



FACILITY OPERATION QUALIFICATION

(_____ BLOCK)

Annexure No.:

Reference Protocol No.:

Page: 1 of 4

Area Name:

Area Code:

Department Name:

Pre Approval

Prepared by:
User Department

Checked by:
User Dept. Head

Reviewed by:
EHS

Reviewed by:
Engineering
Head

Reviewed by:
Quality
Assurance

Approved by:
QA Head

Sign. & Date:

Sign. & Date:

Sign. & Date:

Sign. & Date:

Sign. & Date:

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1.0 General Room Conditions:

S.No.	Description	Acceptance Criteria	Observations	Checked by Sign/ Date
1.1	Cleanliness: Clean the area as per SOP.	Area shall be visually clean.		
1.2	Fumigation: Fumigation of area done as per SOP No. _____.			
1.3	Lighting	Luminance not less than _____ Lux.	Luminance of 5 positions: 1 _____, 2 _____, 3 _____, 4 _____, 5 _____, Avg. Lux: _____	



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2.0 Test to be carried out:

S.No.	Name of test	Acceptance Criteria	Observations	Checked by Sign/ Date
2.1	Air change per hour (For one day at Rest condition)	Not be less than _____ nos. Per hour.		
2.2	Particulate matter count (For one day at Rest condition)	Shall be able to meet requirements of ISO Class _____		
2.3	Temperature and Relative humidity (Carry out the recording at every two hours for one day at rest condition)	Temperature: Limit: _____ to _____ °C	Temperature: 1. _____ °C 2. _____ °C 3. _____ °C 4. _____ °C	
		Relative Humidity: Limit: _____ to _____ %	Relative Humidity: 1. _____ % 2. _____ % 3. _____ % 4. _____ %	
2.4	Differential pressure across adjacent area (Carry out the recording at every two hours for one day)	Pressure difference: Limit: _____ to _____ Pascal with respect to adjacent area.	Pressure difference: 1. _____ 2. _____ 3. _____ 4. _____	
		Pressure gradient: Cubicle shall be Positive/Negative with respect to adjacent area.		
2.5	Air flow pattern (For one day at Rest condition)	The Smoke should be diffused uniformly through the supply location and pass through the return location. There should not be any dead pocket and the air flow should be unidirectional. Smoke should pass from area under positive pressure to area under negative pressure.		



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3.0 Electrical:

S.No.	Description	Acceptance Criteria	Observations	Checked by Sign/ Date
3.1	Electrical Points.	Shall be operational		
3.2	UPS supply	Shall be operational		
3.3	AHU	Shall be operational		
		Indication and alarm Shall be operational.		

4.0 Safety:

S.No.	Description	Acceptance Criteria	Observations	Checked by Sign/ Date
4.1	Smoke detector	Shall be operational.		
4.2	AHU Annunciation system	Shall be operational.		
4.3	Earthing for equipment	Shall be provided.		

5.0 Abbreviations:

SOP= Standard operating procedure

Avg.= Average

%= Percentage

UPS= Uninterrupted power supply

ISO= International standards organization

No.= Number

Nos.= Numbers

Min= Minimum

AHU= Air handling unit

Sr.= Serial Number

°C= Degree Celsius

Max= Maximum

OOS= Out of Specification



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Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:

6.0 Deviations/Incident/Changes/OOS (if any):

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7.0 Recommendations/Conclusion:

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8.0 Post Approval:

Checked by: User Department	Checked by: Engineering	Checked by: Health, Safety and Environment	Reviewed by: Quality Assurance	Approved by: QA Head
Date:	Date:	Date:	Date:	Date: