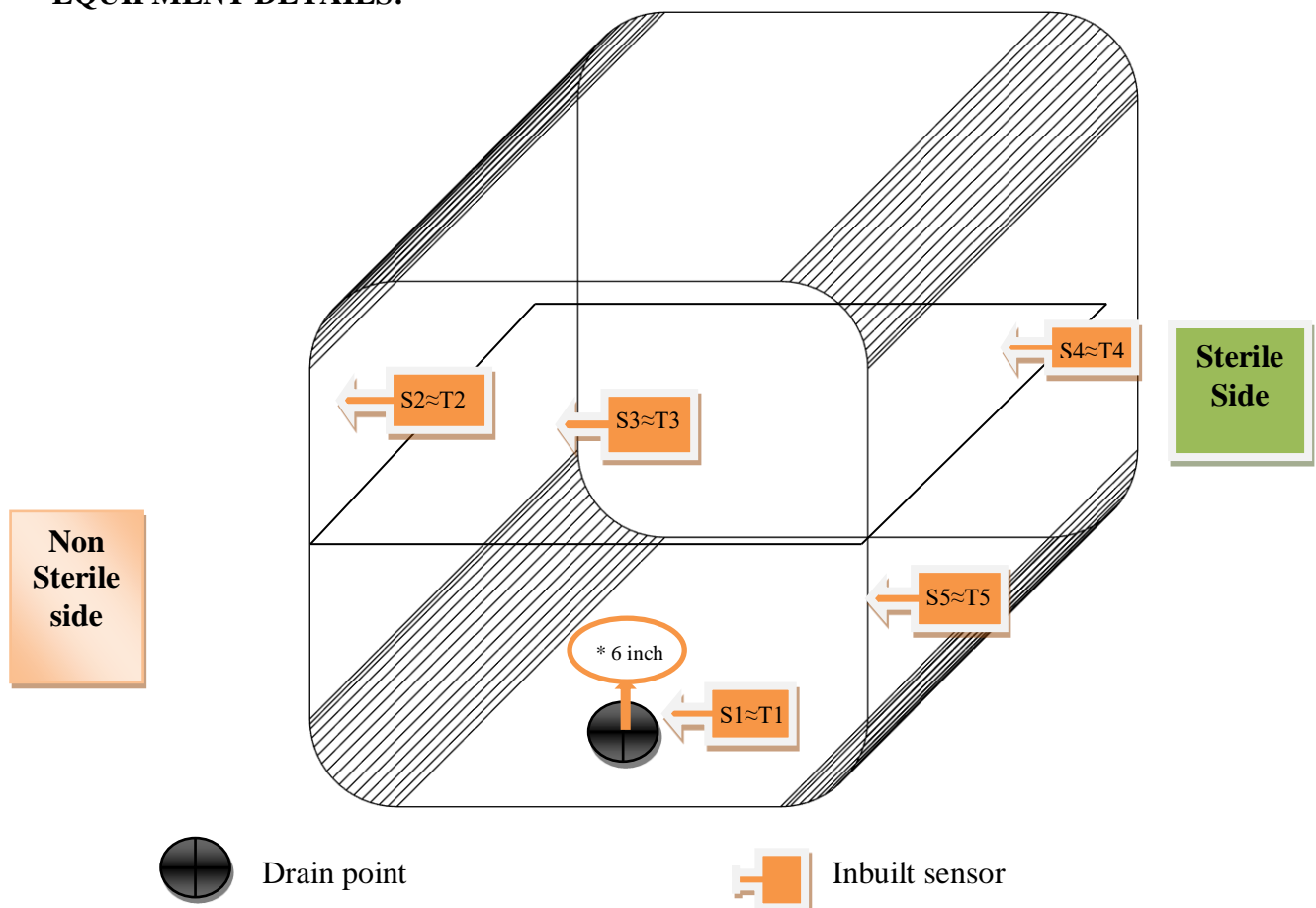


Figure: Location of inbuilt Temperature Sensors



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Sensor No.	Location in the Chamber
S1	In the drain of the autoclave chamber. T1
S2	Left side near non-sterile side door, Inbuilt Sensor T2
S3	Left side near sterile side door Inbuilt Sensor T3
S4	Right side near non-sterile side door, Inbuilt Sensor T4
S5	Right side near sterile side door, Inbuilt Sensor T5
* Bowie Dick kit should place above 6 inch height drain point sensor	

6.3 INSTRUCTION:

- 6.3.1 Soft water supply is available for Vacuum pump.
- 6.3.2 Compressed air supply is available at appropriate utility location.
- 6.3.3 Air pressure is 6.0 to 8.0 kg/cm² (Approx).
- 6.3.4 Pressure of Pure Steam supply is of 2.2 kg/cm² (Approx).
- 6.3.5 Check and ensure that sufficient paper is loaded in strip chart recorder and printer.
- 6.3.6 Ensure the Autoclave unloading side door of sterility area is closed.
- 6.3.7 Before every autoclave cycle, ensure that the Emergency key is release.

6.4 OPERATION OF AUTOCLAVE:

- 6.4.1 Switch "ON" the Main power supply of Machine and Printer.
- 6.4.2 Display appears as below after switching ON:
- 6.4.3 Press MAIN MENU.



- 6.4.4 Enter login ID and password by selecting the "LOGIN SCREEN" in HMI.
- 6.4.5 Enter details by selecting the "BATCH DATA" in HMI.



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6.4.6 Select the program which has to be run as given below table:

PROGRAM	FREQUENCY	LOAD
VACUUM LEAK TEST	Daily	Empty
BOWIE DICK TEST	Weekly \pm 2days	Empty
STANDARD PROCESS I	As per requirement	Mix load, Mfg. load, Filtration load,
HPHV PROCESS I	As per requirement	Garment Load (Inner / Boiler)
HPHV PROCESS II	As per requirement	M/C parts Load

6.4.7 Select the required program by selecting the “START UP SCREEN” in HMI.



6.4.8 Take the printout of selected cycle and check the parameter and batch details.

6.4.9 Take the printout of initial temperature and pressure on strip chart paper and press the “Record” button & enter two times to record the data of temperature and pressure.

6.4.10 Load the articles in Autoclave chamber as per following load pattern and pictorial from the Component preparation area side.

6.4.11 Open the supply of the utility like Compressed air, pure steam & Vacuum line.

6.4.12 Use sterilization indicator for confirmation of the articles sterilization.

6.4.13 The door of autoclave will open when temperature reaches less than 90°C.

6.4.14 Check and verify the respective graph with strip chart as well as dot-matrix printer graph.

6.5 OPERATION OF STRIP CHART RECORDER:

6.5.1 To start strip chart recorder open the cover and push the blue key in below right corner wait till initialization.

6.5.2 After initialization temperature reading of 5 sensors and pressure reading of one sensor shall be displayed on screen.

6.5.2.1 Push the [MENU] key for approx. 3 second main screen shall be displayed.



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To forward the chart paper press [FEED] key.

6.5.3 To start the recording:

6.5.3.1 Press [FUNC] key one time [Func=Print out] shall be displayed on screen.

6.5.3.2 Press [CH UP] key two times and immediate [REC] key recording shall be started.

6.5.4 NOTE:

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

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

6.5.4.3 If VLT cycle is not meeting acceptance criteria in that case immediately inform to engineering department and after rectification of problem VLT cycle shall be run again till Complies the VLT cycle.

6.5.4.4 If any overshoot observed in HPHV cycle in that case cycle shall be consider valid as there is no impact on sterilization process.

6.5.4.5 If any overshoot observed in standard (Media) cycle in that case cycle shall be consider invalid and media shall be discarded.

6.5.4.6 All cycle shall be run as per validated load pattern

6.5.4.7 If sufficient quantity of media bottles/ tubes not required and prepared as per validated load pattern, load shall be completed with purified water bottles/tubes in routine media cycle standard 1.

6.5.5 Interpretation of strip chart recorder graph:



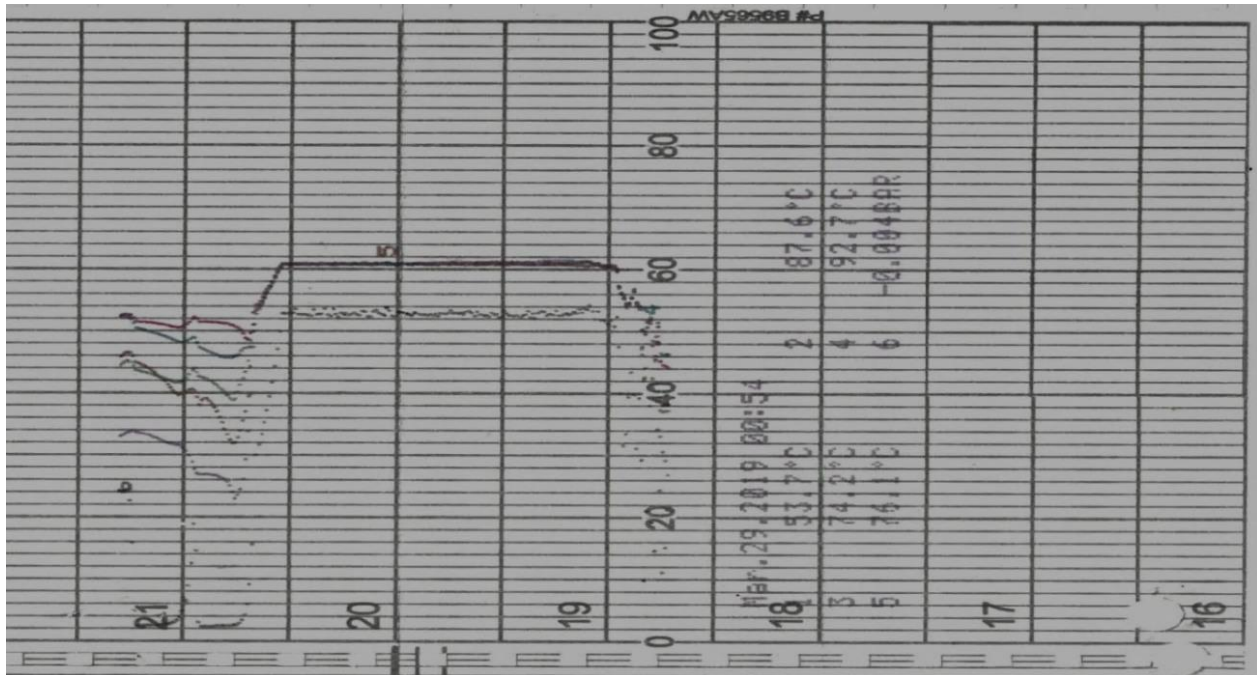
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←

Y-axis

X-axis ↑

X axis = Temp. (°C)
1 Div. = 4°C
Y axis = Time. (Min)
1 Div. = 10 min.

6.6 SELECTION OF CYCLE:

6.6.1 Vacuum Leak Test:

6.6.1.1 Start the Vacuum Leak Test cycle as per following parameter for vacuum leak test of autoclave:

6.6.1.2 **Acceptance Criteria:** Actual vacuum leakage should be not more than **0.013 bar**.
Frequency: Daily

6.6.2 BOWIE DICK TEST:

6.6.2.1 Start the Bowie Dick Test cycle as per parameter to check the air removal from chamber of autoclave:

6.6.2.2 **Acceptance criteria:** The Bowie-Dick Test Indicator should show a **uniform color change**.



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6.6.2.3 No change, Non-Uniform Change and or Air Entrapment (bubble) Spot on the Test Pack indicates inadequate air removal from the sterilization chamber, if test not complies then repeat the process with new Bowie Dick Kit.

Frequency: Weekly ± 2 day.

6.6.3 STANDARD PROCESS:

6.6.3.1 Start the STANDARD Process 1 as per parameter to sterilized the material:

6.6.3.2 Mixed Load: Load pattern No.-

6.6.3.3 Manufacturing Accessory Load: Load pattern No.-

6.6.3.4 Filtration Accessory Load: Load Pattern No. -

6.6.4 HPHV PROCESS-1:

6.6.4.1 Start the HPHV Process 1 as per parameter Annexure I & III to sterilized and dried the material:

6.6.4.2 Inner Garment Load (Minimum) :- Load Pattern No.-

6.6.4.3 Inner Garment Load (Maximum) :- Load Pattern No.-

6.6.4.4 Garment Load (Minimum) :-Load Pattern No.-

6.6.4.5 Garments Load (Maximum) Load Pattern No.:-

6.6.5 HPHV Process 2:

6.6.5.1 Start the HPHV PROCESS 2 as per Annexure No.-I & III parameter to sterilized and dried the material:

6.6.5.2 Filling Machine Part & Accessory Load: Load Pattern No:-

6.6.6 Check the print on the printing paper strip chart record paper.

6.6.7 Enter the details in the log book for each load.

6.6.8 After completion of the cycle, confirm the sterilization print and then unload the articles from the sterile side under the class 100 aseptically.

6.6.9 Transfer the articles through mobile LAF to work station.

6.6.10 Estimation of F0 Value:

The actual observations obtained during the heat penetration studies at different temperature sensing locations are compiled in the table and the observed temperature shall be subjected for calculation of F₀ values at that particular location.



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The lethality factor calculations are done by using the following formula and the computed (during the sterilization period) are given in the following table.

F0 = dt Σ 10^{(T-121)/Z} (a)

F0 = dt Σ (Sum of lethality factors).

Where,

dt = time interval between successive temperature measurements.

T = observed temperature at that particular time (as per the actual temperatures recorded).

Z = change in the heat resistance of Geobacillus stearothermophilus spores as temperature is changed (as Per COA).

6.6.11 F0 Value for Biological Indicators:

The biological F0 value for biological indicator strip exposed during the sterilization can be calculated as follows.

F0 = D121 (log A – log B)..... (b)

Where,

D121	D value of the biological indicator at 121°C.
A	Experimental Biological indicator concentration or spore population.
B	Desired level of sterility (SAL- 10 ⁻⁶).

Acceptance criteria of F0 = 30 or above

6.7 CLEANING OF HIGH PRESSURE HIGH VACUUM AUTOCLAVE :

- 6.7.1 Carry out the cleaning of the Autoclave from the Loading side. Do not open the both doors of autoclave at the same time off outside body of the HPHV Autoclave with wet sponge.
- 6.7.2 Wipe off all the pipe connections.
- 6.7.3 Take out drain cover screen; Scrub it thoroughly using nylon brush and 0.1% SLS Solution Wash it with water thoroughly.
- 6.7.4 Clean the chamber and door with, hot water and Nylon Brush. Wash thoroughly with Purified Water followed by final rinse with WFI.
- 6.7.5 Wash the trolleys and shelves with Purified water. Finally rinse it with WFI.



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6.7.6 Cleaning Record of High Pressure High Vacuum Autoclave and entry done in Annexure No.-II.

Frequency: One in a day or when are required.

7.0 ANNEXURES:

ANNEXURE NO.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Record of HPHV Steam Sterilizer	
Annexure-II	Details of Set Parameter	
Annexure-III	Cleaning Record of High Pressure High Vacuum Autoclave	
Annexure-IV	Pictorial Representation of Validated Load Pattern	

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-II DETAILS OF SET PARAMETER

S.No.	Parameter	Set parameter for VLT	Set Parameter for Bowie Dick	Set Parameter Standard Process-1	Set Parameter HPHV Process-1	Set Parameter HPHV Process-2
1.	Pre Vacuum	-0.700 Bar	-0.600 Bar	0.000 Bar	0.600 Bar	-0.600 Bar
2.	Delay before hold	3 Min.				
3.	Vacuum Hold time	10 Min.				
4.	Acceptable Leakage	0.013 Bar				
5.	Pre pressure	-0.040 Bar	0.500 Bar	0.000 Bar	0.500 Bar	0.500 Bar
6.	No. of pre pulse		05 Nos.	0 Nos.	3 Nos.	03 Nos.
7.	Pre Pressure UP		0.700 Bar	0.700 Bar	0.700 Bar	0.700 Bar
8.	Pre Pressure Down		0.300 Bar	0.300 Bar	0.300 Bar	0.300 Bar
9.	No. of Positive pulses		05 Nos.	05 Nos.	05 Nos.	05 Nos.
10.	Pre pressure Down Final		0.600 Bar	0.600 Bar	0.600 Bar	0.600 Bar
11.	Small valve SP		120.0°C	120.0°C	120.0°C	120.0 °C
12.	Ster. Hold temp.		121.4°C	121.4°C	121.4°C	121.4°C
13.	Ster. Hold time		660 Sec.	30 Minute	30 Min.	30 Min.
14.	Temp. Control Band		0.2°C	0.2°C	124.0°C	0.2°C
15.	Overshoot temp.		124.0°C	124.0°C	120.9 °C	124.0°C
16.	Ster. Stop temp.		120.9°C	120.9 °C	120.5°C	120.9 °C
17.	Ster. Reset temp.		120.5°C	120.5°C	124.0°C	120.5°C
18.	Post Vacuum Start Pressure				0.200 Bar	0.200 Bar
19.	Post Vacuum				0.500 Bar	-0.500 Bar
20.	Vacuum Hold time				05 Min.	05 Min.
21.	Post Pressure				-0.100 Bar	-0.100 Bar
22.	No. of Post Pulses				3 Nos.	02 Nos.
23.	Process End Pressure		0.040 Bar	0.040 Bar	0.040 Bar	-0.040 Bar
24.	Print interval	60 Sec	60 Sec	60 Sec	60 Sec	60 Sec





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ANNEXURE-IV

PICTORIAL REPRESENTATION OF VALIDATED LOAD PATTERN

S. No.	Pictorial Representation of Validated Load Pattern in Operation and Cleaning of High Pressure High Vacuum Autoclave	Load Configuration	No. of Articles
01		Mixed Load (Load pattern No.-) (Standard Process-1)	
		Mopping Bucket	06 Nos.
		Mopping Head	02 Nos.
		Forceps	04 Nos.
		SS Mug (2 liter)	02 Nos.
		SS Perforated box	01 Nos.
		Lint Free Mop	02 Nos.
		Wiper	01 Nos.
02		Manufacturing Accessories Load (Load pattern No.-) (Standard Process-1)	
		SS Mug 5 lit.	02 Nos.
		SS Mug 1 lit.	01 Nos.
		SS Mug 2 lit.	01 Nos.
		SS Ladle	03 Nos.
		Spatula	04 Nos.
		Pressure Vessel 50 lt.	01 Nos.
		Pressure Vessel 30 lt.	01 Nos.
		Mixing Rod	01 Nos.
		SS Container	02 Nos.
		Silicone Tube	02 Nos.
		SS Braded hose Pipe	02 Nos.
		SS Bucket	02 Nos.
		Bio barrier Paper	01 Nos.
		Cable tie	10 Nos.





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S. No.	Pictorial Representation of Validated Load Pattern in Operation and Cleaning of High Pressure High Vacuum Autoclave	Load Configuration	No. of Articles
04		Filtration Accessories Load (Load pattern No.-) (Standard Process-1)	
		Pressure Vessel 50 lt.	01 Nos.
		Pressure Vessel 30 lt.	01 Nos.
		Filter Housing 10 Inch	04 Nos.
		Membrane Filter assembly	01 Nos.
		Autoclavable IPA Bottle	04 Nos.
		SS Bucket	06 Nos.
		SS Mug 5 lt.	02 Nos.
		SS Mug 2 lt.	02 Nos.
		SS Mug 1 lt.	01 Nos.
		Mopping Pad	04 Nos.
		Mixing Rod	01 Nos.
		Glass Measuring Cylinder 1000 ml	01 Nos.
		Glass Measuring Cylinder 100 ml	01Nos.
		Vent Filter with Housing	10 Nos.
		SS Braded hose pipe	02 Nos.
		Silicone Tube	02 Nos.
		Bio barrier paper	01 Nos.
Cable tie	10 Nos.		
SS Container (20 Lit)	01 Nos.		
Waste Solution Tray	01 Nos.		
05		Inner Garment Load (Minimum) (Load Pattern No.:-) (HPHV Process -1)	
		Antistatic Sterile area garments	15 Nos.
		Goggle	15 Nos.
		Booties	15 Pairs
		Head Gears	15 Nos.
		Mopping pads	05Nos.



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S. No.	Pictorial Representation of Validated Load Pattern in Operation and Cleaning of High Pressure High Vacuum Autoclave	Load Configuration	No. of Articles
06		Inner Garment Load (Maximum) (Load Pattern No.:-) (HPHV Process -1)	
		Antistatic Sterile area garments	30 Nos.
		Goggle	30 Nos.
		Booties	30 Pairs
		Head Gears	30 Nos.
		Mopping pads	10Nos.
07		Garment Load (Minimum) (Load Pattern No.:-) (HPHV Process -1)	
		Antistatic Sterile area garments	15 Nos.
		Goggle	15 Nos.
		Booties	15 Pairs
		Head Gears	15 Nos.
		Mopping pads	05Nos.




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08		<p align="center">Garment Load (Maximum) (Load Pattern No.:-) (HPHV Process -1)</p> <table border="1"> <tr> <td>Antistatic Sterile area garments</td> <td>30 Nos.</td> </tr> <tr> <td>Goggle</td> <td>30 Nos.</td> </tr> <tr> <td>Booties</td> <td>30 Pairs</td> </tr> <tr> <td>Head Gears</td> <td>30 Nos.</td> </tr> <tr> <td>Mopping pads</td> <td>10Nos.</td> </tr> </table>	Antistatic Sterile area garments	30 Nos.	Goggle	30 Nos.	Booties	30 Pairs	Head Gears	30 Nos.	Mopping pads	10Nos.																									
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09		<p align="center">Filling Machine Parts & Accessory Load (H.P.H.V Process-02)</p> <table border="1"> <tr> <td>Pump</td> <td>12 Nos.</td> </tr> <tr> <td>Manifold</td> <td>03 Nos.</td> </tr> <tr> <td>Bucket (10 Liter.)</td> <td>03 Nos.</td> </tr> <tr> <td>Needle</td> <td>36 Nos.</td> </tr> <tr> <td>Silicon tube (N₂)</td> <td>24 Nos.</td> </tr> <tr> <td>Silicon tube</td> <td>40 Nos.</td> </tr> <tr> <td>T.C Nipple</td> <td>02 Nos.</td> </tr> <tr> <td>Forceps</td> <td>04 Nos.</td> </tr> <tr> <td>Silicon tube (2 m)</td> <td>03 Nos.</td> </tr> <tr> <td>Gloves</td> <td>06 Nos.</td> </tr> <tr> <td>Autoclavable IPA Bottle</td> <td>04 Nos.</td> </tr> <tr> <td>Silicon tube (2 feet)</td> <td>02 Nos.</td> </tr> <tr> <td>Autoclavable Pen</td> <td>01 Nos.</td> </tr> <tr> <td>Bio barrier Paper</td> <td>02 Nos.</td> </tr> <tr> <td>Autoclavable Paper</td> <td>10 Nos.</td> </tr> <tr> <td>Cable tie</td> <td>10 Nos.</td> </tr> <tr> <td>SS Braded hose pipe</td> <td>02 Nos.</td> </tr> </table>	Pump	12 Nos.	Manifold	03 Nos.	Bucket (10 Liter.)	03 Nos.	Needle	36 Nos.	Silicon tube (N ₂)	24 Nos.	Silicon tube	40 Nos.	T.C Nipple	02 Nos.	Forceps	04 Nos.	Silicon tube (2 m)	03 Nos.	Gloves	06 Nos.	Autoclavable IPA Bottle	04 Nos.	Silicon tube (2 feet)	02 Nos.	Autoclavable Pen	01 Nos.	Bio barrier Paper	02 Nos.	Autoclavable Paper	10 Nos.	Cable tie	10 Nos.	SS Braded hose pipe	02 Nos.	
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