



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Cleaning and Operation of Horizontal Autoclave	Effective Date:
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1.0 OBJECTIVE

1.1 To lay down the Procedure for cleaning and operation of horizontal autoclave.

2.0 SCOPE

2.1 This procedure is applicable for Microbiology Laboratory.

3.0 RESPONSIBILITY

3.1 Lab-attendant / Microbiologist are responsible for cleaning of horizontal autoclave.

3.2 Microbiologist is responsible for operation of horizontal autoclave.

4.0 ACCOUNTABILITY

4.1 Head Microbiology

5.0 EHS CONSIDERATIONS

5.1 Always take care the hot surfaces and wear gloves.

5.2 Open the door of the autoclave when the pressure of the chamber comes to zero.

5.3 Proper handle the media; at the time of loading and unloading.

6.0 PROCEDURE

6.1 Check the water level through glass on the side of boiler, if it is below the water point mark; open the valve to fill the purified water in boiler.

6.2 Switch on the "MAINS" from the front operating panel.

6.3 Switch on the Printer button from the front operating panel.

6.4 Water in the boiler will start heating and temperature rises to produce the steam.

6.5 Close the steam release valve.

6.6 Set main temperature controller, press to the menu key & set the temperature 122°C and cycle hold time (i.e. 20 minutes for culture media and 30 minutes for sterility accessories and cleaning aids), drying time 5 minutes.



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- 6.7 Open the door of the autoclave from loading side present in media preparation room.
- 6.8 Load the autoclave chamber as per load pattern defined in the validation along with chemical steam sterilization strip and autoclave indicator tape on the items to be sterilized.
- 6.9 Close the door of the autoclave and lock it by radial locking system and ensure that it is properly locked.
- 6.10 Press the ESC button from the front panel to start the operation.
- 6.11 Check the temperature of the chamber; it should be 122-124°C.
- 6.12 After completion of cycle, door open LED will glow.
- 6.13 After completion of the cycle allow the chamber steam to exhaust completely and confirm the zero pressure in chamber by chamber pressure gauge.
- 6.14 Enter in to the sterility testing area as per current version of SOP/MB009 of “Entry and exit procedure for Sterility Testing Area”.
- 6.15 Go to the autoclave unloading room.
- 6.16 Ensure the pressure of the autoclave chamber at zero from the pressure gauge provided at the unloading side door.
- 6.17 Open the radial locking of unloading side door of the autoclave and unload the material in SS tray after drying (wiped with 0.2 μ m filtered 70% IPA), check the chemical indicator strip for colour change (described on the indicator strip).
- 6.18 Keep the chemical indicator strip (changed colour) in the pass box.



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- 6.19 If colour is changed then transfer the material to sterility testing room or pass box as required.
- 6.20 If chemical indicator strip colour changes are not proper or satisfactory, immediately inform to your superior for further action and discard the all material and transfer to pass box in aseptic corridor for destruction.
- 6.21 Record the Autoclave usage record as per pattern MHS/XXXX/YY where, MHS=Moist heat sterilization and XXXX=sequential cycle number and YY=financial year i.e. MHS/0001/15
- 6.22 Attach the chemical indicator strip along with printout from the autoclave.
- 6.23 Printout should be signed by the person who has operated the autoclave.
- 6.24 Always run empty cycle first before proceeding to loaded cycle for the day.
- 6.25 **Cleaning:**
- 6.25.1 Clean the chamber internally with lint free cloth soaked with purified water before starting the activity.

7.0 DEFINITIONS AND ABBREVIATIONS

- 7.1 IPA - Isopropyl alcohol
- 7.2 °C - Degree centigrade
- 7.3 SS – Stainless Steel

8.0 REFERENCE

- 8.1 NA

9.0 ANNEXURES

- 9.1 Annexure I Horizontal autoclave usage record
- 9.2 Annexure II Horizontal autoclave load pattern

10.0 DISTRIBUTION DETAILS

- 10.1 Controlled copy of this SOP shall be distributed to Quality Assurance and Microbiology.

11.0 REVISION HISTORY

Supersedes SOP No.	Change Control No.	Reason for revision	Effective Date



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Cycle No.: Autoclave print out:	Cycle No.: Autoclave print out:	Cycle No.: Autoclave print out:	Cycle No.: Autoclave print out:	Cycle No.: Autoclave print out:
Chemical Indicator:	Chemical Indicator:	Chemical Indicator:	Chemical Indicator:	Chemical Indicator:



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ANNEXURE II
HORIZONTAL AUTOCLAVE LOAD PATTERN

Load pattern 01: Empty cycle





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Load pattern 02:

Cleaning aids -Maximum load



Items	Quantity
SS bucket	3 no.
Mopper	3 no.



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Load pattern 02: Cleaning aids -Minimum load



Items	Quantity
SS bucket	1 no.
Mopper	1 no.



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Load pattern 03:

Miscellaneous cycle- Maximum load



Items	Quantity
Filtration funnel	20 no.
Side arm flask	4 no.
Sampling bottles	20 no.
Forceps	20 no.
Scissors	20 no.
Silicon tube	3 no.
Manifold	1 no.
Mopper	5 no.
Beaker (250 ml)	2 no.
Microbial air sampler sieve	2 no.
Tip box	1 no.
Spreader	15 no.
Disinfectant coupon	20 each



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Load pattern 03: Miscellaneous cycle- Minimum load



Items	Quantity
Filtration funnel	1 no.
Side arm flask	1 no.
Sampling bottles	1 no.
Forceps	1 no.
Scissors	1 no.
Silicon tube	1 no.
Manifold	1 no.
Mopper	1 no.
Beaker (250 ml)	1 no.
Microbial air sampler sieve	1 no.
Tip box	1 no.
Spreader	1 no.
Disinfectant coupon	1 each



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Load pattern 04: Sterility testing media- Maximum load



Items	Quantity
Test tube stand (2x6 no.)-100 ml	4 no.
Screw capped conical flask-500 ml	22 no.



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Load pattern 04: Sterility testing media- Minimum load



Items	Quantity
Test tube stand (2x6 no.)-100 ml	1 no.
Screw capped conical flask-500 ml	1 no.



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Load pattern 05: General media- Maximum load



Items	Quantity
Test tube stand (2x6 no.)-100 ml	3 no.
Conical flask-1000 ml	1 no.
Screw capped bottles-1000 ml	7 no.
Screw capped bottles-500 ml	5 no.
Test tube stand 5 x 15	2 no.
Compress air kit	1 no.



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Load pattern 05:

General media- Maximum load



Items	Quantity
Test tube stand (2x6 no.)-100 ml	1 no.
Conical flask-1000 ml	1 no.
Screw capped bottles-1000 ml	1 no.
Screw capped bottles-500 ml	1 no.
Screw capped conical flask-500 ml	1 no.
Test tube stand 5 x 15	1 no.
Compress air kit	1 no.