

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	Nil	Page No.:	1 of 18			
No.:						

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.





PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation of Online	Airborne Partic	le Counter	
SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision	Nil	Page No.:	2 of 18
No.:			

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.

Click on DataPro3.Ink Icon on Desktop. 6.3.2





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	Nil	Page No.:	3 of 18			
No.:						

- **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).

LiMET DataPro	o 3 - CLIMET Security Level 2 - Local clien	nt # 1						(m_n)d=log
e Tools I	Help							
rview View	Alarms Reports Control							
ea:	AMPOULE	 Occupan 	cy state: 💿 li	n Operation	At Rest			
ocation:	BACKGROUND-Class B	Activatio	n state: 🛛 🖉 🤇	Active 💿 Sta	ndby			
elect All	FILLING-CIASSA	In the view b	elow, the activation	state takes a fev	v seconds to			
lear All		Click on the	view below to selec	t the item.				
		Auto-refres	h table 🗵 📄	Sched	ules			
IP Add	dress	Area	Location	Volume	Occupancy State	Activation State		
192.16	68.16.211	3 PIECE	BACKGR	1 CM	In Operation	Active	-	
192.16	68.16.210	3 PIECE	FILLING	1 CM	In Operation	Active		
192.16	68.16.207	AMPOULE	BACKGR	1 CM	At Rest	Active		
192.16	68.16.206	AMPOULE	FILLING	1 CM	At Rest	Active		
192.16	58.16.209	DPI	BACKGR	1 CM	At Rest	Active		
192.16	58.16.208	DPI	FILLING	1 CM	At Rest	Active		
192.10	08.10.212	FFS	FILLING	TOM	ALRESI		_	
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6.3.7 Check in display show IP address, area, location, volume, occupancy state and activation state.

6.3.8	Click the o	overview a	and check	the area	particle	(0.5 &	: 5.0)	micron	limit
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Classification	Maximum concentration limit (particle/m ³)-EU GMP					
	At Rest		In oper	ration		
	>=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		



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	Nil	Page No.:	4 of 18	
No.:				

🌸 CLiMET DataPro 3	- CLIMET Security Level 2 - Local clie	nt # 1					
File Tools Hel	p						
Overview View Ala	arms Reports Control						
	3 PIECE		3 PIECE		AMPOULE		AMPOULE
BA	CKGROUND-Class B		FILLING-Class A	BAC	CKGROUND-Class B	F	ILLING-Class A
≥ 0.5 µm	24,467 /CM	≥ 0.5 µm	7,603 /CM	≥ 0.5 µm	35 /CM	≥ 0.5 µm	0 /CM
≥ 5.0 µm	165 /CM	≥ 5.0 µm	97 /CM	≥ 5.0 µm	0 /CM	≥ 5.0 µm	0 /CM
	ОК		Fine Action		ОК		ОК
	DPI		DPI				
BA	CKGROUND-Class B		FILLING-Class A				
≥ 0.5 μm	13,601 /CM	≥ 0.5 µm	314 /CM				
≥ 5.0 µm	0 /CM	≥ 5.0 µm	0 /CM				
	Fine Action		ОК				
Ready							
							▲ 🔀 🖬 🕼 12:26 PM

- **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				In Operation		
		Alert limit	Action limit	Alert limit	Action limit	
0.5 mi	icron	2464	2,816	2,464	2,816	
Class - A 5.0 mi	icron	14	16	14	16	
Class - B	icron	2,464	2,816	2,46,400	2,81,600	
5.0 mi	icron	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.





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	Nil	Page No.:	5 of 18			
No.:						

- **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.



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	Nil	Page No.:	6 of 18			
No.:						

- **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.

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File	Tools Help								
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Right-click on table to enter comments. (The last 500 rows are shown) Auto-refresh table contents 🕅									
i	Timestamp	Area	Location	Comment					
•	30/11/16 10:19:47	3 PIECE	FILLING-Class A	In Operation ≥ 0.5 µm exceed					
	30/11/16 10:19:13	3 PIECE	FILLING-Class A	In Operation ≥ 0.5 µm exceed					
	30/11/16 10:16:45	3 PIECE	FILLING-Class A	In Operation ≥ 5.0 µm exceed					
	30/11/16 10:16:45	DPI	BACKGROUND-Class B	At Rest ≥ 0.5 µm exceeds fine					
	30/11/16 10:15:25	DPI	BACKGROUND-Class B	At Rest ≥ 0.5 µm exceeds fine					
1	30/11/16 10:15:02	3 PIECE	FILLING-Class A	In Operation ≥ 5.0 µm exceed					
i	30/11/16 10:06:13	DPI	BACKGROUND-Class B	Recovery from fine alert					
	30/11/16 10:06:13	DPI	BACKGROUND-Class B	Recovery from fine action					
1	30/11/16 10:06:02	DPI	BACKGROUND-Class B	At Rest ≥ 0.5 µm exceeds fine					
	30/11/16 10:06:02	DPI	BACKGROUND-Class B	At Rest ≥ 0.5 µm exceeds fine					
	30/11/16 09:56:51	AMPOULE	FILLING-Class A	Recovery from no response (1					
	30/11/16 09:56:51	Local Tower	192.168.16.213	Recovery from no response (1					
	30/11/16 09:38:10	Local Tower	192 168 16 214	Becovery from no response (1					
	30/11/16 09:38:09	DPI	FILLING-Class A	Becovery from no response (1					
	30/11/16 05:28:12	3 PIECE	BACKGROUND-Class B	Bad sensor					
	30/11/16 05:27:30	3 PIECE	FILLING-Class A	Bad sensor					
	30/11/16 05:17:52	AMPOLILE	BACKGROUND-Class B	No rosponso (192 168 16 207)					
	20/11/10 05:17:52		Ell LINC Class A	No response (102.100.10.207)					
	30/11/16 05:17:52	DDI	FILLING-Class A	No response (102,168,16,208)					
	30/11/18 05:17:32	Logal Tanaa	102 169 16 219	No response (102.168.16.208)					
	30/11/16 03:16:26	Local Tower	102.100.10.213	No response (162,168,16,213)					
	30/11/16 05:16:26	Local Tower	192.168.16.214	No response (192.168.16.214)					
	30/11/16 05:16:26	Local Tower	192.168.16.216	No response (192.168.16.216)					
	29/11/16 19:43:07	Local Tower	192.168.16.215	Recovery from no response (1					
	29/11/16 19:42:25	Local Tower	192.168.16.215	No response (192.168.16.215)					
	29/11/16 18:14:17	3 PIECE	BACKGROUND-Class B	Recovery from fine alert					
	29/11/16 18:14:17	3 PIECE	BACKGROUND-Class B	Recovery from coarse alert					
Ready									
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- 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.



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter						
SOD No .		Department:	Production			
SOP NO.:		Effective Date:				
Revision No.:	00	Revision Date:				
Supersede Revision	Nil	Page No.:	7 of 18			
No.:						

- **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).

# CLIMET DataPro 3 - CLIMET Security Level 2 - Local client #	
File Tools Help	
Overview View Alarms Reports Control	
Contin	inuous Monitoring Graphs
Raw	Data Summary EU GMP Annex 1 ISO 2015 FS 209E
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т	emplate: Version Count: Total Count Version
1	Save Template Delete Template
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	O Locations: Image: BACKGROUND-Class B Image: Image: BACKGROUND-Class B Belect All Image: Image: Image: Image: BACKGROUND-Class A Image: Imag
	Clear All
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	Batch No.
	Mfg.Date
	Exp.Date O
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	Use Alternate GMP Create Raw Data Report
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6.5.4.8 Select the flow, volume, unit ID, alarm, sensor type, laser OK, forced counts.

# CLIMET DataPro 3 - CLIMET Security Level 2 - Local client # 1	Constitution of the	or start Composite Statements	
File Tools Help			
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Use Al	ternate GMP	Create Raw Data Report	
Ready			
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6.5.4.9 Enter the Create Raw Data Report.

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



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE						
Title: Operation of Online Airborne Particle Counter						
SOD No .		Department:	Production			
SOP NO.:		Effective Date:				
Revision No.:	00	Revision Date:				
Supersede Revision	Nil	Page No.:	8 of 18			
No.:						

CLIMET DataPro 3 - CLIMET Security Level 2 - Local client # 1	X 0 -
File Tools Help	
Overview View Alarms Reports Control	
Continuous Monitoring Graphs	
Raw Data Summary EU GMP Annex 1 ISO 2015 FS 209E	
Report Define	
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Save Template Delete Template	
AMPOULE - Sizes:	
Image: Select All Image: Select All Image: Select All Image: Select All	
Clear All Prompt Enter purpose of test OK	
Product Name Cancel	
Image: Sector No. Imag	
♥ ô Exp.Date	
User Fields: The report will show the contents of these eight boxes	
Show Available Times Path: EX	
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■ 6 End time: 30/11/16 12:30:10 ■ Overwrite file 0001138153xlsx	
Orientation: Landscape Portrait	
Use Alternate GMP Create Raw Data Report	
Promot for test purpose	
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- **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)



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter						
		Department:	Production			
SOP No.:		Effective Date:				
Revision No.:	00	Revision Date:				
Supersede Revision	Nil	Page No.:	9 of 18			
No.:		_				

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V 🕹 🛛	Locations:	BACKGROUND-Clas	ss B	.5 µm	
<u>s</u>	elect All	FILLING-Class A	▼ ≥ 5	.0 µm	
<u>c</u>	Clear All				
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8	Orientation:	Landscape OP	Portrait	0001138155xisx -	
Use	e Alternate GMP		Cre	eate Summary Report	
Ready	1				
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- 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



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE Title: Operation of Online Airborne Particle Counter Bepartment: Production SOP No.: Department: Production Effective Date: Production Supersede Revision Nil Page No.: 10 of 18 No.: Other Holder Hol

CLIMET DataPro 3 - CLIMET Security Level 2 - Local cl	ient # 1	Concession of the local division of the loca	Inclusion Aller		
File Tools Help					
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	Raw Data Summary	EU GMP Annex 1 ISO 2015 FS 209	E		
	Report Define				
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	🔲 👌 Area:	AMPOULE	🗸 🗆 👌 Size	es:	
	☑ ⁶ Locations:	BACKGROUND-Class B	▼ ≥ 0.5 J	ım	
	Select All	FILLING-Class A	▼ ≥ 5.0 µ	Im	
	<u>Clear All</u>				
	Flow Average	🛛 Minimum	Action		
	Volume	☑ Maximum	Event Log	Select All	
	🛛 Unit ID	Time of Maximum	n 🛛 🛛 Alert Log	Clear All	
	Sensor Type	Events	Action Log		
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		Landscape O Portra	ait	001.xlsx	
	Use Alternate GMP		Creat	e Summary Report	
Ready					
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- **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).



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE Title: Operation of Online Airborne Particle Counter Bepartment: Production SOP No.: Department: Production Effective Date: Production Supersede Revision Nil Page No.: 11 of 18 No.: O Fage No.: 11 of 18

CLIMET DataPro 3 - CLIMET Security Level 2 - Local client # 1	Conception of the American American American	
File Tools Help		
Overview View Alarms Reports Control		
Continuous Monitoring	Graphs	
Raw Data Time Scale		
	Add Alarm Limits EDIT 0 alarm limits enabled.	
Template:	✓ ☐ ⁶ Count Mode: Total Count ✓	
Save Temp	late Delete Template	
🗔 👌 Area:	AMPOULE - Sizes:	
🗷 👌 Locations:	■ BACKGROUND-Class B $\blacksquare \ge 0.5 \mu m$	
Select All	IV FILLING-Class A IV ≥ 5.0 μm	
Clear All		
🗷 👌 Scale:	Use logarithmic scale	
Show Available	Times Path: E:\	
🔤 👌 Start time:	28/11/16 09:30:00 🔲 🗸 🔄 👌 File name: 001.xlsx	
🔤 👌 End time:	28/11/16 17:30:00 Overwrite file 0001138153xlsx	
🔄 👌 Orientation	Contraction Contra	
🔲 Use Alternate GM	Create Raw Data Graph	
Ready		
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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.

CLIMET DataPro 3 - CLIMET Security Level 2 - Local client #	1			
File Tools Help				
Overview View Alarms Reports Control				
Conti	nuous Monitoring Graphs			
Raw	Data Time Scale			
		Add Alarm I	imits EDIT 0 alarm limits enabled.	
т	emplate:	🗸 🔄 👌 Count N	lode: Total Count -	
	Save Template Dele	te Template		
	Area: AMPOULE	👻 🗔 👌 Si	izes:	
	Locations: BACKGROU	ND-Class B	5 µm	
	Select All	ss A 🛛 🗹 ≥ 5.4	0 μm	
	Clear All			
	Scale: 🛛 🖉 Use logarithm	ic scale		
	5 minute 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	es 🔹		
	Label frequency: Every 4	tick marks 👻		
s	how Available Times Path	E:\		
	Start time: 28/11/16 09:3	0:00 🔲 🖛 📄 🍪 File name:	001.xlsx	
	6 End time: 28/11/16 17:3	0:00 🖉 🖉 Overwrite file	0001138153xlsx	
	Orientation: O Landscape	Portrait	0001138155XISX	
	Use Alternate GMP	Cre	ate Time Scale Graph	
		L		
Ready				
				▲ 📴 🗤 12:48 PM 🚺 11/30/2016

- **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.



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE							
Title: Operation of Online Airborne Particle Counter							
	Department:	Production					
	Effective Date:						
00	Revision Date:						
Nil	Page No.:	12 of 18					
	STANDARI Airborne Particle 00 Nil	STANDARD OPERATING PROAirborne Particle CounterDepartment:Effective Date:00Revision Date:NilPage No.:	STANDARD OPERATING PROCEDUREAirborne Particle CounterDepartment:ProductionEffective Date:0000Revision Date:NilPage 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)



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter				
SOD No .		Department:	Production	
SOP NO.:		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision	Nil	Page No.:	13 of 18	
No.:				

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



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

ANNEXURE-I

OPERATION LOG BOOK FOR ONLINE AIRBORNE PARTICLE COUNTER

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



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter					
SOP No .		Department:	Production		
SOP No.:		Effective Date:			
Revision No.:	00	Revision Date:			
Supersede Revision	Nil	Page No.:	15 of 18		
No.:					

ANNEXURE-II PORTABLE PARTICLE COUNTER MONITORING RECORD

Instrument ID No.:		Date :	Date :				
Instrument Calibrat	ion done on:	Instrument Calibrat	Instrument Calibration due on:				
Product Name:		Batch No.:					
Mfg. Date:		Exp. Date:					
Reason for Using Portable particle counter :							
	DU	RATION STATUS					
	Grade A	Grade B	Result	Sign/Date			
Line Clearance (At Rest)							
Initial (In-Operation)							
Middle (In-Operation)							
End (In-Operation)							

Remark:



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

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

Section Name	:	
Product Name	:	
Batch No.	:	

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



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation of Online Airborne Particle Counter						
SOD No .		Department:	Production			
SOF No.:		Effective Date:				
Revision No.:	00	Revision Date:				
Supersede Revision	Nil	Page No.:	17 of 18			
No.:						

ANNEXURE-IV ALARM MANAGEMENT OF ONLINE PARTICLE COUNTER

		Visual and Audible display	Colour		
Alarm Type	Category	inside the Aseptic area	Display	Proposed Action	
			indication		
			at Monitor		
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	 Stop the batch filling activity Operator has to ensure the occurrence duration for OOL with respect to Filling m/c HMI / display watch of vial washing room. Action is to taken as per ANNEXURE-V Production/QA person has to write the justification for the same 	



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

ANNEXURE-V ACTION PLAN FOR EXCURSION IN NVPC

Location	Operation	Grade	Actions to be taken
Near Filling Nozzle	During assembling of machine parts Vials/ ampoules present on tracks	A	Immediately stop the activity. Do not assemble the machine parts till area normalize 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 Before aseptic connection to sterilized parts	В	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 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