

Fact Sheet



For Final Significant Modification Permitting Action Under 45CSR30 and Title V of the Clean Air Act

This Fact Sheet serves to address the changes specific to this Significant Modification, and shall be considered a supplement to the Fact Sheet corresponding with the Title V operating permit issued on December 12, 2006.

Permit Number: R30-06100033-2006
Application Received: October 13, 2009
Plant Identification Number: 03-54-06100033
Permittee: Mylan Pharmaceuticals Inc.
Facility Name: Chestnut Ridge Plant
Mailing Address: 781 Chestnut Ridge Road, Morgantown, WV 26505

Permit Action Number: *SM01*, Revised: *March 30, 2010*

Physical Location:	Morgantown, Monongalia County, West Virginia
UTM Coordinates:	589.6 km Easting • 4390.1 km Northing • Zone 17
Directions:	I-79 to Exit 155. Follow signs for WVU. Follow US Route 19 to Coliseum. Turn left onto SR 705 for approximately 1.2 miles. Turn right to stay on SR 705 (Chestnut Ridge Road). Follow for approximately 0.6 miles to plant on left.

Facility Description

Mylan Pharmaceuticals Inc. is a batch pharmaceutical manufacturing company. Mylan purchases raw materials from suppliers and performs various quality control tests on the raw materials. The manufacturing plant mixes, compounds, and formulates pharmaceutical products. The Standard Industrial Classification code is 2834, Pharmaceutical Compounding and Formulating.

This permit modification incorporates changes made in R13-2068K. These changes include installation and operation of regenerative and catalytic thermal oxidation units, increase fluid bed VOC limits, installation of three additional coating pans, increased particulate matter limits for Coating Pan 215, and changes to existing rotoclone alarm record-keeping language.

Emissions Summary

The changes to this facility associated with this modification will result in the following Potential to Emit (PTE) increases:

Pollutant	PTE Increase (TPY) ¹
NO _x	15.17
CO	10.48
PM	6.01
VOC	23.56
SO ₂	0.06

¹PTE increase data was taken from Engineering Evaluation/Fact Sheet for R13-2068K.

Title V Program Applicability Basis

With this modification, this facility maintains the potential to emit over 100 tons per year of VOCs. Due to this facility's potential to emit over 100 tons per year of a criteria pollutant, it is required to have an operating permit pursuant to Title V of the Federal Clean Air Act as amended and 45CSR30.

Legal and Factual Basis for Permit Conditions

The State and Federally-enforceable conditions of the Title V Operating Permits are based upon the requirements of the State of West Virginia Operating Permit Rule 45CSR30 for the purposes of Title V of the Federal Clean Air Act and the underlying applicable requirements in other state and federal rules.

The modification to this facility has been found to be subject to the following applicable rules:

Federal and State:	45CSR6	Particulate from Combusting Refuse
	45CSR7	Particulate from Manufacturing Processes
	45CSR10	SO _x Emissions
	45CSR13	
	45CSR30	Operating permit requirement.

Each State and Federally-enforceable condition of the draft Title V Operating Permit references the specific relevant requirements of 45CSR30 or the applicable requirement upon which it is based. Any condition of the Title V permit that is enforceable by the State but is not Federally-enforceable is identified in the Title V permit as such.

The Secretary's authority to require standards under 40 C.F.R. Part 60 (NSPS), 40 C.F.R. Part 61 (NESHAPs), and 40 C.F.R. Part 63 (NESHAPs MACT) is provided in West Virginia Code §§ 22-5-1 *et seq.*, 45CSR16, 45CSR34 and 45CSR30.

Active Permits/Consent Orders

Permit or Consent Order Number	Date of Issuance	Permit Determinations or Amendments That Affect the Permit (<i>if any</i>)
R13-2068K	1/5/2010	

Conditions from this facility's Rule 13 permit(s) governing construction-related specifications and timing requirements will not be included in the Title V Operating Permit but will remain independently enforceable under

the applicable Rule 13 permit(s). All other conditions from this facility's Rule 13 permit(s) governing the source's operation and compliance have been incorporated into this Title V permit in accordance with the "General Requirement Comparison Table B," which may be downloaded from DAQ's website.

Determinations and Justifications

45CSR6: To Prevent and Control Particulate Air Pollution from Combustion of Refuse

The regenerative thermal and catalytic oxidation for combusting solvent off-gas streams meets the definition of an "incinerator" in 45CSR§6-1.1.a.

PM emissions from incinerators are limited by the formula from 45CSR§6-4.1.

Based on 45CSR§§6-4.3 & 4., the flare is given a 20% opacity limit with exemptions for start-up operations.

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

This facility meets the definition of a "manufacturing process and associated operations" in 45CSR§7-1.1.

An opacity limit of 20% is placed on all applicable source operations in 45CSR§7-3.1. Particulate emissions from the fluid beds and coating pans are controlled by cartridge collectors, thus opacity from these sources should be kept to a minimum.

As specified by 45CSR§7-4.1, each manufacturing process must meet a particulate matter stack emission limit based on the weight of material processed through the source operation (in this case, the fluid beds and coating pans). These emission limits are given in Table 45-7A of 45CSR7. The particulate matter emission limits based on Table 45-7A for all fluid beds and coating pans 215, 241, and 242 was calculated in the Engineering Evaluation/Fact Sheet for R13-2068K. The emission limits for fluid beds were all 0.50 lb/hr; the PTE for each fluid bed was recorded as 0.10 lb/hr. The emission limits for coating pans ranged from 0.29-0.60 lb/hr; the PTE for the coating pans ranged from 0.28-0.56 lb/hr. To ensure compliance with the Table 45-7A limits, the PTE values were used as the permit limits (Condition 5.1.2 for fluid beds and Condition 7.1.3. for coating pans).

45CSR10: To Prevent and Control Air Pollution from the Emission of Sulfur Oxides

45CSR10 is intended to limit SO₂ emissions from fuel burning units, limit in-stack SO₂ concentrations of manufacturing processes, and limit H₂S concentrations in process gas streams.

The only portion of this rule that applies to the changes at this facility is 45CSR§10-4.1. No in-stack SO₂ concentration can exceed 2000 ppm_v from any manufacturing process source operations, the RTO(s) and CO. Natural gas will be the only fuel combusted in the burners, and the VOCs combusted in the RTO(s) and CO contain no sulphur compounds, therefore, SO₂ would only be in trace amounts.

The following changes were made to this Title V permit:

- The Emission Units table was updated to include all equipment changes made at this facility. Several entries that were previously listed as "TBD" were revised to give more accurate information. The Mylan ID was also added to the Emission Unit Description of each Emission Unit.
- The Active Permits table was updated to indicate R13-2068K instead of R13-2068J.
- Conditions 3.5.3. and 3.5.5. were updated to include submission of the annual certification to the USEPA via e-mail.

- Condition 4.1.5 was updated to match the R13-2068K condition limiting each Bryan Steam Corporation boilers to 20,590 ft³/hr of natural gas consumed.
- Condition 5.1.3. previously only required particulate matter emissions from each fluid bed to be vented through a cartridge collector with a 95% collection efficiency. This condition was revised to match the condition in R13-2068K. This condition was revised to add aggregate dry material loading limits for each fluid bed load, annual dry material loading limits for all fluid beds, a 4 kilograms-VOC/minute spray limit, and a requirement prohibiting the processing of HAP-containing solvents in any fluid bed.
- The hourly and annual VOC emission limits in Conditions 5.1.4. and 5.1.5. were changed from 187.5 lb/hr and 99.0 tons/year to 529.2 lb/hr and 110.0 tons/year to reflect changes made in R13-2068K.
- Condition 5.1.6. was removed. This condition limited non-alcohol HAP emissions. However, this condition was removed from R13-2068K.
- Condition 5.4.1. was combined into Condition 5.2.1. to more closely match language in R13-2068K; both conditions previously referenced condition 6.2.2. of R13-2068.
- Conditions 5.2.3. through 5.2.5. were added to this permit. These monitoring requirements were added to demonstrate compliance with Conditions 5.1.3. and 5.1.5.
- Condition 5.4.1. was rewritten as a recordkeeping requirement requiring a record of all solvents used in the fluidized bed along with a copy of their associated MSDSs to be kept to verify that the solvents do not contain any constituent HAPs. The reference to condition 6.2.2. of R13-2068 was removed leaving the reference for condition 6.4.2.
- Condition 5.4.2. previously required monthly records of non-HAP alcohol used. However, with the removal of condition 5.1.6., this requirement was no longer required and was removed.
- Condition 5.4.2. was rewritten requiring records of weekly inspections done on the cartridge collectors.
- A reference to R13-2068 was added to Condition 6.1.2.
- Condition 6.4.2., rotoclone low water supply pressure sensor alarm recordkeeping requirements, was revised. As requested by Mylan, records of the cause of the alarm and corrective actions are no longer required.
- Coating Pans 241, 242, and 244 were added to the heading for Section 7.0.
- Condition 7.1.2. previously included an exception only for Coating Pan 215. With this modification, Coating Pans 241, 242, and 244 were added to this exception.
- Condition 7.1.3. previously contained particulate matter emission limits for the coating pan venting through Cartridge Collector 215. With this modification, emission limits are also included for emission units 241, 242, and 244.
- Conditions 7.1.4. and 7.1.5. were added limiting the VOC emissions from the coating pans to 396.9 lb/hr and 5.0 tons/year.
- Condition 7.1.6. was added to limit the particulate emissions from each coating pan. The dry material loading was limited, and cartridge collectors with a collection efficiency of 95% are required. The solvent spray rate for Coating Pans 241, 242, and 244 is limited to 3,000 g-VOC/minute for each coating pan; no VOC-containing solvents can be processed in Coating Pan 215. No HAP-containing solvents can be processed in any coating pan.

- Condition 7.2.2. was added to require visual inspections of each cartridge collector and records to be maintained.
- Conditions 7.2.3. and 7.2.4. were added requiring the facility to monitor and record dry material loading to ensure compliance with Condition 7.1.6.
- The monitoring requirements of Condition 7.2.5. were added to ensure compliance with Condition 7.1.5. Mylan is required to monitor and record the monthly and rolling 12-month total amount of VOCs used in Coating Pans 241, 242, and 244.
- The recordkeeping requirements Conditions 7.4.1. and 7.4.2. were added requiring records of weekly inspections performed on the cartridge collectors and records of all solvents used in the coating pans to ensure they do not contain any constituent HAPs.
- Section 8.0 was added to this permit to include all source-specific requirements for the RTO(s) and CO.

Non-Applicability Determinations

The following requirements have been determined not to be applicable to the subject facility due to the following:

45CSR2—To Prevent and Control Particulate Air Pollution from Combustion of Fuel in Indirect Heat Exchangers. 45CSR§2-11.1. exempts all units with a heat input below 10 mmBTU/hr from sections 4, 5, 6, 8, and 9. The CO has a heat input of 1.25 mmBTU/hr, thus it is exempt. The permit application states that the RTO(s) may be exempt after the final heat input is determined. However, the heat input recorded in the permit is 13.75 mmBTU/hr.

45CSR14—Permits for Construction and Major Modification of Major Stationary Sources of Air Pollution for the Prevention of Significant Deterioration. This facility does not meet the definition of a “Major Stationary Source” of air emissions as defined in 45CSR§14-2.43.

45CSR27—To Prevent and Control the Emissions of Toxic Air Pollutants. No toxic air pollutants, as defined in 45CSR§27-2.10., will be discharged into the open air in excess of the amounts specified in Table A of 45CSR27.

40CFR60, Subpart E—Standards of Performance for Incinerators. The CO and RTO(s) are below the 50 tons/day charging rate specified in 40CFR60§50(a). No other changes made at this facility are subject to 40CFR60.

40 C.F.R. 63, Subpart F—National Emissions Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry. With this modification, the facility does not manufacture as a primary product any of the chemicals listed in Table 1 of Subpart F.

40 C.F.R. 63, Subpart G—National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater. Since the changes made with this modification are not subject to Subpart F of this part, they are not subject to Subpart G.

40 C.F.R. 63, Subpart GGG—National Standards for Pharmaceuticals Production. After taking into account emission changes associated with this modification, the facility does not emit hazardous air pollutants at major levels from its pharmaceutical manufacturing operations and is therefore not subject to this subpart as stated in 40CFR63§1250(a)(ii).

40 C.F.R. 63, Subpart FFFF--National Standards for Miscellaneous Organic Chemical Manufacturing.

After taking into account emission changes associated with this modification, the facility does not emit hazardous air pollutants at major levels from its pharmaceutical manufacturing operations and is therefore not subject to this subpart as indicated in 40CFR63§2435(a).

40 C.F.R. 63, Subpart DDDDD--National Standards for Industrial, Commercial, and Institutional Boilers and Process Heaters.

After taking into account emission changes associated with this modification, the facility is a natural minor source of hazardous air pollutants and is therefore not subject to this subpart as indicated 40CFR63§7485.

Request for Variances or Alternatives

None.

Insignificant Activities

Insignificant emission unit(s) and activities are identified in the Title V application.

Comment Period

Beginning Date: February 12, 2010
Ending Date: March 15, 2010

All written comments should be addressed to the following individual and office:

Rex Compston
Title V Permit Writer
West Virginia Department of Environmental Protection
Division of Air Quality
601 57th Street SE
Charleston, WV 25304

Procedure for Requesting Public Hearing

During the public comment period, any interested person may submit written comments on the draft permit and may request a public hearing, if no public hearing has already been scheduled. A request for public hearing shall be in writing and shall state the nature of the issues proposed to be raised in the hearing. The Secretary shall grant such a request for a hearing if he/she concludes that a public hearing is appropriate. Any public hearing shall be held in the general area in which the facility is located.

Point of Contact

Rex Compston
West Virginia Department of Environmental Protection
Division of Air Quality
601 57th Street SE
Charleston, WV 25304
Phone: 304/926-0499 ext. 1209 • Fax: 304/926-0478

Response to Comments (Statement of Basis)

Not applicable.