

DEPARTMENT OF ENVIRONMENTAL QUALITY  
AIR QUALITY DIVISION

**FCE Summary Report**

<b>Facility :</b> Pharmacia & Upjohn Co LLC, a subsidiary of Pfizer	<b>SRN :</b> B3610
<b>Location :</b> 7000 Portage Road	<b>District :</b> Kalamazoo
	<b>County :</b> KALAMAZOO
<b>City :</b> KALAMAZOO <b>State:</b> MI <b>Zip Code :</b> 49001	<b>Compliance Status :</b> Compliance
<b>Source Class :</b> MEGASITE	<b>Staff :</b> Monica Brothers
<b>FCE Begin Date :</b> 5/1/2020	<b>FCE Completion Date :</b> 5/27/2021
<b>Comments :</b> The facility seemed to be in compliance at the time of inspections. This is the first year of the three-year cycle for the megasite.	

**List of Partial Compliance Evaluations :**

Activity Date	Activity Type	Compliance Status	Comments
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.

Activity Date	Activity Type	Compliance Status	Comments
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.
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>


Activity Date	Activity Type	Compliance Status	Comments
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.
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 4CFR60.(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	Other Non ROP		Boiler MACT, 40 CFR, Part 63.7 (h) Waiver of Performance Test Justification Letter
12/11/2020	NSPS (Part 60)	Compliance	Notification of the startup of one natural gas-fired boiler under PTI No. 57-15.
12/08/2020	Other Non ROP	Compliance	Air Permit to Install Exemption Review for B43 Water Tower Blasting and Coating

Activity Date	Activity Type	Compliance Status	Comments
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.
10/29/2020	MACT (Part 63)	Compliance	Initial notification for a 1,490 BHP emergency generator under 40 CFR, Part 63, Subpart ZZZZ.

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>
09/17/2020	Scheduled Inspection	Compliance	Announced scheduled inspection

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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.
09/10/2020	CEMS Test Observation	Compliance	Observation of RATA. One of three CEMS on the TOC was tested on 9/10 (Bernath #4779). The other two were tested at a later date.
08/21/2020	Release Reports	Compliance	Written follow-up report for release of about 2,553 lbs of methylene chloride and 5 lbs methanol to the air on August 6, 2020.
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 rotocloner in the room (PEZ-18) is still running only for room balancing.
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.

Activity Date	Activity Type	Compliance Status	Comments
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
07/01/2020	CEM RATA		TOC Analyzer RATA Test Plan
05/19/2020	Rule 912	Compliance	<p>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.</p>

Name:  Date: 8/24/21 Supervisor: Ric 8/30/21