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ENGINEERING EVALUATION / FACT SHEET

BACKGROUND INFORMATION

Application No.:	R13-2068R
Plant ID No.:	061-00033
Applicant:	Mylan Pharmaceuticals Inc.
Facility Name:	Chestnut Ridge Facility
Location:	Monongalia County
NAICS Code:	325412
Application Type:	Modification
Received Date:	July 13, 2015
Engineer Assigned:	Joe Kessler
Fee Amount:	$1,000
Date Received:	July 15, 2015
Complete Date:	August 12, 2015
Due Date:	November 10, 2015
Applicant Ad Date:	July 17, 2015
Newspaper:	*The Dominion Post*
UTM's:	Easting: 589.6 km Northing: 4,390.1 km Zone: 17
Latitude/Longitude:	39.65923/-79.95824
Description:	Installation of a new coating pan and associated dust collector.

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. They have previously, however, under R13-2068K, permitted the potential products of combustion from use of the oxidizers.

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; and

- 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.

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. Eighteen (18) 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. Five (5) coating pans are currently permitted. At this time, Mylan has taken credit (and permitted) for control of two coating pans (244, 245) 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 to add one additional coating pan (246) with an associated cartridge-type dust collector (CC 246) to control particulate matter emissions). The new coating pan shall have the capability to rout VOC emissions from the unit to the RTO.

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 5, 2013 by Mr. Brian Tephabock 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. 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 241:

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) = [682 lb-material/hr] * [0.015] * [1.5] * [0.05]

E_{CP} (lb-PM/hr) = 0.77 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 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)] * [Safety Factor (150%)]

E_{CP} (lb-VOC/hr) = [180,000 grams/hour] * [0.002205 lb-VOC/gram] * [1.5]

E_{CP} (lb-VOC/hr) = 595.35 lb-VOC/hr

Emissions Summary

As there is no requested change in the aggregate annual VOC or particulate matter emissions from all the coating pans, there is no increase in the facility-wide annual PTE as a result of this permitting action. However, as there is no prohibition in the permit of all the coating pans operating simultaneously, the increase in facility-wide hourly PTE as a result of this permitting action would simply be the worst-case hourly emission rates as calculated above under Equation 1 and 2.

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. The sections that apply to the coating pans 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 coating pan.

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 is controlled by a cartridge collector, opacity from this source is 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 682 pounds per hour (lb/hr). Based on Table 45-7A, the aggregate particulate matter limit for the new coating pan would be 0.82 lb/hr. The maximum particulate matter emission rate from the new coating pan is calculated to be 0.77 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.

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 addition of a coating pan has the potential to increase the emissions of the facility in excess of 144 pounds per calendar day of a regulated pollutant and, therefore, pursuant to §45-13-2.17, the changes are defined as a "modification" under 45CSR13. Pursuant to §45-13-5.1, "[n]o person shall cause, suffer, allow or permit the construction, modification, relocation and operation of any stationary source to be commenced without . . . obtaining a permit to construct." Therefore, Mylan is required to obtain a permit under 45CSR13 for the modification of the facility.

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 July 17, 2015 in *The Dominion Post*. The affidavit of publication for this legal advertisement was submitted on July 22, 2015.

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. Based on information from the R13-2068Q Engineering Evaluation, the facility-wide VOC PTE of the existing facility is greater than 100 TPY. Therefore, the facility is defined as a "major stationary source" under 45CSR14.

As noted above, there is no increase in annual PTE as a result of this addition of a new coating pan as the aggregate particulate matter and VOC limits for all coating pans will be unchanged at 6.25 and 5.00 TPY, respectively. Therefore, this modification will not result in a "significant" emissions increase under 45CSR14 and the PSD review requirements do not apply. It is important to note that the DAQ does not consider this addition of a new coating pan to be part of any other project that would necessitate aggregating multiple project emissions together to compare to the PSD applicability thresholds.

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 January 10, 2012. 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 R13-2068Q

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

- Addition of Coating Pan 246 to Emissions Table 1.0;
- Addition of Coating Pan 246 45CSR7 PM limit in Table 8.1.2. and adjusting other coating pan 45CSR7 limits to individual source as opposed to duplicate source limits;
- Addition of Coating Pan 246 PM hourly emission limit in Table 8.1.3.;
- Addition of Coating Pan 246 dry loading limit to 8.1.6(a)(6); and

- Addition of Coating Pan 246 (with existing coating pans 244 and 245) in various requirements throughout the permit relating to use of the RTO on these 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 R13-2068R to Mylan for the above discussed changes to the Chestnut Ridge Facility located in Morgantown, Monongalia County, WV.

Joe Kessler, PE
Engineer

Date