



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Depyrogenation of Glassware	Effective Date:
Supersedes: Nil	Review Date:
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1.0. OBJECTIVE :

1.1 To lay down a procedure for the cleaning, operation and calibration of Oven for depyrogenation of glassware used in LAL test.

2.0. SCOPE:

2.1 This procedure is applicable for cleaning, operation and calibration of Oven for depyrogenation of glassware used in LAL test In Microbiology Laboratory of the Quality control department at

3.0. RESPONSIBILITY :

3.1 Sr. Officer/Officer – Quality Control

4.0. ACCOUNTABILITY:

4.1.1 Head of the department is accountable to ensure the compliance of SOP for all aspects.

5.0 DEFINITION:

Depyrogenation refers to the removal of pyrogens from solution, most commonly from injectable pharmaceuticals. A pyrogen is defined as any substance that can cause a fever. Bacterial pyrogens include endotoxins and exotoxins, although many pyrogens are endogenous to the host

6.0. PROCEDURE:

6.1 CLEANING:

6.1.1 Remove dust from external surface of Oven with cleaned dry mop.

6.1.2 Cleaned the surface of Oven with wet sponge with freshly prepared 70 % v/v I.P.A.

6.1.3 Mop shelves with freshly prepared 70% v/v IPA with clean sponge.

6.1.4 Clean it with dry mop.

6.1.5 Record the cleaning as per Annex-I “Oven Depyrogenation log record” of this SOP.

6.1.6 Frequency- Daily.

6.2 OPERATION:

6.2.1 Ensure that the oven is clean and free from dust.



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- 6.2.2** Wrap the glassware which are to be depyrogenated, in the aluminum foil.
- 6.2.3** Put the subjective glassware's / material inside the oven and close the door of oven.
- 6.2.4** Switch on the mains and then the oven.
- 6.2.5** The red indicator light will glow.
- 6.2.6** The required temperature (250°C) can be set by up and down keys provided in the panel of oven
- 6.2.7** When the temperature reaches the set temperature note the time, run the cycle for 30 minutes.
- 6.2.8** After completion of holding period switch off the oven and remove the glassware's when the temperature reach at room temperature
- 6.2.9** Fill the Annexure-I "Oven Depyrogenation log record" of this SOP for the depyrogenation record
- 6.3 CALIBRATION:-**
- 6.3.1** QA department shall calibrate the respective equipment as per the predefined frequency ,with the help of a calibrated data logger .
- 6.3.2 Frequency:** Yearly.
- 6.3.3** Tolerance window: ± 15 days.
- 6.4 GENERAL CARE AND PRECAUTIONS:**
- 6.4.1** Use asbestos gloves to remove any object which is lying in the oven if it is hot.
- 6.4.2** Cool the oven by decreasing the temperature gradually.
- 6.4.3** The door of oven should not be open when the oven is in operation

7.0 ABBREVIATION:

Abbreviation	Full form of abbreviation used
QC	Quality Control
Ltd.	Limited
SOP	Standard Operating procedure
LAL	Limulus Amoebocyte Lysate
ID No	Identity Number
N.A.	Not Applicable
Sr.	Senior
v/v	Volume by Volume
IPA	Iso Propyl Alcohol
°C	Degree Celsius
%	Percentage



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8.0 ANNEXURE :

Annexure No.	Title of Annexure	Format No.
Annexure-I	Oven Depyrogenation log record	

9.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Control
- Master Copy Quality Assurance Department

10.0 REFERENCES:

- IH

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

