west virginia department of environmental protection

Division of Air Quality
601 57th Street SE
Charleston, WV 25304
Phone (304) 926-0475 • FAX: (304) 926-0479

Joe Manchin, III, Governor
Randy C. Huffman, Cabinet Secretary
www.dep.wv.gov

ENGINEERING EVALUATION / FACT SHEET

BACKGROUND INFORMATION

Application No.:	R13-2068M
Plant ID No.:	061-00033
Applicant:	Mylan Pharmaceuticals Inc.
Facility Name:	Chestnut Ridge Facility
Location:	Monongalia County
SIC Code:	2834
Application Type:	Modification
Received Date:	August 15, 2010
Engineer Assigned:	Joe Kessler
Fee Amount:	$1,000
Date Received:	March 18, 2010 (submitted for R13-2068L later withdrawn)
Complete Date:	September 13, 2010
Due Date:	December 12, 2010
Applicant Ad Date:	August 16, 2010
Newspaper:	*Dominion Post*
UTM's:	Easting: 589.6 km Northing: 4,390.1 km Zone: 17
Description:	Permit modification to authorize installation and operation of an additional coating pan (245).

Mylan Pharmaceuticals Inc. (Mylan) is a batch pharmaceutical manufacturing company that purchases raw materials from various suppliers and produces solid-dose pharmaceuticals. The Chestnut Ridge Facility was originally constructed in the 1960's and became a grandfathered source when the minor source program was promulgated in 1974. The facility has received, however, 45CSR13 permits for expansions and modifications since that time.

Mylan, under permit R13-2068K issued on January 5, 2010, received authorization to install regenerative thermal oxidation (RTO) and Catalytic Oxidation (CO) to control VOC emissions from various processes at the plant. They stated that their goal was to bring potential facility-wide VOC emissions to below 100 tons per year (TPY). At that time, however, Mylan did not take credit for the reduction of VOC emissions. They planned to install the oxidizers and test them prior to taking credit for the VOC reductions. They did, however, under R13-2068K, permit the potential products of combustion from use of the oxidizers. The application to take credit for the VOC reductions is expected to be submitted in late 2010 or early 2011.

In March 2010, Mylan submitted a permit application (R13-2068L) increase VOC emissions from their fluid beds from 110 TPY to 172 TPY. This application was withdrawn on May 4, 2010.

The application fee from this permitting action was held on account and used as the fee for the action reviewed herein. Mylan is now requesting the addition of one new coating pan (245).

DESCRIPTION OF PROCESS/MODIFICATIONS

As noted above, Mylan is a batch pharmaceutical manufacturing company that purchases raw materials from various suppliers and produces solid-dose pharmaceuticals. This is accomplished by weighing, blending, granulating, formulating, and packaging operations. Air emissions are produced by boiler exhaust, loss of pharmaceutical ingredients as particulate matter during manufacturing processes, and the release/loss of VOC-containing solvents during manufacturing processes. It is important to note that Mylan has eliminated all HAP-containing solvents from their processes. Emission controls include wet scrubbers and cartridge collectors. One existing process is of concern in this modification: coating pans.

Coating Pans

Coating pans are used to coat formulated tablets with a solution containing water and/or non-HAP solvents. Dry materials are loaded into the coating pan and then solutions are sprayed onto the materials at varying rates depending upon the product being manufactured. Mylan's production formulations utilizing the coating pans have been water based since the voluntary elimination of methylene chloride over ten years ago. However, new technology is requiring Mylan to introduce solvents into the production coating process. At this time, Mylan is requesting a permit modification for one (1) additional coating pan for VOC (strictly non-HAP) operation. This will be the fifth coating pan at the Mylan facility. The new coating pan will also include small PM emissions.

SITE INSPECTION

On November 4, 2009, the writer conducted a site inspection of Mylan's Chestnut Ridge facility. The primary contacts for the inspection were Mr. Craig Travis, Senior Manager Global Environmental Compliance and Mr. Dale Stemple, Executive Director Corporate Safety and Environmental Compliance and Global Security. After an initial discussion of permitting issues, the writer was given a tour of the major production areas of the facility including the fluid bed and coating pan areas and shown the proposed location of the RTO and catalytic oxidizer. Some observations from the inspection include:

- The Mylan facility is located in a heavily populated area off of Chestnut Ridge Road (Route 705) in Morgantown. It is closely bounded on all sides by other businesses and residential neighborhoods. There is a school and several hospitals near the location.

- The proposed location of the RTO will be on the west side of the facility. Exhaust from the fluid beds and coating pans will be ducted on the roof to the RTO. The stack of the RTO is expected to rise 20 feet above the roof level of the facility.

- The fluid beds/coating pans are variable, batch type processes. After each use the units must be stripped down and cleaned before the next batch is loaded. Additionally, due to the sizes and design of each fluid bed/coating pan, the units are limited to the range of products they can make. This greatly limits the number of fluid beds/coating pans that can be operating at any one time.

- No odor was noticed outside the facility and no opacity was visible at any time from any of the emission sources.

REVIEW OF APPLICANT'S EMISSIONS ESTIMATE

Particulate matter emissions from each coating pan is based on the amount of dry material feed that is lost in the process (estimated to be 1.5%) and that is not controlled by the cartridge collector (estimated at 95% efficient). Mylan also factors in an additional pre-control safety factor (they refer to it as an "upset/excursion" factor) of 1.5. Annual emissions are based on a maximum operating schedule of 4,950 hours/year. This is demonstrated in the following equation for hourly particulate matter emissions from coating pan 241:

Eq. 3: E_{CP} (lb-PM/hr) = [Dry Feed (lb-material/hr)] * [Feed Loss Rate (1.5%)] * [Safety Factor (150%)] * [1 - Collector Efficiency (95%)]

E_{CP} (lb-PM/hr) = [750 lb-material/hr] * [0.015] * [1.5] * [0.05]

E_{CP} (lb-PM/hr) = 0.84 lb-PM/hr

VOC emissions from the coating pans are calculated by using a material balance methodology. This is accomplished on a hourly basis by calculating the maximum pounds of VOCs used in each coating pan based on the design capacity of the spray guns and the VOC content of the solvents. Mylan also factors in an additional safety factor (they refer to it as an "upset/excursion" factor) of 150%. Annual emissions are set at an aggregate of 5 tons per year or about 13 hours of operation per year. There is no control proposed for VOC emissions. The hourly VOC emission calculation is given below:

Eq. 4: E_{CP} (lb-VOC/hr) = [Spray Gun Capacity (grams/hour)] * [VOC Content of Solvent (lb-VOC/gram)] * [Safety Factor (150%)]

E_{CP} (lb-VOC/hr) = [120,000 grams/hour] * [0.002205 lb-VOC/gram] * [1.5]

E_{CP} (lb-VOC/hr) = 396.9 lb-VOC/gallon

DAQ Review of Emission Calculation Methodologies

The DAQ accepts the Mylan emissions calculations methodology as reasonable and practically enforceable using the requirements contained in the proposed draft permit.

Emissions Summary

The following table summarizes the pre-modification, post-modification, and change in emissions associated with the modified equipment.

Table 1: Emissions Summary

Emission Source	Pre-Modification		Post-Modification		Change	
	lb/hr(1)	TPY	lb/hr(1)	TPY	lb/hr(1)	TPY
Coating Pans						
NO_x	--	--	--	--	--	--
CO	--	--	--	--	--	--
PM	2.52	6.24	3.36	8.32	0.84	2.08
VOC	1,190.70	5.00	1,587.60	5.00	396.90	0.00
SO_2	--	--	--	--	--	--

(1) High short-term emissions shall only occur during very short periods as is represented by relatively low annual emissions. Mylan has stated they will be installing an RTO to control VOC emissions and is expected to apply for lower PTE in last quarter of 2010 or first quarter of 2011.

REGULATORY APPLICABILITY

The proposed modification only affects emissions from the new coating pan and, therefore, for the following review of regulatory applicability will only consider the new coating pan.

45CSR13: Permits for Construction, Modification, Relocation and Operation of Stationary Sources of Air Pollutants, Notification Requirements, Administrative Updates, Temporary Permits, General Permits, and Procedures for Evaluation

As noted above in Table 1, the emissions increase associated with the proposed modifications evaluated herein are in excess of those that would define the changes as a modification under §45-13-2.17a (in this case potential emissions exceed 144 lbs/day) and, therefore, a permit modification under 45CSR13 is required for the changes.

45CSR30: Requirements for Operating Permits

45CSR30 provides for the establishment of a comprehensive air quality permitting system consistent with the requirements of Title V of the Clean Air Act. The Mylan Chestnut Ridge facility, defined under Title V as a "major source," was issued a Title V permit on December 12, 2006. Changes authorized by the proposed permit must also be incorporated into the facility's Title V operating permit. Commencement of the operations authorized by this permit (which is the operation of the plant) shall be determined by the appropriate timing limitations associated with Title V permit revisions per 45CSR30.

TOXICITY ANALYSIS OF NON-CRITERIA REGULATED POLLUTANTS

The addition of the new coating pan will not result in any increase of non-criteria regulated pollutants.

AIR QUALITY IMPACT ANALYSIS

The proposed modification does not meet the definition of a "major modification" pursuant to 45CSR14 and, therefore, an air quality impact (computer modeling) analysis was not required.

MONITORING, COMPLIANCE DEMONSTRATIONS, RECORD-KEEPING, AND REPORTING REQUIREMENTS

The following substantive monitoring, compliance demonstration, and record-keeping requirements are be required at the Chestnut Ridge Facility for the coating pans.

Coating Pans

- Visible emissions monitoring shall be conducted initially at least once per month for all emission points subject to opacity limitations. After three consecutive monthly readings in which no visible emissions are observed from any of the subject emission points, those emission points will be allowed to conduct visible emissions checks once per calendar quarter. If visible emissions are observed during a quarterly monitoring from an emission point(s), then that emission point(s) with observed emissions or opacity shall be required to revert to monthly monitoring. Any emission point that has reverted to monthly monitoring shall be allowed to again conduct quarterly visible emissions checks only after three consecutive monthly readings in which no visible emissions are observed from the subject emission point.

  These visible emission checks shall be conducted in accordance with 40 CFR 60, Appendix A, Method 22 during periods of normal facility operation for a sufficient time interval to determine if the unit has visible emissions. If sources of visible emissions are identified during the survey, or at any other time, Mylan shall conduct a 40 CFR 60, Appendix A, Method 9 evaluation within twenty four (24) hours. A Method 9 evaluation shall not be required if the visible emissions condition is corrected within twenty four (24) hours from the time the visible emission condition was identified and the unit is operated at normal operating conditions. *[8.2.1]*

- Mylan shall operate and maintain the cartridge collectors and shall conduct a weekly visual inspection of the bags, bag connections, and dust hoppers of the cartridge collector at each emission point specified, in order to ensure proper operation of cartridge collectors. Records shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any. *[8.2.2]*

- For the purposes of demonstrating compliance with maximum hourly dry material feed rate set forth in 8.1.6(a), Mylan shall monitor and record the dry feed rate per load for each coating pan. This requirement may be waived if Mylan is able to demonstrate that the maximum reasonable design capacity of each coating pan is equal or less than the rates given under 8.1.6(a). *[8.2.3]*

- For the purposes of demonstrating compliance with maximum annual aggregate dry material feed rate set forth in 8.1.6(b), Mylan shall monitor and record the aggregate monthly and rolling twelve month dry material feed rate into the coating pans. *[8.2.4]*

- For the purposes of demonstrating compliance with maximum annual VOC emission limit set forth in 8.1.5, Mylan shall monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in the coating pans. *[8.2.5]*

- Records of weekly inspections conducted on the cartridge collector shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any. *[8.4.1]*

- Mylan shall maintain a record of all solvents used in the fluid beds and keep a copy of the associated MSDS to verify that the solvents did not contain any constituent HAPs. *[8.4.2]*

TESTING OF OPERATIONS

The coating pans are subject to the general testing requirements given under 3.3 of the permit.

CHANGES TO PERMIT R13-2068K

The substantive changes made to Permit R13-2068K are:

- Addition of Coating Pan 245 45CSR7 PM limit in Table 8.1.2.;

- Addition of Coating Pan 245 PM hourly emission limit and increased aggregate Coating Pan limit in Table 8.1.3.;

- Addition of Coating Pan 245 dry loading limit to 8.1.6(a)(5); and

- Addition of Coating Pan 245 to solvent spray processing limit in 8.1.6(d).

RECOMMENDATION TO DIRECTOR

The information provided in the permit application indicates that compliance with all applicable regulations will be achieved. Therefore, I recommend to the Director the issuance of a

Permit Number R13-2068M to Mylan for the above discussed modification to the Chestnut Ridge Facility located in Morgantown, Monongalia County, WV.

Joe Kessler, PE
Engineer

Date