INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER (GRADE-A)

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SUPERSEDED PROTOCOL NO.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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER

PROTOCOL CONTENTS

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER

1.0 PROTOCOL 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)			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER

2.0 OBJECTIVE:

- To carry out the Installation Qualification of Online Airborne Particle Counter in Grade-A to monitor the Non Viable Particle Counts during filling operation.
- To confirm that the instrument and its components are as per the Specifications and Installed as per the Approved Design and complies with cGMP practices.
- To prove that each Operation proceeds as per the Design Specification and the tolerances prescribed there in the Document, are the same at utmost transparency.
- To ensure that there is sufficient information available to enable the instrument to be Operated and Maintained Safely, Effectively and Consistently.

3.0 SCOPE:

- The scope of this protocol limited to installation qualification of Online Airborne particle counter in Grade-A (Under LAF) of filling room.
- To verify the critical dimensions of the unit and record Model No. of Critical Components, such as Particle counter and associated components etc.
- To verify that the correct hardware & Software have been installed, System Initializes correctly.
- To record the as-Built Drawing numbers of Equipment Drawing and layouts.

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER

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 Protocol.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• Review of Protocol cum Report. • Execution of Installation Qualification.
Engineering	• Review of Protocol cum Report. • To co-ordinate and support Installation Qualification Activity. • Calibration of Process Instruments.

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5.0 EQUIPMENT DETAILS:

Equipment Name	**Online Particle Counter**
Equipment ID	
Manufacturer's Name	**Climet**
Supplier's Name	**Climet**
Model No.	**CI 3100**
Location of Installation	**Grade-A of Filling Room**

Checked By
(Production)
(Sign/Date)……

Verified By
(Quality Assurance)
(Sign/Date)……

Inference:……

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Reviewed By
(Manager QA)
(Sign/Date)……

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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.

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7.0 CRITICAL VARIABLE TO BE MET:

7.1 PRE-QUALIFICATION REQUIREMENTS:

Verify that the DQ of the Online Particle Counter has been executed and approved.

S.No.	DOCUMENT NAME	DOCUMENT No.	COMPLETED (YES / NO)	CHECKED BY (PRODUCTION) (SIGN/DATE)	VERIFIED BY (QA) (SIGN/DATE)
1.	DQ Protocol				

7.2 GENERAL CHECKS AND LOCATION SUITABILITY:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Mounting of Instrument	Eng. / Production / QA to Certify		
Instrument Should Be Properly Balanced & Leveled			
All The Metal Parts Should Be Properly Fitted Without Any Sharp Edges.			
Welding of Joints Without Any Welding Burrs			
Place of Installation	Grade-A (Under LAF) Filling Room		
Location of Probe of particle Counter	Grade-A as per report No. GNR/009-00		
Room Condition	Temp 25 ± 2^0C RH 55 ±5 %		
Illumination	NLT 300 Lux.		
Working space around the Instrument	Should be sufficient for easy Operation, Cleaning, Sanitation and Maintenance		

Checked By
(Production)
(Sign/Date)……

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Inference:……

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER

7.3 UTILITIES REQUIRED:

PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED By (ENGINEERING) (SIGN/DATE)
Electricity	230 VAC – 24VDC		
Light Indication for Machine Working Condition	Shall be properly connected and identified		
POWER BACKUP			
UPS	Power: 230VAC Capacity: 15 KVA		

Checked By
(Production)
(Sign/Date)……

Verified By
(Quality Assurance)
(Sign/Date)……

Inference:……

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Reviewed By
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(Sign/Date)……

7.4 DRAWING VERIFICATION:

REFERENCE ENGINEERING DRAWINGS	AVAILABLE [Y/N]	OBSERVED BY (ENGINEERING) SIGN & DATE
Drawings of Equipment		
Electrical Drawings of Equipment		

Checked By
(Production)
(Sign/Date)……

Verified By
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(Sign/Date)……

Inference:……

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Reviewed By
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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER

7.5 EQUIPMENT VERIFICATION:

7.5.1 TECHNICAL SPECIFICATIONS:

PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
PANEL CONFIGURATION			
Cabinet Dimension	22 (L) X16 (B) X13 (H) Inches		
Cable Entry	From Bottom		
Doors	1 frontal with a pad lock		
Power	UPS 230VAC		
Selector Switch	ON/OFF at front end		
SMPS	230 VAC – 24VDC		
PLC System	Delta PLC analog input and Digital		
PLC SYSTEM CONFIGURATION			
ETHERNET MODULE			
Manufacturer	Delta		
Model	DVPEN01-SL		
Type	CPU		
Power Supply	24VDC		
PROCESSOR			
Manufacturer	Delta		
Model	DVP28SV		
Type	Ethernet Module		
Power Supply	24VDC		
PARTICLE COUNTER'S SPECIFICATION			
Dimensions	6" x 4" x 11.25" (15.2 x 10.16 x 28.6 cm)		
Weight	6.2 lbs (2.81 Kg)		
Fuses	T250V 1.25 A "Slow Blow", 5x20 mm (Two)		
Operating Temperature	$0\text{-}37.8^0$ C		
Storage Temperature	$0\text{-}68.3^0$C		
Humidity	0-100 %, non condensing		
Pump	Brushless DC Blower		
Sample time	1 second or 1 minute updated once per second		
Display	LED Power, Alarm, Count, Flow Status and Laser Status		
HARDWARE			
Cabinet	Acer		
CPU	G645- 2.90GHz		
Motherboard	Intel Pentium (R)		
Hard disc	500 GB		
Read Access Memory(RAM)	2 GB		
Monitor	Make: Acer		

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PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
	Model No.: P166HQL Type: LCD Screen size: 15 inches		
Keyboard	Acer		
Mouse	Acer		
Printer	Make: Canon Model No.: LBP2900		
SYSTEM SOFTWARE			
Software for Particle Counter	Movicon 11.3 Make: mk1teknology Pvt. ltd		
Operating System	Microsoft Window XP Professional Version: 2002 Service Pack: 3		

Checked By
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Verified By
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(Sign/Date)……

Inference:……

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Reviewed By
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(Sign/Date)……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER

7.6 INSTALLATION CHECKS:

7.6.1 FOR PARTICLE COUNTER:

S.No.	CHECKLIST	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN & DATE
1.	Serial No. of the Particle Counter		
2.	Location of Particle Counter		
3.	Location ID defined in Software		
4.	Precise sampling Location		
5.	Probe position should be 6 inches above the working height		
6.	The length of BEV-A-LINE tube should be within 1.5 meter		
7.	ID No. assigned to the attached isokinetic probe to the particle counter		

Checked By
(Production)
(Sign/Date)……

Verified By
(Quality Assurance)
(Sign/Date)……

Inference:……

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Reviewed By
(Manager QA)
(Sign/Date)……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER

7.6.2 PANEL INSTALLATION CHECKLIST

S. No.	CHECKLIST	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
1.	Panel Mounting Position	Vertical at Service floor above filling room of G-1 line		
2.	MOC of Panel box	Powder coated MS		
3.	Length of communication among sensor, PLC Panel & Protocol	Should not be more than 1200 mtr		
4.	Communication Protocol between PLC and Software	TCP/IP		
5.	Length of Communication Cable between PC and PLC Panel (Max 100 Mtr.)	Should not be more than 100 mtr		

Checked By
(Production)
(Sign/Date)……

Verified By
(Quality Assurance)
(Sign/Date)……

Inference:……

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Reviewed By
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(Sign/Date)……

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7.7 SAFETY:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING (SIGN/DATE)
Electrical Wiring and Earthing	Electrical Wiring should be as per Approved Drawings. Double External Earthing to Control instrument and Operator should be provided		
Noise Level	Below 70 db		

Checked By
(Production)
(Sign/Date)……

Verified By
(Quality Assurance)
(Sign/Date)……

Inference:……

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Reviewed By
(Manager QA)
(Sign/Date)……

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8.0 REFERENCES:

The Principle Reference is the following:

- 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.

The following references are used to give addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- 21 Code of federal regulation, Part 11 Electronic Records: Electronic Signatures; Final Rule-USFDA.
- 21 Code of Federal Regulation, Part 210-211.
- EU Guide to Good Manufacturing Practice, Part 4, 2009.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Calibration Certificates
- Operation and Maintenance Manual

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER

10.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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11.0 CHANGE CONTROL, IF ANY:

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

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13.0 CONCLUSION:

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14.0 RECOMMENDATION:

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE AIRBORNE PARTICLE COUNTER

15.0 EXECUTED PROTOCOL –APPROVAL:

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

AUTHORIZED BY:

DESIGNATION	NAME	SIGNATURE	DATE
VICE PRESIDENT (QUALITY ASSURANCE)			

16.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
ISPE	:	International Society for Pharmaceutical Engineers
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
DQ	:	Design Qualification
RH	:	Relative Humidity
Mm	:	Millimetre