| National Cancer Institute-Frederick, Frederick, MD BDP | STANDARD OPERATING PROCEDURE | Effective Date Apr 19 2010 | Procedure Number 22308 | | | |
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| Title: Use of the High Pressure Diffuser Attachment with the MET One Model 3315 Particle Counter | | | | | | |
| Author/Date: | | | | | | |
| Approvals/Date: | | | | | | |
| SOP References: 22929 | | Supersedes: REV 01 | | | | |
| Purpose:This procedure d MET One Model measurement of the MET One PaScope:This procedure will sampling compreseContents:1.0 Authority and Response2.0 Equipment3.0 Materials4.0 Procedure5.0 Maintenance | lescribes the attachment of 1 3315 Particle Counter. Thi i the number of particles in article Counter. I be performed by Process A ssed gases and air in use a sibility | the high pressure diffu is attachment allows compressed gases an Analytics (PA) personr t the BDP. | user to the d air using nel when | | | |
| 6.0 Documentation | | | | | | |

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- 1.0 Authority and Responsibility
 - 1.1 The Director, Process Analytics (PA) has the authority to define this procedure.
 - 1.2 PA personnel are responsible for implementation and performing this procedure.
 - 1.3 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this operation.

2.0 Equipment

- 2.1 High Pressure Diffuser.
- 2.2 Met One Particle Counter Model 3315.

3.0 Materials

- 3.1 Gaskets, BDP PN 21895, or approved BDP equivalent.
- 3.2 Tubing with ID of 1/4 inch, BDP PN 21897, or approved BDP equivalent.
- 3.3 70% Ethanol, BDP PN 30129, or approved BDP equivalent.
- 3.4 High Vacuum Grease, BDP PN 21896, or approved BDP equivalent.

4.0 Procedure

- 4.1 Verify the gaskets in the VCR tube adaptor are new.
- 4.2 Using correctly sized hardware, attach the pressurized gas line to the orifice at the "Pressure" end of diffuser.
- 4.3 Screw one end of the VCR tube adaptor onto the diffuser and tighten the nut finger-tight.
- 4.4 While holding the diffuser nut with a wrench, tighten the VCR tube adaptor 1/8 turn past finger-tight.
- 4.5 Attach the tubing from the VCR tube adaptor to the particle counter sample inlet tube.

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- 4.6 Pressurize the sample input line, then turn the particle counter power on and press start. (See SOP 22929, Operation of the MET One Model 3315 Laser Particle Counter for the parameters of the instrument.)
- 4.7 Operate the MET One and record results as described in SOP 22929.

5.0 Maintenance

- 5.1 If the diffuser is suspected of contributing particles to the overall count (the particle counts are abnormally high), then clean the diffuser in a class 100 laminar flow hood.
 - 5.1.1 Disconnect the diffuser from the high pressure line by removing both inlet and outlet tubing from the diffuser.
 - 5.1.2 Remove the orifice from the inlet end of the diffuser and remove the sample tube from the outlet end of the diffuser.
 - 5.1.3 Unscrew the outlet end from the diffuser body; remove the O-ring from inlet end.
 - 5.1.4 Unscrew the sample end from the body of the diffuser; remove the O-ring from body.
 - 5.1.5 Spray all parts in the laminar flow hood liberally with 70% ethanol.
 - 5.1.6 Place all parts except the body into an ultrasonic bath of RODI water (under a Biological Safety Cabinet) for 15 minutes.
 - 5.1.7 Remove the parts, rinse them with RODI, and allow to dry in the hood.
 - 5.1.8 For ease in assembly, place the O-rings onto diffuser and coat with a thin layer of high vacuum grease.
 - 5.1.9 Reassemble the diffuser by repeating steps 5.1.1 5.1.4 in reverse order.

6.0 Documentation

6.1 Record use, calibration, and preventative maintenance in the equipment logbook.