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

INSTRUMENT I.D. No.	
LOCATION	**FILLING ROOM**
DATE OF QUALIFICATION	
SUPERSEDES No.	**NIL**

PROTOCOL CONTENTS

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

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)			

2.0 OBJECTIVE:

- To carry out the Operational Qualification of Online Airborne Particle Counter in Grade-A (Under LAF) to monitor the Non Viable Particle Counts during filling operation.
- To demonstrate that the Online Airborne Particle Counter operates in accordance with User Requirement Specifications and Designed Specifications and complies with relevant cGMP requirements.
- To verify user friendly features during Operation.
- To establish that the entire system as a whole is functioning with respect to electrical and instrumentation as specified.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The scope of this protocol limited to Operational Qualification of Online Airborne particle counter in Grade-A (Under LAF) of filling room.
- The Protocol covers all aspects of Operational Qualification for the Online Particle Counter.
- This Protocol will define the Methods and Documentation used to qualify the Online Particle Counter for OQ. Successful completion of this protocol will verify that the Online Particle Counter meets all acceptance criteria.

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 Operation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operation Qualification. • Monitoring of Operation Process.
Production	• Review of Operation Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operation Qualification study as per Protocol. • Post Approval of Operation Qualification Protocol after Execution.
Engineering	• Review of Operation Qualification. • To co-ordinate and support Operation Qualification Activity. • Calibration of Process Instruments.

The Operations of the Online Airborne Particle Counter is qualified by performing the prescribed tests and comparing the results against the given Acceptance Criteria. Exceptions are documented in the space provided and resolved prior to closing the OQ.

Upon completion of the above tests, the team will review the test results and indicate their Acceptance by signing the Authorization Page.

5.0 INSTRUMENT DETAILS:

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

6.0 SYSTEM DESCRIPTION:

The Climet Model CI-3100 is a microprocessor based remote two channels 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 exists 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 feet per minute or 0.1 cubic feet per minute depending on the model number of the unit. The concentration limit of this unit is 1 million particles per cubic feet for a 1.0 CFM sensor and 10 million particles per cubic feet for a 0.1 CFM sensor.\

7.0 CRITICAL VARIABLE TO BE MET:

7.1 PRE-QUALIFICATION REQUIREMRNTS:

INSTRUMENT CALIBRATION:

Verify that all Critical component associated with the System will be in a Calibrated state. Review the Calibration Status for the component to be utilised and record the Calibration due dates in the table below.

EQUIPMENT / INSTRUMENTS NAME	EQUIPMENT / INSTRUMENT I.D.	CALIBRATION ON	DUE ON	OBSERVED BY SIGN / DATE

DOCUMENTATION:

Verify that the DQ / IQ of the Online Particle Counter has been executed and approved. Verify that the Operating and Cleaning SOP of the Online Particle Counter has been prepared.

S.No.	DOCUMENT NAME	DOCUMENT / SOP No.	COMPLETED (YES / NO)	CHECKED BY (PRODUCTION) (SIGN/DATE)	VERIFIED BY (QA) (SIGN/DATE)
1.	DQ Protocol				
2.	IQ Protocol				
4.	Draft Operating Procedure SOP				
5.	Draft Cleaning Procedure SOP				

7.2 OPEARATIONAL AND FUNCTIONAL CHECKS:

Operate the Online Airborne Particle Counter as per Manufacturer's Manual / SOP on "Operation of Online Airborne Particle Counter" and Check for the following functions of instrument.

7.2.1 POWER SUPPLY TEST:

A) Purpose:

To ensure that the PLC panel and the remote sensor turn **ON** and the Power, Count, Laser Status and Flow Status LED's are turn **ON.**

B) Requirements (if any)

Digital Multimeter

C) Procedure

i. To turn ON the PLC Power

First turn ON the selector switch available in front of the control panel. Then turn ON the MCB, which is available inside the PLC panel. This will turn green indicator ON,

ii. To turn ON the sensor Power

First remove inlet cap of the sensor probe. Then turn ON the sensors with the Tek1 Pro Software. Procedure to turn on the sensor with Tek1 Pro is as under:

a) Double click on Tek1 Pro, then find the Tek1 Pro window on full screen.
b) Click on concern user tab (Operator /Administrator/Supervisor) and find a page for User ID & Password.
c) Enter User ID & Password and find Sampling Method page (ready to start).
d) Click on Cubic Feet ON/OFF and find that Cubic Feet ON/OFF tab turns GREEN to RED.
e) Click on Cubic Feet tab for cubic feet sampling.
f) Click on ON tab of sensor and find that the sensor ON status turns GREEN.
g) Sensor starts sampling

D) Acceptance Criteria

a) When turn on the selector switch and turn on the MCB. This should also turn ON the green indicator of the PLC panel.
b) When turn ON command to the sensor from the software, the remote sensor should TURN ON and start sampling.

E) Observations:

PLC Panel Power …… (Recommended Power 230AC)

PLC Panel green indicator turns ☐ ON ☐ OFF

Applied Power For Sensor*	Sensor ON Status	Power LED (ON/OFF)	ACCEPTED (Y/N)

*** Applied power to the sensor should be 24VDC (Recommended)**

F) Results:

Power Supply test ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.2 STANDARD LED TEST:

A) Purpose:

To ensure that the front Panel LEDs of the sensor are functioning properly as per design specifications.

B) Requirements (if any):

NA

C) Procedure:

a) Make sure the sensor will power up and start sampling.

b) Check the status of all four LEDs.

D) Acceptance Criteria:

a) The Power LED should be Green.

b) The Count LED should flash yellow if the air has particles.

c) The Laser status LED should be Green.

d) The Flow status LED should be Green.

Note: LED Color Coding

S.No	LED Status	Remarks
1.	If power LED is green	Sensor Power OK
2.	If count LED is flashing yellow	Particle counts available
3.	If laser status LED is green	Laser status OK
4.	If flow status LED is green	Flow status OK

E) Observations:

Power LED	Count LED	Laser LED	Flow LED	Accepted (Y/N)

F) Results:

Standard LED test ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.3 ALARM LED TEST:

A) Purpose:

To ensure the red alarm LED of the sensor is functioning properly in case any obstruction in air flow.

B) Requirements (if any):

NA

C) Procedure:

a) Ensure the remote sensor is switched ON.

b) Use the inlet cap to obstruct the air-flow to the inlet of the sensor.

c) Check the status of the red alarm LED after obstructing the air flow.

D) Acceptance Criteria:

a) During the first five seconds only the Power and Laser status LEDs should be green.

(If there are particles leaking into the inlet, then you will see the Count LED flash yellow.)

b) After five seconds the red alarm LED must turn ON and the Power and Laser status LEDs should green.

E) Observations:

Before closing the inlet (before obstructing the air-flow):

Power LED	Laser LED	Flow LED	Alarm LED	Accepted (Y/N)

After five seconds of obstructing air-flow:

Power LED	Laser LED	Flow LED	Alarm LED	Accepted (Y/N)

F) Results:

Alarm LED test ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.4 ZERO COUNT TEST:

A) Purpose:

To perform the zero count test on particle counter by using zero count filter to ensure the initial stabilization of particle counter to avoid any false counts.

B) Requirements (if any):

Zero Count Filter

C) Procedure:

a) Ensure the remote sensor is switched ON.

b) Put zero count filter on inlet of the remote sensor.

c) Purge the system (zero count filter on inlet of remote sensor), which ensure that remote sensor is particle free.

d) Select the Cubic Feet sampling mode from MENU in Tek1 Pro Software and checks the particle counts of 0.5 & 5.0 µm.

D) Acceptance Criteria:

After putting Zero Count filter on inlet of the remote sensor particle counts of 0.5 & 5.0 microns should be zero for at least six consecutive samples out of ten consecutive one minute samples.

E) Observations:

Start time…… **End Time ……..**

a) Make sure Zero- Count filter put on to the sensor ☐ YES ☐ NO

b) No. of Zero-Count sample in Ten consecutive one minute sample……

F) Result:

Zero Count Test ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

_____

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

7.2.5 PARTICLE COUNTING TEST:

A) Purpose:

To verify the function of particle counter with respect to particle counting test as per design and acceptance criteria defined in particle counter.

B) Requirements (if any):

NA

C) Procedure:

a) Ensure that all the sensors are connected to the Panel.

b) All the sensors are turn ON and in online mode.

c) Select the Cubic Feet Monitoring (CFM) mode from MENU in Tek1 Pro Software and checks the particle counts of 0.5 & 5.0 µm.

D) Acceptance Criteria:

a) The sensor should start sampling when we click on "ON" tab.

b) The sensor should stops sampling when we released the ON button.

E) Observations:

Status		Duration		Counts		Accepted (Y/N)
ON	OFF	Start Time	End Time	0.5µm	5.0µm	

Cubic Feet Monitoring (CFM) mode is selected ☐ YES ☐ NO

F) Result:

Particle Count Test: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.6 ALARM VALUE TEST:

7.2.6.1 ALARM VALUE TEST FOR PARTICLE COUNTS PER CUBIC FEET:

A) Purpose:

To perform the Alarm function of particle counter at set parameter for Alert and Action limit described in particle counter.

B) Requirements (if any):

NA

C) Procedure:

a) Ensure the remote sensors and alarm towers are switched ON.

b) Select the CFM mode in Tek1 Pro Software and find the Cubic feet monitoring screen. Then click on Alarm setting tab.

c) Then select the value tab and enter the values for Alert Limits.

d) Alert Limits set should be lower than Acceptance Limit.

** (The acceptance value is defined by the FS209E according to the classified areas. The dynamic and static conditions can be defined by the corresponding limits in the respective boxes)

D) Acceptance Criteria:

If the number of particles is equal or exceed the values of alarm limits, the alarm indication should be displayed.

E) Observations:

Alert limit set for Grade A Sensor - 0.5µm _____ 5.0µm_____

Action limit set for Grade A Sensor - 0.5µm _____ 5.0µm_____

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.6.2 ALARM VALUE TEST FOR PARTICLE COUNTS PER CUBIC METER

A) Purpose:

To perform the Alarm function of particle counter at set parameter for Alert and Action limit described in particle counter.

B) Requirements (if any):

NA

C) Procedure:

a) Ensure the remote sensors and alarm towers are switched ON.

b) Select the CFM mode in Tek1 Pro Software and find the Cubic feet monitoring screen. Then click on Alarm setting tab.

c) Then select the value tab and enter the values for Alert Limits.

d) Alert Limits set should be lower than Acceptance Limit.

** (The acceptance value is defined by the EUGMP according to the classified areas. The dynamic and static conditions can be defined by the corresponding limits in the respective boxes)

D) Acceptance Criteria:

If the number of particles is equal or exceed the values of alarm limits, the alarm indication should be displayed.

E) Observations:

Alert limit set for Grade A Sensor - 0.5µm _____ 5.0µm_____

Action limit set for Grade A Sensor - 0.5µm _____ 5.0µm_____

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.7 VIEW ALARM TEST:

A) Purpose:

To test the function of Cubic Feet Alarm View Tab.

B) Requirements (if any):

NA

C) Procedure:

a) Ensure the remote sensors are switched ON.
b) Select the CFM mode from MENU in Tek1 Pro Software.
c) Change the activation state of the sensor to OFF.
d) Change back the activation state of the sensor to active.
e) Wait one minute for the first sample.
f) Check the reading in the display box of the corresponding sensor.
g) Check the counts of 0.5 µm and 5.0 µm particle.

D) Acceptance Criteria:

If the number of particles is equal or exceed the values of alarm limits, the alarm indication should be displayed in alarm window.

E) Observations:

Counts		Alert Limits		Alarm Indication Displayed	Accepted (Y/N)
0.5µm	5.0µm	0.5 µm	5.0 µm		

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.8 TRACE COMMENT UTILITY TEST:

A) Purpose:

To perform the Trace Comment utility test of online airborne particle counter to verify the comments entered display in audit trail report.

B) Requirements (if any):

NA

C) Procedure:

a) Ensure the remote sensors are switched ON.

b) Select CFM mode of sampling.

c) Go to [Alarm View] tab and find the Alarm Screen.

(i) After clicking the [Alarm View] tab , find the User ID & Password pop-up

(ii) Enter user ID & password then click on [view alarm] tab

(iii) Find the Alarm Screen

d) Select events displayed on alarm screen.

e) Click on [Comments] and enter the informative comment.

f) Check in audit trail that alarm event comment is displayed.

D) Acceptance Criteria:

Comment entered should display in Audit Trial.

E) Observations:

i. The sensors are turned ON	☐ YES	☐ NO
ii. CFM mode of sampling is generated	☐ YES	☐ NO
iii. Find the Alarm Screen.	☐ YES	☐ NO
iv. Alarm event selected & its description	……..	
v. Comment entered	……..	
vi. Comment entered is displayed in attached Audit trial report.	☐ YES	☐ NO

Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

_____

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

7.2.9 CUBIC FEET REPORT TEST:

7.2.9.1 Raw Data Report:

A) Purpose:

To perform particle count and to verify Raw Data Report is generated for particle counts per cubic feet.

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Feet Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select DATE & TIME From and To on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test and Location ID in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the Raw Data Report tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window.

D) Acceptance Criteria:

Raw Data report should generate.

E) Observations:

Raw Data report Generated	Accepted (Y/N)	Comments (if any)

F) Result ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____
_____
_____

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

7.2.9.2 Combined Raw data Report:

A) Purpose:

To perform particle count and to verify Combined Raw data report is generated for particle counts per cubic feet.

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Feet Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select DATE & TIME From and To on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test and Location ID in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the Combined Raw Data Report tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window.

D) Acceptance Criteria:

Combined Raw Data report should generate.

E) Observations:

Combined Raw Data report Generated	Accepted (Y/N)	Comments (if any)

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.9.3 Summary Report:

A) Purpose:

To perform particle count and to verify Summary Report is generated for particle counts per cubic feet.

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Feet Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select DATE & TIME From and To on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test and Location ID in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the Summary Report tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window.

D) Acceptance Criteria:

Summary report should generate.

E) Observations:

Summary Report Generated	Accepted (Y/N)	Comments (if any)

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.9.4 FS-209E Report:

A) Purpose:

To create the report as per standard FS-209E.

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Feet Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select DATE & TIME From and To on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test and Location ID in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the FS-209E Report tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window.

D) Acceptance Criteria:

FS-209E report should generate.

E) Observations:

FS-209E Report Generated	Accepted (Y/N)	Comments (if any)

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____
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Reviewed By:_____
(Manager QA)
(Sign / Date)

7.2.10 ALARM REPORT:

A) Purpose:

To perform Alarm Report test for particle counts per cubic feet to verify that alarm report is generated

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Feet Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select From DATE & TIME and To DATE & TIME on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test, Location Id in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the Alarm Report Tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window

D) Acceptance Criteria:

Alarm report should generate.

E) Observations:

Alarm report Generated	Accepted (Y/N)	Comments (if any)

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.11 AUDIT TRAIL REPORT:

A) Purpose:

To perform Audit trail report test to verify that audit trail report is generated.

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Feet Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select From DATE & TIME and To DATE & TIME on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test, Location Id in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the Audit Trail Report Tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window

D) Acceptance Criteria:

Audit –trail report should generate.

E) Observations:

Audit trial report Generated	Accepted(Y/N)	Comments (if any)

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

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

7.2.12 GRAPH REPORT:

A) Purpose:

To perform particle count test to verify that graph report is generated.

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Meter Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select From DATE & TIME and To DATE & TIME on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test, Location Id in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the Graph Tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window

D) Acceptance Criteria:

Graph report should generate**.**

E) Observations:

Graph report Generated	Accepted (Y/N)	Comments (if any)

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____
_____
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Reviewed By:_____
(Manager QA)
(Sign / Date)

7.2.13 CUBIC METER REPORT TEST:

7.2.13.1 Raw Data Report:

A) Purpose:

To create the Raw Data Report for particle counts per cubic meter.

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Meter Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select DATE & TIME From and To on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test and Location ID in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the Raw Data Report tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window.

D) Acceptance Criteria:

Raw Data report should generate.

E) Observations:

Raw data report Generated	Accepted (Y/N)	Comments (if any)

F) Result ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____
_____
_____

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

7.2.13.2 Combined Raw data Report

A) Purpose:

To create the Combined Raw Data Report for particle counts per cubic meter.

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Meter Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select DATE & TIME From and To on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test and Location ID in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the Combined Raw Data Report tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window.

D) Acceptance Criteria:

Combined Raw Data report should generate.

E) Observations:

Combined Raw data report Generated	Accepted (Y/N)	Comments (if any)

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____
_____
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Reviewed By:_____
(Manager QA)
(Sign / Date)

7.2.13.3 Summary Report:

A) Purpose:

To create the Summary Report for particle counts per cubic meter.

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Meter Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select DATE & TIME From and To on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test and Location ID in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the Summary Report tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window.

D) Acceptance Criteria:

Summary report should generate.

E) Observations:

Summary Report Generated	Accepted (Y/N)	Comments (if any)

F) Result ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____
_____
_____

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

7.2.13.4 EU-GMP Report:

A) Purpose:

To create report as EU-GMP standard.

B) Requirements (if any):

NA

C) Procedure:

a) Select the Cubic Meter Tabs on sampling method selection screen.
b) Select the Location of particle counter on reports development screen.
c) Select DATE & TIME From and To on reports development screen.
d) Select Hour, Minute, Second on reports development screen.
e) Enter the Batch No, Purpose of Test and Location ID in Value tab.
f) Write the name of reviewed by and approved by in Value tab.
g) Click on the EU-GMP tab.
h) Click on the Save Tab to save the report in different location.
i) Click on the Print Tab to take print of Report.
j) Click on Exit Tab to close the Report window.

D) Acceptance Criteria:

EU-GMP Report should generate.

E) Observations:

EU-GMP Report Generated	Accepted (Y/N)	Comments (if any)

F) Result ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____
_____
_____

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

7.2.14 AUDIT LOG TEST:

A) Purpose:

Test that the audit events are correctly logged.

B) Requirements (if any):

NA

C) Procedure:

Log on as a member of Tek1 Pro for audit-trail window. Enter the comment and click on OK.

D) Acceptance Criteria:

Audit log report should generate.

E) Observations:

a) Log on as a member of Tek1 Pro for audit-trail window ☐ YES ☐ NO

b) Enter the comment and click OK ☐ YES ☐ NO

c) Audit log report is generated ☐ YES ☐ NO

F) Result ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

_____

_____

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

7.2.15 BACK-UP OF TEK1 PRO TEST

A) Purpose:

To test the Tek1 Pro Back-up function.

B) Requirements (if any):

NA

C) Procedure:

a) Click on to START of computer go to My Computer or go directly to My Computer (Icon displayed at desktop)

b) Double click on to My Computer

c) Go to D: drive and double click on it.

d) Find Tek1 Pro icon in D: drive.

e) Double click on Tek1Pro and find pb.

D) Acceptance Criteria:

Data Backed-up of Tek1 Pro should be from Location E:/Tek1 Pro/Testing

E) Observations:

The backed-up of Tek1 Pro from Location E:/Tek1 Pro/testing ☐ YES ☐ NO

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)
Inference:_____

Verified By
(Quality Assurance)
(Sign/Date)

_____

_____

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

7.2.16 SECURITY TEST

7.2.16.1 Manage Security Group Test:

A) Purpose:

To test the authorization of users of different group (level).

B) Requirements (if any):

NA

C) Procedure:

You must be member of Tek1 Pro.

a) Double click on Tek1 Pro Icon on desktop and find the maximized Tek1 Pro Screen.

b) Click on to Create tab. Define the group and user name.

c) If you have a level 1 user, then log on under that user.

d) User at this level will be able to ON/OFF, Trends, Alarm View.

e) If you have a level 2 user, then log on under that user.

f) User at this level will have the above user rights and Alarm Setting and Reports.

g) If you have a level 3 user, then log on under that user.

h) User at this level will be able to have full function control.

D) Acceptance Criteria:

Security groups define should follow the following hierarchy and its capability.

Security level	Capability
Level 3	Activate\Deactivate CI-3100's to turn off\on. Can view the Data in Cubic Feet/ Cubic Meter. Acknowledge alarm events with comments. Can view the live trends of the particle. Can set the alarm limits. Create Reports. Add\Delete\Edit up to any number of users.
Level 2	Activate\Deactivate CI-3100's to turn off\on. Can view the Data in Cubic Feet/ Cubic Meter. Acknowledge alarm events with comments. Can view the live trends of the particle. Can set the alarm limits. Create Reports.
Level 1	Activate\Deactivate CI-3100's to turn off\on. Can view the Data in Cubic Feet/ Cubic Meter. Acknowledge alarm events with comments. Can view the live trends of the particle.

E) Observations:

Security level	Capability	Accepted	
		Yes	NO
Level 3	▪ Activate\Deactivate CI-3100's to turn off\on.		
	▪ Can view the Data in Cubic Feet/ Cubic Meter.		
	▪ Acknowledge alarm events with comments.		
	▪ Can view the live trends of the particle.		
	▪ Can set the alarm limits.		
	▪ Create Reports.		
	▪ Add\Delete\Edit up to any number of users.		
Level 2	▪ Activate\Deactivate CI-3100's to turn off\on.		
	▪ Can view the Data in Cubic Feet/ Cubic Meter.		
	▪ Acknowledge alarm events with comments.		
	▪ Can view the live trends of the particle.		
	▪ Can set the alarm limits.		
	Create Reports.		
Level 1	▪ Activate\Deactivate CI-3100's to turn off\on.		
	▪ Can view the Data in Cubic Feet/ Cubic Meter.		
	Acknowledge alarm events with comments. ▪ Can view the live trends of the particle		

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____
_____
_____

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

7.2.16.2 USER ACCOUNT SECURITY TEST:

A) Purpose:

To test security of user account.

B) Requirements (if any):

NA

C) Procedure:

a) Double click on to Tek1 Pro Icon displayed on desktop and find the maximized Tek1 Pro screen.

b) Click on to the concern User account and find the corresponding user login page.

c) Enter the wrong password for more than three consecutive times.

d) Find that the user account is blocked.

D) Acceptance criteria:

After enter three consecutive wrong passwords to concerned user account, the user account should be blocked.

E) Observations:

a) Find the maximized Tek1Pro ☐ Yes ☐ No

b) No. of wrong attempts to enter password ……

c) Is the user account blocked ☐ Yes ☐ No

F) Result: ☐ PASS ☐ FAIL

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____
_____
_____

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

7.3 POWER FAILURE VERIFICATION:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Main Power Shut Down	Instrument should stop in a Safe and Secure condition.		
Main Power Restored	Instrument should restart with no problems or adverse conditions.		

Checked By
(Engineering)
(Sign/Date)

Verified By
(Quality Assurance)
(Sign/Date)

Inference:_____

_____

_____

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

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:

- Operation and Maintenance Manual
- Copy of draft SOP
- Any other relevant documents

10.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

11.0 CHANGE CONTROL, IF ANY:

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

13.0 CONCLUSION:

14.0 RECOMMENDATION:

15.0 EXECUTED PROTOCOL –APPROVAL:

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

16.0 ABBREVIATIONS:

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
SOP	:	Standard Operating Procedure