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

Jim Justice, Governor
Austin Caperton, Cabinet Secretary
www.dep.wv.gov

ENGINEERING EVALUATION / FACT SHEET

BACKGROUND INFORMATION

Application No.:	R13-2068T
Plant ID No.:	061-00033
Applicant:	Mylan Pharmaceuticals Inc.
Facility Name:	Chestnut Ridge Facility
Location:	Monongalia County
SIC/NAICS Code:	2834/325412
Application Type:	Class II Administrative Update
Received Date:	February 28, 2017
Engineer Assigned:	Joe Kessler
Fee Amount:	$300
Date Received:	March 3, 2017
Complete Date:	February 28, 2017
Due Date:	April 29, 2017
Applicant Ad Date:	March 4, 2017
Newspaper:	*The Dominion Post*
UTM's:	Easting: 589.6 km Northing: 4,390.1 km Zone: 17
Latitude/Longitude:	39.65923/-79.95824
Description:	Addition of one (1) coating pan (247) and an associated dust collector (CC 10024526) and the addition of one (1) additional cartridge-type dust collector (CC 10030432) to control particulate matter emissions from specific production rooms (Rooms 74-101 to 74-110).

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.

Significantly, under permit R13-2068K, issued on January 5, 2010, Mylan received authorization to install a regenerative thermal oxidizer (RTO) to control VOC emissions from various processes at the plant. They stated, at the time, that their goal was to bring potential facility-wide VOC emissions to below 100 tons per year (TPY). As of yet, however, Mylan has not taken credit for all the potential reductions of VOC emissions associated with the installation of the RTO.

Since the issuance of R13-2068K, Mylan's Chestnut Ridge facility has been the subject of the following permitting actions:

- On May 4, 2010, Mylan withdrew a permit application that had proposed to increase fluid bed VOC emissions to account for change in product formulations. After looking at product forecasts, Mylan decided this modification was unnecessary;

- On November 3, 2010, Mylan was issued R13-2068M to authorize installation and operation of an additional coating pan (245);

- On January 5, 2011, Mylan was issued R13-2068N as a Class II Administrative Update to authorize Mylan to take credit for VOC destruction in the RTO for Fluid Beds 534, 538, 572, 574 – 578, and 580 and to remove authorization for use of a Catalytic Oxidizer;

- On September 14, 2011, Mylan was issued R13-2068O for the: (1) Increase of the permitted capacity of various fluid beds, (2) Addition of an absorber to the permit, (3) Controlling of two fluid beds (573, 579) with the absorber, (4) Controlling of two coating pans (244, 245) with the RTO, and (5) Controlling of previously grandfathered oven dryers with the RTO;

- On August 12, 2013, Mylan was issued R13-2068P as a Class II Administrative Update for various equipment replacements and the addition of an Oven Dryer and a Coating line;

- On September 29, 2014, Mylan was issued R13-2068Q as a Class II Administrative Update for installation of a new roof mounted cartridge collector to control particulate matter emissions generated in fifteen (15) existing production rooms;

- On November 3, 2015, Mylan was issued R13-2068R for the installation of a new coating pan (246) and associated dust collector (CC 246); and

- On October 28, 2016, Mylan was issued R13-2068S as a Class II Administrative Update for installation of: (1) a new fluid bed (583, 583) and associated cartridge collector (CC 10024247), (2) a new 6.0 mmBtu/hr boiler (016, 016), and (3) the replacement of three old cartridge collectors.

DESCRIPTION OF PROCESS/MODIFICATIONS

Existing Facility

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.

The manufacturing process 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 the manufacturing processes, and the release/loss of VOC-containing solvents during manufacturing processes. Existing emission controls include wet scrubbers, cartridge-type dust collectors, an absorber, and an RTO. Mylan primarily uses the following production equipment and emission controls in the manufacturing process:

Fluid Beds

Fluid beds are used to mix, compound, formulate and/or dry powders or particles utilizing water and/or non-HAP solvents depending on the product and formulation. The fluid beds are equipped with integral dust collection filters (cartridge collectors) capturing the powders within the fluid bed. The exhaust of each fluid bed is controlled by a cartridge collector filter system for particulate matter. Nineteen (19) fluid beds are currently permitted.

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. Six (6) coating pans are currently permitted. At this time, Mylan has taken credit (and permitted) for control of three coating pans (244, 245, 246) with the RTO.

Oven Dryers

Three existing oven dryers (260, 261, and 264) are used for drying solvent from product that has been granulated using solvent and/or water in a separate mixer operation. Wet product is placed on trays and racks which are placed inside the ovens for a specific amount of time. The heat of the ovens drives off the volatiles which are sent to the RTO for control.

Regenerative Thermal Oxidation

The RTO has been installed at the Mylan facility to oxidize solvent emissions from selected VOC sources. Exhaust from sources selected for control by the RTO are ducted to a main line which conveys the air stream to the RTO with a combined burner rating not to exceed 16.00 million BTU/hr. The air stream passes through heat recovery media prior to entering the burner chamber where oxidation of the VOCs occurs. The combustion gases exit the burner chamber through the additional heat exchange media prior to exiting the unit through the stack. The manufacturer guarantees a VOC destruction efficiency of at least 99% (Mylan conservatively estimates a minimum 98% VOC destruction efficiency for emissions estimates).

Absorber

The Absorber is a typical packed bed-design that uses fresh water (maximum design flow rate of 100 gal/min) to control ethanol and/or isopropyl alcohol solvent emissions from Fluid Beds 573 and 579. The VOC control efficiency from use of the absorber is 95%.

Rotoclones & Cartridge Collectors

Rotoclones are control devices (using internal water sprays) that are used to control particulate matter emissions from general exhaust fans servicing production rooms. Cartridge collectors are fabric filters used to control particulate matter from individual fluid beds and coating pans.

Proposed Modifications

Mylan is now proposing the addition of one (1) coating pan (247) and an associated dust collector (CC 10024526) and the addition of one (1) additional cartridge-type dust collector (CC 10030432) to control particulate matter emissions from specific production rooms (Rooms 74-101 to 74-110). The collector will achieve a minimum control percentage of 95%. The new coating pan shall have the capability to rout VOC emissions (produced using VOC-containing solvents) to the RTO (with a minimum DRE of 98%). Mylan is not requesting any increase in the aggregate annual particulate matter or VOC emission limits for the coating pans as they will be able to operate under the existing limits. The new cartridge collector will achieve a minimum control percentage of 98% of the particulate matter emissions generated in the production rooms listed above.

SITE INSPECTION

Due to the nature of the proposed changes, the writer did not conduct a site inspection. According to information in the DAQ database, the last "full on-site" inspection occurred on September 29, 2015 by Ms. Rebecca Johnson of the Compliance/Enforcement Section. The facility was given a status code of "30 - In Compliance" as a result of the inspection.

REVIEW OF APPLICANT'S EMISSIONS ESTIMATE

The following will review Mylan's methodology of calculating emissions from those units that are added or modified as a result of this permitting action.

Coating Pan

Particulate matter emissions from each coating pan are 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 (however, aggregate annual emissions from all coating pans are limited to 6.25 TPY and that will not change as a result of this permit). This is demonstrated in the following equation for hourly particulate matter emissions from coating pan 247:

Eq. 1: 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. Annual emissions from all coating pans are set at an aggregate of 5 TPY. Mylan has requested to have the option of sending the VOC emissions from the new pan to the RTO or venting directly to the atmosphere. The hourly VOC emission calculation is given below when venting directly to the atmosphere. When controlled by the RTO, the VOC emissions would be reduced by 98%.

Eq. 2: E_{CP} (lb-VOC/hr) = [Spray Gun Capacity (grams/hour)] * [VOC Content of Solvent (lb-VOC/gram)]

E_{CP} (lb-VOC/hr) = [180,000 grams/hour] * [0.002205 lb-VOC/gram]

E_{CP} (lb-VOC/hr) = 396.90 lb-VOC/hr

Production Rooms General Exhaust

Uncontrolled particulate matter emissions from Production Rooms 74-101 to 74-110 (ten total rooms) are based on the worst-case scenario where 1,000 kg (2,205 pounds) of pharmaceutical powder is processed over 24 hours in each of the 15 rooms (total for all rooms of 919 lb/hr). Of this material, a maximum 1% estimated to become airborne and exhausted through the general exhaust fans. Annual emissions are based on production rooms operating a maximum of 6,300 hours/year.

Mylan will control Production Rooms 74-101 to 74-110 with a cartridge collector (98%). Therefore, controlled particulate matter emissions are estimated to be 2% of the uncontrolled emissions. The controlled emission increase of particulate matter (assumed to be $PM_{2.5}$ or less) is 0.18 lbs/hour and 0.58 tons/year.

Emissions Summary

The addition of the new coating pan will increase the maximum hourly short-term particulate matter potential-to-emit (PTE) of the facility (0.84 lb/hr) but will not change the annual PTE as Mylan has not requested an increase in the aggregate particulate matter emission limit of the coating pans. Additionally, there will be no increase in either the short or long-term emissions of VOCs as a result of the new coating pan. The permit will contain a provision under 8.1.6(h) that will limit the use of solvent in only five (5) coating pans at a time therefore limiting the maximum hourly VOC emissions from the coating pans to what the potential is currently. The annual coating pan VOC limit will remain unchanged at 5.0 TPY.

The new cartridge collector controlling the additional production rooms will increase both the hourly and annual particulate matter PTE of the facility (0.18 lb/hr and 0.58 TPY). Therefore, the PTE increase of particulate matter associated with this project is (all particulate matter emissions are assumed to be $PM_{2.5}$ or less) 1.02 lb/hr and 0.58 TPY. The new facility-wide annual PTE of the Morgantown facility is given in the following table:

Table 1: Post-Modification Facility-Wide Annual PTE

Permit	NO_x	CO	VOCs	SO_2	PM[1]	HAPs
R13-2068S[2]	67.08	87.50	141.96	0.62	75.46	24.40
2068T Change	*0.00*	*0.00*	*0.00*	*0.00*	*0.58*	*0.00*
R13-2068T	**67.08**	**87.50**	**141.96**	**0.62**	**76.04**	**24.40**

(1) All particulate matter emitted is assumed to be $PM_{2.5}$ or less and includes condensables.
(2) Existing PTE calculated from data in R13-2068Q, R, and S Engineering Evaluations/Fact Sheets.

REGULATORY APPLICABILITY

This section will address the potential regulatory applicability/non-applicability of substantive state and federal air quality rules relevant to this permitting action.

45CSR7: To Prevent and Control Particulate Air Pollution from Manufacturing Process Operations

45CSR7 applies to "source operations" located at "manufacturing processes" that, excluding those manufacturing processes specified under §45-7-10.5 and §45-7-10.6, have the potential-to-emit particulate matter and acid gases. Mylan's manufacture of various solid-dose pharmaceuticals meets the definition of a "manufacturing process" as defined under 45CSR7. Source operations would include the coating pans and the production rooms as exhausted by the general exhaust fans. The sections that apply to these source operations are the opacity requirements under Section 3 and the mass emission standards under Section 4. Each of these sections will be discussed below as they specifically relate to the new emission sources.

45CSR7 Opacity Standards - Section 3

Section 3.1 sets an opacity limit of 20% on all applicable source operations. As the particulate matter emissions from the new coating pan are controlled by a cartridge collector, opacity from this source is expected to be minimal. As the particulate matter emissions from the Production Rooms 74-101 to 74-110 are controlled by cartridge collectors, opacity from these sources are also expected to be minimal.

45CSR7 Weight Emission Standards - Section 4

Section 4.1 of 45CSR7 requires that each manufacturing processes meet a particulate matter stack emission limit based on the weight of material processed through the source operation (PWR). The emission limits are given under Table 45-7A and are based on the type source operation as defined in the Rule. Coating pans are defined, pursuant to §45-7-2.39(a), as type 'a' source operation types. The maximum amount of material charged through the new coating pan is 750 pounds per hour (lb/hr). Based on Table 45-7A, the aggregate particulate matter limit for the new coating pan would be 0.90 lb/hr. The maximum controlled particulate matter emission rate from the new coating pan is calculated to be 0.84 lbs/hr, which is below the 45CSR7 limit.

It is noted here that previously the coating pans have been collectively defined as "duplicate sources" under §45-7-2.13 and that individual particulate matter limits determined using the equation as given under §45-7-4.8. However, Mylan has requested, based on the nature of the coating pans, that these units not be considered duplicate sources. It is the view of the writer that Mylan's request is reasonable and that the coating pans should not have 45CSR7 emission limits calculated under the duplicate source definition. The basis of this determination is that each individual coating pan is designed to make specific products (and are, therefore, different) and all coating pans could not replaced by one larger coating pan. The intent of the duplicate source definition under 45CSR7 is to prevent sources from breaking up a single large unit into smaller units to avoid having a smaller total particulate matter limit under the "flattening curve" of emission limits given under Table 45-7A. It is clear that there is no intent in the case of Mylan and the coating pans and that they are, not, in any event, duplicate sources.

The tablet manufacturing operations are defined as a type 'a' source type operation under §45-7-2.38. The aggregate maximum amount of material charged through Production Rooms 74-101 to 74-110 is 919 pounds per hour (lb/hr). Based on Table 45-7A, the aggregate particulate matter limit for Emission Point 324 would be 1.10 lb/hr. The PTE from Emission Point 323 is 0.18 lbs/hr, or 16.36% of the 45CSR7 limit.

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

The proposed changes to the Chestnut Ridge Facility will increase the PTE of a regulated pollutant (see Table 1 above). However, the increase in PTE is below six (6) lbs/hour and ten (10) TPY of any regulated pollutant that would, pursuant to §45-13-2.17, define the change as a "modification" under 45CSR13. Therefore, pursuant to §45-13-4.2(b)(1), Mylan is requesting a Class II Administrative Update to make a "[c]hange in a permit condition as necessary to allow changes in operating parameters, emission points, control equipment or any other aspect of a source which results in an increase . . . of any existing regulated air pollutant . . . "

Therefore, as required under §45-13-8.3 ("Notice Level A"), Mylan placed a Class I legal advertisement in a "newspaper of general circulation in the area where the source is . . . located." The ad ran on March 4, 2017 in *The Dominion Post*. Mylan provided verification that the legal advertisement ran on March 14, 2017.

45CSR14: Permits for Construction and Major Modification of Major Stationary Sources of Air Pollution for the Prevention of Significant Deterioration - (NON APPLICABILITY)

Mylan's Chestnut Ridge Facility is located in Monongalia County, WV. Monongalia County is classified as "in attainment" with all National Ambient Air Quality Standards. Therefore, as the facility is a "listed source" under §45-14-2.43 (Chemical Process Plant - first two digits of the SIC Code are 28), the individual major source applicability threshold for all NSR pollutants is 100 TPY. As the facility-wide VOC PTE of the existing facility is greater than 100 TPY, the facility is defined as a "major stationary source" under 45CSR14.

Therefore, to determine if the proposed changes are defined as a "major modification" to the Chestnut Ridge Facility, pursuant to §45-14-3.4(a), the project is examined under a two-step applicability test: "[A] project is a major modification for a regulated NSR pollutant if it causes two types of emissions increases -- a significant emissions increase (as defined in subsection [§45-14-2.75]), and a significant net emissions increase (as defined in subsections [§45-14-2.46] and [§45-14-2.74]). The proposed project is not a major modification if it does not cause a significant emissions increase. If the proposed project causes a significant emissions increase, then the project is a major modification only if it also results in a significant net emissions increase."

Therefore, for the proposed changes to meet the definition of a major modification, the addition of the coating pan and additional cartridge collector must alone result in a significant emissions increase. The methodology for calculating the emissions increase under the first step is given under Sections §45-14-3.4(b), 3.4(c), 3.4(d) and 3.4(f). The substantive language relevant to the changes evaluated herein is given below:

> **[§45-14-3.4(b)]**
> The procedure for calculating (before beginning actual construction) whether a significant emissions increase (i.e., the first step of the process) will occur depends upon the type of emissions units being modified, according to subdivisions 3.4.c through 3.4.f.
>
> **[§45-14-3.4(d)]**
> Actual-to-potential test for projects that only involve construction of a new emissions unit(s). -- A significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the difference between the potential to emit (as defined in subsection 2.58) from each new emissions unit following completion of the project and the baseline actual emissions (as defined in subdivision 2.8.c) of these units before the project equals or exceeds the significant amount for that pollutant (as defined in subsection 2.74).

Based on the PTE associated with the proposed chagnes as given above under Table 1, no PSD pollutant exceeds the significant emissions threshold under 2.74 and, therefore, the proposed chagnes are not defined as a "major modification" under 45CSR14.

It is important to note that the DAQ does not necessarily consider this addition of a new coating pan and cartridge collector to be part of any other project that would necessitate aggregating multiple project emissions together to compare to the PSD applicability thresholds. However, Mylan did include in the permit application a summary of changes made over the last five (5) years that included other new sources of particulate matter. This analysis shows that the previous modifications (including the one evaluated herein) have increased the particulate matter emission rate by 1.34 TPY - still far below the significant emissions threshold under 2.74.

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 last issued a Title V permit on March 9, 2017. 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

No increase in non-criteria regulated pollutants will result from the changes evaluated herein.

AIR QUALITY IMPACT ANALYSIS

The proposed changes do not meet the definition of a "major modification" pursuant to 45CSR14 and, therefore, an air quality impact (computer modeling) analysis was not required. Additionally, based on the nature of the proposed changes, modeling was not required under 45CSR13, Section 7.

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

No substantive changes to the existing monitoring, compliance demonstrations, reporting or record-keeping requirements were made as part of this permitting process.

PERFORMANCE TESTING OF OPERATIONS

No new performance tests were required as a result of the changes permitted herein. The coating pans are subject to the general testing requirements given under 3.3 of the permit.

CHANGES TO PERMIT R13-2068S

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

- Addition of the new coating pan (247) and cartridge collector (324) to Emissions Table 1.0;
- Added the cartridge collector 45CSR7 limit to Table 7.1.2.;
- Increased the aggregate Production Rooms' particulate matter limit under 7.1.6. of the permit;
- Addition of coating pan 247 45CSR7 PM limit in Table 8.1.2.;
- Addition of coating pan 247 PM hourly emission limit in Table 8.1.3.;
- Addition of coating pan 247 dry loading limit to 8.1.6(a)(7);

- Added new language under 8.1.6(h) limiting coating pan solvent use to any five (5) coating pans at a time; and

- Addition of coating pan 247 to other sections of the permit dealing with solvent usage in the coating pans.

RECOMMENDATION TO DIRECTOR

The information provided in the permit application indicates that compliance with all applicable state and federal air quality regulations will be achieved. Therefore, I recommend to the Director the issuance of Permit Number R13-2068T to Mylan for the above discussed changes to the Chestnut Ridge Facility located in Morgantown, Monongalia County, WV.

Joe Kessler, PE
Engineer

4/04/17
Date