PERFORMANCE QUALIFICATION OF DISPENSING/ SAMPLING BOOTH (RLAF)

PHARMAGUIDEHUB

Location

REPORT CONTENTS

1.0 Protocol Approval

This is a specific Protocol for Performance Qualification of Dispensing/Sampling Booth which is installed in the Warehouse.

This report has been approved by the following:

	Name	Department	Signature	Date
Prepared By				
Checked By				
Approved By				

Final Approval

Final approval has been given by the following:

	Name	Signature	Date
Approved By (Plant Head)			
Approved By (Head – QA)			

2.0 Overview

2.1 Objective:

To establish the Methodology for the performance qualification of Dispensing/Sampling Booth this is installed in the Warehouse.

2.2 Purpose and Scope

The purpose is to provide an outline for the performance qualification of equipment for its intended use:

- Demonstrate that the RLAF of Dispensing/Sampling Booth shall perform reproducibly and consistently within its full dynamic range of operation according to pre-laid specifications.
- The RLAF unit of Dispensing/Sampling Booth shall be able to perform in worst cases.
- Assure that the RLAF unit performance of Dispensing/Sampling Booth shall be adequate to support the process for which the system is intended.
- Ensure that the unit shall be included in preventive maintenance program.

The **scope** of this qualification exercise is limited to the performance qualification of RLAF unit. The protocol is applicable to RLAF unit, Equipment Code no.XXXXXXXX.

2.3 Responsibility

- **Protocol / Report Preparation:** Production Executive / Manager, QA Executive / Manager and Service Engineer.
- **Approval of Protocol / Report:** QA Manager
- **Execution of Qualification Activity:** Production Executive / Manager, Service Engineer

2.4 Qualification Team:

- User Department Executive / Manager
- Project Executive / Manager

- Validation Manager
- Quality Assurance Manager

3.0 Training Record

3.1 Purpose

The purpose of the training was to familiarize the trainees with the Performance Qualification, Performance Qualification procedure, Documentation Procedure and Overall Strategy of Performance Qualification.

3.2 Scope

This Training is applicable to the RLAF unit of Dispensing/Sampling Booth installed in Warehouse.

3.3 Topics

The following topics were covered during training:

- Performance Qualification Procedure.
- Documentation Practices for filling of report.
- Overall strategy of Qualification process.
- General precautions / guidelines to be followed during qualification.
- List of SOP's used for training

S.No.	SOP's No.	Title
01	XXXXXXX	SOP on operating procedure for Dispensing/Sampling Booth
02	XXXXXXX	SOP on cleaning procedure for Dispensing and Sampling Booth
03	XXXXXXX	SOP for Preventive Maintenance of Dispensing/Sampling Booth

- Attach training record with the report as Annexure - 01

4.0 Pre – Performance Qualification Requirements

Following instruments shall be required for the Performance Qualification of RLAF unit of Dispensing/Sampling Booth installed in warehouse.

S. No.	Equipment Name	Equipment Code / S. No.	Calibration Certificate No.	Calibration Due On
1.	Aerosol DOP Generator			
2.	Aerosol DOP detector			
3.	Anemometer			
4.	Titanium Tetrachloride (Smoke Test)			
5.	Particle Counter			
6.	Camera			
7.	Stop Watch			

5.0 System / Equipment Description

5.1 System / Equipment details

The RLAF shall be used for the Dispensing/Sampling of raw material & excipients for attaining a dust free & bacteria free workstation

Description

- Equipment Tag Number : XXXXXXXXXXXXXX
- Location : Warehouse
- Block : XXXXXXXXXXX
- Room No : XXXXXXXX
- Name of the system : RLAF
- Manufacturer's Name / Address: XXXXXXXXXXXX
- Model : XXXXXXXXXXXXXX
- Dimensions : Overall Diamentation

  Height: XXXXX

  Width: XXXXXXX

  Length: XXXXXXXX

- Purchase Order Number : XXXXXXXXXXX, Dated: XXXXXXXX
- Date of Installation : XXXXXXXXXX

5.2 Generic Design

5.2.1 Working Principle

The sampling Booth is designed in accordance with cGMP principles. Sampling Booth shall be used for Dispensing/sampling of raw materials. It shall be Reverse laminar airflow type.

Brief Machine Description

The RLAF comprises of following parts:

- Main body structure
- Supply Filters
  a. Pre-filter (EU-5)
  b. Intermediate filter (EU-7)
  c. HEPA filter (EU-12)
- Motor blower
- Side panels
- Exhaust filter (EU-12)

Magnahelic gauges measures pressure differentials across all filters.

1. Main Body Structure:

Main body structure of RLAF of Dispensing/Sampling Booth provides a platform for fixing the supply filters, motor blower, side panels, magnahelic gauges & exhaust filter. Main body structure is fabricated using SS 304.

2. Supply Filters:

The function of supply filters is to supply dust free & bacteria free air. Supply filters consists, pre-filter of 10 micron rating with efficiency of 90% down to 10 microns (EU5 grade); intermediate filter of (3 micron rating) with efficiency 97% down to 3 microns (EU7 grade, microvee filter) and final HEPA filter of 0.3 micron rating with efficiency of 99.997% down to 0.3 micron.

3. Motor Blower:

The motor blower is situated inside the main body structure. Motor blower is fabricated by using MS powder coated.

4. Side Panels

Side panels are provided to give the support to the main body structure. Side panels are fabricated by using SS304.

5. Exhaust Filter

Exhaust filter consists of Minipleat HEPA filter of 0.3 micron rating with efficiency of 99.997% down to 0.3 micron.

6. Finishing:

Outside surface of RLAF of Dispensing/Sampling Booth is matt finish.

5.3 Safety Features Description:

1. Noise Level:

The noise level should not more than 50db of blower motor.

2. Safety Guards:

The safety guards are provided for all moving parts.

3. Earthing Connections:

The Earthing connections are installed to reduce risk of any accident by overloading, voltage variation or any other electrical fault. MCB should be provided.

4. Indicators Switches for Fluorescent lights

The Indicators should be provided for Fluorescent lights.

5.4 Testing Procedures

The following tests were done to evaluate the performance of RALF of Dispensing/Sampling Booth:

Air velocity Test

Measure the air velocity at five points (four at corners and one at the middle) 6 inches below the surface of the filter / diffuser using calibrated anemometer. Calculate average of the five reading of the filter.

1. CFM of the filter

Calculate air quantity of filter in CFM with the help following formula.

CFM = Average velocity of the air x Effective surface area of the filter

2. Air Laminarity Test

Smoke test was performed to check laminarity of air coming through HEPA Filter. Swab stick shall be dipped in titanium tetrachloride and shall be placed 6.0" below the HEPA filter. The air shall move in linear pattern. The path of air movement shall be monitored & safe zone shall be marked on the basis of movement shown by smoke test study.

3. Differential Pressure between the filters

Differential Pressure between the filters was monitored every 10 minutes for half hour on megnehelic gauges of all three filters.

4. Air Particle Count

The particle count of Sampling Booth was done through particle counter at 5 locations on working height.

6.0 Performance Qualification Procedure:

The following procedure shall be used for the performance qualification of the RLAF unit of Dispensing/Sampling Booth installed in Warehouse.

6.1 Ensure that OQ of system is completed and system is cleared for performance qualification.

6.2 The air velocity test and CFM calculation shall be done for each HEPA filter. The observations were recorded as per Exhibit – E01.

6.3 The differential pressures between filters shall be checked. The observations shall be recorded as per Exhibit – E02.

6.4 The smoke test shall be performed to check laminarity, air movement & safe zone determination. The observations were recorded as per Exhibit – E03.

6.5 The particle count shall be done to ensure that booth complies ISO class 5 area specifications. The observations were recorded as per Exhibit – E04.

The reports generated were attached in Annexure – 02.

6.6 The preventive maintenance list of the maintenance department shall be updated. The observations were recorded as per Exhibit – E05.

6.7 No Deviation was observed.

7.0 Acceptance Criteria

Performance qualification shall be considered acceptable when requirements listed in section 6.0 of this protocol have been fulfilled and are as per the design specifications of the system.

8.0 Summary and Conclusion

The Dispensing/Sampling Booth bearing Tag No: XXXXXXXXXXX have undergone the following below mentioned testing parameter as per Protocol No: XXXXXXXXXX

Observations pertaining to the parameter were listed in **Exhibit: 01 to Exhibit: 04**

S.No.	Testing Parameter	Observation
01	Air Velocity & DOP	Complies
02	Air Laminarity	Complies
03	Differential Pressure between the filters	Complies
04	Air particle count	Complies

On the basis of above observation it is concluded that the Equipment is meeting the acceptable criteria. Hence is qualified.

9.0 Approval of Qualification Report

The report shall be evaluated and proper references / conclusions / recommendations shall be recorded by Quality Assurance.

The installation qualification report shall be evaluated and finally approved by quality assurance.

10.0 Observed Deviation

Sr. No.	Page No.	Point No.	Observed Deviation	Deviation Reported By	Deviation Approved By	Corrective Action Taken	Justification of Corrective Action	Corrective action taken and justification given by	
Report Approved By									
Department Head						**Quality Head**			

11.0 List of Exhibits / Annexure

11.1 List of Exhibits

Exhibit No.	Exhibit Title	No. of Pages
E01	Air Velocity Test, CFM Calculation and DOP Testing Verification Checklist	01
E02	Differential Pressure Monitoring Data Sheet	01
E03	Smoke Test & Safe Zone Marking Verification Checklist	01
E04	Particle Count Verification Checklist	01
E05	Preventive Maintenance List Up-dating Verification Checklist	01
Total No. of Pages		05

11.2 List of Annexure

Annexure No.	Annexure Title	No. of Pages
01	Training Record	01
02	Particle Counting Reports	01
Total No. of Pages		02

DOCUMENT No.	PERFORMANCE QUALIFICATION OF DISPENSING / SAMPLING BOOTH (RLAF)	EFFECTIVE DATE
XXXXXXXXX		

Exhibit – E01

Air Velocity Test, CFM Calculation and DOP Testing Verification Checklist

Equipment Name / Description:

Tag no.: XXXXXXX

Location: Warehouse

Date:

S. No.	Filter No.	Filter Area	Air Velocity	Avg. Air Velocity		Rated CFM	Actual CFM	DOP Testing
				Limit	Actual			

Remarks:

Checked By:_____ _____ _____
(Name) (Sign) (Date)

Verified By:_____ _____ _____

(Name) (Sign) (Date)

Title: Report for Performance Qualification of sampling Booth

Report No.: XXXXX	Protocol No.: XXXXXXXX

Exhibit – E02

Differential Pressure Monitoring Data Sheet

Equipment Name / Description:

Tag no.: XXXXXXX

Location: Warehouse

S. No.	**Date:**						
	Start Time:			**End Time:**			
		Pre-filter		**Intermediate Filter**		**HEPA Filter**	
		Limit	**Actual**	**Limit**	**Actual**	**Limit**	**Actual**
	Magnehelic Gauge No. (➔)						
	Time (Mins.) (🡻)						
1.	0						
2.	10						
3.	20						
4.	30						

Remarks:

Checked By:_____ _____ _____
(Name) (Sign) (Date)

Verified By:_____ _____ _____
(Name) (Sign) (Date)

Exhibit – E03

Smoke Test & Safe Zone Marking Verification Checklist

Equipment Name / Description:

Tag no.: XXXXXXX

Location: Warehouse

S. No.	Filter No.	Nature of Flow	Movement of Smoke		Safe Zone Marking Done	Marking Done By
			From	To		
1.						
2.						
3.						
4.						
5.						

Remarks:

Checked By:_____ _____ _____
(Name) (Sign) (Date)

Verified By:_____ _____ _____
(Name) (Sign) (Date)

Exhibit – E04

Particle Count Verification Checklist

Equipment Name / Description:

Tag no.: XXXXXXX

Location: Warehouse

S. No.	Specification	Observations
1.	Ensure that particle count of area shall be performed as per SOP Title: - _____ & equipment shall complies to the ISO Class 5 grade	
2.	Reports shall be attached with the qualification report	

Remarks:

Checked By:_____ _____ _____
(Name) (Sign) (Date)

Verified By:_____ _____ _____
(Name) (Sign) (Date)

Exhibit – E 05

Preventive Maintenance List Up-dating Verification Checklist

Equipment Name / Description:

Tag no.: XXXXXXX

Location: Warehouse

Preventive Maintenance Program no.	Frequency of Preventive Maintenance	Due Date	Entry Done by

Remarks:

Checked By:_____ _____ _____
(Name) (Sign) (Date)

Verified By:_____ _____ _____
(Name) (Sign) (Date)

Annexure – 01

Training Record

Equipment Name:	Dispensing/Sampling Booth
Equipment Tag No.:	XXXXX
Location:	Warehouse
No. of Pages:	

Annexure – 02

Particle Counting Reports

Equipment Name:	Dispensing/Sampling Booth
Equipment Tag No.:	XXXXXXX
Location:	Warehouse
No. of Pages:	

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