DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: Scheduled Inspection

B361050017

FACILITY: Pharmacia & Upjohn Co LLC, a subsidiary of Pfizer		**SRN / ID:** B3610
LOCATION: 7000 Portage Road, KALAMAZOO		**DISTRICT:** Kalamazoo
CITY: KALAMAZOO		**COUNTY:** KALAMAZOO
CONTACT: Nathan Lucas , EHS Specialist-Environmental		**ACTIVITY DATE:** 08/20/2019
STAFF: Monica Brothers	**COMPLIANCE STATUS:** Compliance	**SOURCE CLASS:** MEGASITE
SUBJECT: Announced, scheduled inspection		
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 and Chance Collins arrived on-site at 9:00am and met with Nathan Lucas, EHS Specialist, and Scott Zabik, Environmental Professional from Pfizer. We began the inspection by observing the control devices in Appendix 12-S3 and 10-S2 in their ROP, MI-ROP-B3610-2014h. Arie Baartman, 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.

Rotoclone/ 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		1.8
	U3	EUPCKF&OEQUIP		0.025/2	0.3
H-22		EUPKDRYPKGEQUIP	3		3.4
	HV-24.2	EUPKDRYPKGEQUIP		0.5	OUT OF SERVICE
	GG-6	EUPSPECIALPKG		0.25/3	0.6
GG-6C		EUPSPECIALPKG	0.5		1.16
HH-6C		EUPSPECIALPKG	0.5		0.5
	HH-6	EUPSPECIALPKG		0.25/3	0.5
	JJ-6	EUPSPECIALPKG		0.25/3	0.5
JJ-6C		EUPSPECIALPKG	0.5		0.8
	KK-6	EUPSPECIALPKG		0.25/3	0.6
V-4		EUPLSTERINJ	2		3.7
Z-18		EUPEWEIGHRM5&6	2		4.2
	EE-33	EUC41MICRONIZING		0.25/2.0	0.3
	KK-33	EUC41MICKK33		0.25/2.6	0.7
G-33		EUC41MICRONIZING	2		4.72
	Y-32	EUC41MICRONIZING		0.4/1.5	0.4, 0.566, 0.537, and 0.707. There are 4 HEPA banks associated with Y-32.
T-18		EUC41MILLING	1		1.2
T-26		EUC41NEOSPRAYDRYER	3		Not Running; Only Runs on Weekends
G-26		EUC41NEOSTOR&HANDL	2		3.5

Arie then took us up to the roof to see all of the associated stacks. 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 and then took a tour of the processes in Building 41. 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:

EUPCKF&OEQUIP-S2:

This is the Non-Sterile Liquids area of Building 41. It includes modules 1,2,3, and 4 and associated weigh module used for manufacturing both alcohol and non-alcohol containing fluids. It also includes a charging room with bag cart, charging hoods, and associated tanks. This EU is now a Rule 290 group, but I looked at records for 2017, which indicate compliance with all of the recordkeeping requirements. Before this EU became a Rule 290 group, they had a limit of 95,000 lbs/month of particulate containing material produced Their highest number for 2017 was 15,098 lbs in October. They also had a limit of 2,900 lbs/month of VOC containing material produced. Their highest for 2017 was 1,003 lbs, also in October. They also had a VOC emission limit of 3.2 lbs/month, and their highest number for 2017 was 0.97 lbs in February. They also had a PM emission limit of 1.4 lbs/month, and their highest number for 2017 was 0.07 lbs in both February and August. They were keeping the required monthly visible emissions records, which indicated that no visible emissions have been observed in 2017. They are also keeping monthly records of the water scrubber flow rate and the fabric filter differential pressure. The water scrubber has a limit of between 0.5-2 GPM, and their records show that it is usually around 1.7 GPM. The fabric filter has a limit of between 0.025-2 inches of water, and their records show that it is usually around 0.35 inches of water.

EUPEWEIGHRM5&6-S2:

This is a manual powder weighing process that uses a 270 kg ribbon blender and a 5 cubic foot PK blender in Rooms 5 and 6 of the dry products manufacturing blending area of Building 41. Nathan and Scott said that they are getting rid of this emission unit, but that it ran in 2017 and 2018. I viewed records for 2018. Their permit limits them to processing no more than 967,200 kg/month of raw material, and in February and March of 2018, they processed only 1,080 kg. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2018. Their water scrubber is required to operate above 2 gpm, and their monthly records show that it is usually around 4.2 gpm.

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 2019 was 518 lbs in June. They also have a limit of 220,000 lbs/month of product produced in Modules 2-4, and their highest number for 2019 was 4,570 lbs in April. They are also limited to 0.05 tons VOC/month or 100 lbs VOC/month, and their highest number for 2019 was 0.3 lbs in June. They are also limited to 0.015 tons PM/month or 30 lbs PM/month, and their highest number for 2019 was 0.57 lbs in June. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2019. Their water scrubber is required to operate above 2 gpm, and their monthly records show that it is usually around 3.7 gpm.

EUPKDRYPKGEQUIP-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 2019 was 21,840 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 2019 was 5,713 lbs in June. They also have a PM limit of 215 lbs/month, and the highest I saw for 2019 was 9.49 lbs in January. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2019. 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, Nathan said that they no longer use any VOC-containing materials in this equipment and that it could be removed from the ROP. 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 2019 was 21.6 lbs in January. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2019. Their HEPA filter is required to operate between 0.25-3 inches of water, and their monthly records show that it is consistently within that required range.

FGRULE 287(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 paint usage rate for 2019 was 5.37 gallons in July, and that their highest ink usage rate was 3.93 gallons in February. Their records show compliance with this exemption.

FGRULE290-S2:

This flexible group covers EUPGELFOAM, EUPATGAMFILTERTEST, EUPDPMANUALCLN, EUPFILTERTESTINJ, EUPNSLMANUFACTCLN, EUPDR-18, EUPATGAMPDN, EUPANVISA, EUPNSLLINE72, and now EUPCKF&OEQUIP-S2. I viewed Rule 290 records for each of these emission units, and they were all under the required monthly limits. The emission unit that I saw come closest to it's 1000 lbs/month limit was EUPDPMANUALCLN, which emitted 811.21 lbs in June 2019.

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 0.01 tpy. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2019. Their water scrubber is required to operate above 1 gpm, and their monthly records show that it is usually around 1.5 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 only 5 lots in May 2019, and only 39 lots the entire year of 2018. They also have a limit for PM emissions, which is 500 lbs/month. Their records indicate that the highest number for 2018 was 112.7 lbs in December. They emitted a total of 627 lbs of PM in 2018. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2019. Their water scrubber is required to operate above 2 gpm, and their monthly records show that it is usually around 3.5 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 168 lbs/month. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2019. Their water scrubber is required to operate above 3 gpm, and their monthly records show that it is usually around 6.5 gpm.

EUC41MICRONIZING-S3:

This emission unit is for the equipment in the micronizing area in Building 41. This includes the equipmen in the micronizing area Module #1, which vents to Stack EE-33, the equipment in micronizing area Module #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 45 lbs in April 2017. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2019. 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 tha it typically operates at about 0.35 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 at 0.69, 0.54, 0.56, and 0.5 inches of water, respectively which are all within the allowable range. I did observe that the readings indicated 0.4 inches of water for three of the four HEPA filters in March 2019, which is very close to being out of 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 2.21 lbs/year in November 2014. They are keeping the required monthly visible emissions readings and indicated that no visible emissions had been seen in 2019. 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 0.65 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 2017 number being 1,452 lbs in both January and August. Their highest number so far in 2019 was 726 lbs in February, April, and June. 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 29 lbs in February, April, and June. Their highest number recorded in 2017 was 58 lbs in both January and August.

FGRULE290-S3:

Nathan 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.

NAME Monica Butler DATE 9/24/19 SUPERVISOR RIL 9/30/19