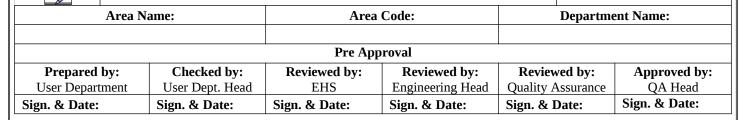
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Reference Protocol No.:

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1.0 General Room Conditions:

Sr. No.	Description	Acceptance Criteria	Observations	Checked by Sign/ Date
1.1	Cleanliness: Clean the area as per SOP.	Area shall be visually clean.		

2.0 Tests to be carried out: To be checked over a period of 24 hours for 3 consecutive days at operating condition.

Sr. No.	Name of test	Acceptance Criteria	Observations	Checked by Sign/ Date
2.1	Air changes per hour (ACPH)	Should not be less than nos. per hour.	Day 1: Day 2: Day 3:	
2.2	Particulate matter count (Carry out the test for three consecutive working days at operation condition of area)	Should meet the requirement of ISO class 	Day 1: Day 2: Day 3:	
2.3	Temperature Mapping Study in the area. (Carry out the study for three consecutive working days at operation condition of area as per SOP No. IA/QAD-89)	Limit: to ⁰ C	Day 1 to 3: Min: ⁰ C Max: ⁰ C Hottest Point: Coldest Point: Fluctuating Point:	
2.4	Relative Humidity Mapping Study in the area. (Carry out the study for three consecutive working days at operation condition of	Limit: to %	Day 1 to 3: Min.: % Max.: %	

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Department Name:

Annexure No.:

Area Name:

Area Code:

Pre Approval

i i e Appiovai						
Prepared by:	Checked by:	Reviewed by:	Reviewed by:	Reviewed by:	Approved by:	
User Department	User Dept. Head	EHS	Engineering Head	Quality Assurance	QA Head	
Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:	

Sr. No.	Name of test	Acceptance Criteria	Observations	Checked by Sign/ Date
	area as per SOP No. IA/QAD-89)			
2.5	Pressure difference in the area with respect to adjacent area. (Record the observation every 2 hours for three consecutive working days at operation condition of area)	Limit: to Pascal	Day 1: Day 2: Day 3:	
2.6	Air flow pattern	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.	Day 1: Day 2: Day 3:	



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Annexure No.: Reference Protocol No.:

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Area N	ame:	Area Code:		Department Name:	
Pre Approval					
Prepared by:	Checked by:	Reviewed by:	Reviewed by:	Reviewed by:	Approved by:
User Department	User Dept. Head	EHS	Engineering Head	Quality Assurance	QA Head
Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:

3.0 Environmental Microbiological count: To be checked over a period of 3 consecutive days by Settle plate and air sampling method.

Sr. No.	Name of test	Acceptance Criteria	Observations	Checked by Sign/ Date
3.1	Microbial count:		Day 1:	
	(By Settle Plate Method for three	Total viable count: NMT cfu/Plate	Day 2:	
	consecutive working days at operation condition of area)		Day 3:	
			Day 1:	
		Fungal count: NMT cfu/Plate	Day 2:	
			Day 3:	
3.2	Microbial count:		Day 1:	
	(By Air Sampling Method for three	Total viable count: NMT cfu/m ³	Day 2:	
	consecutive working days at operation condition of area)		Day 3:	
	,		Day 1:	
		Fungal count: NMT cfu/m ³	Day 2:	
			Day 3:	

4.0 Abbreviations:

SOP= Standard operating procedureNo.= NumberSr.= Serial NumberQA= Quality AssuranceNos.= Numbers°C= Degree Celsius%= PercentageCFU= Colony Forming unitOOS= Out of SpecificationM³= Meter cubeISO= International standards organization



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Reference Protocol No.:

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Annexure No.:

Area N	ame:	Area Code:		Department Name:	
Prepared by:	Checked by:	Reviewed by:	Reviewed by:	Reviewed by:	Approved by:
User Department	User Dept. Head	EHS	Engineering Head	Quality Assurance	QA Head
Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:	Sign. & Date:

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

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6.0 Recommendations/ Conclusion:

7.0 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: