PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	**SOP No.:**
Title: Area Recovery Test	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 PURPOSE

1.1 To define a procedure for the Area Recovery Test.

2.0 SCOPE

2.1 This SOP is applicable for the Area Recovery Test.

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 ISO 14644 - 1, ISO 14644 - 2 and ISO 14644 - 3.

3.1.2 HAS (Health Sciences Authority) 2013.

3.1.3 EU GMP Annex 1.

3.1.4 WHO technical report series no. 961, 2011 Annex 5.

3.1.5 WHO technical report series no. 961, 2011 Annex 6.

3.2 Attachments

3.2.1 Nil.

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 **Clean area / Clean room**: An area or Room or Zone with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.

4.1.2 **Acceptance criteria**: Measurable terms under which a test results will be considered acceptable.

4.2 Abbreviations

4.2.1 CC : Change Control.

4.2.2 QA : Quality Assurance.

4.2.3 SOP : Standard Operating Procedure.

4.2.4 Sl. No. : Serial No.

4.2.5 UDAF : Unidirectional Airflow.

4.2.6 ISO : International organization for standardization.

4.2.7 AHU : Air Handling Unit.

4.2.8 WHO : World Health Organization.

4.2.9 HVAC : Heating Ventilation and Air Conditioning.

5.0 RESPONSIBILITY:

5.1 Engineering Person:

5.1.1 To inform quality assurance and concerned department.

5.1.2 To follow the procedure defined in the SOP for the Area Recovery Test.

5.2 Engineering Head:

5.2.1 To ensure that the Area Recovery Test is done according to the procedure defined in the SOP.

5.3 Quality Assurance Head:

5.3.1 To ensure implementation of the defined procedure.

5.4 Plant Head:

5.4.1 To ensure implementation of the defined procedure.

6.0 Distribution:

I. Quality Assurance

II. Engineering

7.0 PROCEDURE:

7.1 This test is applicable for only non-unidirectional air flow systems.

7.2 Ensure that HVAC / UDAF / Clean air cabinet are operational and catering area is clean.

7.3 Ensure that particle counter is calibrated and certificate is available.

7.4 Ensure that non-viable particle counts are measured.

7.5 Identify the location in a room / UDAF / Clean room cabinet where maximum count has been observed.

7.6 Set the particle counter at a sampling rate of 1 CFM with delay time (time between two sampling intervals) of not more than 10seconds.

7.7 Take the particle count at the identified location in clean room condition.

7.8 Contaminate the monitoring area by using aerosol generator by 100 or more times more than the cleanliness class/ target cleanliness level. Generally clean up time for ISO - 8 area is not recommended as practically is not possible to measure the contamination level more than 100time from the target cleanliness level by DPC.

But cleanup time for ISO - 8 area shall be stabilized by contaminating the maximum possible level of contaminated particles (may be 10times more than the cleanliness class).

7.9 Continue the particle counting.

7.10 Stop the particle contamination when desired contamination level is reached. Note the time (Tl).

7.11 Continue the particle counting.

7.12 Note the time (T2) when particle count reduces up to the initial cleanliness class level.

7.13 Calculate the cleanup time by deducting T2 – Tl.

Note: Recovery time shall be measured at two locations (i.e. location where maximum count observed and also second highest count observed location) as and when agreed upon by the third party and the Client.

7.14 Acceptance Criteria:

Note:

In case of tests not meeting the acceptance criteria's following actions shall be taken:

Stop further testing activities.

Immediately inform the client representative.

Re-start the testing activities after corrective actions taken by the client as per client's quality management system and get clearance.

7.14 REQUALIFICATION / REVALIDATION PERFORMANCE VERIFICATION

Grade/ Class of Area	**Frequency**	
	Re-Validation	**Scheduled**
A / ISO 5	In case any major modification in the clean room or HVAC Design.	Once in every two years
B / ISO 6		
C / ISO 7		
D / ISO 8		

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8.0 REVISION HISTORY

Version No.		Effective Date	
Details of revision: New SOP Prepared			