

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

B361035915

FACILITY: Pharmacia & Upjohn Co LLC, a subsidiary of Pfizer		SRN / ID: B3610
LOCATION: 7000 Portage Road, KALAMAZOO		DISTRICT: Kalamazoo
CITY: KALAMAZOO		COUNTY: KALAMAZOO
CONTACT: John Ring , Manager, EHS		ACTIVITY DATE: 08/03/2016
STAFF: Dennis Dunlap	COMPLIANCE STATUS: Compliance	SOURCE CLASS: MEGASITE
SUBJECT: Day 2 of Building 41.		
RESOLVED COMPLAINTS:		

This was an announced inspection. This is day 2 of the Building 41 inspection. The inspection brochure was handed out the day before. John Ring is the contact person. AQD staff included Dennis Dunlap and Monica Brothers.

This is the 2nd year of the 3-year inspection cycle. The purpose of this inspection was to complete Section 2 of the ROP (Building 41) and the part of Section 3 that includes Building 41.

Gel Foam and Gel Film

Gel foam is a mixture of gelatin and formaldehyde that when dried form a material that looks like Styrofoam. It is used in surgery. This is a Rule 290 group. The only emissions from the process is formaldehyde which is tracked monthly. The gel foam process consists of mixing, extrusion, drying, cutting, packaging, and sterilization.

EUSPECIALPKG

This area is used to package powders. There are four modules, A, B, C, and D. Modules A and D are for human health and Module C is for animal health. Module B is for reproductive health. The hepa filters are GG-6, HH-6, JJ-6, and KK-6. The rotoclones are GG-6C, HH-6C, and JJ-6C, associated with Modules A, B, and C. The three rotoclones are associated with a stack. A Hoffman vac is associated with Module D. All four modules have hepa filters. KK-6 is associated with a stack.

Line 72

This is a pouch filling line for Clinimycin products. This is a Rule 290 group. The filling area has a vent to the outside. IPA is used in the process and is tracked. Pouches are folded, cut, filled, and sealed in this operation. There are also printing machines for labels. Ink usage is tracked in EUPPRINTING. This is a Rule 290 group.

EUPEWEIGHRM5&6

Room 5 is used to weigh and blend ingredients. Finished material may be put into drums. Neopred topical powder for animals is one of the products. There is a 270 kg ribbon blender and 5 cubic foot PK blender. Room 6 is also used to weigh materials. There are exhaust drops in each room for Z-18 and the associated rotoclone.

EUPDR-18

This is a Rule 290 group. There are two rooms. The equipment has not been used for 4-5 years. Included is a 69 cubic foot blender. R-18 is the exhaust drop. The rotoclone has been taken off the inspection list. The only area used here is a wash area.

EUPKDRYPKGGEQUIP

This is associated with Lines 2 and 16. Line 16 is divided into two rooms. 16A is for animal product filling and 16H is for human product filling. H-22 and the associated rotoclone is the control device here.

EUPATGAMPDN

This is a Rule 290 group. It was under construction and was not inspected. The drum filling area is included with this group.

EUPLSTERINJ and EUPANVISA

These areas required special gowning and were not inspected.

EUPATGAMFILTERTEST, EUPDPCMANUALCLN, EUPFILTERTESTINJ, EUPNSLMANUFACTCLN

These Rule 290 groups were evaluated by looking at records.

EUPRINTING

This Rule 287 group was evaluated by looking at records.

Records ReviewEUPCKF&OEQUIP

This emission unit has monthly limits for VOC and Particulate and Material limits for VOC and particulate raw materials used per month. Based on records from the last 12 months the facility was in compliance.

EUPEWEIGHRM5&6

This emission unit has a monthly limit of kilograms of raw material used. Based on records from the last 12 months the facility was in compliance.

EUPLSTERINJ

This emission unit has emission limits for VOC and particulate emitted per month. There are separate raw material limits per month for Modules 2 through 4 and Module 1. Based on records from the last 12 months the facility was in compliance.

EUPNSLMANUFACTCLN

This is a Rule 290 group for manual cleaning with 3A alcohol (IPA and methanol). Based on records from the last 12 months the facility was in compliance.

EUPKDRYPKG EQUIP

This emission unit has an emission limit for particulate emissions per month. There are also material limits for pounds of material processed per month in bottle packaging equipment and separately for material processed in packets. Based on records from the last 12 months the facility was in compliance.

EUSPECIALPKG

This emission unit was modified from the previous ROP (from EUPOTENTDRUG). One of the changes was to change the particulate and VOC yearly limits to a 12-month rolling time period calculated each month. The emission limits did not change. The facility needed to change to the 12-month rolling time period calculation. The facility was in compliance with the emission limits and changed to 12-month rolling time period calculations.

EUPGELFOAM

This is a Rule 290 emission unit. It tracks formaldehyde emissions and assumes loss of 0.12 pounds per lot. Based on records from the last 12 months the facility was in compliance.

EUPATGAMFILTERTEST

This a rule 290 group for filter integrity testing equipment. It tracks ethyl alcohol and uses a loss factor. Based on records from the last 12 months the facility was in compliance.

EUPATGAMPDN, EUPDR-18, EUDPCMANUALCLN, EUPFILTERTESTINJ, EUPANVISA, EUPNSLLLINE72

These are Rule 290 groups. Based on records from the last 12 months the facility was in compliance. EUDPCMANUALCLN was assuming hand-held spray bottles of alcohol were exempt by Rule 285hh. It was pointed out that this exemption was only for aerosol cans. The facility added these into the Rule 290 group.

EUPPRINTING

This is a Rule 287(c) group and tracks Building 41 ink usage. Monthly usage is under 200 gallons per month.

EUC41MILLING

This emission unit has a particulate limit of tons per year based on a 12-month rolling time period. Based on records from the last 12 months the facility was in compliance.

EUC41NEOSTOR&HANDL

This emission unit has a monthly particulate emission limit and a material limit of lots per month. Based on records from the last 12 months the facility was in compliance.

EUC41NEOSPRAYDRYER

This emission unit has a monthly particulate emission limit. Based on records from the last 12 months the facility was in compliance.

EUC41MICRONIZING

The facility is calculating emissions on a monthly basis. This emission unit was modified by a permit that was incorporated into the ROP. It appears that compliance with the new emission limits can only be verified by stack tests.

EUC41MICKK33

This emission unit has a pounds per year particulate limit based on a 12-month rolling average. Based on records from the last 12 months the facility was in compliance.

FGC41MICVOC

This flexible group is for VOC emissions from EUC41MILLING, EUC41MICKK33, and EUC41MICRONIZING. There is a pounds per month VOC limit and a material limit for alcohol based cleaner. Based on records from the last 12 months the facility was in compliance.

Monthly stack visible emission checks and monthly check of control equipment operating ranges.

Stacks with control devices in the ROP are required to have a monthly visible emission check. These are recorded. Control devices that have operating parameters in Appendix 10-S2 and Appendix 12-S3

are required to have the operating parameter recorded monthly. Monthly records were checked for 2016 through July. The stacks that were checked included U-3, H-22, V-4, T-18, Z-18, G-26, T-26, KK-33, G-33, EE-33, GG-6C, JJ-6C, HH-6C, Y-32, and HV-24.2. Filters only and no stacks were JJ-6, HH-6, and GG-6.

The following were found:

GG-6C- 4/12/16 the gpm reading was 0.4 and below the lower limit of 0.5 gpm. The water nozzles were cleaned on 4/15/16. The rotoclone was not used in over a month. Note: This rotoclone is usually turned on just for the monthly inspection.

H-22- Many records were right at the lower limit of 3.0 gpm.

Y-32- 7/1/16 Reading 0.337, lower limit is 0.4, changed pre-filter and rechecked on 7/1/16. For filter B2 of Y-32.

5/8/16 Reading 0.269, lower limit is 0.4, replaced pre-filter and rechecked on 5/8/16. For filter B3 of Y-32

3/10/16 Reading 0.345, lower limit is 0.4, changed pre-filter on 3/10/16. For filter B2 of Y-32. Y-32 is a new stack and needs to be added to monthly visible emission checks. The facility indicated that this would be done. The control devices are checked monthly, which consists of four filters.

When the control device is out of range there is a Malfunction Abatement Program in Appendix 9-S2 or Appendix 9-S3. It appears that this followed in the above incidences.

NAME Dennis Dunlap

DATE 8/12/16

SUPERVISOR MOB/16/2016