

DEPARTMENT OF ENVIRONMENTAL QUALITY

AIR QUALITY DIVISION

FCE Summary Report

Facility : Pharmacia & Upjohn Co LLC, a subsidiary of Pfizer	SRN : B3610
Location : 7000 Portage Road	District : Kalamazoo
	County : KALAMAZOO
City : KALAMAZOO State: MI Zip Code : 49001	Compliance Status : Compliance
Source Class : MEGASITE	Staff : Monica Brothers
FCE Begin Date : 09/18/2020	FCE Completion Date : 4/17/2023
Comments : The facility seemed to be in compliance at the time of inspections. This is the end of the three-year cycle for the megasite.	

List of Partial Compliance Evaluations :

Activity Date	Activity Type	Compliance Status	Comments
04/17/2023	On-site Inspection	Compliance	Announced scheduled inspection
04/06/2023	Other Non ROP	Compliance	Notification of completion of modification of the EUCR491COM-S3 and EUCR3225-S3 to be able to process 1MAV and 2MAV in B225 and B91.
03/21/2023	MAERS	Compliance	2022 Emission Inventory Report via MAERS on 3/14/23
03/21/2023	MAERS	Compliance	2022 Emission Inventory Report via MAERS on 3/14/23
03/14/2023	MAERS	Compliance	2022 MAERS Report and SCT Form submitted.
03/09/2023	Other Non ROP	Compliance	Notification of completion of modification of EUCR491COM-S3 for installation of TANK3418 and TANK3419 for B91, under PTI No. 23-23. This modification was completed on February 10, 2023.
03/09/2023	Other Non ROP	Compliance	Notification of completion of modification of EUC120R6ALL-S3 for installation of B120 Scrubber replacement, under PTI No. 103-22. This modification was completed on March 10, 2023.
03/09/2023	ROP Annual Cert	Compliance	The company reported no deviations for this time period.
03/09/2023	ROP SEMI 2 CERT	Compliance	The company reported no deviations for this time period.
03/09/2023	ROP Annual Cert	Compliance	The company reported no deviations for this time period.
03/09/2023	ROP SEMI 2 CERT	Compliance	The company reported no deviations for this time period.

Activity Date	Activity Type	Compliance Status	Comments
03/09/2023	ROP SEMI 2 CERT	Compliance	The company reported no deviations for this time period.
03/09/2023	ROP Annual Cert	Compliance	The facility reports three deviations, one for EUCR41MICRONIZING-S3, one for FGPHARMAMACT-S3, and one for EUCRALLTOX-S3 during the first half of 2022.
02/21/2023	CEMS Test Observation	Compliance	NOx RATA on Boiler 9
02/09/2023	NSPS (Part 60)	Compliance	Third quarter Subpart Db compliance report for Boiler #9, 10, and 11. They report 3 hours of CEMS downtime and no excess emissions for Boilers 9, 2 hours of CEMS downtime and no excess emissions for Boiler 10 and 0 hours of CEMS downtime and no excess emissions for Boiler 11.

Activity Date	Activity Type	Compliance Status	Comments
01/30/2023	MACT (Part 63)	Compliance	<p>Periodic report for 40 CFR Part 63 Subpart GGG (Pharmaceutical MACT): 4th Quarter. This includes their LDAR Report and Cylinder Gas Audit Report. They report 0 hours (0%) of CEM downtime and no exceedances, excess emissions, or excursions. They report 3,755 minutes of TOx downtime or malfunction from three separate events. One of these events had a downtime of 3,721 minutes or about 2.5 days. The report stated that for this event, "December 23, 2022 at 05:24 through December 26, 2022 at 13:25. At 04:48 the TOX2 scrubber started to experience water flow problem at the same time a high heat event at the scrubber occurred. Water flow is controlled by a capillary level control instrument which can freeze. Due to the cold weather the capillary froze providing a false reading. The high heat event melted the packing in the scrubber which plugged up the water lines not allowing the scrubber to maintain the required flow rate listed in the renewable operating permit. The damaged caused to TOX2 scrubber required TOX1 to be warmed up but due to the weather it took longer than normal to start up and become operational. When TOX1 got up to compliance temperature the process valve was opened. Power to the heat trace was increased to prevent freezing and a different flow control technology is being installed which has less freezing risk." There were no excess emissions or exceedances as a result of this event.</p>
01/23/2023	CEM RATA	Compliance	<p>Boilers 9, 10, and 11 NOx CEMS RATA Test Plan. The RATA will be performed on February 21-23, 2023.</p>

Activity Date	Activity Type	Compliance Status	Comments
11/03/2022	NSPS (Part 60)	Compliance	Third quarter Subpart Db compliance report for Boiler #9, 10, and 11. They report 2 hours of CEMS downtime and no excess emissions for Boilers 9, 24 hours of CEMS downtime and no excess emissions for Boiler 10 and 3 hours of CEMS downtime and no excess emissions for Boiler 11.
10/31/2022	MACT (Part 63)	Compliance	Third quarter periodic report for the pharmaceutical MACT Subpart GGG. LDAR report was not included because these reports are semi-annual. No parameter exceedances, no periods of excess emissions, and no excursions were reported. They also reported 0 hours of CMS downtime and no malfunction events on the TOx for this reporting period.
09/15/2022	ROP Semi 1 Cert	Compliance	The company reported no deviations for this time period.
09/15/2022	ROP Semi 1 Cert	Compliance	The company reported no deviations for this time period.
09/15/2022	ROP Semi 1 Cert	Compliance	The facility reports three deviations, one for EUCR41MICRONIZING-S3, one for FGPHARMAMACT-S3, and one for EUCRALLTOX-S3. Corrective actions were taken and no Violation Notice will be sent at this time.
09/15/2022	CEM RATA	Compliance	Relative Accuracy Test Audit (RATA) Test Report for TOx stack 1, stack 1/2 backup and Stack 2 analyzers Continuous Emissions Monitoring System (CEMS)
08/11/2022	NSPS (Part 60)	Compliance	Second quarter Subpart Db compliance report for Boiler #9, 10, and 11. They report 10 hours of CEMS downtime and no excess emissions for Boilers 9, and 0 hours of CEMS downtime and no excess emissions for Boilers 10 and 11.
08/08/2022	Other Non ROP	Compliance	Notification of completion of modification of EUCR2149-S3 for the two solids drum charging glove boxes for B149, under PTI No. 30-21A. This modification was completed on August 8, 2022.

Activity Date	Activity Type	Compliance Status	Comments
07/29/2022	MACT (Part 63)	Compliance	Second quarter Subpart GGG periodic report. Includes semi-annual LDAR report. No exceedances, excess emissions, or excursions were reported for this period. They had 2 hours of CEMS downtime and reported 1 malfunction event for this period.
07/26/2022	CEMS Test Observation	Compliance	Observation of RATA. Primary CEMS in Stack 1 and backup tested on this date.
05/05/2022	MACT (Part 63)	Compliance	Pharmaceutical MACT periodic report for 40 CFR Part 63 Subpart GGG. These reports are quarterly, however the LDAR reports are semi-annual, so they were not included during this quarter. They report 6 hours of CEM downtime, and 0 minutes of TOx malfunction time.
05/05/2022	NSPS (Part 60)	Compliance	First quarter Subpart Db compliance report for Boiler #9, 10, and 11. They report 2 hours of CEMS downtime and no excess emissions for Boilers 9, and 0 hours of CEMS downtime and no excess emissions for Boilers 10 and 11.
05/05/2022	CEM RATA	Compliance	RATA Report for Boilers 9, 10, and 11.
04/26/2022	On-site Inspection	Compliance	Announced scheduled inspection of Building 41, which is in both Section 2 and 3 of the ROP.
04/15/2022	Stack Test	Compliance	Relative Accuracy Test Audit (RATA) Test Report for TOx stack 2 and stack 1/2 backup
03/15/2022	CAM Excursions/Exceedances	Compliance	CAM Semi-Annual Monitoring Report. No excursions or exceedances were reported.
03/15/2022	ROP Annual Cert	Compliance	Facility reports one deviation for Boilers 10 & 11. The second quarter cylinder gas audit (CGA) test for boilers 10 & 11 was not conducted until 7/16/21. Corrective actions were taken so that this does not happen again.
03/15/2022	ROP Annual Cert	Compliance	The facility reports one deviation that occurred for EUDPMANUALCLN-S2/FGRULE290-S2 in February 2021. The 1,000 lb/month threshold was exceeded for the month of February 2021. The facility obtained PTI #135-20 in March 2021 to increase this limit.

Activity Date	Activity Type	Compliance Status	Comments
03/15/2022	ROP Annual Cert	Compliance	The facility reports six deviations, one for FGCFUG-S3, two for EUCR138-S3, and three for EUCRALLTOX-S3. Corrective actions were taken and no Violation Notice will be sent at this time.
03/15/2022	ROP SEMI 2 CERT	Compliance	The company reported no deviations for this time period.
03/15/2022	ROP SEMI 2 CERT	Compliance	The company reported no deviations for this time period.
03/15/2022	ROP SEMI 2 CERT	Compliance	The facility reports three deviations, two for FGCFUG-S3, and two for EUCRALLTOX-S3. Corrective actions were taken and no Violation Notice will be sent at this time.
02/16/2022	CEMS Test Observation	Compliance	NOx RATA on Boiler #10.
02/15/2022	CEMS Test Observation	Compliance	NOx RATA on Boiler #9.
02/07/2022	Release Reports		NRC #1328141: CALLER IS REPORTING THE RELEASE OF AN UNKNOWN AMOUNT OF TOLUENE FROM A RUPTURED DISC AT THE FACILITY. THE RELEASED MATERIAL WENT INTO THE AIR AND ATMOSPHERE. THE CAUSE OF THE RELEASE IS DUE TO EQUIPMENT FAILURE. REPAIRS MADE, CLEAN UP UNDERWAY. PEAS Report stated, "NRC #1328144: UPDATE: ONE EMPLOYEE WAS EXPOSED TO TOLUENE AND ENTERED THE SAFETY SHOWER. THE EXTENT OF INJURIES TO THE PERSON ARE UNKNOWN AND IT IS UNKNOWN IF THEY WERE TAKEN TO A HOSPITAL." Staff, Monica Brothers, followed up with the facility.
02/04/2022	MACT (Part 63)	Compliance	40CFR63.Subpart DDDDD Boiler MACT Compliance Report 63.7550(a)

Activity Date	Activity Type	Compliance Status	Comments
02/04/2022	NSPS (Part 60)	Compliance	Fourth quarter Subpart Db compliance report for Boiler #9, 10, and 11. Includes cylinder gas audit. They report 1 hours of CEMS downtime and no excess emissions for Boiler 9. They report 29 hours of CEMS downtime and no excess emissions for Boiler 10. They report 2 hours of CEMS downtime and no excess emissions for Boiler 11.
01/31/2022	MACT (Part 63)	Compliance	Periodic report for 40 CFR Part 63 Subpart GGG (Pharmaceutical MACT): 4th Quarter. This includes their LDAR Report and Cylinder Gas Audit Report. They report 45 hours (2.04%) of CEM downtime, which were from seven events. They reported no exceedances, excess emissions, or excursions. They report 24 minutes of TOx downtime or malfunction.
01/31/2022	ROP Other	Compliance	Notification of Completion of Modification of EUCR3225-S3 for B225. The High-Performance Liquid Chromatography was completed on January 31,2022 and satisfies PTI No. 66-21 special condition VII.1.
01/31/2022	ROP Other	Compliance	Notification of Completion of Modification of EUCR491COM-S3 and EUCR3225-S3 for the B91 and B225 Tank 3650 and 3660. This modification was completed on January 31,2022 and satisfies PTI No. 116-21 special condition VII.1.
12/27/2021	CEM RATA	Compliance	Boiler 9-11 RATA Test Protocol
12/27/2021	MACT (Part 63)	Compliance	Relative Accuracy Test Audit (RATA) Test Report for TOx stack 1, per 40CFR63 Subpart GGG
11/01/2021	NSPS (Part 60)	Compliance	Third quarter Subpart Db compliance report for Boiler #9, 10, and 11. Includes cylinder gas audit. They report 0 hours of CEMS downtime and no excess emissions for Boiler 9. They report 29 hours of CEMS downtime and no excess emissions for Boiler 10. They report 1 hour of CEMS downtime and no excess emissions for Boiler 11.

Activity Date	Activity Type	Compliance Status	Comments
10/29/2021	MACT (Part 63)	Compliance	<p>Third quarter periodic report for the pharmaceutical MACT Subpart GGG. LDAR report was not included because these reports are semi-annual. No parameter exceedances, no periods of excess emissions, and no excursions were reported. They reported 2 hours of CMS downtime in September 2021 for quality assurance testing and maintenance activities. They reported no malfunction events on the TOx for this reporting period. They also described the recent changes to their CEMS, stating "The continuous emission system was updated to a completely different system since second quarter 2021. The two Bernath EuroFID were demoed on August 16, 2021. The Thermo Electron TECO FIA was demoed on Wednesday, September 1, 2021. The Two Bernath EuroFID and Thermo Electron TECO FIA unit were demoed to add the three CAI 700 HFID analyzers and four extraction systems. There is a primary analyzer and extraction system on stack 1 and stack 2. There is also a redundant analyzer that has two additional extraction system which can read either stack 1 or stack 2. The redundant analyzer reads and records only one of the two stacks at a time. The hardware was updated to be based on Pfizer standards so we have spare parts in stores in the event that there is an issue with the hardware. The data acquisition and handling system (DAHS) was replaced with VIM Technology CEMLink 6."</p>
10/27/2021	CEMS Test Observation	Compliance	<p>Observation of RATA. Primary CEMS in Stack 1 tested on this date.</p>
09/24/2021	ROP Semi 1 Cert	Compliance	<p>Facility reports one deviation for Boilers 10 & 11. The second quarter cylinder gas audit (CGA) test for boilers 10 & 11 was not conducted until 7/16/21. Corrective actions were taken so that this does not happen again.</p>

Activity Date	Activity Type	Compliance Status	Comments
09/24/2021	ROP Semi 1 Cert	Compliance	The facility reports one deviation that occurred for EUDPMANUALCLN-S2/FGRULE290-S2 in February 2021. The 1,000 lb/month threshold was exceeded for the month of February 2021. The facility obtained PTI #135-20 in March 2021 to increase this limit.
09/24/2021	ROP Semi 1 Cert	Compliance	The facility reports three deviations, two for EUCR138-S3, and one for EUCRALLTOX-S3. Corrective actions were taken and no Violation Notice will be sent at this time.
09/24/2021	CAM Excursions/Exceedances	Compliance	CAM Semiannual Monitoring Report. No excursions or exceedances were reported.
08/24/2021	CEM RATA	Compliance	TOx CEMS Equipment Monitoring Plan for replacement of the TOx CEMS.
08/24/2021	MACT (Part 63)	Compliance	Semi-annual compliance report for 40 CFR Part 63 Subpart DDDDD. Includes Boilers #1, 6, 5, 7, 8, and 9, 10, and 11. Coal boilers 1,3, 4, 5, and 6 have been removed. No deviations were reported. Four malfunction events were reported with a total duration of 80 minutes. The Gas Stream 1 lime injection system failed due to line plugging. They corrected this issue by unplugging the line and restarting the system.
08/24/2021	NSPS (Part 60)	Compliance	Second quarter Subpart Db compliance report for Boiler #9, 10, and 11. Includes cylinder gas audit. They report 2 hours of CEMS downtime and no excess emissions for Boiler 9. They report 49 hours of CEMS downtime and no excess emissions for Boiler 10. They report 49 hours of CEMS downtime and no excess emissions for Boiler 11.
08/24/2021	Stack Test	Compliance	TOx CEMS RATA Test Plan. Testing will be performed on September 28-29, 2021.
07/27/2021	MACT (Part 63)	Compliance	Subpart GGG periodic report. Includes semi-annual LDAR report. No exceedances, excess emissions, or excursions were reported for this period. They had 74 hours of CEMS downtime and reported 2 malfunction events for this period.

Activity Date	Activity Type	Compliance Status	Comments
07/15/2021	Other Non ROP	Compliance	Notification of completion of modification of the EUCR3173-S3 for the B173 slurry tank (ID#173TANK1040-1), under PTI No. 30-21. This modification was completed on June 13, 2021.
06/21/2021	ROP Tech Review Notes	Compliance	ROP Technical Review Notes
05/27/2021	Meeting Notes	Non Compliance	Two acetone tanks installed without PTI
05/27/2021	On-site Inspection	Compliance	Scheduled Inspection: ROP Section 1
05/26/2021	NSPS (Part 60)	Compliance	40CFR60-Subpart Db NSPS Compliance Report 60.7(c-d) and 60.49b (h) & (i). First quarter Subpart Db compliance report for Boiler #9. They report 3 hours of CEMS downtime and no excess emissions.
05/26/2021	CEM RATA	Compliance	Boiler 9-11 RATA Test Report
05/18/2021	Malfunction Abatement Plan	Compliance	MAP for Boilers 10 & 11. Approval Letter was sent on May 20, 2021.
05/05/2021	MACT (Part 63)	Compliance	Pharmaceutical MACT periodic report for 40 CFR Part 63 Subpart GGG. These reports are quarterly, however the LDAR reports are semi-annual, so they were not included during this quarter. They report 1 hour of CEM downtime, and 88 minutes of TOx malfunction time during one event on February 8, 2021.
03/17/2021	CEMS Test Observation	Compliance	NOx RATA on Boiler 10
03/15/2021	ROP SEMI 2 CERT	Compliance	The company reported no deviations.
03/15/2021	ROP SEMI 2 CERT	Compliance	The company reported no deviations.
03/15/2021	ROP SEMI 2 CERT	Compliance	The company reports six deviations. One was on August 24, 2020 for FGCFUG-S3, and the other 5 were on September 11, 2020, September 13, 2020, October 7, 2020, October 13, 2020, and November 9, 2020 for FGCRALLTOX-S3. Corrective actions were taken to fix the issues.
03/15/2021	CAM Excursions/Exceedances	Compliance	CAM Semi-Annual Monitoring Report. No excursions or exceedances were reported.
03/15/2021	ROP Annual Cert	Compliance	The company reported no deviations.

Activity Date	Activity Type	Compliance Status	Comments
03/15/2021	ROP Annual Cert	Compliance	The company reported no deviations.
03/15/2021	ROP Annual Cert	Compliance	<p>The company reports three deviations for the first half of 2020. The first was on April 21, 2020 related to EUC41Micronizing, the second was on April 28, 2020 related to EUCR138, and the third was on June 11, 2020 related to FGCFUG-S3. Corrective actions were taken to fix the issues.</p> <p>The company reports six deviations for the second half of 2020. One was on August 24, 2020 for FGCFUG-S3, and the other 5 were on September 11, 2020, September 13, 2020, October 7, 2020, October 13, 2020, and November 9, 2020 for FGCRALLTOX-S3. Corrective actions were taken to fix the issues.</p>
01/29/2021	MACT (Part 63)	Compliance	Periodic report for 40 CFR Part 63 Subpart GGG (Pharmaceutical MACT): 4th Quarter. This includes their LDAR Report and Cylinder Gas Audit Report. They report 107 hours (4.85%) of CEM downtime, which were from six events. On 10/02/2020 the CMS (TOC unit) calibration failed and there was instrument failure. On 12-08-2020, 12-17-2020, and 12-18-2020 the CMS (TOC unit) missed calibration check. On 10-09-2020, and 10-28, 2020 the CMS (TOC unit) missed data during calibration. They reported no exceedances, excess emissions, or excursions. They report 498 minutes of TOx downtime or malfunction.
01/29/2021	MACT (Part 63)	Compliance	40 CFR Part 63, Subpart DDDDD: Boiler Semi-annual Compliance Report. Includes Boilers #1, 6, 5, 7, 8, 9, 10 and 11. No deviations were reported. Six malfunction were reported, which lasted a total of 1,249 minutes.
01/29/2021	NSPS (Part 60)	Compliance	Fourth quarter Subpart Db compliance report for Boiler #9. Includes cylinder gas audit. They report 4 hours of CEMS downtime and no excess emissions.

Activity Date	Activity Type	Compliance Status	Comments
01/22/2021	CEM RATA	Compliance	Relative Accuracy Test Audit (RATA) test report, per 40 CFR Part 63 Subpart GGG.
01/22/2021	CEM RATA	Compliance	Boiler 9-11 RATA Test Protocol
01/22/2021	NSPS (Part 60)	Compliance	40CFR60.7(a)(3) and 40CFR60.(b) (a). Notification of Startup of EUEBLR43-10-S1 on 12/28/2020.
12/15/2020	Other Non ROP		Signed construction waivers for the B41 Process 1B and 1C project under PTI No. 135-20 and the Modular Aseptic Processing (MAP) project under PTI No. 167-20.
12/11/2020	NSPS (Part 60)	Compliance	Notification of the startup of one natural gas-fired boiler under PTI No. 57-15.
12/11/2020	Other Non ROP		Boiler MACT, 40 CFR, Part 63.7 (h) Waiver of Performance Test Justification Letter
12/08/2020	Other Non ROP	Compliance	Air Permit to Install Exemption Review for B43 Water Tower Blasting and Coating
11/20/2020	ROP Other		Startup, shutdown and Malfunction plan for Boilers 10 and 11 as required by PTI No. 49-20.
11/13/2020	MACT (Part 63)	Compliance	Relative Accuracy Test Audit (RATA) Test Report, per 40 CFR Part 63 Subpart GGG
11/06/2020	NSPS (Part 60)	Compliance	Third quarter Subpart Db compliance report for Boiler #9. They report 1 hours of CEMS downtime and no excess emissions.

Activity Date	Activity Type	Compliance Status	Comments
10/29/2020	MACT (Part 63)	Compliance	<p>Third quarter periodic report for the pharmaceutical MACT Subpart GGG. LDAR report was not included because these reports are semi-annual. No parameter exceedances, no periods of excess emissions, and no excursions were reported. They reported 4 hours of CMS downtime on September 8, 2020. The online TOC unit ran out of calibration gas. During the setup for the RATA test of the offline TECO THC, a valve on the calibration line was left open and the supply of calibration gas was lost. Upon discovery, a new gas cylinder was put in place as soon as possible. A procedure (job-aid) discussing the correct position of the calibration gas valve was developed to help prevent a future occurrence. They reported two events of TOx malfunction on 9/11/2020 and 9/13/2020 that lasted 3 minutes for each occurrence. The report stated, "For the malfunction on 9/11/2020, during a process setup a building 335 scrubber/knockout pot vented offline briefly (3 minutes), The event was caused by a step being conducted prior to a temperature condition being reached. Upon discovery, the setup was stopped and reset to close the vent. In order to prevent occurrence, a note is being added to the procedure to not proceed until the temperature condition is reached. For the malfunction on 9/13/2020, during processing the building 335 scrubber/knockout pot vented offline briefly (3 minutes). The event was caused when an incorrect control cable was removed while resetting an adjacent monitoring instrument. Upon discovery, the cable was immediately reconnected to close the vent" The company stated that for both incidents, all SSM provisions were followed.</p>
10/29/2020	MACT (Part 63)	Compliance	<p>Initial notification for a 1,490 BHP emergency generator under 40 CFR, Part 63, Subpart ZZZZ.</p>

Name: Monica Brothers Date: 4/21/2023 Supervisor: *RA* 4/26/23