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# Performance Qualification Of Reverse Laminar Air Flow System

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**Abstract-**
This document provides guidance for performance qualification of a RLAF. These article will be help full to person who engaged in dispensing of material specially where the quality, quantity, safety, efficacy & purity is big concern. It outlines objectives, responsibilities & requirements for qualifying the RLAF to ensure it performs reproducibly within specifications. Key areas covered include performance qualification procedures, acceptance criteria, documentation requirements, does & don'ts with respect to RLAF. Based on the objective, the aims of study were decide as "PQ of RLAF system". Due to its efficacy removal of 99.97% of airborne particles as small as 0.3 micron,8 this equipment is widely used in life science research, mushroom cultivation, microbiology, IVF, IUI and histopathology / pathology lab, plant tissue and cell culture and pharmaceutical and electronics industry and many more. Considering its susceptibility of operation here we also focused its cleaning procedure with safety precaution. In this article annexure for recording of qualification test reading also provided.

**Keywords-**
RLAF, Dispensing Booth, airborne particles

**Introduction-**
RLAF is a purifying device that's also known as a sampling or dispensing booth. It's used in sterile manufacturing areas to protect products and operators from airborne contaminants. RLAF works by circulating air in a downward motion, which contains and directs contaminants away from critical areas. (RLAF), also known as Sampling Booth OR Dispensing Booth is designed for providing highest level of protection from airborne contaminants generated during powder handling operations such as sampling, charging & dispensing. RLAF ( Sampling Booth OR Dispensing Booth ) provides Operator Protection, Product Protection, and Environment Protection.

The main principle behind reverse laminar airflow is negative pressure inside the booth. This pressure prevents the escape of fine powder from the work area to the external environment. The downward-flowing direction of the air is very beneficial as it provides full protection to the operator & the product. Due to its efficacy removal of 99.97% of airborne particles as small as 0.3 micron,8 this equipment is widely used where quality & quantity is big concern.

Reverse Laminar Air Flow System

Reverse laminar air flow workstations (Sampling Booth OR Dispensing Booth ) are suitable for sampling / dispensing of powder and chemicals

and to minimize the risk of contaminating the work zone and ensure health safety for person working with chemicals/powder. Reverse Laminar Air Flow (RLAF) is a type of air filtration system that's important in many industries, including pharmaceuticals, biotechnology, and laboratories. It's used to create a clean and contamination-free environment by directing filtered air from the ceiling downward in a controlled manner.

**Method of PQ Qualification-**

**First arranged Pre-requisites for performance qualification are**:

- Inform the concerned department in advance.
- Respective equipment is properly cleaned.
- The pre-filter of RLAF unit are cleaned and Magnehelic gauges are calibrated.
- The instruments for performance qualification are in calibration state and Calibration certificates with traceability to national or international standards are available.

**Filter Integrity test:**

- Filter leakage test is performed to confirm that the filter system is properly installed and that leaks have not developed during use.
- The test shall be performed by introducing the aerosol challenge upstream of the filters and scanning immediately downstream of the filters and support frame.
- The test shall be done at rest occupancy states.
- Specifications of aerosol photometer: Poly Alpha Olefin (PAO). The concentration of the aerosol shall be 20 - 80 mg/m3. The mass median particle diameter of the aerosol particles shall be between 0.5 to 0.7 μm. The instrument used shall be linear aerosol photometer.
- Average reading value for the aerosol shall be provided.
- The aerosol concentration measurement shall be taken immediately upstream of the filters and it should not be more than ±15% than the average measured value.
- Probe shall be adequate size.
- Probe shall be held in a distance of approximately 3 cm from the downstream filter face or the frame structure.
- Scanning shall be performed over the entire downstream face of each filter, the perimeter of each filter, the seal between the filter frame and the grid structure.
- Measurement of the aerosol upstream of the filters shall be repeated at reasonable time intervals between and after scanning leaks, to confirm the stability of the challenge aerosol concentration
- Acceptance criteria: Leaks are considered to have occurred if the reading is greater han 0.01 % of the upstream challenge aerosol concentration.

**Air Velocity Test:**

- The purpose of this test is to measure air flow velocity and uniformity and supply air flow ate in the GMP areas.
- The supply air flow rate shall be measured downstream of final filters.
- The uniformity of velocity shall be measured at approximately 150 mm to 300mm from he filter face.
- The air flow velocity shall be measured with the help of vane type anemometer.
- The measuring time at each position should be sufficient to ensure a repeatable reading.
- Calculation of air flow supply: Air velocity at each filter = S Air velocity at different locations of filter / Number of locations per filter
- Measure the Air velocity at 5 different locations preferably at 4 corners and at the centre of Measure the Air velocity at 5 different locations preferably at 4 corners and at the filter.
- Acceptance Criteria: 90 ± 20 feet per minute.

**HEPA filter pressure difference test**:

- The purpose of this test is to verify the capability of complete installation to maintain specific pressure differentials across HEPA.
- Check and record the pressure difference across HEPA
- Acceptance criteria: - Between 8 mm - 15 mm of WG

**Air borne particulate count**:

- Air borne particle counting is done to measure the airborne particle count concentrations of size 0.5 mm and 5 mm.
- Check that following tests are passing

before starting airborne particle count: Airflow velocity, Installed filter leakage test, HEPA filter pressure difference test

- Particle count shall be checked at 3 locations per filter for RLAF and LAF and 1 location per filter for Dynamic Pass Box at the height of the work activity. The particle counter shall be set to provided print with Instrument details, Date and time, Measurement of particle count ranging from 0.3 µm to 25.0 µm.
- 3 consecutive readings for 1 minutes shall be taken and3 consecutive readings tor 1 minutes shall be taken and Average at each location
- Acceptance criteria: (At rest)

| **ISO classification number** | **Maximum concentration** | **(Particles/m 3)** |
|---|---|---|
| | 0.5 mm | 5.0 mm |
| ISO-class 5 | 3.520 | 29 |

**Recovery Test:**

- Recovery test is done to find out recovery time of the LAF, RLAF after stoppage or break down.
- Particle size used in this test shall be same as that used for the determination of cleanliness class.
- Sampling Location of the room showing maximum count shall be selected for monitoring the recovery time.
- A duplicate reading shall be taken at this location while the equipment is in ON condition.
- The counter is maintained in running mode. The equipment is then put off.
- The Particle count for each minute is taken until the clean room condition is disturbed i.e. the particle count exceeds clean room specification limits.
- The time period required to disturbed the cleanliness condition is noted. (This is HOLD Time).
- The Equipment is restarted: the particle count is taken every minute from the start.
- The time noted at which the particulate count regains the clean room specification.

**Air Visualization pattern (air flow pattern test):**

- This test shall be done to demonstrate Laminar pattern of the air supplied. A recorded flow pattern shall be maintained as CD.
- Noise and illumination Test: This test shall be done to demonstrate Noise level and light illumination of the equipment.
- Noise level shall be checked by using sound level meter. Check calibration status of the instrument before use. Noise level should not be more than 85 dB.
- Light illumination shall be checked by using lux meter. Check calibration status of the instrument before use. Lux level should not be less than 150 lux.
- After completion of the activity, raw data shall be evaluated by engineering and QA person. If the results are found to be within the specified limits, affix qualification status labels.

Observation of the entire performance qualification test should be recorded in respective annexure. Format for annexure are also covered in these article.

**Annexure format for performance qualification are guided as below.**

**(1)Annexure-I (air flow test)**

| **Filter no.** | **Location** | | | | | **Average Velocity ft/min** |
|---|---|---|---|---|---|---|
| | **1** | **2** | **3** | **4** | **5** | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**(2)Annexure-II (Filter leakage test)**

| **Filter no.** | **Observed Reading (% of the upstream challenge aerosol concentration)** | **Observed Reading (% of the upstream challenge aerosol concentration)** |
|---|---|---|
| | | |
| | | |
| | | |

**(3)Annexure-III (Non-viable particle count)**

| Filter no. | Location no. | ISO classification no. | Reading | Max. Concentration limit (particles /$m^3$) | |
|---|---|---|---|---|---|
| | | | | 0.5µm | 5.0 µm |
| | | | | | |
| | | | | | |
| | | | | | |
| | Average concentration | | Particle | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Average concentration | | Particle | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Average concentration | | Particle | | |
| Overall mean average | | | | | |

**(4) Annexure-IV Recovery test(For Airborne Particle Count Recovery Test)**

| Equipment | Equipment Status | Count time | Count cycle | Max. Concentration limit (particles /$m^3$) | |
|---|---|---|---|---|---|
| | | | | 0.5 µm | 5.0 µm |
| | | | | | |
| | | | | | |

**(5) annexure-V (Pressure differential, noise and Illumination test)**

**Pressure differential test:**

| | |
|---|---|
| Magnehelic gauge No- | |
| Air Pressure difference Across HEPA | |
| Acceptance criteria: | 8 to 15 mmwc |

**Noise test:**

| | |
|---|---|
| Sound Level Meter No. | |
| Noise level observed | |
| Acceptance criteria | NMT 80 dB |

**Illumination Test:**

| | |
|---|---|
| Lux meter No. | |
| Illumination Intensity | |
| Acceptance criteria | Illumination Intensity |

For better practice SOP of cleaning & operation must be available. Guidance for cleaning & operation of RLAF provided as below.

## SOP FOR CLEANING AND OPERATION OF RLAF

### 1.0 OBJECTIVE:

To lay down the procedure for cleaning and operation of RLAF unit in Sampling Room at Raw Material Store.

### 2.0 SCOPE:

This SOP shall be applicable for operation and cleaning of RLAF unit in Sampling Room at Stores Department.

### 3.0 RESPONSIBILITY:

Stores Assistant/QC Pharmacist

### 4.0 ACCOUNTABILITY:

Head of department

### 5.0 PROCEDURE:

**5.1 CLEANING AT THE BEGINNING OF THE SHIFT**:

5.1.1 Store person shall ensure that the RLAF power supply is switched off before starting cleaning activity.

5.1.2 Clean the external surface of the RLAF with a vacuum cleaner.

5.1.3 Mop the external surfaces with a clean dry lint-free cloth damped with potable water.

5.1.4 Finally wipe with a clean dry lint-free cloth dampened with 70% IPA solution and allow it to dry.

5.1.5 Affix the status label as ‘cleaned’ with duly sign it.

**5.2 CLEANING DURING ACTIVE MATERIAL SAMPLING:**

5.2.1 Switch off the RLAF and clean the outer surface of pre-filter frame and side panel with a vacuum cleaner.

5.2.2 Mop the entire surface of pre-filter frames and side panel with a clean dry lint-free cloth dampened with 70% IPA solution.

5.2.3 Ensure that surface is visually clean.
5.2.4 Af Affix the status label as 'cleaned' with duly sign it.fix the status label 'cleaned' with duly sign it.

**5.3 CLEANING DURING EXCIPIENT MATERIAL SAMPLING:**

5.3.1 Clean the area under RLAF, SS Table and Balances with clean dry lint free cloth and mopped with 70% IPA solution.

**5.4 WEEKLY CLEANING:**

5.4.1 Store person shall ensure that the RLAF power supply is switched off before starting cleaning activity.
5.4.2 Remove the pre-filter, cover it in intact polythene bags and transfer it on to washing area.
5.4.3 Clean the pre-filter as per SOP for cleaning of RLAF filters.
5.4.4 Transfer the cleaned pre-filter to respective area duly covered in clean polyethylene bags.
5.4.5 Clean the inner area of RLAF with a vacuum cleaner. Wipe with a clean dry lint-free cloth.
5.4.6 Refix the clean pre-filter by screwing the fixtures. 5.4.7 Clean the RLAF as per the procedure described under point number 5.1.1 to 5.1.4 5.4.8 Record the cleaning activity.

**5.5 OPERATION OF RLAF:**

5.5.1 QC person shall check and ensure the 'Zero' reading in all three magnehelic gauges of RLAF unit when the RLAF unit is switched off.
5.5.2 Check for the "CLEANED" status label.
5.5.3 Switch on the Blower.
5.5.4 Switch on the light.
5.5.5 Allow the RLAF to run for at least 15 minutes before the start of observation & recording.

PRESSURE DROP ACROSS FINAL ( HEPA) FILTER Limit: 8 mm – 16 mm Observe the reading and record the pressure on HEPA filter. In case reading is out of limit, Stop the operation & intimate Head-Store and Maintenance for rectification.

PRESSURE DROP ACROSS INTERMEDIATE FILTER Limit: 3 mm – 6 mm Observe the reading and record. In case reading is out of limit, clean /replace the intermediate filter.

PRESSURE DROP ACROSS PREFILTER FILTER Limit: 1 mm – 6 mm Observe the reading and record. In case reading is out of limit, clean /replace the pre-filter.

5.5.6 On completion of the operation, allow RLAF to run for 15 minutes. Then switch off the light and Blower.
5.5.7 Affix status label "TO BE CLEANED"

**5.6 FREQUENCIES**:

Pressure differential - Daily (In-house) Air velocity - Twice in a year.(Outside Agency)
DOP test - Twice in a year. (Outside Agency)
Particle count - Twice in a year. (Outside Agency)
Viable microbial test - Twice in month. (In-house)

**Result & discussion:**

Article covered Principle, working process, cleaning and performance qualification guidance with respect to RLAF system. SOP and supporting annexure are also provided to record the observation for performance qualification of equipment.

**Conclusion:**

RLAF systems are also known as dispensing or sampling booths and are often used by pharmaceutical manufacturers, chemical manufacturers, and bulk drug manufacturers. They work by creating a controlled airflow pattern using a HEPA filter to draw away airborne contaminants. Reverse Laminar Air Flow (RLAF) is a contamination control system that's important because it protects personnel and products, and prevents cross-contamination. Since weighing activity impact on quality & quantity of material, every person who engaged in dispensing activity, must be known about qualification of RLAF system.

**Reference**:

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