

**DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: On-site Inspection**

B361067162

FACILITY: Pharmacia & Upjohn Co LLC, a subsidiary of Pfizer		SRN / ID: B3610
LOCATION: 7000 Portage Road, KALAMAZOO		DISTRICT: Kalamazoo
CITY: KALAMAZOO		COUNTY: KALAMAZOO
CONTACT: Tim Swainston , Senior EHS Specialist		ACTIVITY DATE: 04/17/2023
STAFF: Monica Brothers	COMPLIANCE STATUS: Compliance	SOURCE CLASS: MEGASITE
SUBJECT: Announced scheduled inspection		
RESOLVED COMPLAINTS:		

This was an announced scheduled inspection. This inspection covered the rest of Section 3 of the ROP that was not inspected during the Building 41 inspection the previous year, as well as the wastewater and leak detection provisions in 40 CFR, Part 63, Subparts GGG and H. This was the third and final year in the three-year inspection cycle. Staff, Monica Brothers arrived on-site at 9:00 am and met with Tim Swainston and Jeff Robey from Pfizer. No visible emissions, other than steam, were observed upon arrival or during the facility walk-through.

We first went to a conference room to conduct the records review portion of the inspection. After reviewing records, we went to view the TOX (thermal oxidizer system) and associated CEMS, and pollution control equipment for this section of the ROP. I also observed some of the LDAR sampling that was being conducted that day.

The following table shows each piece of pollution control equipment that was observed and the corresponding operating ranges.

Rotoclone/ Scrubber	Fabric Filter	Emission Unit	Acceptable min/max or min GPM water	Acceptable minimum water pressure (psi)	Acceptable min/max differential pressure (inches of water)	Acceptable minimum water level (inches)	Observed readings from observations or photos
EX-104		EUCR138		40			We could not take a reading from this unit during the inspection because it was in an area where pack-out was occurring, which required special gowning and masking.
038ROTO0214-1		EUCR138		40			55
EX-T245		EUCR138				1	Dismantled or Removed
EX-OT354		EUCR138				1	No gauge. The facility checks this manually to see if

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							there is water in the unit. There was greater than one inch of water in the 2 units like this that were in operation at the time of the inspection.
	DUST1018	EUCR138			0.6/8		Not operating at the time of inspection
127ROTO3127-1		EUCR1127		40			49
127ROTO3128-1		EUCR1127		40			50
SCRB1044		EUCR1155	30/70				64.82
EX-OT356		EUCR1166				1	No gauge. The facility checks this manually to see if there is water in the unit. There was greater than one inch of water in the 2 units like this that were in operation at the time of the inspection.
EX-T288		EUCR1166				1	Not operating at the time of inspection
EX-T289		EUCR1166				1	Not operating at the time of inspection
EX-17		EUCR1195-S3		40			Not operating at the time of inspection
EX-19		EUCR1195-S3			0.1/10		4.1
EX-31		EUCR244		40			54

Rotoclone/ Scrubber	Fabric Filter	Emission Unit	Acceptable min/max or min GPM water	Acceptable minimum water pressure (psi)	Acceptable min/max differential pressure (inches of water)	Acceptable minimum water level (inches)	Observed readings from observations or photos
EX-9		EUCR2149		40			55
EX-10		EUCR2149		40			Dismantled or Removed
EX-28		EUCR2149		40			52
SCRB-1003		EUCR2149-S3	40/100				Dismantled or Removed
SCRB-1004		EUCR2149	120/200				155.6
SCRB-1005		EUCR2149	70/150				75.7
	DUST1008	EUCR373			0.2/5.0		0.2
EX-6		EUCR3173		40			45
EX-25		EUCR3173		40			49
EX-34		EUCR3173		40			Dismantled or Removed
SCRB1002		EUCR3173	300/400				340.7
	DC1/207	EUCR3207			0.2/5.0		1.7
SCRB1036		EUCR3207	52/132 upper nozzle				92
SCRB1036		EUCR3207	52/132 lower nozzle				92
SCRB1006		EUCR3225	175/275				Not operating at the time of inspection
SCRB1007		EUCR3225	75/150				85.1

Rotoclone/ Scrubber	Fabric Filter	Emission Unit	Acceptable min/max or min GPM water	Acceptable minimum water pressure (psi)	Acceptable min/max differential pressure (inches of water)	Acceptable minimum water level (inches)	Observed readings from observations or photos
	EF1C1HB1	EUCR3225			0.1/2.5		Not operating at the time of inspection
	EX-27	EUCR3225			0.1/2.5		1.25
	EX-30	EUCR3225			0.1/2.5		Not operating at the time of inspection
	EX-34	EUCR3225			0.1/2.5		0.3
	FILT1	EUCR466			0.05/2.5		Could not go into this area because of allergy risk
	FILT3114	EUCR466			0.1/2.5		Could not go into this area because of allergy risk
	FILT1543	EUCR466			0.1/2.5		Could not go into this area because of allergy risk
	HEPE1517	EUCR466			0.1/2.5		Could not go into this area because of allergy risk
EX-23		EUCR476		15			Unit currently out of service
	DUST1010	EUCR491COM			2.0/12.0		6.0
	EX-27 1049	EUCR491COM			0.1/2.5		1.4
	EX-27 1056	EUCR491COM			0.1/2.5		1.4
	EX-117	EUCR491COM			0.1/3		1.2
	EX-118	EUCR491COM			0.1/3		1.3
	EX-119	EUCR491COM			0.1/3		1.5

Rotoclone/ Scrubber	Fabric Filter	Emission Unit	Acceptable min/max or min GPM water	Acceptable minimum water pressure (psi)	Acceptable min/max differential pressure (inches of water)	Acceptable minimum water level (inches)	Observed readings from observations or photos
	DC25C	EUCR4335-S3			0.1/2.5		Unit currently out of service
	DC22C	EUCR4335-S3			0.1/2.5		0.6
	DUST242	EUCR4335-S3			0.1/2.5		Unit currently out of service
	DC39	EUCR4335-S3			0.1/2.5		Unit currently out of service
	335DUST5000-1	EUCR4335-S3			0.05/6.5		0.8
	FANE0210-1	EUCR4335-S3			0.2/3.0		Not operating at the time of inspection
SB180		EUCR4335-S3	132/475				296
SB385		EUCR4335-S3	20/50				34
	FILT0841-1	EUCR4335-S3			0.1/4.0		0.2
	FILT0842-1	EUCR4335-S3			0.1/4.0		Dismantled or Removed
	335DUST3007-1	EUCR4335-S3			0.2/8.0		1.3
	DUST3010	EUCR4335-S3			0.2/8.0		1.1
038ROTO0217-1		EUC38R6ALL		40			58
SCRB1047		EUC120R6ALL	80/100				Not operating at the time of inspection

Records:

EUCR138-S3:

- Lots of product produced per month (Limit = 295 lots/month)
 - Onsite Observations: They are consistently under this limit, with 39 lots/month in January 2021 being the highest since 2021.
- Actual particulate emission rates/month (Limit = 1180 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 156 lbs/month in January 2021 being the highest since 2021.
- Mean particle size and category of each lot of processed material controlled through the W-Rotoclone (038ROTO0214-1) on a monthly basis (Limit = no Particle Size A allowed)
 - Records show that they are only processing Category B

EUCR1127-S3:

- Lots of product produced per month (Limit = 152 lots/month)
 - Onsite Observations: They are consistently under this limit, with 60 lots/month in October 2021 being the highest since 2021.
- Actual PM PM10 and PM2.5 emission rates/month. (PM Limit = 570 lbs/month, PM10 limit = 570 lbs/month, PM2.5 limit = 570 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 225 lbs/month in October 2021 being the highest since 2021.

EUCR1155-S3:

- Lots of product produced in TSP process/month (Limit = 160 lots/month)
 - Onsite Observations: They are consistently under this limit, with 59 lots/month in January 2023 being the highest since 2021.
- Particulate emissions/month (limit = 400 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 148 lbs/month in January 2023 being the highest since 2021.

EUCR1166-S3:

- Lots of product produced in TSP process/month (Limit = 50 lots/month)
 - Onsite Observations: None. This emission unit has been out of service since before 2021.
- Particulate emissions/month (limit = 25 lbs/month)
 - Onsite Observations: None. This emission unit has been out of service since before 2021.

EUCR1195-S3:

- Lots of product produced in TSP process/month (Limit = 120 lots/month)
 - Onsite Observations: They are consistently under this limit, with 76 lots/month in August 2021 being the highest since 2021.
- Particulate emissions/month (limit = 240 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 152 lbs/month in August 2021 being the highest since 2021.

EUCR244-S3:

- Lots of product produced in TSP process/month (Limit = 60 lots/month)
 - Onsite Observations: They are consistently under this limit, with 18 lots/month in March 2022 being the highest since 2021.
- Particulate emissions/month (limit = 300 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 90 lbs/month in March 2022 being the highest since 2021.

EUCR2149-S3:

- Lots of product produced in TSP process/month (Limit = 225 lots/month)
 - Onsite Observations: They are consistently under this limit, with 161 lots/month in January 2021 being the highest since 2021.
- Particulate emissions/month (limit = 675 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 483 lbs/month in January 2021 being the highest since 2021.

EUCR373-S3:

- Lots of product produced in TSP process/month (Limit = 20 lots/month)
 - Onsite Observations: They are consistently under this limit, with 8 lots/month in May 2021 being the highest since 2021.
- Particulate emissions/month (limit = 0.8 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 0.3 lbs/month in May 2021 being the highest since 2021.

EUCR3173-S3:

- Lots of product produced in TSP process/month (Limit = 150 lots/month)
 - Onsite Observations: They are consistently under this limit, with 80 lots/month in both January and February 2021 being the highest since 2021.
- Particulate emissions/month (limit = 240 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 128 lbs/month in both January and February 2021 being the highest since 2021.

EUCR3207-S3:

- Lots of product produced in TSP process/month (Limit = 70 lots/month)
 - Onsite Observations: They are consistently under this limit, with 30 lots/month in October 2021 being the highest since 2021.
- Particulate emissions/month (limit = 105 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 45 lbs/month in October 2021 being the highest since 2021.

EUCR3225-S3:

- Lots of product produced in PM-emitting processes/month (Limit = 115 lots/month)
 - Onsite Observations: They are consistently under this limit, with 41 lots/month in June 2021 being the highest since 2021.

- Lots of product produced in VOC processes/month (limit = 30 lots/month)
 - Onsite Observations: None. They have not processed any lots with VOC since before 2021.
- Actual PM PM10 and PM2.5 emission rates/month. (PM Limit = 188.6 lbs/month, PM10 limit = 188.6 lbs/month, PM2.5 limit = 188.6 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 67 lbs/month in June 2021 being the highest since 2021.
- VOC emissions/month (limit = 75 lbs/month)
 - Onsite Observations: None. They have not processed any lots with VOC since before 2021.
- VOC emissions in TPY for unconnected silica slurry exhaust hood (limit = 3.91 tpy on a 12-month rolling time-period)
 - Onsite Observations: They have not yet started running this process.
- Visible emissions observation once/month
 - Onsite Observations: Visible emissions observations are being conducted monthly. If visible emissions are observed, it is recorded, and appropriate actions are taken to fix the issue.

EUCR466-S3:

- Lots of product produced in TSP process/month (Limit = 190 lots/month)
 - Onsite Observations: They are consistently under this limit, with 22 lots/month in February 2022 being the highest since 2021.
- Particulate emissions/month (limit = 475 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 55 lbs/month in February 2022 being the highest since 2021.

EUCR476-S3:

- Product produced in TSP processes/month (Limit = 100,000 lbs/month)
 - Onsite Observations: None. They have not run this process since before 2021.
- Particulate emissions/month (limit = 14.5 lbs/month)
 - Onsite Observations: None. They have not run this process since before 2021.

EUCR491COM-S3:

- Lots of product produced in TSP processes/month (Limit = 30 lots/month)
 - Onsite Observations: They are consistently under this limit, with 20 lots/month in May 2021, February 2022, and February 2023 being the highest since 2021.
- Lots of VOC emitting product produced in equipment not controlled by the thermal oxidizer/month (limit = 5 lots/month)
 - Onsite Observations: They have not processed any lots with VOC since before 2021.
- Actual PM emission rate/month. (PM Limit = 90 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 50 lbs/month in May 2021, February 2022, and February 2023 being the highest since 2021.
- VOC emissions/month (limit = 50 lbs/month)
 - Onsite Observations: They have not processed any lots with VOC since before 2021.
- VOC emissions/lot (limit = 10 lbs/lot)

- Onsite Observations: They have not processed any lots with VOC since before 2021.
- Methanol emissions per hour (limit = 0.1 pph)
 - Onsite Observations: They have not run any processes with these emissions since before 2021.
- Methylene Chloride emissions per hour (limit = 1 pph)
 - Onsite Observations: They have not run any processes with these emissions since before 2021.
- Ozone emissions per hour (limit = 0.2 pph)
 - Onsite Observations: They have not run any processes with these emissions since before 2021.

EUCR4335-S3:

- Monthly water flow rate for particle scrubber and ventilation scrubber
 - Ventilation scrubber min/max water flow rates = 132/475 gpm
 - Onsite Observations: Monthly check of water flow rate are being conducted. If flow rates are observed to be out of range, it is recorded, and appropriate actions are taken to fix the issue.
 - Particle scrubber min/max water flow rates = 20/50 gpm
 - Onsite Observations: Monthly check of water flow rate are being conducted. If flow rates are observed to be out of range, it is recorded, and appropriate actions are taken to fix the issue.
- PM lbs/month (limit = no limit)
 - Onsite Observations: These records are being kept monthly.
- Process vent 335DUST5000-1:
 - Hours of operation while handling isoflupredone acetate-containing materials per month (no limit)
 - They are keeping these records.
 - Hours of operation while handling isoflupredone acetate-containing materials per per 12-month rolling (no limit)
 - They are keeping these records.
 - Isoflupredone acetate emission calculations per month and per 12-month rolling (limit = 38 lbs/year)
 - Onsite Observations: They are consistently under this limit, with 0.5 lbs in June 2021 being the highest since 2021.
 - VE readings once per month (limit = 10%)
 - Onsite Observations: Visible emissions observations are being conducted monthly. If visible emissions are observed, it is recorded, and appropriate actions are taken to fix the issue.

EUCR38R6ALL-S3:

- Lots of product produced per month (Limit = 95 lots/month)
 - Onsite Observations: None. This process has not run since before 2021.
- Actual PM PM10 and PM2.5 emission rates/month. (PM Limit = 428 lbs/month, PM10 limit = 428 lbs/month, PM2.5 limit = 428 lbs/month)
 - Onsite Observations: None. This process has not run since before 2021.

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EUC120R6ALL-S3:

- Lots produced in TSP processes/month (Limit = 279 lots/month)
 - Onsite Observations: They are consistently under this limit, with 36 lots/month in June 2021 being the highest since 2021.
- Particulate emissions/month (limit = 1493 lbs/month)
 - Onsite Observations: They are consistently under this limit, with 193 lbs/month in June 2021 being the highest since 2021.
- Wet venturi Scrubber monthly flow rates recorded monthly (Limit = between 80-100 GPM)
 - Onsite Observations: Monthly check of water flow rate are being conducted. If flow rates are observed to be out of range, it is recorded, and appropriate actions are taken to fix the issue.

FGCRALLPART-S3:

- Visible emissions observations once per month
 - Onsite Observations: Visible emissions observations are being conducted monthly. If visible emissions are observed, it is recorded, and appropriate actions are taken to fix the issue.
- Operating range inspections for N-Rotoclones W-rotoclones, scrubbers and baghouses once per month
 - Onsite Observations: Monthly checks of operating ranges are being conducted. If readings are observed to be out of range, it is recorded, and appropriate actions are taken to fix the issue.

FGCRALLTOX-S3:

This flexible group encompasses all of the equipment located in Region I process Buildings 38, 127, 155, 195; Region II process Buildings 44, 149; Region III process Buildings 73, 173, 207, 225; and Region IV process Buildings 66, 76, 91 commercial, 172, 335 that is connected to and controlled by the regional thermal oxidizer (TOX).

During the inspection and on-site tour, I recorded the following data from the TOX:

- TOX temperature (limit = 1635°F at minimum)
 - Onsite Observation: 1757.1°F
- Inlet gas flow rate to TOX (limit= 5200 scfm at maximum)
 - Onsite Observation: 2543.5 scfm
- Water flow rate in gal/min in scrubber (limit = 750 gal/min at minimum)
 - Onsite Observation: 901.6 gal/min
- pH in scrubber liquid effluent (minimum daily average = 7.0)
 - Onsite Observation: 7.9

These parameters are continuously monitored and recorded. There are also alarms that are set to indicate when one of these parameters is out of range.

- TOX Records: after-control records were viewed for compliance.

- Other VOC (VOC, methylene chloride, and acetone) (limit = 37 tpy on 12-month rolling time period)
 - Onsite Observation: 0.6 tpy in July and August 2022 was the highest recorded since 2021.
- Other VOC (VOCs, Methylene Chloride and Acetone) (Limit = 20 ppm on a 24-hour average)
 - Onsite Observations: They are consistently under this limit, with 2.42 ppm in May 2022 being the highest since 2021.
- For the before-control emission limits, they have simply calculated the worst-case scenario for each Region, which are essentially their emission limits in the ROP.
- They are also keeping track of after-control Dioxins and Furans.

FGCR6FERM-S3

- # lots of product code KCF in EUC121R6ALL-S3 on 12-month rolling time period (monthly) (limit = 14 lots/ year 12-month rolling)
 - Onsite Observation: 1 lot per 12-month rolling time period was the highest since 2020.
- Aeration rate once per month (limit = 150,000 scf/min at maximum)
 - Onsite Observation: They are consistently under this limit.
- VOC and acetone emission rate (not during KCF production) per month on 12-month rolling time period (limit = 34.5 tpy)
 - Onsite Observation: The highest emission rate since 2021 was 9.9 tpy during January 2021.
- VOC emission rate 12-month rolling after each month (limit = 45.7 tpy)
 - Onsite Observation: The highest emission rate since 2021 was 9.9 tpy during January 2021.
- VOC cumulative emissions from April through September (monthly) (limit = 24.0 tons)
 - Onsite Observation: The highest emission rate since 2021 was 2.87 tpy during 2021.
- Acetaldehyde 12-month rolling per month (limit = 9.6 tons/year)
 - Onsite Observation: The highest emission rate since 2021 was 0.41 tpy in January 2021 and January 2022.
- Formaldehyde 12-month rolling per month (limit = 1.9 tons/year)
 - Onsite Observation: The highest emission rate since 2021 was 0.18 tpy in both November and December 2021.
- Number of NM fermentations each calendar day (limit = 13)
 - Onsite Observation: The highest number of fermentations since 2021 was 5 fermentations in the entire month of January in 2023.
- Number of AX and 1DF fermentations each calendar day (limit = 4)
 - Onsite Observation: The highest number of fermentations since 2021 was 3 fermentations in the entire month of January in 2021.
- Number of KCF fermentations each calendar day (limit = 4)
 - Onsite Observation: None have been run since before 2021.

RULE 290 Records for S3

- There are over forty Rule 290 emission units. I viewed the records for each of these emission units, and they were all under the required limits.

New PTI #167-20

- Construction has not yet been completed for the Modular Aseptic Processing (MAP) building and associated equipment. Start-up may occur late this year or early next year.

40 CFR, Part 63, Subpart GGG and Subpart H Leak Detection Program

During the inspection, Jeff Robey from Pfizer discussed the leak detection program (LDAR). This program is a continual process. A contracted technician uses a monitor to detect leaks on connectors, valves, pumps, agitators, and relief devices. Jeff said that the technician uses Method 21 to do the monitoring and calibrates the monitor three times per day. The data from the monitor gets stored electronically.

They have about 11,000 valves that currently require annual monitoring. However, there is a provision that allows for bi-annual monitoring if the leak rate is low enough. Jeff said that they were recently able to qualify for this and began bi-annual monitoring in 2021. There are about 27,000 connectors that are monitored on a 4-year cycle. Pumps and agitators are currently monitored on a quarterly basis and are also required to have a weekly visible leak check, which is performed by operators in each area of the plant.

Pfizer has about 500 different pressure test trains. These trains tend to be batch processes that are not easily tested with LDAR monitoring. Continuous processes are monitored with LDAR monitoring. Pressure tests are performed once per year, and whenever changes to the test trains occur. For connectors, valves, and pressure release devices, readings above 500 ppm are considered leaks. For pumps, readings above 2,000 ppm are considered leaks. For agitators, readings above 10,000 ppm are considered leaks. If a leak is detected, it is recorded, and an orange tag is put on the equipment. They have five days to make a first attempt at repairing the unit. If that does not work, they have 15 days to make the repair. However, pressure release devices are only allowed five days to be fixed, otherwise, it must be removed from service. They can also delay repair on a leaking unit, but the unit must be taken out of service and emptied until it is fixed. They also keep records of follow-up monitoring after repairs, how and when leaks were repaired, and line entries. They also have a facility hotline to report leaks. Pfizer is required to submit to EGLE semi-annual reports that summarize the LDAR monitoring. They have been submitting these reports.

During the inspection I was able to observe a calibration and sampling of a few valves. Eric from Alliance Technical Group does all of Pfizer's LDAR sampling and showed me how the equipment is calibrated. They use three different zero gases to calibrate the unit, which were 0, 2000, and 10,000 ppm. The calibration needs to stay within 10% to be in compliance. They are required by the regulation to do one calibration every morning, but Pfizer also does one in the afternoon and one in the evening as well, just to make sure the data they are getting is accurate. If any of those calibrations are over the 10% limit, they throw out the previous data collected and sample them again.

40 CFR, Part 63, Subpart GGG Wastewater Provisions

This regulation designates wastewater as "affected" if the annual average concentration of partially soluble HAP in the wastewater is greater than 1,3000 ppmw, or if the average annual concentration of partially soluble HAP and/or soluble HAP in the wastewater is greater than

5,200 ppmw. This regulation was promulgated on October 21, 1998 and had a compliance date for existing sources on October 21, 2002. Because of this, in 2001, Pfizer installed the steam stripper, associated inlet tanks, and tanks to hold the treated water before it goes to the city wastewater treatment plant. Various affected streams are treated with the steam stripper, which separates out the solvents. The solvents are then sent to the solvent recovery area for further processing. This includes many distillation columns that are connected to the TOX. All affected wastewater from the facility is processed either through the steam stripper, the distillation columns, sent to the south tank farm, or to the deep injection well. The wastewater that is sent to the Kalamazoo Water Reclamation Plant or sanitary sewer is not considered "affected". It is below the required 1,300 ppmw for partially soluble HAP and 5,200 ppmw for partially soluble and/or soluble HAP.

The facility seemed to be in compliance at the time of inspection.

NAME Monica Brothers

DATE 4/21/2023

SUPERVISOR R/L 4/26/23