PERFORMANCE QUALIFICATION PROTOCOL FOR ONLINE AIRBORNE PARTICLE COUNTER

EQUIPMENT ID No.	
LOCATION	**FILLING ROOM**
DATE OF QUALIFICATION	
SUPERSEDED PROTOCOL	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR ONLINE AIRBORNE PARTICLE COUNTER	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR ONLINE AIRBORNE PARTICLE COUNTER	PROTOCOL No.:

1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

The objective of this protocol is to establish that Online Particle Counter unit meets the following criteria:

A) The Online Particle Counter unit is performed as per the pre-defined parameter and/ or quality attributes.

B) The Online Particle Counter unit is capable for monitoring of Non-Viable Particle Counts in Grade A (Under LAF) of Filling Room.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the Online Particle Counter Unit installed in Grade A (Under LAF) of Filling Room.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following Departments, shall be responsible for overall compliance of this Protocol:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Approval and Compilation of the Performance Qualification Protocol. • Protocol Training. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Performance Qualification Protocol. • To co-ordinate and support Performance qualification Activity.
Engineering	• Review of Performance Qualification Protocol. • To co-ordinate and support Qualification Activity. • Responsible for Trouble shooting during execution (If Occurs).

5.0 EQUIPMENT DETAILS:

Equipment Name	**Online Particle Counter**
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Place of Installation	**Grade A of Filling Room**

6.0 SYSTEM DESCRIPTION:

The Climet Model CI-3100 is a microprocessor based remote two channel Airborne Particle Sensor. It can be configured as a 3 or 4 wire transducer and meets the requirements of the instrument society of America Standard S50.1 "Compatibility of Analog Signals for Electronic Industrial Process Instrument". It is designed for use in a cleanroom facility monitoring system, or other process environments where particle contamination is controlled or monitored.

There are five visual indicators on the front of the unit: Power, Alarm, Count, Laser Status and Flow Status.

The CI-3100 provides an open collector alarm signal which may be used as a high alarm from seven different internal alarm setting.

The 4-20mA analog signal outputs from this unit represent the two particle size channels. The full-scale values of these outputs range from 16 particles to 1,600,000 particles for the counts per minutes scales and 10 particles for the counts per second scales.

A 7-pin connector exist on the rear of the unit for access to the outputs, open collector alarm signal, and power connections (if required).

The CI-3100 is available in two power configuration, remote DC power, or an AC powered, both units come with an internal pump.

The CI-3100 sizes particles greater than 0.5µm and 5.0µm or 0.3 µm and 5.0 µm. standard flow rate for this unit is 1.0 cubic foot per minute or 0.1 cubic foot per minute depending on the model number of the unit. The concentration limit of this unit is 1 million particles per cubic foot for a 1.0 CFM sensor and 10 million particles per cubic foot for a 0.1 CFM sensor.

7.0 REASON FOR QUALIFICATION:

- Installation of New System. □
- Any major modification in the existing system. □
- Change of Location. □
- **(Specific Reason)**

8.0 SITE OF STUDY:

Filling Room.

9.0 FREQUENCY OF REQUALIFICATION :

- Initially Once.
- After any major breakdown or after major modification.

10.0 PRE-REQUALIFICATION REQUIREMENTS :

10.1 TEST EQUIPMENT:

S.No.	Test Instrument
1.	Duly Calibrated Online Particle Counter

10.2 TRAINING OF EXECUTION TEAM:

Provide the training to a team for the execution of protocol before execution of the same. Record of training shall be recorded in Performance qualification report.

11.0 TESTS & CHECKS:

11.1 NON VIABLE PARTICLE COUNT TEST:

A) OBJECTIVE:

To establish the consistency of online particle counter in performance in dynamic condition.

B) EQUIPMENT / INSTRUMENT USED:

Online Non- Viable Particle Counter

C) METHOD APPLIED:

a) The Particle Count Test should be performed by Qualified and / or Trained Personnel only.

b) Ensure that the Isokinetic Probe is not covered by Cap provided with it.

c) The Laminar Air Flow unit of the area and AHU shall be in continuous operation for at least 20 minutes prior to performing this test.

d) Perform the test in Dynamic Condition i.e. in Dynamic condition Filling Operation shall be carried out. All personnel shall work as per routine operation in the area.

e) Particle counting shall be performed for 3 consecutive days in Dynamic Condition.

f) After Completion of three days all following reports generated shall be printed out, reviewed and attached with Performance Qualification Report.

CUBIC FEET REPORT	CUBIC METER REPORT
Raw Data Report	Raw Data Report
Combined Raw Data Report	Combined Raw Data Report
Summary Report	Summary Report
FS-209E Report	EU-GMP Report

D) ACCEPTANCE CRITERIA:

- All the reports should be generated in formats as per Operational Qualification.
- 0.5µ particle should not be more than 3500 and 5.0µ particle should not be more than 0 in $1m^3$ of air in dynamic condition.
- 0.5µ particle should not be more than 100 and 5.0µ particle should not be more than 0 in per cubic feet of air at dynamic condition.

12.0 CHECKLIST OF ALL TESTS AND CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol to be executed and consisting of following tests.

TESTS OR CHECKS
Non Viable Particle Count Test

13.0 REFERENCES:

- Master Validation Plan.
- Schedule – M "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2.Good Manufacturing Practices and Inspection.

14.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates for Online particle counter.

15.0 NON COMPLIANCE:

- All non-compliance, during the execution of protocol shall be handled as per current version of **SOP "Handling of General Non-Compliance Incidence"** and same shall be a part of Validation Report.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- All protocol deviation, non conformances and out of specification results obtained shall be investigated as per current version of **SOP "Handling of Deviation"** and same shall be a part of Validation Report.

17.0 CHANGE CONTROL, IF ANY:

- All change control, during the execution of protocol shall be handled as per current version of **SOP "Change Control"** and same shall be a part of Validation Report.

18.0 ABBREVIATIONS:

QA : Quality Assurance

No. : Number

Ltd. : Limited

ID No. : Identification Number