



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Microbiology Start up procedure after Shut down

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

To lay down the procedure for start up procedure after shut down.

2.0 SCOPE:

This procedure applies to microbiology lab for carrying out the procedure for shutdown and start up of the microbiology lab.

3.0 RESPONSIBILITY:

Microbiologist.

4.0 PROCEDURE:

4.1 Definitions

4.1.1 Major Shut Down: The activities which have a major impact on the quality of the microbiology lab environment in terms of viable and non viable particulate counts and includes activities such as

4.1.1.1 Civil works in the area.

4.1.1.2 Major Maintenance activity

4.1.1.3 HVAC shutdown / Power failure for more than 12 hours

4.1.2 Minor Shut Down: The activities which have a low impact on the quality of the microbiology lab environment in terms of viable and non viable particulate counts and includes activities such as

4.1.2.1 HVAC shutdown for less than 12 hours.

4.1.2.2 Preventive maintenance activity.

4.1.2.3 Minor modifications in the area.

4.1.2.4 Power failure for less than 12 hours.

4.1.3 Interruptions: The activities which has very low or no impact on the quality of the microbiology lab environment in terms of viable and non viable particulate counts and includes



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activities such as

4.1.3.1 HVAC shutdown for less than 30 minutes.

4.1.3.2 Minor maintenance activity.

4.1.3.3 Power failure for less than 30 minutes.

4.1.3.4 Validation activity.

4.2 Procedure

4.2.1 Procedure for restart after major shut down

4.2.1.1 For restart after major shut down thorough cleaning of floors, walls, ceiling, doors and window panels by mopping with purified water and detergents.

4.2.1.2 Instruct Engineering personnel to Start Air Handling units.

4.2.1.3 Allow the area to be purged for at least 1 hour.

4.2.1.4 Re-clean and sanitize the area as per SOP ensuring that the floors, walls and ceiling are cleaned and sanitized.

4.2.1.5 Clean all the equipments present in the lab thoroughly externally and internally as per their respective SOP's, if required.

4.2.1.6 Perform microbial environmental monitoring SOP.

4.2.1.7 Perform Non viable particle counts in the area. Particle counting should be carried out in all rooms.

4.2.1.8 Testing operations should be performed only after achieving the environmental conditions suitable for non-viable and viable particle counts.

4.2.1.9 The final approval to start the area should be given by Quality Assurance after reviewing all the data and ensuring compliance to the requirements.

4.2.2 Procedure for restart after minor Shut Down

4.2.2.1 Before taking the lab under operation after minor shut down following operations should be



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carried out.

4.2.2.2 Ensure that the Air Handling units are in operation.

4.2.2.3 Allow the area to be purged for at least 1 hr.

4.2.2.4 Clean and sanitizes the area as per SOP ensuring that all the floors, walls and ceiling are cleaned and sanitized.

4.2.2.5 Clean all the equipments present in the lab thoroughly externally and internally as per their respective SOP's, if required.

4.2.2.6 Perform microbial environmental monitoring SOP.

4.2.2.7 Perform Non viable particle counts in the area. Particle counting should be carried out in all rooms.

4.2.2.8 Testing operations should be performed after achieving the environmental conditions suitable for non-viable particle counts.

4.2.2.9 The final approval to start the area should be given by Quality Assurance after reviewing all the data and ensuring compliance to the requirements.

4.2.3 Procedure for restart after Interruptions.

4.2.3.1 Before taking the lab operation after interruptions, following activity should be carried out.

4.2.3.2 Ensure that the Air Handling units are in operation.

4.2.3.3 Clean and sanitizes the area as per SOP ensuring that the floors and walls are cleaned and sanitized.

4.2.3.4 Perform microbial environmental monitoring as per SOP.

4.2.3.5 Testing operations can be initiated after Quality Assurance checks for proper cleaning.

5.0 ABBREVIATIONS AND DEFINITIONS

SOP	Standard Operating Procedure
QCM	Quality Control Microbiology
QAD	Quality Assurance Department



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Rev. Revision
No. Number
HVAC Heating Ventilating Air Conditioning

6.0 REFERENCE DOCUMENTS:

SOP: Cleaning and sanitization of microbiological area
SOP: Monitoring of microbiology laboratory

7.0 ANNEXURE / ATTACHMENTS:

None

8.0 REVISION LOG:

Revision Number	Effective Date	Reason for Revision