STANDARD OPERATING PROCEDURE				
Title: Operation of Online Airborne Particle Counter				
SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 18	

1.0 OBJECTIVE:

To lay down a procedure for Operation and cleaning of Online Airborne Particle Counter.

2.0 SCOPE:

This SOP is applicable for the Operation of Online Airborne Particle Counter used for online monitoring of non-viable particle counts during filling operation installed in Grade A & Grade B of Filling Room.

3.0 RESPONSIBILITY:

Operating Person - Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

Ltd.   Limited
No.   Number
QA   Quality Assurance
SOP   Standard Operating Procedure
Pvt.   Private
OPC   Online Particle Counter
LAN   Local Area Network

6.0 PROCEDURE:

6.1 Precautions:

6.1.1 Before starting online airborne particle counter, cap of probe shall be removed & probe shall be covered by cap only after switch off of Online Airborne Particle Counter.

6.1.2 Before starting non-viable particle monitoring, ensure the availability of power supply to the online particle counter system.

6.1.3 Don't run the particle counter during Fogging, Cleaning & Sanitization activity in the area and cap of probe should be close.

6.1.4 During yearly calibration by external agency, LAN connector should be replaced of OPC instruments to avoid data transmission error in routine and same shall be mentioned in respective calibration certificate.

6.1.5 Alarm management shall be followed as per Annexure-IV.

6.1.6 Refer Annexure-V to handle excursion in NVPC.

6.1.7 No online non-viable particle count monitoring shall be performed during powder filling operation because the process i.e. powder filling is itself particle generating.

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter

SOP No.:		**Department:**	Production
		Effective Date:	
Revision No.:	00	**Revision Date:**	
Supersede Revision No.:	Nil	**Page No.:**	2 of 18

6.1.8 Ensure that during filling activity of DPI batches, the online particle counter should be in "off mode" and the cap of online particle count sensor probe should be closed.

6.2 Procedure to switch on and switch off the online particle counter:

6.2.1 Procedure to Switch ON the Online Particle Counter:

6.2.1.1 Switch ON the power supply of OPC sensor, green light illuminates.

6.2.1.2 Check the sensor ON status in CI-3100-21 Software.

6.2.1.3 If sensor status found ON then online particle counter should be ON from computer system.

6.2.2 Procedure to Switch OFF the Online Particle Counter:

6.2.2.1 OFF the online particle counter from computer system.

6.2.2.2 Convert the Occupancy state from in operation to at rest and Activation state from Active to Standby from Control Panel of software.
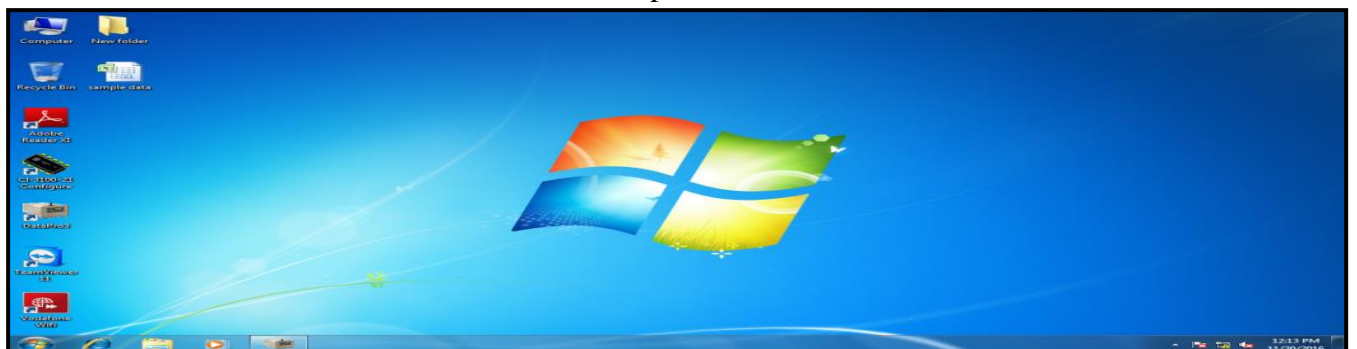
6.2.2.3 Switch OFF the power supply of OPC sensor.

6.3 Operation of Online Airborne Particle Counter:

6.3.1 Open the computer and select the level and password.

**6.3.2** Click on DataPro3.Ink Icon on Desktop.

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	3 of 18	

6.3.3 On clicking DataPro3.Ink following screen shall display, select the control option.

6.3.4 Click the Area to choice the operational section like:-Ampoule.

6.3.5 Click the location (FILLING Grade-A or BACKGROUND Grade-B or BOTH) as per required.

6.3.6 Select the occupancy state (in operation / at rest) & activation state (active / stand by).
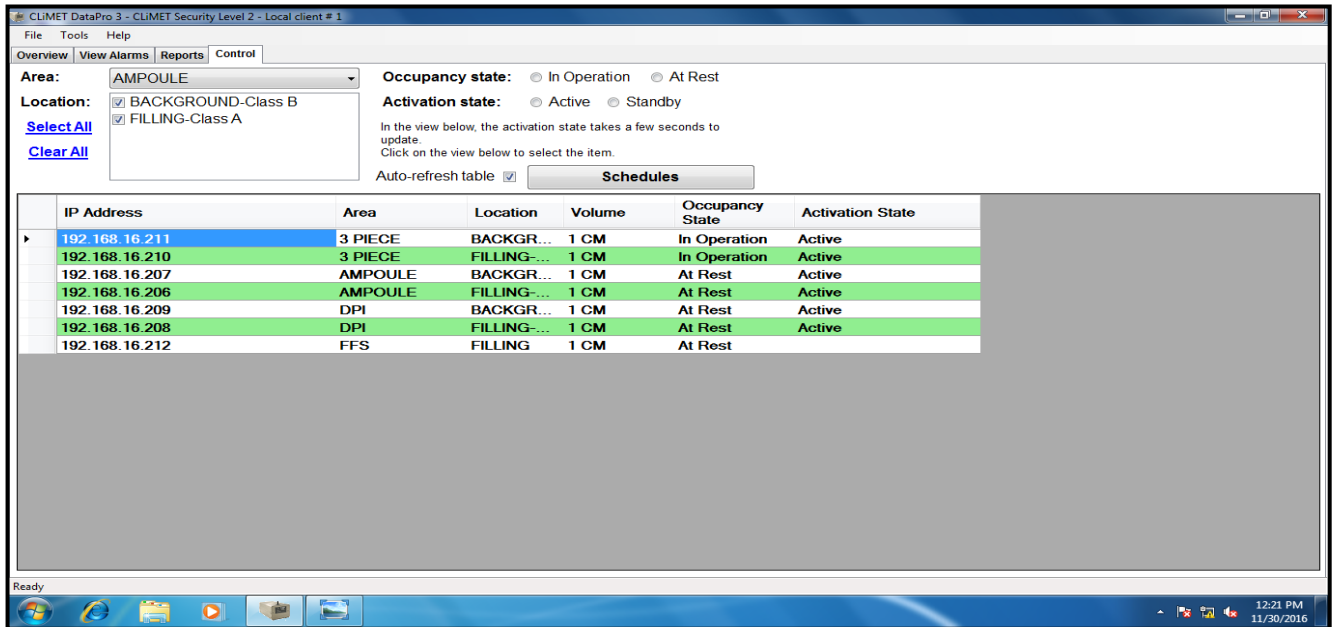
6.3.7 Check in display show IP address, area, location, volume, occupancy state and activation state.

6.3.8 Click the overview and check the area particle (0.5 & 5.0) micron limit.

Classification	Maximum concentration limit (particle/m^3)-EU GMP			
	At Rest		**In operation**	
	>=0.5 micron	**>=5.0 micron**	**>=0.5 micron**	**>=5.0 micron**
Class A	3,520	20	3,520	20
Class B	3,520	29	3,52,000	2,900
Class C	3,52,000	2,900	35,20,000	29,000
Class D	35,20,000	29,000	Not Defined	Not Defined

STANDARD OPERATING PROCEDURE				
Title: Operation of Online Airborne Particle Counter				
SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	4 of 18	

6.3.9 Alarm indication tower are fixed in Respective area for alert and action limit with different color code.

6.3.10 During continue monitoring if no. of particle are in set limits it will be indicated to green light in alarm tower.

6.3.11 If no. of particle cross above alert limit, it will be indicated as yellow light in alarm tower.

6.3.12 If no. of particle cross above action limit, it will be indicated as Red light in alarm tower& also a buzzer sound start in Alarm tower.

Alert (70% of maximum concentration limit) and action (80% maximum concentration limit) criteria for Grade –A & Grade –B are as mentioned below:-

Particle size		At Rest		In Operation	
		Alert limit	**Action limit**	**Alert limit**	**Action limit**
Class - A	**0.5 micron**	2464	2,816	2,464	2,816
	5.0 micron	14	16	14	16
Class - B	**0.5 micron**	2,464	2,816	2,46,400	2,81,600
	5.0 micron	14	16	2,030	2,320

6.3.13 In case yellow light glow for exceed in alert limit then following steps to be taken.

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	5 of 18	

6.3.13.1 Person inside filling need to control their movement in the area to bring down the particle counts below alert limit.

6.3.13.2 To identify if any material is present which might be creating turbulence in the area.

6.3.13.3 To identify if any disturbance is been created by machine e.g. Filling machine, particle counter etc. present during operation.

6.3.13.4 In case particle counts exceeding the action limit then being alarm will be start and red light of tower glow then following steps to be taken.

6.3.13.5 Stop all activity running in the area.

6.3.13.6 If filling operation is running immediately stop filling activity.

6.3.13.7 Man and material movement shall be avoided.

6.3.13.8 After recovery of particle counts below alert limit filling activity will be start after 5 minutes.

6.3.13.9 Record the excursion details and maintain the action plan in **Annexure –III.**

6.3.14 **Frequency of Particle Counting:**

6.3.14.1 Particle counter shall be started 20 minutes before assembling of machine parts in filling area or any aseptic activity. On the basis of 20 minutes particle counts data IPQA officer/Executive shall be provided line clearance for aseptic assembling & filling activity and continuous monitoring shall be done after 10 min end of filling activity.

6.3.14.2 In case of DPI section, the online non-viable particle count monitoring of grade A and grade B shall be performed before start of filling operation and based on satisfactory data of NVPC monitoring for 20 minutes, line clearance shall be provided to production department for execution of batch filling and sealing activity. No online non-viable particle count monitoring shall be performed during powder filling operation because the process i.e. powder filling is itself particle generating.

6.3.14.3 In case any breakdown in online Airborne particle counter (ampoule and three piece section), use stand by sensor by using IP Address of same and if both are not working then use portable particle counter immediately to perform non-viable particle counts at rest for line clearance before start filling activity, Initial in operation, middle in operation and end in operation also at any breakdown/malfunctions/verification.

PHARMA DEVILS			
PRODUCTION DEPARTMENT			

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	6 of 18	

6.3.14.4 In case any breakdown in online Airborne particle counter, use stand by sensor by using IP Address of same and if both are not working then use portable particle counter to perform non-viable particle counts before start of filling operation and based on satisfactory data of NVPC monitoring for 20 minutes, line clearance shall be provided to production department for execution of batch filling and sealing activity. No online non-viable particle count monitoring shall be performed during powder filling.

6.3.14.5 Initiate the breakdown as well as Incident in case of breakdown in online particle counter.

6.3.14.6 Maintain monitoring record of portable particle counter in **Annexure-II** with proper justification for monitoring of non-viable particle counts.

6.4 **Cleaning and Sanitation and Cleaning Frequency Procedure:**

6.4.1.1 Ensure particle counter in off mode before initiation of cleaning and sanitation activity at end of filling activity or any preventive activity.

6.4.1.2 Perform the Iso-kinetic probe cleaning by wiping of inner and outer surface with lint free mop soaked with filtered WFI followed by OPC tube and particle counter module then perform the external surface sanitation with lint free mop soaked with filtered 70% IPA.

6.4.1.3 Change the OPC Tube after any physical discrepancy found or as per vendor recommendation.

6.4.1.4 Frequency of its cleaning is with daily routine practice cleaning of filling machine or at the end of filling activity or in between of preventive maintenance.

6.5 **Reporting System:**

6.5.1 The interval count is an individual data point. Whereas, the sample count and rolling count are both moving total count over a set of sixty data pints in a time series. The sample count get updated every sixty data points. The sample count & rolling count represent a complete sample volume. Each sensor has been set by the user to accumulate data per cubic meter.

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	7 of 18	

6.5.2 The rolling count contains the counts of the most recently sampled volume. It is updated at the interval rate, 60 times per volume, which is second or 35.5 seconds.

6.5.3 The data pro 3 raw data & summary report can convert the data to cubic foot or cubic meter. Data pro 3 also uses a straight forward concept called a "Total Count" total count is in cubic foot if the sensor is in cubic foot otherwise, the total count is cubic meter.

6.5.4 **Click on the Continuous Monitoring**

6.5.4.1 Click on the tab on **"Raw Data".**

6.5.4.2 Select the area like:-Ampoule.

6.5.4.3 Select the BACKGROUND-CLASS B & FILLING-CLASSA.

6.5.4.4 Select & click particle size (0.5 & 5.0) micron.

6.5.4.5 Give the batch details in provided column.

6.5.4.6 Select the start & end time, file name & orientation (landscape/ portrait).
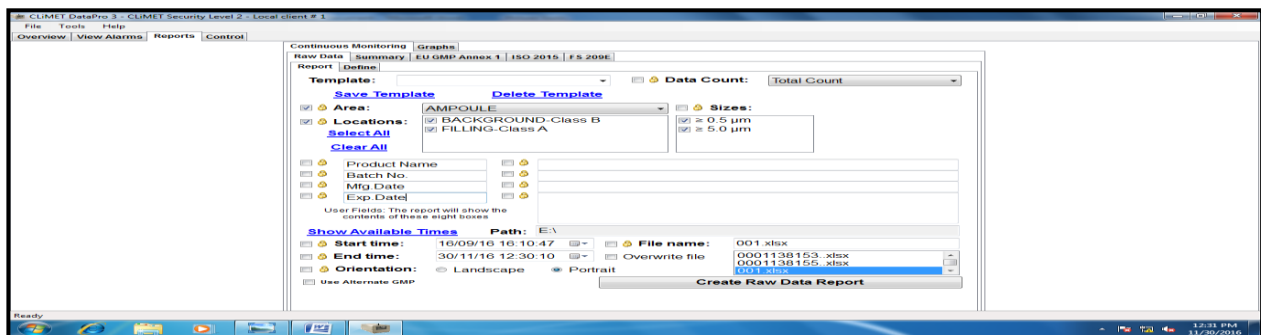
6.5.4.7 Click on the tab **"Define"** report.

6.5.4.8 Select the flow, volume, unit ID, alarm, sensor type, laser OK, forced counts.
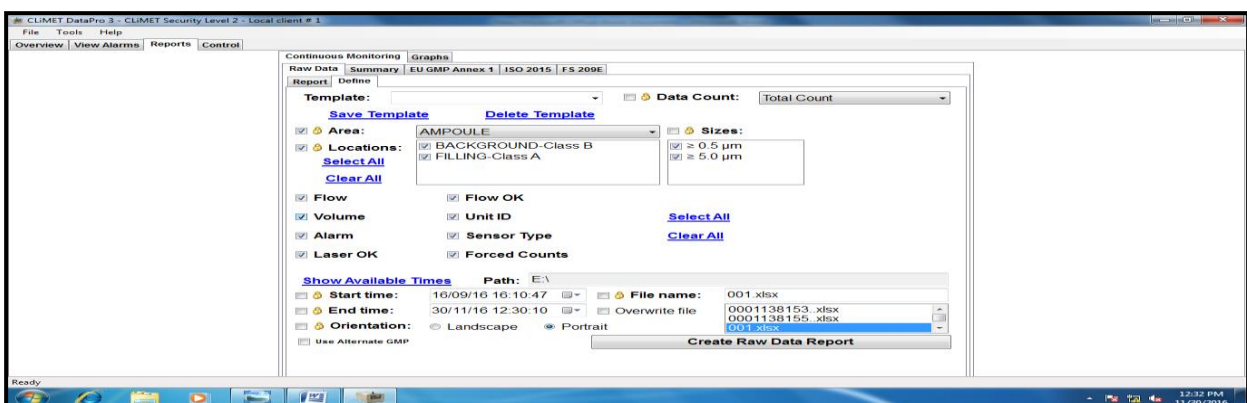
6.5.4.9 Enter the Create Raw Data Report.

6.5.4.10 The window will open automatically and enter purpose of test.

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	8 of 18	
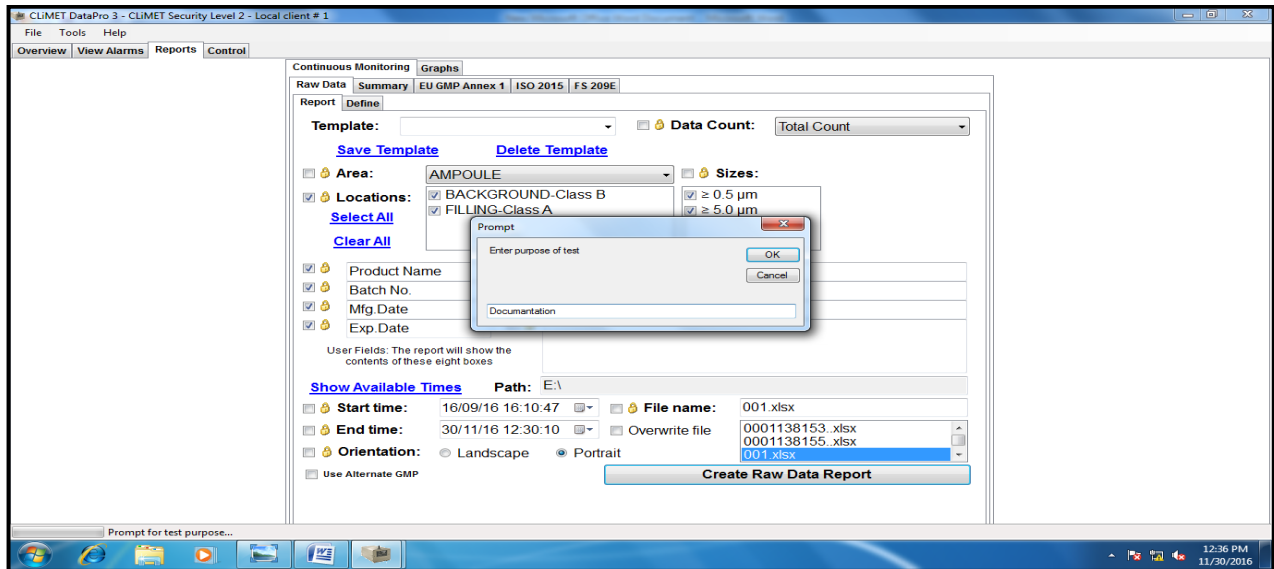
6.5.4.11   Open the data in Microsoft excel and take print of the data.

6.5.4.12   **For Summary report**:-Click on the tab on **"summary"**.

6.5.4.13   Select the area like:-Ampoule

6.5.4.14   Select the BACKGROUND-CLASS B & FILLING-CLASSA.

**6.5.4.15**   Select & click particle size (0.5 & 5.0) micron.

6.5.4.16   Give the batch details in provided column

6.5.4.17   Select the start & end time, file name & orientation (landscape / portrait)

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	9 of 18	

6.5.4.18   Click on the tab on the **"Define"** report

6.5.4.19   Select the required parameter.

6.5.4.20   Enter the Summary Report

STANDARD OPERATING PROCEDURE				
Title: Operation of Online Airborne Particle Counter				
SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	10 of 18	
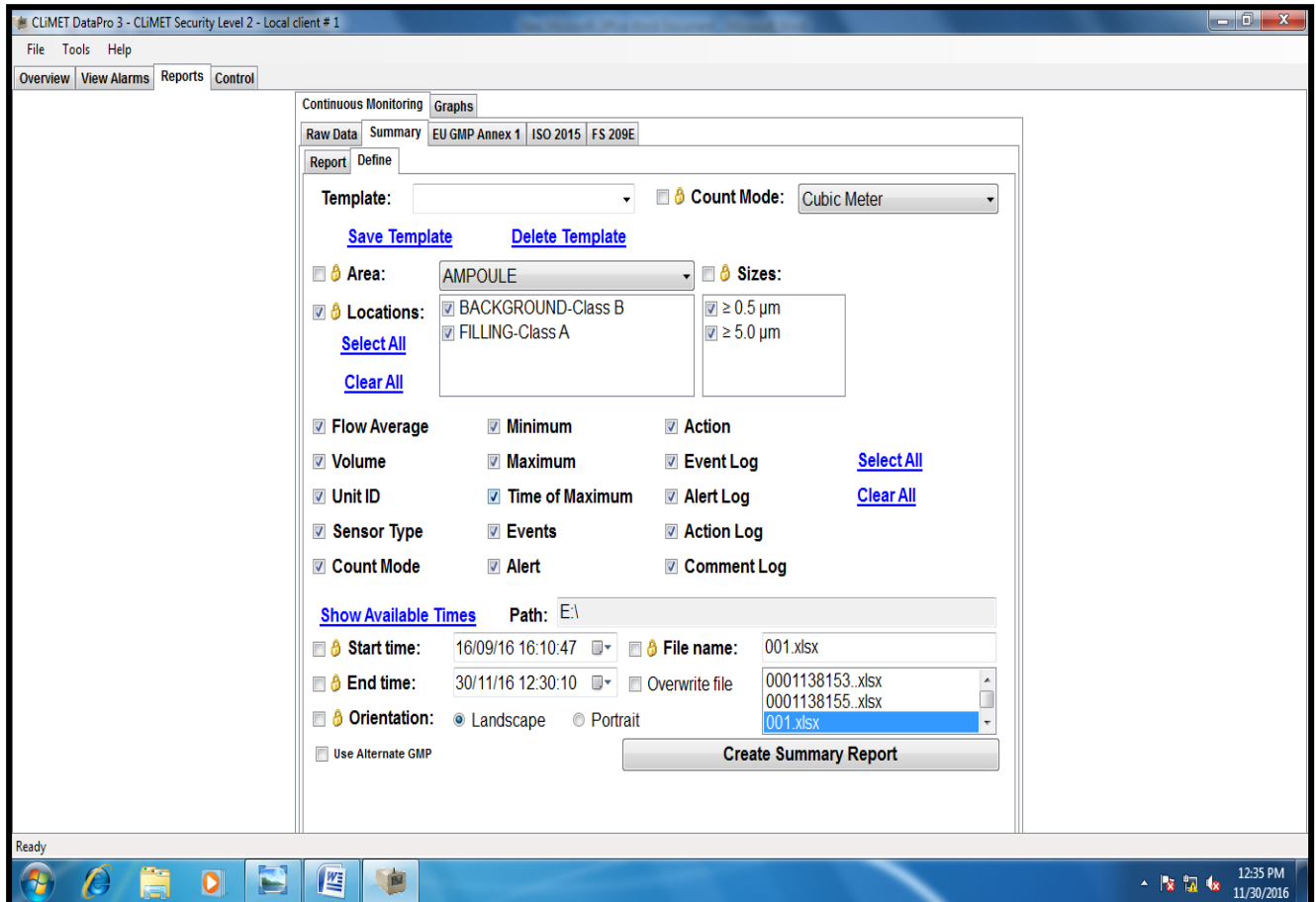
6.5.4.21   The window will open automatically and enter purpose of test.

6.5.4.22   Open the data in Microsoft excel and take print of the data same as raw Data.

6.5.5   **Click on the Graphs:**

6.5.5.1   Click on the tab on **"Raw Data".**

6.5.5.2   Select the area like:-AMPOULE.

6.5.5.3   Select the BACK-GROUND B &FILLING-CLASS A.

6.5.5.4   Select & click particle size (0.5 & 5.0) micron.

6.5.5.5   Select the start & end time, file name & orientation (landscape/ portrait).

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE				
Title: Operation of Online Airborne Particle Counter				
SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	11 of 18	
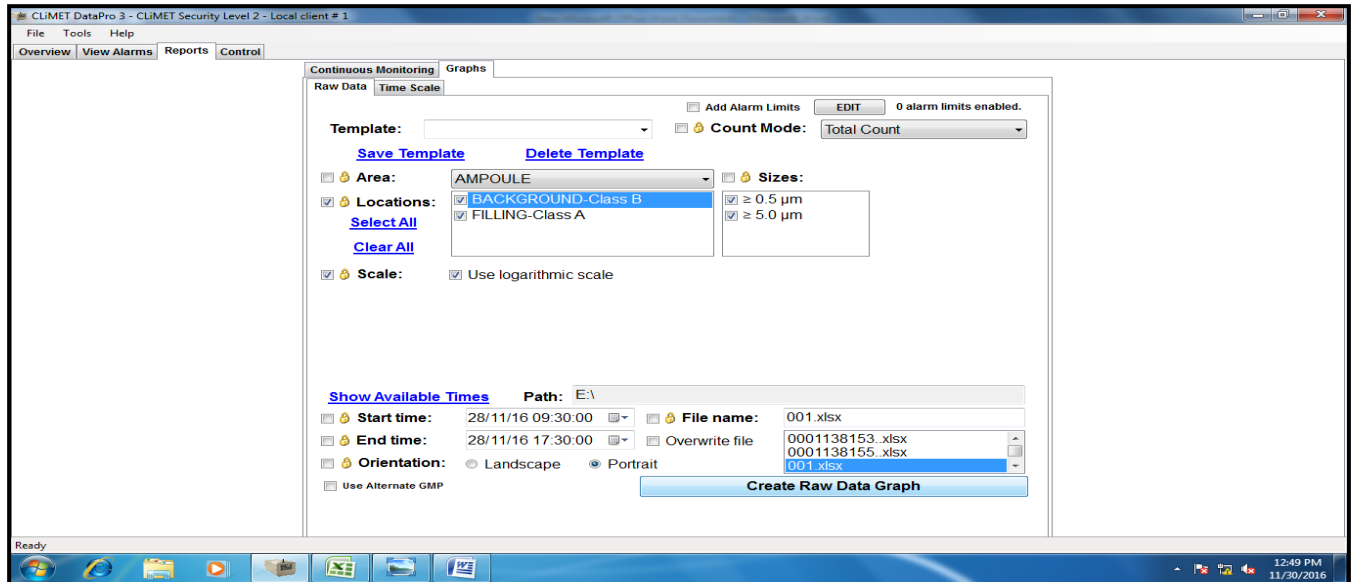
6.5.5.6   Select & click on tab **"time scale".**

6.5.5.7   Click on the scale& tick use logarithmic scale.

6.5.5.8   Click on Tick period, Label frequency, start & end time.

6.5.5.9   Also click Orientation and File Name.
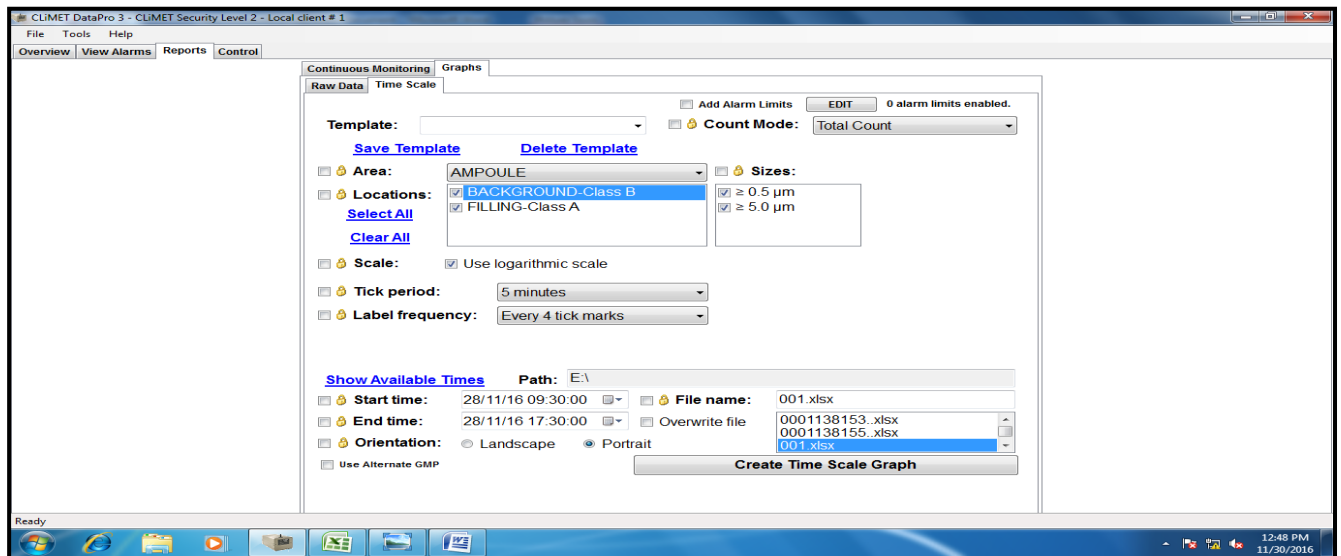
6.5.5.10   After that create time scale graph.

6.5.5.11   Open the window and enter purpose of test report.

6.5.5.12   Open the data in Microsoft excel and print of the graph.

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE			
Title: Operation of Online Airborne Particle Counter			
SOP No.:		**Department:**	Production
		Effective Date:	
Revision No.:	00	**Revision Date:**	
Supersede Revision No.:	Nil	**Page No.:**	12 of 18
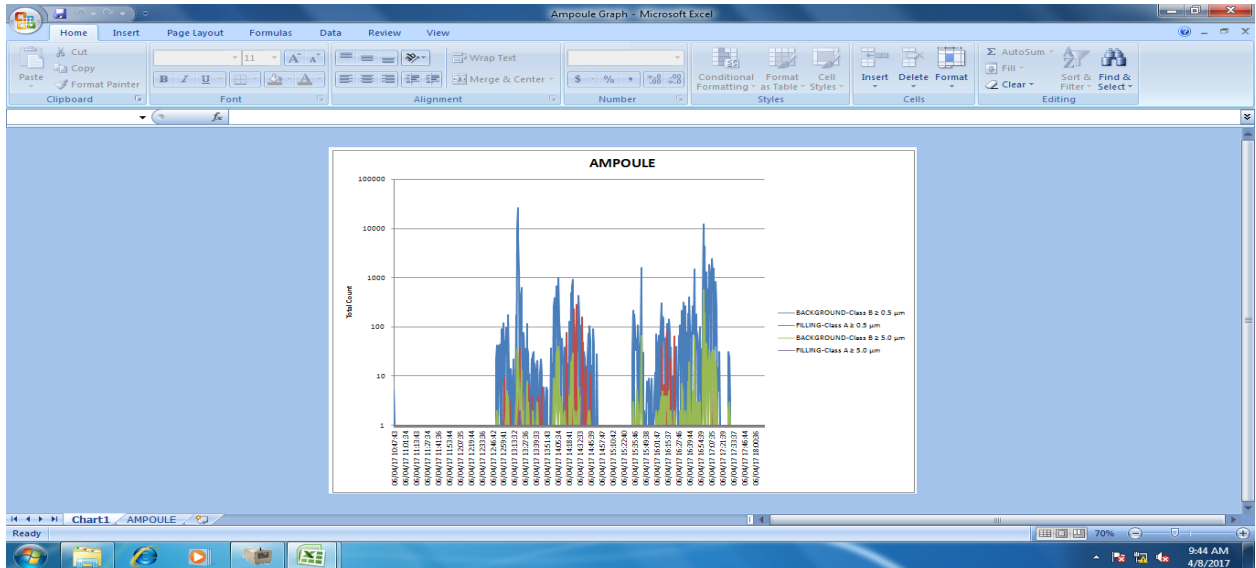
6.6 Record the operation details in **"Operation Log Book for Online Airborne Particle Counter"** as per **Annexure-I**.

6.7 **Data Time, Reporting Particle Data:**

6.7.1 Climet particle counter are not time based measurement sensor. They measure particle count for a measured volume.

6.7.2 The stamp is the time of information recorded by the software same as in any other windows based program.

6.7.3 Particles are measured as follows:

6.7.3.1 Particles are physically measured in the optics.

6.7.3.2 Information of particle count and sample volume is processed by the electronic system.

6.7.3.3 Information of number of particles in a measured volume is delivered to the data acquisition system via the Ethernet hardware.

6.7.3.4 Particle information is the further processed and recorded by the software.

6.7.4 Any fluctuation in the time stamp is not the fluctuation of sample volume and particle information. Particle data and the measured volume are the actual particle information.

7.0 **REFERENCES:**

1. Instrument Manual

2. EU-GMP Annexure-1 (2008)

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE				
Title: Operation of Online Airborne Particle Counter				
SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	13 of 18	

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Operation Log Book for Online Airborne Particle Counter	
Annexure – II	Portable particle counter monitoring record	
Annexure – III	Excursion Details & Action Plan of online particle counter	
Annexure – IV	Alarm Management of Online Particle Counter	
Annexure – V	Action Plan For Excursion In NVPC	

ENCLOSURES: SOP Training Record

9.0 DISTRIBUTION:

- Controlled Copy No.01   Quality Assurance
- Controlled Copy No.02   Production
- Master Copy   Quality Assurance

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter					
SOP No.:		**Department:**	Production		
		Effective Date:			
Revision No.:	00	**Revision Date:**			
Supersede Revision No.:	Nil	**Page No.:**	14 of 18		

ANNEXURE-I

OPERATION LOG BOOK FOR ONLINE AIRBORNE PARTICLE COUNTER

S.No.	Date	Product Name	Batch No.	Time		Done By Sign & Date	Checked By QA Sign & Date	Remarks
				Start	**End**			

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	15 of 18	

ANNEXURE-II
PORTABLE PARTICLE COUNTER MONITORING RECORD

Instrument ID No.:	Date :
Instrument Calibration done on:	Instrument Calibration due on:
Product Name:	Batch No.:
Mfg. Date:	Exp. Date:

Reason for Using Portable particle counter :

DURATION STATUS

	Grade A	Grade B	Result	Sign/Date
Line Clearance (At Rest)				
Initial (In-Operation)				
Middle (In-Operation)				
End (In-Operation)				

Remark:

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter					
SOP No.:		**Department:**	Production		
		Effective Date:			
Revision No.:	00	**Revision Date:**			
Supersede Revision No.:	Nil	**Page No.:**	16 of 18		

ANNEXURE-III
EXCURSION DETAILS & ACTION PLAN OF ONLINE PARTICLE COUNTER

Section Name	:	
Product Name	:	
Batch No.	:	

Date	Alarm Excursion		Out of Limit (Grade A/ B)	Justification	Signed By
	From	**To**			

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	17 of 18	

ANNEXURE-IV
ALARM MANAGEMENT OF ONLINE PARTICLE COUNTER

Alarm Type	Category	Visual and Audible display inside the Aseptic area	Colour Display indication at Monitor	Proposed Action
Alert level 70% of acceptance limit	Severity -1	Blinking display at respective OPC sensor location with beep-beep sound	Yellow	Minimize the activity / personnel movement to regain the acceptance limit to continue the activity.
Action level 80% of acceptance limit	Severity -2	Visual display glow with audible alarm at respective OPC sensor location for continuous **two occurrences** of NVPC excursion.	Red	Stop the batch filling activity to regain the acceptance limit to continue batch filling the activity.
HI HI level **(OOL for more than defined acceptance limit)** **0.5 µ : 100** **5.0 µ : 1**	Severity -3	Visual display glow with audible alarm at respective OPC sensor location for **three consecutive occurrences** of NVPC excursion	Red	**1.**Stop the batch filling activity **2.**Operator has to ensure the occurrence duration for OOL with respect to Filling m/c HMI / display watch of vial washing room. **3.Action is to taken as per ANNEXURE-V** 4.Production/QA person has to write the justification for the same

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	18 of 18	

ANNEXURE-V
ACTION PLAN FOR EXCURSION IN NVPC

Location	Operation	Grade	Actions to be taken
Near Filling Nozzle	During assembling of machine parts	A	Immediately stop the activity. Do not assemble the machine parts till area normalize
	Vials/ ampoules present on tracks		Immediately stop the activity. After recovery of particle counts below alert limit filling activity will be start after 5 minutes Discard all open vials /unstoppered vials/ unsealed ampoules from track
	Before entry of sterilized/ depyrogenated empty vials/ ampoule		Do not allow vials/ ampoules to come on to turn table till non-viable particle count came within limit After recovery of particle counts below alert limit filling activity will be start after 5 minutes
Filling Room Background	Before filling machine parts assembly	B	Stop the filling m/c parts assembling till non-viable particle count came within limit After recovery of particle counts below alert limit, activity will be start after 5 minutes
	Before aseptic connection to sterilized parts		Stop the activity. Do not start the operation till area normalize After recovery of particle counts below alert limit, activity will be start after 5 minutes