



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Operation and Cleaning of Dry Heat Sterilizer/ Depyrogenator	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 1.0 OBJECTIVE:**
To lay down a procedure for Operation and Cleaning of Dry Heat Sterilizer/ Depyrogenator.
- 2.0 SCOPE:**
This SOP is applicable for Operation and cleaning of Dry Heat Sterilizer/ Depyrogenator in Microbiology laboratory.
- 3.0 RESPONSIBILITY:**
Officer / Executive - Microbiology
- 4.0 ACCOUNTABILITY:**
Head – QC
- 5.0 ABBREVIATIONS:**
- | | |
|------|------------------------------|
| IPA | Iso Propyl Alcohol |
| Ltd. | Limited |
| No. | Number |
| Pvt. | Private |
| QA | Quality Assurance |
| QC | Quality Control |
| SOP | Standard Operating Procedure |
- 6.0 PROCEDURE:**
- 6.1 OPERATION:**
- 6.1.1** Open the door of the Dry Heat Sterilizer / Depyrogenator with the help of handle.
- 6.1.2** Double wrapped the materials with aluminum foil and Keep in Dry Heat Sterilizer/Depyrogenator as per load details described in table-1.



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Page No.:

Table-1

Name of materials	Load details	Load Configuration
10 ml Vials	100 Numbers	100 vials on upper left shelf toward back side.
12x75 mm dilution tubes	100 Numbers	10 X 10 dilution tubes (12 X 75 mm) on middle of upper shelf toward back side.
10x75 mm assay tubes	400 Numbers	10 X 10 assay tubes (10 X 75 mm) on right of upper shelf toward backside. 10 X 10 assay tubes (10 X 75 mm) on right of upper shelf toward front side. 10 X 10 assay tubes (10 X 75 mm) on right of lower shelf toward backside. 10 X 10 assay tubes (10 X 75 mm) on right of lower shelf toward front side.
Glass Bottle 100 ml	02 Numbers	100 ml Glass Bottle on middle of upper shelf toward front side.
Scissor	02 Number	2 Nos. Scissor on left of lower shelf toward front side.
Vial Opener	04 Number	4 Nos. vial opener on right of lower shelf toward front side.
Spatulas	10 Number	10 Nos. spatula on left of lower shelf toward back side.
Scoop	02 Number	1 Nos. scoop on right of lower shelf toward back side. 1 Nos. scoop on left of lower shelf toward front side.
Spoon	02 Number	2 Nos. spoon on middle of lower shelf toward back side.



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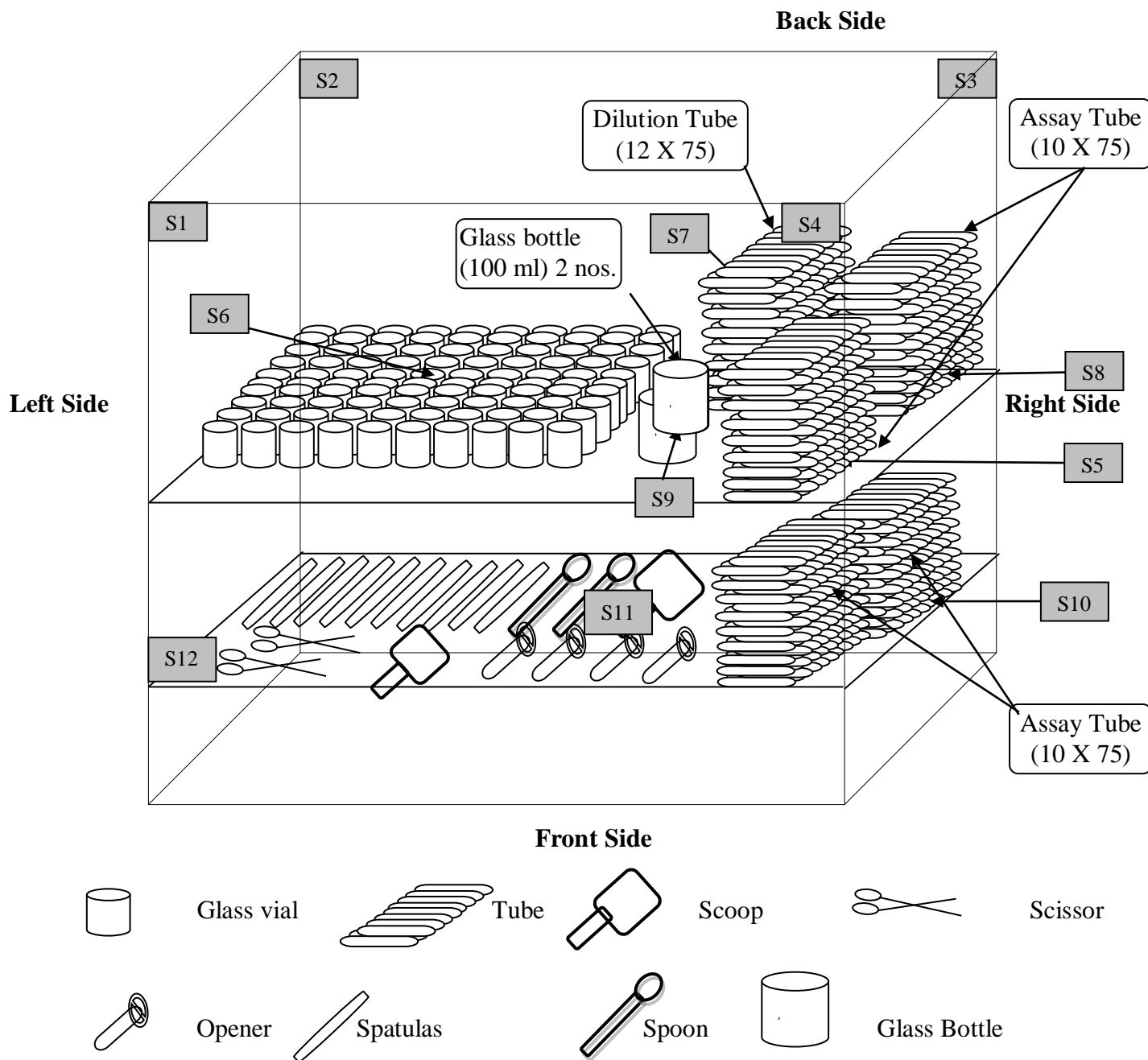
Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Figure 1: Schematic Diagram of Dry Heat Sterilizer



6.1.3 Switch 'ON' the mains by turning on the key.

6.1.4 Main indicator will glow as Red colour.



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Issue Date:	Page No.:

- 6.1.5 Now record the Load details and start time of Dry Heat Sterilizer in **Annexure –II** “Material Depyrogenation record”.
- 6.1.6 Record the time in “Material Depyrogenation record” when temperature achieved 250°C.
- 6.1.7 Temperature shall be maintained at 250 ± 5°C for 60 minutes.
- 6.1.8 After completion of Depyrogenation cycle Switch “OFF” the key by pressing Mains of the equipment.
- 6.1.9 Approximately 30 minute of cycle completion; open the door & take out the glassware with the help of tong and place it in Bacterial Endotoxin Test room/ Dry Heat sterilizer/Depyrogenator.

6.2 CLEANING:

- 6.2.1 Switch off the Mains of Dry Heat Sterilizer/Depyrogenator inside the PID control.
- 6.2.2 Ensure that equipment having normal temperature.
- 6.2.3 Ensure that Dry Heat Sterilizer/Depyrogenator should be empty for cleaning.
- 6.2.4 Clean the Internal surfaces of Dry Heat Sterilizer weekly with clean and dry mop and Record the cleaning details in **Annexure-I, “Cleaning Record of Dry Heat sterilizer/Depyrogenator”**.
- 6.2.5 Clean the External surface of Dry Heat Sterilizer daily working day with 0.22 μ filtered 70 % IPA and Record the cleaning details in **Annexure-I, “Cleaning Record of Dry Heat sterilizer/Depyrogenator”**.
- 6.2.6 During cleaning of Dry Heat Sterilizer do not spray disinfectant on PID controller.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Cleaning Record of Dry Heat Sterilizer / Depyrogenator	
Annexure-II	Material Depyrogenation Record	

ENCLOSURES: SOP Training Record.



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8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality assurance
- Controlled Copy No. 02 Microbiology
- 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



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

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ANNEXURE- I

CLEANING RECORD OF DRY HEAT STERILIZER/DEPYROGENATOR

Equipment ID No.:

Date of Cleaning	Name of Cleaning agent used	External surface	Internal surface	Cleaning Done by (Sign & Date)	Reviewed by (Sign & Date)

√-Done and X- Not Done

