PERFORMANCE QUALIFICATION REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER (GRADE-A)

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SUPERSEDED PROTOCOL NO.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

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

REPORT CONTENTS

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

1.0 REPORT PRE 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:

- To compile the Validation report carried out as per Protocol for Online Airborne Particle Counter unit installed in Grade A (Under LAF) of Filling Room used to monitor Non viable Particle Counts during operation to maintain Grade 'A' under the Laminar Air Flow.

3.0 SCOPE:

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

4.0 RESPONSIBILITY:

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

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• To compile and approval of report. • To monitor all Validation Activities and ensure the Validation is carried out as per the Protocol. • To review Report for completeness and Technical Accuracy.
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Review of Performance Qualification Report. • To co-ordinate and support Validation Activity. • Responsible for Trouble shooting during execution (If Occurs).

5.0 EQUIPMENT DETAILS:

Equipment Name	**Online Particle Counter**
Equipment ID.	
Model No.	
Manufacturer's Name	
Place of Installation	**Grade A of Filling Room**

6.0 PRE-QUALIFICATION REQUIREMENTS :

6.1 SYSTEM PRE-REQUISITES:

S.No.	DOCUMENT NAME	DOCUMENT/ SOP No.	COMPLETED (YES/NO)	VERIFIED BY (SIGN & DATE) QA

6.2 TEST EQUIPMENT CALIBRATION:

S.No.	EQUIPMENT/ INSTRUMENTS NAME	CALIBRATION DONE ON	CALIBRATION DUE ON	VERIFIED BY (SIGN & DATE) QA

6.3 TRAINING OF EXECUTION TEAM:

S.No.	Name of Trainee	Department	Designation	Acceptance Criteria	Signature of Trainee	Checked By (Sign & Date) QA
1.				All personnel involved in execution of protocol should be trained in the required procedure and should be documented		
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Name of the Trainer: _____

Inference:

_____

_____

_____

_____

Reviewed By: _____
(Manager QA)
(Sign & Date)

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

7.0 TESTS AND CHECKS:

7.1 NON VIABLE PARTICLE COUNT TEST (DAY-1):

Date of Test		**Instrument ID**	
Name of Instrument used		**Block**	
Test Condition		**Area**	
Test Instrument Calibrated on		**Test Instrument Calibration due on**	
Name of Product		**Batch No.**	

OBSERVATION			
REPORT TYPE : CUBIC FEET REPORT			
Report	**Generated (Yes/No)**	**Complies / Not Complies**	**Remarks**
Raw Data Report			
Combined Raw Data Report			
Summary Report			
FS-209E Report			
REPORT TYPE : CUBIC METER REPORT			
Raw Data Report			
Combined Raw Data Report			
Summary Report			
EU-GMP Report			

NOTE: Report for Each test should be attached with report.

Compiled by:
(QA)
(Sign & Date)
Inference:

_____

_____

_____

Reviewed By:_____
(Manager QA)
(Sign & Date)

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

NON VIABLE PARTICLE COUNT TEST (DAY-2):

Date of Test		**Instrument ID**	
Name of Instrument used		**Block**	
Test Condition		**Area**	
Test Instrument Calibrated on		**Test Instrument Calibration due on**	
Name of Product		**Batch No.**	

OBSERVATION			
REPORT TYPE : CUBIC FEET REPORT			
Report	**Generated (Yes/No)**	**Complies / Not Complies**	**Remarks**
Raw Data Report			
Combined Raw Data Report			
Summary Report			
FS-209E Report			
REPORT TYPE : CUBIC METER REPORT			
Raw Data Report			
Combined Raw Data Report			
Summary Report			
EU-GMP Report			

NOTE: Report for Each test should be attached with report.

Compiled by:
(QA)
(Sign & Date)
Inference:

_____

_____

_____

Reviewed By:_____
(Manager QA)
(Sign & Date)

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

NON VIABLE PARTICLE COUNT TEST (DAY-3):

Date of Test		**Instrument ID**	
Name of Instrument used		**Block**	
Test Condition		**Area**	
Test Instrument Calibrated on		**Test Instrument Calibration due on**	
Name of Product		**Batch No.**	

OBSERVATION			
REPORT TYPE : CUBIC FEET REPORT			
Report	**Generated (Yes/No)**	**Complies / Not Complies**	**Remarks**
Raw Data Report			
Combined Raw Data Report			
Summary Report			
FS-209E Report			
REPORT TYPE : CUBIC METER REPORT			
Raw Data Report			
Combined Raw Data Report			
Summary Report			
EU-GMP Report			

NOTE: Report for Each test should be attached with this report.

Compiled by:
(QA)
(Sign & Date)
Inference:

_____

_____

_____

Reviewed By:_____
(Manager QA)
(Sign & Date)

8.0 CHECKLIST OF ALL TESTS AND CHECKS:

TESTS OR CHECKS	EXECUTED [Y/N]	Checked By (Sign & Date) QA	COMMENT
Non Viable Particle Count Test			

Compiled by:
(QA)
(Sign & Date)

Inference:

_____

_____

_____

Reviewed By:_____
(Manager QA)
(Sign & Date)

9.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates for Online Non Viable Particle Counter.
- Raw Data of Online Particle Counter

10.0 NON COMPLIANCE:

……

……

……

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

……

……

……

12.0 CHANGE CONTROL, IF ANY:

……

……

……

……

……

……

13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY) :

……

……

……

……

……

……

14.0 CONCLUSION:

……

……

……

……

……

……

15.0 RECOMMENDATION:

……

……

……

……

……

……

16.0 ABBREVIATIONS:

QA	:	Quality Assurance
QC	:	Quality Control
No.	:	Number
Ltd.	:	Limited

17.0 REPORT POST 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)			`