



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Operation of Liquid Borne Particle Counter	Effective Date:
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1.0 OBJECTIVE

1.1 To describe the procedure for Operation of Liquid borne particle counter.

2.0 SCOPE

2.1 This procedure is applicable for PAMAS-SVSS in Microbiology Laboratory.

3.0 RESPONSIBILITY

3.1 Microbiologist is responsible for operation of Liquid borne particle counter.

4.0 ACCOUNTABILITY

4.1 Head Microbiology

5.0 EHS CONSIDERATIONS

5.1 Handle the Liquid borne particle counter carefully.

5.2 Switch 'OFF' the Liquid particle counter after completion of analysis.

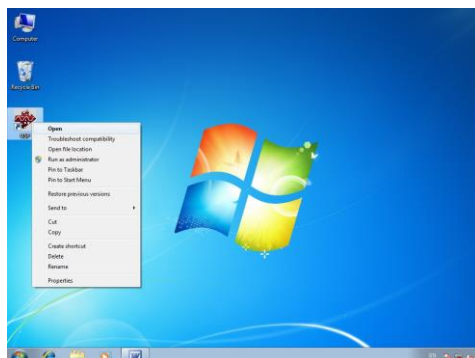
5.3 Use 0.22 μ filtered 70% IPA for rinsing the intake tube after completion of analysis.

5.4 Always keep the intake tube dipped in 70% Isopropyl alcohol (filtered through 0.22 μ m).

6.0 PROCEDURE

6.1 Operation of LPC:

6.1.1 Switch on the system and operate only through the computer using USP software.





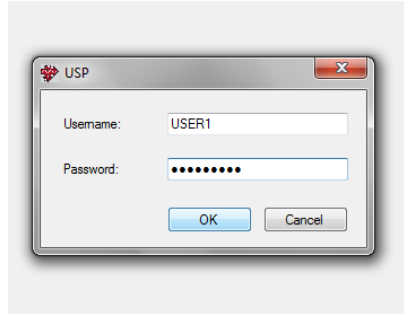
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6.1.2 Enter user ID and password in the software to log in.



6.1.3 Rinse the system with 70% Isopropyl alcohol (0.22 µm filtered).

6.1.4 Before starting rinsing ensures that the intake tube of the system is completely immersed in the rising fluid.

6.1.5 There should be sufficient volume (100 ml) to complete the test. The particle counter should not take in air while rinsing.

6.1.6 Click on the “Rinse” button to start rinsing.

6.2 Environment Test:

6.2.1 Perform the Environment Test with the WFI (filtered through 0.2µm) before starting the analysis of sample.

6.2.2 Observe the display of instrument for “sensor ok” message is present. If sensor fail message is there, reverse cleaning is required and error has to be reset.

6.2.3 In the software “Open” menu click on the “New Sample” and dialog box “Sample Measurement info” opens.

6.2.4 Enter the sample name as “Environment Test”.

6.2.5 Select “Environment Test” from the drop down menu of Set up.

6.2.6 All the parameters will set automatically as per stored settings.

6.2.7 Click “start” to measure.



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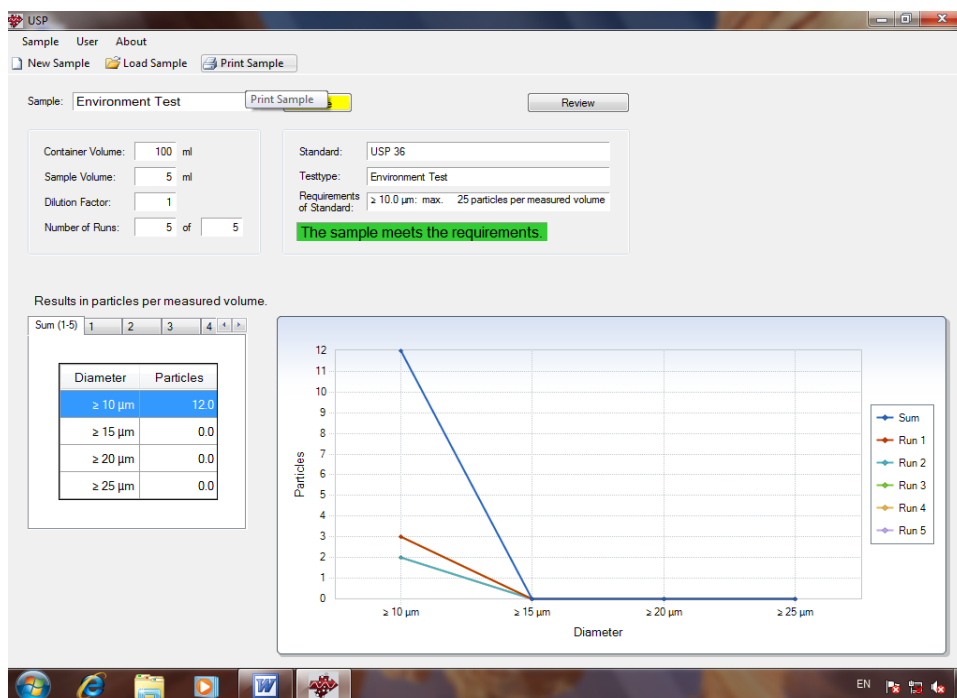
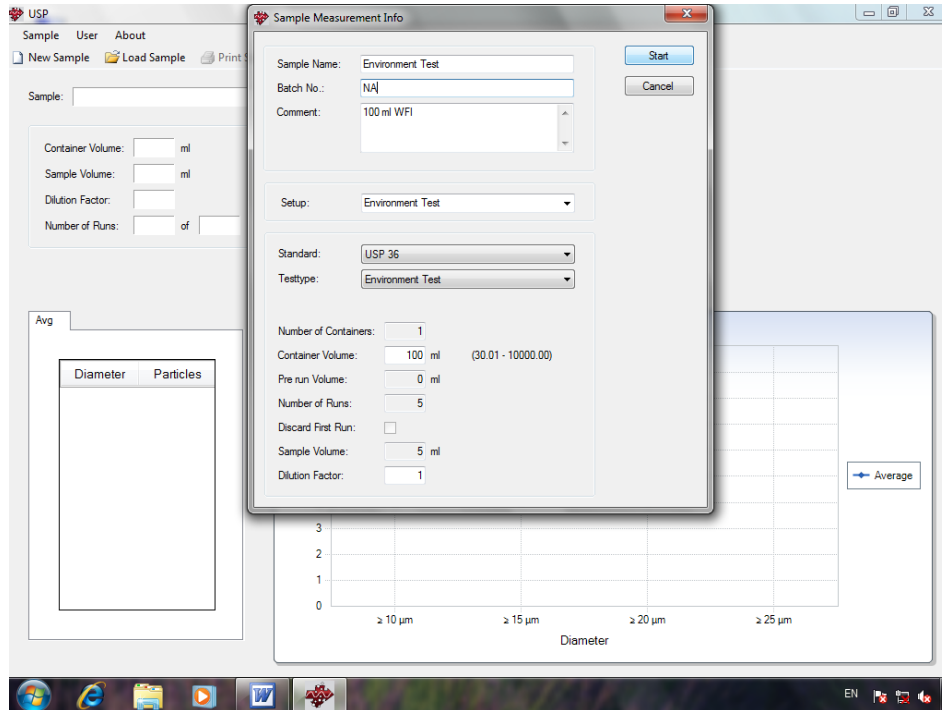
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6.2.8 After completion of analysis, results will be displayed in the screen.

6.2.9 Click "Print Sample" to take the print the results.



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6.2.10 Environment Test should be passed before starting the analysis of sample.

6.3 Analysis of Sterile API Sample:

6.3.1 For LBPC analysis clean and dried 100 ml conical flasks are used.

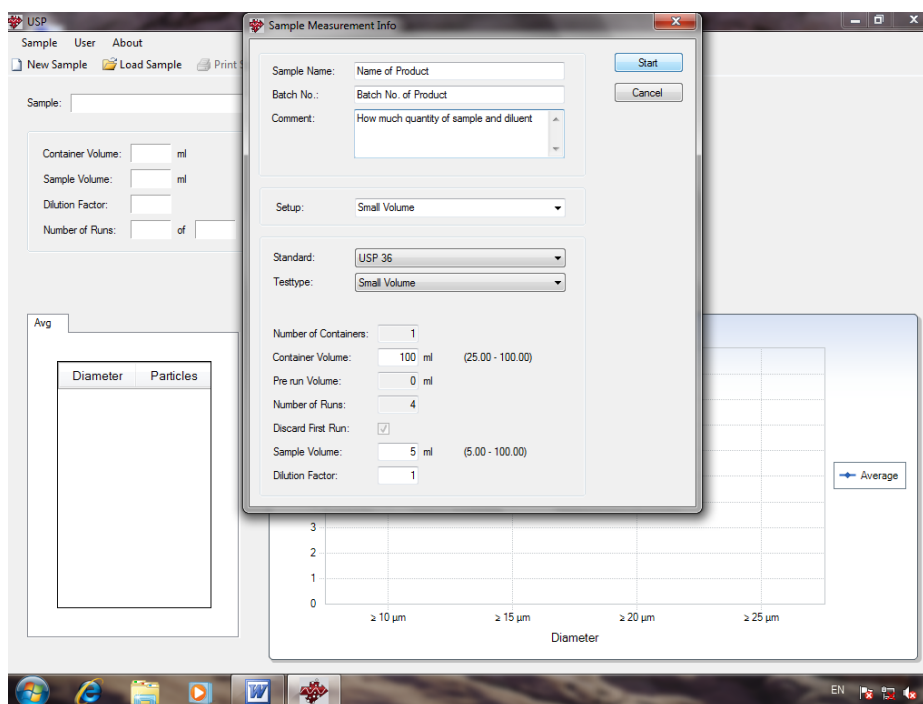
6.3.2 Take 1.0 gm of sample in 100 ml conical flask. Dissolve the sample in 100 ml WFI (filtered through 0.22 μ m) and ensure sample must be completely dissolved by sonication for 30 seconds.

6.3.3 After completion of sonication, sample is ready for analysis.

6.3.4 Place the sample conical flask on to the platform and place the intake tube inside.

6.3.5 Observe the display of instrument for “sensor ok” message is present. If sensor fail message is there, reverse cleaning is required and error has to be reset.

6.3.6 In the software “Open” menu click on the “New Sample” and dialog box “Sample Measurement info” opens.



6.3.7 Enter the sample name, batch no. and comments in the window.

6.3.8 Select “Small Volume Test” from the drop down menu of Set up.

6.3.9 All other parameters will be taken automatically as stored settings.



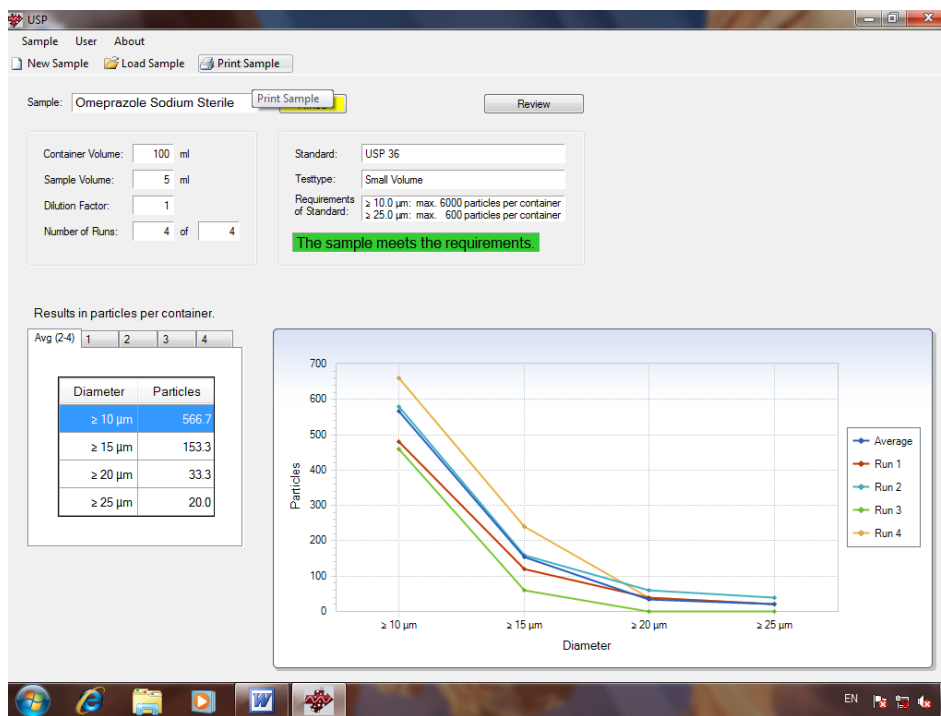
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6.3.10 Now click “start” to measure.

6.3.11 After completion of analysis, results will be displayed in the screen

6.3.12 Click “Print sample” to take the print the results.



6.3.13 Previous sample information can be loaded using the “Load Sample” button from sample menu. Data is stored date wise.

6.3.14 First injection results are not considered and only cumulative counts are considered as result as per stored settings.

6.4 Analysis of Dry powder vial and lyophilized vials:

6.4.1 For LBPC analysis clean and dried 100-200 ml conical flasks are used.

6.4.2 Take 10 sample vials and reconstitute with $0.2 \mu\text{m}$ filtered WFI as per recommended volume.

6.4.3 Mix the contents of the sample by slowly inverting the container 20 times successively.

6.4.4 If necessary, cautiously remove the sealing closure. Clean the outer surfaces of the container opening using a jet of particle-free water and remove the closure, avoiding any contamination of the contents.



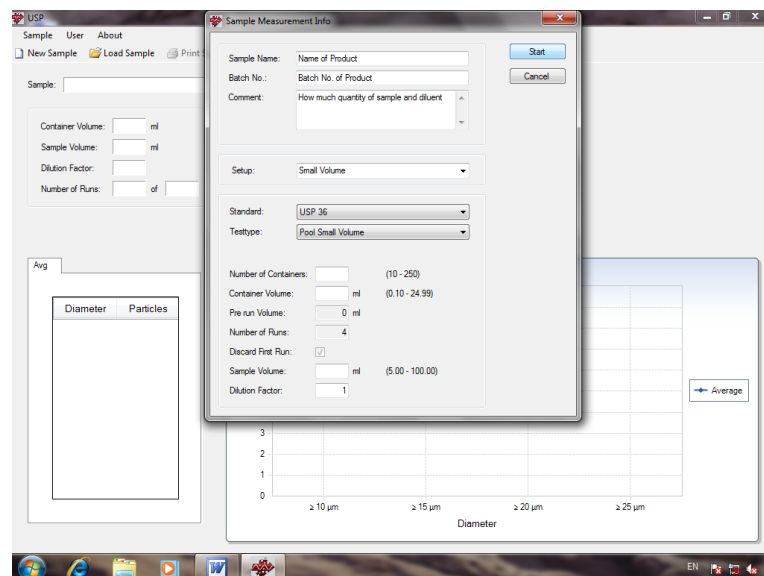
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- 6.4.5 Mix well and pool the content of the vials in the clean conical flask. Pooled sample volume should not less than 100 ml. If needed, take sufficient number of vials for reconstitution.
- 6.4.6 Eliminate gas bubbles by appropriate measures such as allowing to stand for 2 minutes or sonicating.
- 6.4.7 Now the sample is ready for analysis.
- 6.4.8 Observe the display of instrument for “sensor ok” message is present. If sensor fail message is there, reverse cleaning is required and error has to be reset.
- 6.4.9 Place the sample conical flask on to the platform and place the intake tube inside.
- 6.4.10 In the software “Open” menu click on the “New Sample” and dialog box “Sample Measurement info” opens.
- 6.4.11 Enter the sample name, batch no. and comments in the window.
- 6.4.12 Now select “Small Volume Test” from the drop down menu of Set up.
- 6.4.13 Then select “Pool Sample Small Volume”.
- 6.4.14 Enter the container number to be pooled and volume in each container.
- 6.4.15 Click “start” to measure.



- 6.4.16 After completion of analysis, results will be displayed in the screen.



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6.4.17 Click “Print sample” to take the print the results.

6.4.18 Previous sample information can be loaded using the “Load Sample” button from sample menu. Data is stored date wise.

6.4.19 First injection results are not considered and only cumulative counts are considered as result as per stored settings.

6.5 Analysis of Empty glass vials:

6.5.1 For LBPC analysis dedicated glassware must be used, clean and dried 100-200 ml conical flasks are used.

6.5.2 Take 10 sample vials and rinse with 10 ml 0.2 µm filtered WFI. Rinse well and pool the content of the vials in the clean conical flask. Pooled sample volume should not less than 100 ml. If needed, take sufficient number of vials for reconstitution.

6.5.3 Now the sample is ready for analysis.

6.5.4 Observe the display of instrument for “sensor ok” message is present. If sensor fail message is there, reverse cleaning is required and error has to be reset.

6.5.5 Place the sample conical flask on to the platform and place the intake tube inside.

6.5.6 In the software “Open” menu click on the “New Sample” and dialog box “Sample Measurement info” opens.

6.5.7 Enter the sample name, batch no. and comments in the window.

6.5.8 Now select “Small Volume Test” from the drop down menu of Set up.

6.5.9 Then select “Pool Sample Small Volume”.

6.5.10 Enter the container number to be pooled and volume in each container.

6.5.11 Now click “start” to measure.

6.5.12 After completion of analysis, results will be displayed in the screen.

6.5.13 Click “Print sample” to take the print the results.

6.5.14 Previous sample information can be loaded using the “Load Sample” button from sample menu. Data is stored date wise.

6.5.15 First injection results are not considered and only cumulative counts are considered as result as per stored settings.



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6.6 Analysis of cleaned rubber stoppers:

- 6.6.1 For LBPC analysis dedicated glassware must be used, clean and dried 100 ml conical flasks are used.
- 6.6.2 Take 10 cleaned rubber stoppers in 100 ml cleaned conical flask and add 100 ml 0.2 μm filtered WFI. Shake well so that rubber stoppers get rinsed well.
- 6.6.3 Now the sample is ready for analysis.
- 6.6.4 Observe the display of instrument for “sensor ok” message is present. If sensor fail message is there, reverse cleaning is required and error has to be reset.
- 6.6.5 Place the sample conical flask on to the platform and place the intake tube inside.
- 6.6.6 In the software “Open” menu click on the “New Sample” and dialog box “Sample Measurement info” opens.
- 6.6.7 Enter the sample name, batch no. and comments in the window.
- 6.6.8 Now select “Small Volume Test” from the drop down menu of Set up.
- 6.6.9 Then select “Pool Sample Small Volume”.
- 6.6.10 Enter the container number (rubber stopper number) to be samples and volume (10 ml) in each container.
- 6.6.11 Now click “start” to measure.
- 6.6.12 After completion of analysis, results will be displayed in the screen
- 6.6.13 Click “Print sample” to take the print the results.
- 6.6.14 Previous sample information can be loaded using the “Load Sample” button from sample menu. Data is stored date wise.
- 6.6.15 First injection results are not considered and only cumulative counts are considered as result as per stored settings.

6.7 Cleaning of the System

- 6.7.1 Before Switch off the system, rinse with 70% Isopropyl alcohol (0.22 μm filtered).
- 6.7.2 Rinse before starting the measurement and at the end of the day before switching off the instrument.

6.8 Calibration of the System



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6.8.1 Once in a year by outside party.

7.0 DEFINITIONS AND ABBREVIATIONS

7.1 LBPC –Liquid Borne Particle Counter

7.2 WFI – Water for Injection

7.3 % - Percentage

7.4 μm – micron meter

7.5 ml - milliliter

8.0 REFERENCE

8.1 USP monograph <788> Particulate matter in injections

8.2 Operating manual of LBPC PAMAS-SVSS

9.0 ANNEXURES

9.1 Annexure I: Liquid borne particle counter usage record.

10.0 DISTRIBUTION DETAILS

10.1 Controlled copy of this SOP shall be distributed to Quality Assurance and Microbiology.

11.0 REVISION HISTORY

Supersedes SOP No.	Change Control No.	Reason for revision