

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 : 9/15/2019	FCE Completion Date : 9/17/2020
Comments :	

List of Partial Compliance Evaluations :

Activity Date	Activity Type	Compliance Status	Comments
09/17/2020	Scheduled Inspection	Compliance	Announced Scheduled Inspection
09/11/2020	ROP Semi 1 Cert	Compliance	The company reports three deviations. 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.
09/11/2020	ROP Semi 1 Cert	Compliance	The company reported no deviations.
09/11/2020	ROP Semi 1 Cert	Compliance	The company reported no deviations.
08/17/2020	ROP Other	Compliance	Facility submitted photos of EUPEWEIGHRM5&6 being used as storage room. This EU has been dismantled and will be removed from the ROP during the renewal process. This EU has not been in use since May 2019. The rotoclone in the room (PEZ-18) is still running only for room balancing.

Activity Date	Activity Type	Compliance Status	Comments
07/28/2020	MACT (Part 63)	Compliance	Semi-annual compliance report for 40 CFR Part 63 Subpart DDDDD. Includes Boilers #1, 6, 5, 7, 8, and 9. Boilers 3 and 4 have been removed. No deviations were reported. One malfunction event was reported with a duration of 4 minutes. The Gas Stream 2 lime injection system failed due to line plugging. They corrected this issue by unplugging the line and restarting the system.
07/28/2020	NSPS (Part 60)	Compliance	Second quarter Subpart Db compliance report for Boiler #9. Includes cylinder gas audit. They report 0 hours of CEMS downtime and no excess emissions.
07/28/2020	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 0 hours of CEMS downtime and reported 0 malfunction events for this period.
07/24/2020	ROP Tech Review Notes		ROP Technical Review Notes

Activity Date	Activity Type	Compliance Status	Comments
05/19/2020	Rule 912	Compliance	Building 41: EUC41MICRONIZING-S3); Rotoclone G-33. On Tuesday, April 21 at about 4:00pm, operators at Pfizer Kalamazoo discovered that the rotoclone G-33 located in B41 (EUC41MICRONIZING-S3) had shut down because of excessive foaming in the unit. Some foam was visible in the rotoclone stack and had also been emitted from the rotoclone stack onto the roof of B41. Upon discovery, the process was shut down and the unit began investigating the cause. Based on the process running at the time, the event may have occurred intermittently over a total processing time that day of up to 3.15 hours. The roof area and rotoclone were cleaned up immediately after discovery. Preliminary investigations indicate that the exhaust pick-up may have been placed too close to the micronizer feed funnel/feeder outlet and was a contributing factor in the foaming incident. Investigation of this release is ongoing. In order to prevent recurrence a spool piece is being manufactured for the exhaust pick-up to ensure an adequate distance from the exhaust pick-up to the micronizer feed funnel/feeder outlet. The rotoclone was cleaned and brought back into operating condition.
03/14/2020	ROP SEMI 2 CERT	Compliance	The company reported no deviations.
03/13/2020	ROP SEMI 2 CERT	Compliance	The company reported no deviations.
03/13/2020	ROP SEMI 2 CERT	Compliance	The company reports two deviations. One was on August 17, 2019 for FGCFUG-S3, and the second was on August 21, 2019 for EUC41Micronizing-S3. Corrective actions were taken to fix the issues.
03/13/2020	ROP Annual Cert	Compliance	The company reported no deviations.
03/13/2020	ROP Annual Cert	Compliance	The company reported no deviations.

Activity Date	Activity Type	Compliance Status	Comments
03/13/2020	ROP Annual Cert	Compliance	<p>The company reported four deviations for the first half of 2019. One was on May 5, 2019 for FGCFUG-S3, the second was on May 31, 2019 for General Condition 41, the third was on June 4, 2019 for EUCR138-S3, and the fourth was on June 8, 2019 for FGCRALLTOX-S3. Corrective actions were taken to fix the issues.</p> <p>The company reported two deviations for the second half of 2019. One was on August 17, 2019 for FGCFUG-S3, and the second was on August 21, 2019 for EUC41Micronizing-S3. Corrective actions were taken to fix the issues.</p>
03/13/2020	MAERS	Compliance	MAERS report was submitted.
03/13/2020	MAERS	Compliance	MAERS Report was received.
03/13/2020	MAERS	Compliance	MAERS report was submitted.

Activity Date	Activity Type	Compliance Status	Comments
03/02/2020	Other Non ROP	Compliance	Refrigerant Annual Report, per 40 CFR 82.157(j). A refrigerant circuit (100 pound charge of Non-Ozone Depleting Substance R-507) on a freeze dryer (041LYOP3044-1, Circuit 1) leaked 140 pounds in calendar year 2019. Three leaks and subsequent repairs were conducted. 1. On 1/14/2019 a leak occurred at a gauge port on top of the condenser. It was determined that the gauge port was not needed so the port was eliminated with a brass cap and rubber gasket. It was repaired on the same day. This was proactively completed on four additional appliances as well. 2. On 5/30/2019 a leak occurred when the bolts on the cap to the suction side line check valve (shelf exchanger) stripped out. The bolts were re-tapped and replaced. It was repaired on the same day. The tightness of these bolts is now specifically checked every six months to prevent leaks. 3. On 11/26/2019 a leak occurred when the bolts on the cap to the suction side line check valve (condenser exchanger) stripped out. The bolts were re-tapped and replaced. It was repaired on the same day. The tightness of these bolts is now specifically checked every six months to prevent leaks. The freeze dryer is leak checked on a monthly basis.
02/27/2020	CEMS Test Observation	Compliance	NOx RATA on Boiler #9.
01/31/2020	CEM RATA		Boiler 9 NOx CEMS Stack Test Protocol

Activity Date	Activity Type	Compliance Status	Comments
01/31/2020	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 48 hours (2.2%) of CEM downtime, which were from two events. On 10/16/19 the CMS (TOC unit) calibration failed due to a loose fitting/o-ring on the sample line to CEMs unit and the calibration drift was greater than 4X PS for a single day. On 12/03/19 the CMS (TOC unit) calibration failed and required a manual calibration. The calibration drift was greater than 4X for a single day. The reported no exceedances, excess emissions, or deviations. They report zero minutes of TOx downtime or malfunction.
01/31/2020	MACT (Part 63)	Compliance	40 CFR Part 63, Subpart DDDDD: Boiler Semi-annual Compliance Report. Includes Boilers #1, 6, 5, 7, 8, and 9. No deviations were reported. One malfunction was reported, which lasted four minutes. A software download shut down the lime injection system.
01/31/2020	NSPS (Part 60)	Compliance	Fourth quarter Subpart Db compliance report for Boiler #9. Includes cylinder gas audit. They report zero hours of CEMS downtime and no excess emissions.
12/10/2019	Stack Test Observation	Compliance	Observation of PM and CO tests for coal-fired Boiler 5.

Activity Date	Activity Type	Compliance Status	Comments
10/28/2019	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 CEMS downtime, no parameter exceedances, no periods of excess emissions, and no excursions were reported. They reported one event of TOx malfunction that lasted 33 minutes. The report stated, "For the malfunction on 9/09/2019, a thermocouple that supplies the read-out of the TOx operating temperature failed. As a result, the TOx temperature drifted down below the permitted minimum temperature of 891C for 33 minutes. After a diagnostic review of the failure, the TOx was switched over to a redundant back-up thermocouple and the temperature returned to normal. A new thermocouple was installed and a thermowell was added to the probe with may provide additional protection."
10/28/2019	NSPS (Part 60)	Compliance	Third quarter Subpart Db compliance report for Boiler #9. They report 2 hours of CEMS downtime during a manual calibration, and no excess emissions.
10/24/2019	CEM RATA	Compliance	RATA Test Report for total organic carbon (TOC) analyzers that are downstream of the regenerative thermal oxidizers and hydrogen chloride wet scrubbers.
09/16/2019	ROP Semi 1 Cert	Compliance	The company reported no deviations.
09/16/2019	ROP Semi 1 Cert	Compliance	The company reported no deviations.
09/16/2019	ROP Semi 1 Cert	Compliance	The company reports four deviations. One was on May 5, 2019 for FGCFUG-S3, the second was on May 31, 2019 for General Condition 41, the third was on June 4, 2019 for EUCR138-S3, and the fourth was on June 8, 2019 for FGCRALLTOX-S3. Corrective actions were taken to fix the issues.

Name: Martin R. K. Date: 9/30/2020 Supervisor: RIL 10/2/20