



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Use of the High-Pressure Diffuser Attachment with the MET One Laser Particle Counters
SOP Number: 22308
Revision: 03

TABLE OF CONTENTS

1. PURPOSE	1
2. SCOPE	1
3. RESPONSIBILITIES	1
4. MATERIALS AND REAGENTS.....	2
5. EQUIPMENT	2
6. PROCEDURE.....	2
7. PREVENTATIVE MAINTENANCE	3
8. DOCUMENTATION AND RECORDS.....	3
9. REFERENCES AND RELATED DOCUMENTS	3

1. PURPOSE

This procedure describes the attachment of the high-pressure diffuser to the MET One Model 3415 or 3445 Particle Counter. This attachment allows measurement of the number of particles in compressed gases and air using the MET One Particle Counter

2. SCOPE

This procedure will be performed by Process Analytics (PA) personnel when sampling compressed gases and air in use at the BDP.

3. RESPONSIBILITIES

3.1 Director / Functional Area Process Analytics (PA)

- Defines procedure

3.2 PA Personnel

- Performs procedure

3.3 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight

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4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
21895	Gaskets	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
21896	High Vacuum Grease	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
21897	Tubing with ID of 1/4 inch	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
30129	70% Isopropyl Alcohol	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

5. EQUIPMENT

- High Pressure Diffuser
 - Low flow diffuser for use with Model 3415
 - High flow diffuser for use with Model 3445
- Met One Particle Counter Model 3415 or 3445

6. PROCEDURE

- 6.1 Verify the gaskets in the VCR tube adaptor are new.
- 6.2 Using correctly sized hardware, attach the pressurized gas line to the orifice at the "Pressure" end of diffuser.
- 6.3 Screw one end of the VCR tube adaptor onto the diffuser and tighten the nut finger tight.
- 6.4 While holding the diffuser nut with a wrench, tighten the VCR tube adaptor 1/8 turn past finger tight.
- 6.5 Attach the tubing from the VCR tube adaptor to the particle counter sample inlet tube.
- 6.6 Pressurize the sample input line, then turn the particle counter power on and press start. (See **SOP 22929 Operation of the MET One Laser Particle Counters** for the parameters of the instrument).
- 6.7 Operate the MET One and record results as described in **SOP 22929**.

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7. PREVENTATIVE MAINTENANCE

- 7.1 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.
- 7.1.1 Disconnect the diffuser from the high-pressure line by removing both inlet and outlet tubing from the diffuser.
 - 7.1.2 Remove the orifice from the inlet end of the diffuser and remove the sample tube from the outlet end of the diffuser.
 - 7.1.3 Unscrew the outlet end from the diffuser body; remove the O-ring from inlet end.
 - 7.1.4 Unscrew the sample end from the body of the diffuser; remove the O-ring from body.
 - 7.1.5 Spray all parts in the laminar flow hood liberally with 70% ethanol.
 - 7.1.6 Place all parts except the body into an ultrasonic bath of RODI water (under a Biological Safety Cabinet) for 15 minutes.
 - 7.1.7 Remove the parts, rinse them with RODI, and allow to dry in the hood.
 - 7.1.8 For ease in assembly, place the O-rings onto diffuser and coat with a thin layer of high vacuum grease.
 - 7.1.9 Reassemble the diffuser by repeating steps 7.1.1 - 7.1.4 in reverse order.

8. DOCUMENTATION AND RECORDS

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

9. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
22929	Operation of the MET One Laser Particle Counters