



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Moist Heat Sterilizer

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 10

1.0 OBJECTIVE

To lay down procedure for cleaning, calibration and operation of Moist Heat sterilizer.

2.0 SCOPE

This SOP is applicable for Moist Heat sterilizer, Make - Pharma lab in microbiology laboratory.

3.0 RESPONSIBILITY

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE

4.1 Pre startup checklist

4.1.1 Before operating the steam sterilizer check all the utilities are available as per the pre startup checklist.

4.1.2 Ensure that chamber is empty.

4.1.3 Before starting the autoclave ensure that the autoclave chamber is clean.

4.1.4 Ensure that the Sterile Area door is closed.

4.1.5 Steam pressure should not be less than 1.7 kg/ cm².

4.1.6 Compressed air pressure should not be less than 6.0 kg/ cm².

4.1.7 Ensure that strip chart recorder is 'ON' and there is sufficient chart in the in the recorder.

4.1.8 Ensure that Auto / Manual switch is in Auto mode.

4.2 Description of Digital Temperature Controller

4.2.1 Switch on the mains.

4.2.2 The following screen appears on the PLC.

DD:MM:YY	HH:MM:SS
P H A R M A L A B	E N G G (I)
L T D	
S A N T E J,	A H M E D A B A D

4.2.3 Open door 1 (Non sterile door) by pressing “DOOR-1 OPEN” button (green colour).

4.2.4 Door 1 slides down automatically and “Door 1 gasket vacuum ON ” message displays on the PLC and Door I gets open and “Door 1 OPEN” message displays on the PLC.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Moist Heat Sterilizer

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	2 of 10

4.2.5 Keep the material to be sterilized in the autoclave chamber.

4.2.6 Close door 1 by pressing DOOR -1CLOSE button (red colour). Door automatically slides up and get close.

4.2.7 Door - 1 and Door - 2 gasket vacuum readings should between 1.5 to 2.0 kg/ cm².

4.2.8 Switch on the printer and load the paper.

4.2.9 The following screen appears on the PLC.

P H A R M A L A B E N G G .
P: 0.00 kg/ cm²
T: XXX. XX Deg 01- 01- 08

F1	F2	F3	F4
-----------	-----------	-----------	-----------

4.2.10 Select DATA by gently pressing F1 key.

4.2.11 Following parameters displays on the PLC.

LOAD	EDIT	PRINT	EXIT
-------------	-------------	--------------	-------------

F1	F2	F3	F4
-----------	-----------	-----------	-----------

4.2.12 Select print option by pressing F3 key and select any one of the following cycles to be run using UP and DOWN arrow keys.

4.2.13 Select the cycle to be run with the help of arrow keys

Sr.No.	Cycle Description
1	G &C CYCLE
2	GRAVITY CYCLE
3	LEAK TEST
4	BOWIE DICK TEST

4.2.14 Press enter key.

01 DATA - RECORDS



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Moist Heat Sterilizer

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	3 of 10

F1	F2	F3	F4
-----------	-----------	-----------	-----------

4.2.15 After selecting the cycle press enter key to accept the parameters and to print all the parameters of the cycle, on top of the page, before start of the cycle.

4.2.16 Press ESC key twice to return the data record menu.

4.2.17 Following parameters displays on the PLC.

LOAD	EDIT	PRINT	EXIT
-------------	-------------	--------------	-------------

F1	F2	F3	F4
-----------	-----------	-----------	-----------

4.2.18 Press F1 key to load the cycle. Select the cycle, to be run, with the help of arrow keys.

Sr.No.	Cycle Description
1	G &C CYCLE
2	GRAVITY CYCLE
3	LEAK TEST
4	BOWIE DISK TEST

4.2.19 Press enter key to select the cycle and view the below given screen.

Source:	Dest:
	Accept:

4.2.20 In source enter the serial no of the data record and press enter key.

4.2.21 Press down arrow key two times to select "Accept:" option.

4.2.22 Press enter key.

4.2.23 * Icon display in between the screen, indicating processing is going on.

4.2.24 Following message displays on the screen.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Moist Heat Sterilizer

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	4 of 10

Start the cycle? ###

Sr. No. **0**
Date: **DD- MM- YY**
Time: **HH: MM: YY**

- 4.2.25 Press shift key and with the help of up and down key select YES, select No to discard the cycle.
- 4.2.26 After selecting yes cycle will automatically starts.
- 4.2.27 Press RCD button of the chart recorder.
- 4.2.28 After completion of sterilization hold, vacuum or slow exhaust will start, depending on the type of cycle.

Slow Exhaust

P: 0.00 kg/ cm²
T: 121. 54 Deg

- 4.2.29 Door open temperature of autoclave is 85 or 90 degree depending on the type of cycle.
- 4.2.30 When cycle is completed buzzer starts indicating completion of cycle.
- 4.2.31 Gently Press F3 key to acknowledge the buzzer.
- 4.2.32 After completion of cycle following message displays on PLC.

Cycle is over
Fo value:

- 4.2.33 On sterile side cycle over indicator glows on right side.
- 4.2.34 To unload the sterile load press “Door 2 open” button from sterile side, sterile side door will open. Unload the load and press “Door- 2 close” button to close the door.
- 4.2.35 Top the chart recording by pressing RCD button on the chart recorder after the completion of the cycle.
- 4.2.36 Start the autoclave sterilization load no. as XX/YYYY.
- 4.2.37 XX represent the last two digit of the current year for e.g. 07 and YYYY represent the serial no. of the first cycle of the autoclave for year 2007 for e.g. 0001.
- 4.2.38 For example - Autoclave Load No. - 07/0001.
- 4.2.39 Autoclave operation and usage details are to be recorded as per Annexure - I.

4.3 Setting of Chart Recorder

- 4.3.1 Press ESC key of chart recorder for 5 -7 sec.
- 4.3.2 Menu of the chart recorder appears on the display of the chart recorder.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Moist Heat Sterilizer

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	5 of 10

- 4.3.3 Scroll the menu to CLOCK option by using up key.
- 4.3.4 Press enter key.
- 4.3.5 Adjust date of the chart recorder with the help of up and feed key.
- 4.3.6 Press enter key to save the change setting.
- 4.3.7 After pressing enter time setting comes.
- 4.3.8 With the help of up and feed key adjust the time of the chart recorder.
- 4.3.9 Press enter key to save the setting.
- 4.3.10 Hold ESC key for 5 -7 sec to exit the menu.

4.4 Interpretation of Chart

X - Axis Scale		Each Division Represent
0 to 100	In case of MM	2 mm
0 to 200	In case of Temperature	4 deg. C
- 1 to 3	In case of Pressure	0.08 mm Kg/cm ²

4.4.1 Inspection of chart

Both pressure and temperature are represented on X-axis.

Temperature Five sensors with different colour

- S-1 - Temperature sensor (Red colour)
- S-2 - Temperature sensor (Green colour)
- S-3 - Temperature sensor (Blue colour)
- S-4 - Temperature sensor (Brown colour)
- S-5 - Temperature sensor (Black colour)

Pressure - Purple colour

4.5 Cleaning

- 4.5.1 Cleaning should be done at the end of all operations.
- 4.5.2 Ensure that the power supply is switched off before starting the cleaning operations.
- 4.5.3 Clean the inner surfaces of chamber and doors thoroughly with mops soaked with purified water.
- 4.5.4 Wipe the cleaned surfaces with lint free cloth.
- 4.5.5 Cleaning detail are to be recorded in annexure - I.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Moist Heat Sterilizer

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	6 of 10

4.6 Calibration

- 4.6.1 Pressure gauge and digital display units of temperature sensors are to be calibrated once in six months by Engg.deptt.
- 4.6.2 Strip chart recorder is to be calibrated once in six months by Engg.deptt..
- 4.6.3 Temperature sensors are to be calibrated once in six months by Engg.deptt.
- 4.6.4 In case, validation fails, immediately call the service/maintenance engineer. Also, put a label on the equipment indicating its breakdown.
- 4.6.5 Put a label on the equipment indicating its breakdown.
- 4.6.6 If a major breakdown lasts for more than a day, load to be taken in vertical autoclave ensuring that a empty cycle is run before the media load and discard load.
- 4.6.7 If the cycle is terminated due to breakdown or power failure the media inside the autoclave has to be discarded and prepared again.

4.7 Frequency of cycle

- 4.7.1 Frequency of the cycle of moist heat sterilizer are mentioned in table - I

Table - I

Sr. No.	Cycle Description	Frequency
1	G & C CYCLE	As and when required
2	GRAVITY CYCLE	As and when required
3	LEAK TEST	Daily before starting any other cycle
4	BOWIE DICK TEST	Once in a week

4.8 Acceptance criteria

LEAK TEST: The vacuum leak rate should not exceed 1.0 mmHg/min.

4.9 Parameter of the cycles

Parameter of the cycle of moist heat sterilizer are mentioned in table - II



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Moist Heat Sterilizer

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	7 of 10

Table - II

Cycle Description / Parameter	
G & C CYCLE	
INITIAL VACUUM TIME	2 minutes
PULSATION	2
PRE HEATING TEMP.	85 Deg.
PREHEATING TIME	2 minutes
STERILE TEMP	121 - 124 Deg.
STERILE TIME	30 minutes
STRL PRINT TIME	1 minutes
DRY VACUUM TIME	5 minutes
VACUUM VALUE	300.0 mm of Hg
DOOR OPEN TEMP	85 Deg.
PRINTING DURING CYCLE	YES
Leak Tests	
LEAK VAC VALUE	532 mm of Hg
LEAK VAC TIME	15 minutes
PRINTING DURING CYCLE	YES



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Moist Heat Sterilizer

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	8 of 10

Table - II

Cycle Description / Parameter	
GRAVITY CYCLE	
INITIAL VACUUM TIME	0
PULSATION	0
PRE HEATING TEMP.	85 Deg.
PREHEATING TIME	0
STERILE TEMP	121 - 124 Deg.
STERILE TIME	30 minutes
STRL PRINT TIME	1 minutes
DRY VACUUM TIME	0
VACUUM VALUE	0
DOOR OPEN TEMP	99 Deg.
PRINTING DURING CYCLE	YES
BOWIE DICK TEST	
INITIAL VACUUM TIME	2 minutes
PULSATION	2
PRE HEATING TEMP.	85 deg
PREHEATING TIME	2 minutes
STERILE TEMP	121 - 124 Deg.
STERILE TIME	8 minutes
STRL PRINT TIME	1 minutes
DRY VACUUM TIME	2 minutes
VACUUM VALUE	300.0 mm of Hg
DOOR OPEN TEMP	85 Deg.
PRINTING DURING CYCLE	YES



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Moist Heat Sterilizer

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	9 of 10

5.0 SAFETY & PRECAUTIONS

5.1 After completion of cycle remove the strip chart and write date, load No., and signature of the operator on graph paper of strip chart recorder.

5.2 Select the cycle as per requirement.

6.0 REVISION HISTORY

Revision No.	Reason for Revision	Superseded from & date
00	First Issue	-----

7.0 REFERENCES

Not applicable.

8.0 ABBREVIATIONS

SOP	:	Standard Operating Procedure
°C	:	Degree centigrade
Sq	:	Square
Kg	:	Kilogram
cm	:	Centimeter
PLC	:	Program Logic Control
mm	:	Millimeter
div	:	Division
RCD	:	resistance temperature detector

9.0 ANNEXURES

Annexure - I : Cleaning and operation record of moist heat sterilizer



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Moist Heat Sterilizer

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	10 of 10

ANNEXURE - I

CLEANING AND OPERATION RECORD OF MOIST HEAT STERILIZER

Autoclave ID: _____

Date of Sterilization - _____ Autoclave Load No. - _____

Sterilization Cycle: G & C cycle / Gravity cycle / Leak test / Bowie disk test cycle

Sr.No.	Media /Articles to be Sterilized	Medium Lot No.	Qty.	Media / Articles to be used for

Operation of Steam sterilizer: (Load the articles as per loading pattern)

Operation started at		Vacuum Hold/Sterilization started at	
Vacuum hold /Sterilization completed at		Operation completed at	

Critical Area Unloading

Unloading completed at	Article unloaded by	Checked by

Equipment Cleaning Operation

Started at		Completed at	
Cleaned by			

Operated by		Checked by	
-------------	--	------------	--

Remarks (if any)

Paste Indicator and sign