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

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.: _____ %	

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:**	**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: _____	

Format No.

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:**	**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:** (**By Settle Plate Method** for three consecutive working days at operation condition of area)	Total viable count: NMT _____ cfu/Plate	Day 1: _____ Day 2: _____ Day 3: _____	
		Fungal count: NMT _____ cfu/Plate	Day 1: _____ Day 2: _____ Day 3: _____	
3.2	**Microbial count:** (**By Air Sampling Method** for three consecutive working days at operation condition of area)	Total viable count: NMT _____ cfu/m^3	Day 1: _____ Day 2: _____ Day 3: _____	
		Fungal count: NMT _____ cfu/m^3	Day 1: _____ Day 2: _____ Day 3: _____	

4.0   Abbreviations:

SOP= Standard operating procedure   No.= Number   Sr.= Serial Number
QA= Quality Assurance   Nos.= Numbers   ºC= Degree Celsius
%= Percentage   CFU= Colony Forming unit   OOS= Out of Specification
M^3= Meter cube   ISO= International standards organization

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

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

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6.0   Recommendations/ Conclusion:

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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:**