



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**FAT FOR HPHV STEAM STERILIZER**

EQUIPMENT NAME : **HPHV STEAM STERILIZER**

EQUIPMENT MAKE : MACHIN FABRIK

EQUIPMENT MODEL (& SR NO.) : (Sr. No.....)

**TEST CRITERION:**

**OK / NOT OK**

(If not ok, then list them under deficiency and corrective action report)

1. Verification of P & ID walk down, resulting in an as -built P & ID, and other drawings
2. Verification of the proper operation of the unit operations , including test sequences, shut down & start up
3. Alarms & interlock testing verification
4. Safety features verification
5. Documentation check & certification of the vessel and jacket, pressure rating.
6. Instrument components including sensors Locations, calibration certificates and their traceability.
7. Alignment of pumps.
8. Pressure/ vacuum testing.
9. Temperature uniformity check in empty chamber.
10. Vacuum leak testing checks.
11. Pressure & vacuum display on PLC up to 03 decimal places.
12. Cycle step through timer verification.
13. Cycle programming verification
14. Drainage system.
15. Utilities/ validations ports/connections.
16. Electrical power test.
17. Pneumatic system/ lubrication checks.
18. Welding and/or surface finish.
19. Material of construction with certificate.



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20. PLC documentation (Ledder logics prinouts)

21. Any other

**Remark:** Please fill-in the check-list given below also as a part of FAT.

**Design Verification Check list:**

S.No.	Contents	URS	Final Specification	Remarks
1.	Capacity	972 Liters		
2.	Dimensions (Internal)	900 x 900 x 1200 mm		
3.	Dimensions (Outer)			
4.	Powder supply			
5.	Utility Details			
6.	<b>WORKING &amp; TEST CODITIONS:</b>  1. Working pressure a) Chamber b) Jacket c) Condensor - Shell - Tube  2. Hydro test pressure a) Chamber b) Jacket c) Condensor - Shell - Tube  3. Working temperature a) Chamber b) Jacket  4. Vacuum a) Chamber b) Jacket c) Condensor - Shell - Tube	  2.2kg/cm <sup>2</sup> 2.2kg/cm <sup>2</sup>  4.0kg/cm <sup>2</sup> 2.2kg/cm <sup>2</sup>   3.3kg/cm <sup>2</sup> 4.4kg/cm <sup>2</sup>  6.0kg/cm <sup>2</sup> 3.3kg/cm <sup>2</sup>   121 deg. C 134 deg. C  Full - - - Full		



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S.No.	Contents	URS	Final Specification	Remarks
7.	Material of construction & finishing 1. Chamber 2. Jacket a) Inner b) Outer 3. Nozzles 4. Stand for mounting 5. Panelling 6. Contamination seal 7. All pipings 8. Steam condensor 9. Shelf 10. Carriage 11. Trolley	SS AISI 316 & Ra<1.0 micro meter  SS304 SS AISI 304 & Ra< 0.8 micro meter  SS304 SS AISI 304 SS AISI 202 & Ra < 1 micro meter SS AISI 304 SS AISI 304 SS AISI 304 SS304 SS304 SS304		
8.	DOORS 1. Type 2. No. of doors 3. Material of construction 4. Reinforcement 5. Finishing 6. Door sealing 7. Door sealing actuation 8. Door gasket retraction 9. Door movement	Horizontal sliding doors Two SS AISI 316 Mild steel Ra< 0.8 micro meter Silicon gasket With compressed air By vacuum With the help of Pneumatic cylinder		
9.	Door cylinders 1. Make 2. Model 3. Quantity	As per Vendor DQ		
10.	Pneumatic solenoid valve 1. Make 2. Model 3. Quantity	As per Vendor DQ		
11.	Pressure switch 1. Make 2. Model 3. Quantity	As per Vendor DQ		
12.	Vacuum switch 1. Make 2. Model 3. Quantity	As per Vendor DQ		



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S.No.	Contents	URS	Final Specification	Remarks
13.	Pressure / compound gauge 1. Make 2. Model 3. Quantity 4. Range	As per Vendor DQ		
14.	Ejector 1. Make 2. Model 3. Quantity	As per Vendor DQ		
15.	Control valves 1. Make 2. Model 3. Type	As per Vendor DQ		
16.	Safety valves 1. Make 2. Model 3. Type 4. Size for jacket 5. Size for chamber	As per Vendor DQ		
17.	Door safety	1.To prevent simultaneous opening of doors 2.Process lock to prevent opening of doors during the process. 3.Insulated doors to avoid scalding & heat loss.		
18.	Temperature sensors 1. Make 2. Type 3. Quantity 4. Place of installation	As per Vendor DQ		
19.	Pressure transmitter 1. Make 2. Model 3. Range 4. Output	As per Vendor DQ		
20.	Temperature transmitter 1. Make 2. Model 3. Range 4. Input 5. Output	As per Vendor DQ		



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S.No.	Contents	URS	Final Specification	Remarks
21.	Temperature indicator/controller 1. Make 2. Model 3. No. of set point 4. Input	As per Vendor DQ		
22.	Strip chart recorder 1. Make 2. Model 3. Type			



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**DEFICIENCY & CORRECTIVE ACTION REPORT:**

**Description of deficiency and date observed:**

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**Person, responsible for corrective action and date assigned:**

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**Corrective action taken and date conducted :**

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**Any other (Please specify):**

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**PRE INSTALLATION REQUIREMENTS AT THE USER SITE:**


**FINAL REPORT**

**Summary:**


**Analysis / Evaluation of Design:**


**Certification:**
