1. **Purpose:**

   To describe the operation & qualification procedure of autoclave.

2. **Scope:**

   This SOP is applicable to the autoclave ID No –

3. **Reference & Attachment:**
   3.1. Reference: Autoclave manual

   3.2. Attachments:

   Attachment – I Format of autoclave logbook.
   Attachment – II Format of qualification record.
   Attachment – III Format of qualification status label.

4. **Responsibility:**

   4.1. Quality Head:
   - **4.1.1.** To ensure proper implementation of SOP.
   - **4.1.2.** Review, audit & approval of SOP.

   4.2. Microbiologist:
   - **4.2.1.** Implementation of SOP.

5. **Distribution:**
   5.1. Head Quality (Master Copy)
   5.2. QC - Microbiology Section.
   5.3. Corporate Quality

6. **Definitions of Terms:**
   None

7. **Procedure:**

   7.1. Precautions:
   - **7.1.1.** Before using the equipment, check the inner wall of the equipment for deposition of scales. There should be no scales on the inner wall. The equipment should be thoroughly clean, including the lid of the equipment.
   - **7.1.2.** Check the pressure gauge & ensure that it is calibrated & not over due for recalibration.
   - **7.1.3.** Always maintain the standard water level in the equipment.
   - **7.1.4.** Never run the autoclave without water.
   - **7.1.5.** Tighten the lid of the autoclave so that there is no leakage.

   7.2. Operating procedure:

7.2.1. Fill the autoclave with water up to the level mark.
7.2.2. Load the autoclave with the materials to be sterilized in a provided 'SS' basket.
7.2.3. The loading pattern shall be designed that the autoclave shall not occupy more than 2/3rd of its capacity.
7.2.4. Any item to be loaded shall have intact packed with Lid / cover / cotton plug (if necessary) and shall be wrapped in butter paper to avoid steam / water inlet into the material.
7.2.5. All Items like water, diluents, fresh or used media containers shall be kept vertically straight to prevent leakages.
7.2.6. The tight cap fitted boxes, shall be preferably kept in lower side and the media, and butter paper wrapped item shall be kept in upper side.
7.2.7. Permutation / Combination for arrangement of sample shall done to reduce the cycle time requirements
7.2.8. Tighten the valve on the lid.
7.2.9. Switch on the main.
7.2.10. The screen of controller show the temperature & time set during last autoclave cycle.
7.2.11. The temperature & time of exposure can be changed by using set key.
7.2.12. Normally autoclave is set at 121^{o} C for 15 minutes.
7.2.13. Push the start switch to on.
7.2.14. When the temperature is reached upto the set temperature the clock of the autoclave starts the count down for the set time.
7.2.15. After completion of autoclave cycle, the screen of controller show the message "cycle over" & a beep alarm is given.
7.2.16. Put off the mains switch.

7.2.17. Gradually release the steam by a steam valve to 0 psi.
7.2.18. Open the lid of autoclave by opening facing screws.
7.2.19. Open the lid of autoclave, avoid to fall the condensed water drops on controller.
7.2.20. Remove the sterilized material.
7.2.21. Record the details after completion of each run as per Attachment – I.

7.3. Qualification procedure:

7.3.1. For internal (in-house) qualification:

7.3.1.1. Frequency: Every three months or after any breakdown./maintenance work.
7.3.1.2. Ensure that pressure gauge is calibrated.
7.3.1.3. Keep two self-indicator strips (Steam-Clox) in or on any material to be sterilized in upper & lower s.s.basket of the autoclave.
7.3.1.4. Place 6 ampoules of biological indicators containing spores of *Bacillus stearothermophilus* in the in six different glass containers.

7.3.1.5. Keep three ampoules in each basket to make a triangle in each basket.

7.3.1.6. Adjust the basket so that all six points of ampoule should form a hexagon.

7.3.1.7. Mark all these ampoules as 'test'.

7.3.1.8. Subject all these to the autoclave cycle as usual.

7.3.1.9. After autoclave cycle is over take out all the items from autoclave carefully.

7.3.1.10. Incubate the 'test'ampoules at 60 ± 2^0 C temp.for 48-72 hours.

7.3.1.11. Incubate a nonsterilised ampoule with 'test' as a positive control.

7.3.1.12. Interpretation:

7.3.1.12.1. Check Steam-Clox self-indicator strip for the color change from purple to green on the three upper side squares except the circle in the middle.

7.3.1.12.2. After incubation check the ampoules for the colour change.

7.3.1.12.3. If the ampoules remain a clear red-violet coloured it indicate that the temperature of 121^0 C has been attained.

7.3.1.12.4. Fill the qualification record as per attachment – II.

7.3.1.12.5. Affix qualification, status label as per attachment – III.

7.3.1.12.6. In case of any discrepancy observed, inform supervisor immediately and put "NOT TO BE USED" label duly signed with date.

7.3.2. For external qualification:

7.3.2.1. Frequency: Yearly

7.3.2.2. Ensure that heat distribution study is carried out by concern out side party as per the frequency & record is available.

8. History

Version No.	3	Effective Date	

Changes:

1. Qualification procedure using biological indicator included.
2. Qualification procedure using chemicals removed.
3. Attachment for sterilization record included.
4. Qualification status label included.

Attachment – I

Format No.
BQA/F/150/00

		Quality Control
		Autoclave Logbook/ Sterilization Record

Autoclave ID: _____

Date	Sterilization Run No.	Materials sterilized	Cycle start time	Cycle end time	Done by	Checked By	Indicator

Attachment – II

For

		Quality Control
		Autoclave Qualification Record

Instrument ID :
Make & model :
Qualification frequency :
Date of qualification :
Next qualification due on :
Pressure gauge calibration due date: :
Qualification aids: : Paper indicator & biological indicator.

Steam clox indicator:

Sr No.	Location Of indicator	Observations	Acceptance criteria		
			Indicator part	From	To
1	Upper		Three upper squares		
2	Lower		Circle		

Biological indicator:
Name of indicator: *Bacillus Stearothermophilus*
Incubation date : _____ Incubation time : _____ Incubation temp. : _____

Observations:

Indicator No./Position	Observation on incubation day			Remark
	1	2	3	
1/				
2/				
3/				
4/				
5/				
6/				
Observed by				

Remarks: The Instrument is qualified / not qualified for use.

Done by Checked by Approved by
Date : Date : Date :

Attachment – III

	Quality Assurance
	Qualification Status

INSTRUMENT:

MAKE: **MODEL:**

QUALIFICATION DONE ON: **BY:**

NEXT QUALIFICATION DUE ON: