

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

B361062831

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: 04/26/2022
STAFF: Monica Brothers	COMPLIANCE STATUS: Compliance	SOURCE CLASS: MEGASITE
SUBJECT: Announced scheduled inspection of Building 41, which is in both Section 2 and 3 of the ROP.		
RESOLVED COMPLAINTS:		

This was an announced, scheduled inspection. This is the second year of the 3-year inspection cycle. This inspection included all of Section 2 of the ROP, along with the parts of Section 3 that are associated with Building 41. Staff, Monica Brothers arrived on-site at 9:00am and met with Tim Swainston, Senior EHS Specialist, and Anne-Marie Hart, Senior Environmental Manager from Pfizer. We began the inspection by observing the control devices in Appendix 12-S3 and 10-S2 in their ROP, MI-ROP-B3610-2021. Jason Hall, who does the required monthly readings was our guide. We looked at only the devices that were for Building 41. Below is a list of these devices and what their monitoring devices showed during the inspection.

Rotoclene/ Scrubber	Fabric Filter	Emission Unit	Acceptable Operating Range, min or min/max GPM	Acceptable Operating Range, min/max DP, inches water column	Observed During Inspection
U-3		EUPCKF&OEQUIP	0.5/2		1.5
	U3	EUPCKF&OEQUIP		0.025/2	0.03
H-22		EUPKDRYPKG EQUIP	3		3.4
	HV-24.2	EUPKDRYPKG EQUIP		0.5	OUT OF SERVICE
	GG-6	EUPSPECIALPKG		0.25/3	0.6
GG-6C		EUPSPECIALPKG	0.5		OUT OF SERVICE
HH-6C		EUPSPECIALPKG	0.5		OUT OF SERVICE
	HH-6	EUPSPECIALPKG		0.25/3	0.6

	JJ-6	EUPSPECIALPKG		0.25/3	0.6
JJ-6C		EUPSPECIALPKG	0.5		OUT OF SERVICE
	KK-6	EUPSPECIALPKG		0.25/3	0.7
V-4		EUPLSTERINJ	2		3.0
	EE-33	EUC41MICRONIZING		0.25/2.0	0.3
	KK-33	EUC41MICKK33		0.25/2.6	0.9
G-33		EUC41MICRONIZING	4		5.25
	Y-32	EUC41MICRONIZING		0.4/1.5	0.5, 0.6, 0.7, and 0.7. There are 4 HEPA banks associated with Y-32.
T-18		EUC41MILLING	1		1.1
T-26		EUC41NEOSPRAYDRYER	3		OUT OF SERVICE
G-26		EUC41NEOSTOR&HANDL	2		4.0

Jason then took us up to the roof to see some of the associated stacks. We viewed G33, Y32, KK33, GG6, HH6, KK6, and JJ6. No visible emissions were seen, and the areas around the stacks looked clean. GG6C and GG6 have a combined stack, along with HH6 and HH6C, and JJ6 and JJ6C.

After looking at the control devices, we went back to a conference room to view records. Below are my observations for each emission unit and flexible group. The facility seemed to be in compliance at the time of inspection.

Section 2:

EUPLSTERINJ-S2:

This emission unit includes all particulate emitting equipment in the sterile injectables production area of Building 41. They have a limit of 55,000 lbs/month of product produced in Module 1, and

their highest number in 2020 was 836 lbs in January. They also have a limit of 220,000 lbs/month of product produced in Modules 2-4, and their highest number for 2020 was 3,789 lbs in January. They are also limited to 0.05 tons VOC/month or 100 lbs VOC/month, and their highest number for 2020 was 0.1 lbs in January, February, March, April, and July. They are also limited to 0.015 tons PM/month or 30 lbs PM/month, and their highest number for 2020 was 0.63 lbs in April. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2020, 2021, or so far in 2022. Their water scrubber is required to operate above 2 gpm, and their monthly records show that it is usually around 3.7 gpm.

EUPKDRYPKGEOQUIP-S2:

This emission unit is for all particulate emitting equipment in the dry products packaging production area of Building 41. This area fills various powder products into bottles and packets. They are limited to processing no more than 196,530 lbs/month of product into bottles, and the highest number I saw in their records for 2020 was 28,392 lbs in January. They are also limited to processing no more than 171,394 lbs/month of product into packets, and the highest number I saw in their records for 2020 was 7,616 lbs in January. They also have a PM limit of 215 lbs/month, and the highest I saw for 2020 was 14.20 lbs in January. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2020, 2021 or so far in 2022. Their water scrubber is required to operate above 3 gpm, and their monthly records show that it is usually around 3.5 gpm.

EUSPECIALPKG-S2:

This emission unit is for all associated equipment used in the special packaging area of Building 41. They have a VOC emission limit of 1.43 tpy on a 12-month rolling timescale. However, they no longer use any VOC-containing materials in this equipment, and it can be removed from the ROP during the next renewal. There is also a PM emission limit of 0.13 tpy on a 12-month rolling timescale. They are keeping these records, and they show that their highest emission value in 2020 was 21.8 lbs in August. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2020, 2021, or so far in 2022. Their HEPA filters, GG6, HH6, JJ6, and KK6, are required to operate between 0.25-3 inches of water, and their monthly records show that they are consistently within that required range, usually around 0.6 inches. Their wet rotoclones, GG6C, HH6C, and JJ6C, are required to operate above 0.5 gpm, and their monthly records show that they are consistently above this minimum limit.

FGRULE 287(b&c)-S2:

This flexible group covers some aerosol paint can use in maintenance areas, as well as ink usage for label printing. They are limited to 200 gallons/month of paint or ink. Their records indicate that their highest coating usage rate for 2020 was 3.96 gallons in August. Their records show compliance with this exemption.

FGRULE290-S2:

This flexible group covers EUPGELFOAM, EUPATGAMFILTERTEST, EUPDPMANUALCLN, EUPFILTERTESTINJ, EUPNSLMANUFACTCLN, EUPDR-18, EUPATGAMPDN, EUPANVISA, EUPNSLLINE72, and EUPCKF&OEQUIP-S2. I viewed Rule 290 records for each of these emission units, and they were all under the required monthly limits.

Section 3:

EUC41MILLING-S3:

This emission unit is for all portable equipment that is used for milling, sieving, screening, and bolting, located in rooms 1-4 in Building 41. They have a PM emission limit of 0.2 tpy on a 12-month rolling timescale. I viewed these records, which were consistently under this limit and typically around 0.007 tpy. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2020, 2021 or so far in 2022. Their water scrubber is required to operate above 1 gpm, and their monthly records show that it is usually around 1.7 gpm.

EUC41NEOSTOR&HANDL-S3:

This emission unit is for storage and handling equipment located in the neomycin area of Building 41. They are limited to weighing or processing no more than 31 lots of raw material per month. I viewed these records and they processed 15 lots in March 2022, which was the most for any month in 2020-2022. They also have a limit for PM emissions, which is 500 lbs/month. Their records indicate that the highest number for 2022 was 242.0 lbs in March. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2020, 2021 or so far in 2022. Their water scrubber is required to operate above 2 gpm, and their monthly records show that it is usually around 4.0 gpm.

EUC41NEOSPRAYDRYER-S3:

This emission unit is for the spray dryer that is located in the neomycin area of Building 41. They are required to keep records of how many lots of raw material are weighed and processed for this emission unit but do not have a limit. They are keeping these records. They also have a limit for PM emissions, which is 740 lbs/month. The highest number I observed in their records for the past few years was around 360 lbs/month for March 2022. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2020, 2021 or so far in 2022. Their water scrubber is required to operate above 3 gpm, and their monthly records show that it is usually around 7.0 gpm.

EUC41MICRONIZING-S3:

This emission unit is for the equipment in the micronizing area in Building 41. This includes the equipment in the micronizing area Module #1, which vents to Stack EE-33, the equipment in micronizing area Modules #3, #4, and #5, which vent to Stacks G-33 and Y-32, and the equipment in the washer/dryer area for the micronizing area, which also vents to Stack Y-32.

They have a PM10 and PM2.5 limits of 112 lbs/month. I viewed their records, which showed that their highest number in recent years was 44 lbs in 2020. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2020, 2021, or so far in 2022. Their water scrubber, G-33 is required to operate above 4 gpm, and their monthly records show that it is usually around 4.8 gpm. Fabric filter EE-33 must operate between 0.25 and 2.0 inches of water, and their monthly records show that it typically operates at about 0.37 inches of water. Fabric filter Y-32 must operate between 0.4 and 1.5 inches of water. There are four HEPA filters associated with Y-32, and they take monthly readings from all four. Their

records indicated that they typically run between 0.4 to 0.72 inches, which is within the allowable range.

EUC41MICKK33-S3:

This emission unit is for equipment in the micronizing area JETPHAR1 Module, which vents to Stack KK-33 and is located in Building 41. They have a limit for PM emissions, which is 57 lbs/year on a 12-month rolling timescale. The highest number I observed in their records for the past few years was 3.3 lbs/year in January 2022. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2020, 2021, or so far in 2022. Their fabric filter is required to operate between 0.25 and 2.6 inches of water, and their monthly records show that it is usually around 1.00 inches of water.

FGC41MICVOC-S3:

This flexible group covers the VOC requirements for the entire Building 41 micronizing and milling areas, which include EUC41MILLING, EUC41MICKK33, and EUC41MICRONIZING. They are limited to using less than 4,365 lbs/ month of alcohol-based cleaner. Their records indicate that they are consistently under this limit, with their highest 2020 and 2021 number being 1,089 lbs. Their highest number so far in 2022 was 363 lbs in February. They are also limited to emitting no more than 174.6 lbs VOC/month, and their records show that their highest number for this year so far is 14.5 lbs in February. Their highest number recorded in 2020 was 44 lbs.

FGRULE290-S3:

Tim said that this flexible group was for a temporary process that hasn't been used since 2006. He said that it could probably be removed from the ROP during the next renewal. There are currently no Rule 290 emission units in Building 41 for Section 3.

NAME Monika LohseDATE 5/19/22 SUPERVISOR RIL 5/20/22