



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation, Monitoring and Cleaning of Sterility testing cRABS

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
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1.0 PURPOSE

To lay down the procedure for operation and cleaning of Sterility testing cRABS.

2.0 SCOPE

It is applicable to Sterility testing cRABS Equipment installed in microbiology laboratory.

3.0 RESPONSIBILITY

Microbiologist

4.0 PROCEDURE

4.1 Operation of Sterility testing cRABS.

4.1.1 Ensure equipment is in a clean state.

4.1.2 Switch on the main supply.

4.1.3 Switch on the blower of the pass box

4.1.4 Switch on the UV of the pass box.

4.1.5 Switch on the blower of the chamber.

4.1.6 Switch on the light of the chamber.

4.1.7 Run the sterility testing cRABS for at least 30 minutes before starting the activities.

4.1.8 Record the differential pressure of the pass box, pressure differential across HEPA filter and pressure differential across work chamber.

4.1.9 Clean the sterility testing cRABS interior and exterior before starting the activities and after completion of the activities with 70 % isopropyl alcohol / disinfectant using non fiber shedding mop.

4.1.10 Shut down the sterility testing cRABS by switching off the blower, UV light and the main supply.



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4.1.11 Record the Details like Differential pressure, Analysis done, Cleaning, Instrument switched On/Off in Annexure-I.

4.2 Monitoring of Sterility testing cRABS

Monitoring of Sterility testing cRABS can done by following ways,

4.2.1 Passive air sampling

4.2.1.1 Transfer the petriplate into pass box (LAL test room to Incubator).

4.2.1.2 Enter the respective area as per the SOP.

4.2.1.3 Decontaminate the external surface of the petriplates with the help of a sterile mop soaked in a filtered sporocidal agent.

4.2.1.4 Transfer the petriplate into pass box (Buffer room to LAL test room).

4.2.1.5 Enter the respective area as per the SOP.

4.2.1.6 Place one petriplate into the sterility testing cRABS pass box and two into the work chamber of sterility testing cRABS and remove the upper lid of the petriplates and keep it in inverted position.

4.2.1.7 Mark the petriplates at the base with the following details with marker,

Media lot no

Name of the location

Date of exposure

Exposed by

4.2.1.8 Expose the media plate for 4 hours, After 4 hours of exposure, close the petriplate with lid. Collect the petriplate and transfer the plates into the incubator.

4.2.1.9 Incubate the exposed petriplate in inverted position in the incubator at $32.5 \pm 2.5^{\circ}\text{C}$ for 5 day.

4.2.1.10 After incubation observe and count the number of colonies on the colony counter or in the light source with the help of marker.

4.2.1.11 Note down the observation in the form.



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4.2.1.12 If the counts obtained are above the limits specified below investigate the results and take necessary actions as per SOP.

4.2.1.13 Frequency of Monitoring

Class A: Once in a day whenever there is activity.

4.2.1.14 Acceptance criteria

Action limit:

Class A: 1 CFU / plate

4.3 Active air sampling

4.3.1 Transfer the required number of media cassette, plate, Air sampler and accessories into pass box (LAL test room to Incubator).

4.3.1.1 Enter the respective area as per the SOP.

4.3.1.2 Decontaminate the external surface of the petriplates with the help of a sterile mop soaked in a filtered sporicidal agent.

4.3.1.3 Mark the petriplates at the base with the following details with marker,

Media lot no

Name of the location

Date of exposure

Exposed by

4.3.1.4 Place all media cassette, plate, Air sampler and accessories into pass box (Buffer room to LAL test room).

4.3.1.5 Place the media cassette / plates on the Air sampler and operate the instrument as per SOP.

4.3.1.5 After completion of sampling collect all the plates and incubate in inverted position in the incubator at $32.5 \pm 2.5^{\circ}\text{C}$ for 5 day.

4.3.1.6 After incubation observe and count the number of colonies on the colony counter or in



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the light source with the help of marker.

4.3.1.7 Note down the observation in the form no SOP.

4.3.1.8 If the counts obtained are above the limits specified below investigate the results and take necessary actions as per SOP.

4.3.1.9 Frequency of Monitoring

Class A: Once in a day

4.3.1.10 Acceptance criteria

Action limit

Class A: 1 CFU / plate

4.4 Non viable particle count

4.4.1 Keep the non-viable particles counter and accessories in the pass box (LAL test room to Incubator).

4.4.2 Decontaminate the external surface of the petriplates with the help of a sterile mop soaked in a filtered sporicidal agent.

4.4.3 Place non-viable particles counter and accessories into pass box (Buffer room to LAL test room).

4.4.4 Operate the sampler according to SOP.

4.4.5 Perform the non-viable particle count at two different locations after completion of the activities.

4.4.6 Record the details of non-viable particles count in form.

4.4.5 Frequency

4.4.6 Once in day.

Note: If activity if there perform the non-viable count after completion of the sterility.

4.4.7 Acceptance criteria



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Alert Limit
0.5 μ / ft³
50

Action Limit
0.5 μ / ft³
100

Action Limit
5 μ / ft³
Nil

Action Limit
5 μ / ft³
Nil

4.5 Leak Test for sterility cRABS

4.5.1 For gloves

4.5.1.1 Remove all the gloves from the isolator and number them from 1 to 6.

4.5.1.2 Place the gloves one by one in the suitable assembly being used to carry out the test.

4.5.1.3 From the inlet of the assembly allow the compressed air to pressurize the gloves to the required level (200 Pascal).

4.5.1.4 Record the pressure displayed on the magnehelic gauge fitted with the assembly after 5 minutes in Annexure IV. The allowable pressure drop is < 0.5 mm of WC (5 Pascal) over 5 minutes.

4.5.1.5 Again attach the gloves at the respective position on the isolator.

4.5.2 For chamber

4.5.2.1 Ensure all the access ports are closed.

4.5.2.2 Prior to testing, each isolator seal and fittings are to be checked.

4.5.2.3 Invert all the gloves to the outside of the isolator.

4.5.2.4 Change the magnehelic inlet tubing's position to the extremes (high and low).

4.5.2.5 Allow the compressed air to pressurize the chamber of the isolator to the required level (200 Pascal).

4.5.2.6 Record the pressure displayed on the magnehelic gauges after 5 minutes in Annexure IV. The allowable pressure drop is < 4.0 mm of WC (40 Pascal) over 5 minutes.

4.6 Frequency: Leak test should be carried out monthly.

5.0 ABBREVIATIONS AND DEFINITIONS



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SOP	Standard Operating Procedure
QCM	Quality Control Microbiology
QAD	Quality Assurance Department
Rev.	Revision
No.	Number
UV	Ultra Violet
%	Percent
°C	Degree Centigrade
CFU	Colony Forming Unit
μ	Micron
Ft ³	Cubic feet

Air Sampler: Devices or equipment used to sample a measured amount of air in a specified time to quantitative microbiological status

Settle plate: This method is still widely used as a simple and in expensive way to qualitative assess the environments over prolonged exposure time.

Action limit: Established criteria, requiring immediate follow-up and corrective action if exceeded

Alert limit : established criteria giving early warning of potential drift from normal condition which are not necessarily grounds for definitive corrective action but which require follow-up investigation.

6.0 REFERENCE DOCUMENTS

- SOP: Entry and Exit procedure for Routine microbiology testing area, Sterility area
- SOP: Handling of out of trend results in environmental monitoring and water analysis.
- SOP: Passive air sampling (Settle plate) microbiology lab
- SOP: Active air sampling microbiology lab
- SOP: Procedure for Operation of Air samplers
- SOP: Operation and Cleaning of Air Sampler SAS 180 L
- SOP: Operation of air borne Particle Counter.
- SOP: Non viable count record
- USP chapter No.<1116> Microbiological evaluation of clean rooms and other controlled environments
- USP chapter No. <61> Microbiological examination of non sterile products



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7.0 ANNEXURE / ATTACHMENTS

Annexure I: Form 1- Sterility cRABS log sheet.

Annexure IV: Form 4 - Leak test data sheet for sterility testing cRABS.

8.0 REVISION LOG

Revision Number	Effective Date	Reason for Revision