

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

B361035908

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: 08/02/2016
STAFF: Dennis Dunlap	COMPLIANCE STATUS: Compliance	SOURCE CLASS: MEGASITE
SUBJECT: Day 1 inspection of Building 41.		
RESOLVED COMPLAINTS:		

This was an announced inspection. The inspection brochure was handed out. 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.

The first part of the inspection was to observe control devices and stacks that have parameters in the ROP. Rule 290 emission units do not have parameters in the ROP, however, these were observed when possible.

#### Control Devices and Stacks

U-3 Particulate Scrubber 1.5 gpm, no visible emissions at stack EUPCKF&OEQUIP compliance  
H-22 Rotoclone 3.5 gpm, no visible emissions at stack EUPKDRYPKGEQUIP compliance  
T-11 Dry Rotoclone, no longer used as a control device and not in ROP  
V-4 Rotoclone 2.5 gpm, no visible emissions at stack EUPLSTERINJ compliance  
T-18 Rotoclone, 1.6 gpm, no visible emissions at stack, EUC41MILLING compliance  
Z-18 Rotoclone, 3.5 gpm, no visible emissions at stack, EUPEWEIGHRM5&6 compliance  
G-26 Rotoclone, 4 gpm, no visible emissions at stack, EUC41NEOSTOR&HANDL compliance  
T-26 Rotoclone, not operating, no visible emissions at stack, EUC41NEOSPRAYDRYER compliance  
KK-33 Fabric Filter, 0.62 in, no visible emissions at stack, EUC41MICKK33 compliance  
G-33 Rotoclone, 3.15 gpm, no visible emissions at stack, EUC41MICRONIZING compliance  
EE-33 Fabric Filter, 0.35 in, no visible emissions at stack, EUC41MICRONIZING compliance  
R-18 Rule 290 group, pickups in two rooms, includes 60 cubic foot PK blender, not used for 4-5 years, EUPDR-18  
KK-6, Fabric Filter, 0.65, There is a stack, but was not seen during the inspection, EUSPECIALPKG compliance  
JJ-6 Fabric Filter, 0.6 in., precedes rotoclone, no stack, EUSPECIALPKG compliance  
HH-6, Fabric Filter, 0.6 in., no stack, EUSPECIALPKG compliance  
GG-6 Fabric Filter, 0.6 in., no stack, EUSPECIALPKG compliance  
GG-6C Rotoclone, 1.1 gpm, rotoclone emissions go through filter, no visible emissions at stack, EUSPECIALPKG, compliance  
JJ-6C Rotoclone, 1.1 gpm, rotoclone emissions go through filter, no visible emissions at stack, EUSPECIALPKG, compliance  
HH-6C Rotoclone, 0.5 gpm, rotoclone emissions go through filter, no visible emissions at stack, EUSPECIALPKG, compliance  
Y-32 Fabric Filters, this actually consists of four fabric filters, B1 0.679 in, B2 0.574 in., HB3 0.5 in., HB-4 0.5 in. there is one stack EUC41MICRONIZING compliance we did not see the stack

HV-24.2 Fabric Filter, we saw the stack for the Hoffman Vac, it has been out of service for over a year EUPKDRYPKGEQUIP

JJJ-6, LLL-6, NNN-6 These stacks are for rotoclones in the ATGAM area. This a 290 group and the control devices and stacks do not have any specific requirements in the ROP.

Four cold cleaners were seen. These had the lid closed and the rules were posted:

1. Halls freeze dry mechanical room
  2. Building 41 lubrication shop
  3. Injectable Maintenance shop.
  4. NSL maintenance shop.
- One that was not seen is in the sterile liquids area.

**EUC41MICKK33**

This is the JETPHAR1 module venting to stack KK-33 (fabric filter) in the micronizing area.

**EUC41MICRONIZING**

In the micronizing area particles in powders are reduced in size to about 3-8 microns. This is generally done by colliding the particles in a micronizer. Modules 3, 4, and 5 are controlled by rotoclone G-33. Module 1 is controlled by filter EE-33. In Module 1, T-33 is a recirculating filter.

**Neomycin Area.**

The spray dryer (EUC41NEOSPRAYDRYER) converts a liquid neomycin blend to powder. Some of this may be micronized or some may be milled and packaged. The spray dryer is controlled by Rotoclone T-26. There is also a handling and storage area in this room (EUC41NEOSTOR&HANDL) that is controlled by Rotoclone G-26.

The milling area (EUC41MILLING) consists of 4 rooms. Room 1 is for storage only. This area is controlled by Rotoclone T-18.

**EUPCKF&OEQUIP**

This is the non-sterile liquids area and includes modules 1, 2, 3, and 4. This area uses 3A alcohol, which is a mixture of IPA and methanol. Module 3 is for Clinimycin products. It has a vacuum mixer. There are 4 exhaust drops for U-3 particle scrubber. Module 2 is also used for Clinimycin products. It has 2 exhaust drops for U-3. Room 177 is used to weigh materials. Module 1 is under construction. it has a 3500 mixer. Module 4 has a bulk bag dispensing system. Liquids are mixed here including Dilantin oral solution. This module has 4 drops for U-3.

This completes Day 1<sup>A</sup>

NAME Dennis Durdap

DATE 8/12/16

SUPERVISOR MO 8/15/2016