

Fact Sheet



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

Permit Number: **R30-06100033-2017**
Applications Received: **July 11, 2016**
Plant Identification Number: **03-54-061-00033**
Permittee: **Mylan Pharmaceuticals, Inc.**
Facility Name: **Morgantown**
Mailing Address: **781 Chestnut Ridge Road, Morgantown, WV 26505**

Revised: N/A

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 renewal also includes changes to the previous permit requested in a minor modification application, R30-06100033-2012 (MM05). This modification application addresses the installation of a new fluid bed and a new boiler. It also addresses the replacement of three dust collectors.

Emissions Summary

Plantwide Emissions Summary [Tons per Year]		
Regulated Pollutants	Potential Emissions	2015 Actual Emissions
Carbon Monoxide (CO)	87.7	12.94
Nitrogen Oxides (NO _x)	66.9	8.02
Particulate Matter (PM _{2.5})	77.16	2.69
Particulate Matter (PM ₁₀)	77.16	2.69
Total Particulate Matter (TSP)	77.16	2.69
Sulfur Dioxide (SO ₂)	0.62	0.06
Volatile Organic Compounds (VOC)	142.0	34.5
<i>PM₁₀ is a component of TSP.</i>		
Hazardous Air Pollutants	Potential Emissions	2015 Actual Emissions
Methanol	5.0	0.28
Acetonitrile	5.0	0.09
Xylene	1.0	0.0002
Toluene	1.0	0.0003
Vinyl acetate	1.0	-
Ethyl Benzene	1.0	-
Acetaldehyde	1.0	0.0002
Triethylamine	1.0	0.001
N, N-Dimethylformamide	1.0	0.0002
Hydrochloric Acid	1.0	0.06
Benzene	1.0	0.0003
Chloroform	1.0	0.0035
Formaldehyde	1.0	0.009
Hexane	1.0	0.002
Total HAPs	22.0	0.445
NOTE: Permit limits are:	9.4 tpy of any single HAP or 24.4 tpy of any combination of HAPs	

Some of the above HAPs may be counted as PM or VOCs.

Title V Program Applicability Basis

This facility has the potential to emit 142.0 TPY of VOC. Due to this facility's potential to emit over 100 tons per year of criteria pollutant, Mylan Pharmaceuticals, Inc. 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.

This facility has been found to be subject to the following applicable rules:

Federal and State:	45CSR2	Particulate matter air pollution
	45CSR6	Open burning prohibited
	45CSR7	Particulate matter air pollution from manufacturing processes
	45CSR10	Emissions of sulfur oxides
	45CSR11	Standby plans for emergency episodes
	45CSR13	NSR permits
	45CSR16	New stationary sources
	WV Code § 22-5-4 (a) (14)	The Secretary can request any pertinent information such as annual emission inventory reporting.
	45CSR30	Operating permit requirement.
	45CSR34	Emission standards for HAPs
	40CFR60, Subpart Dc	Small industrial-commercial-institutional Steam generating units
	40CFR60, Subpart IIII	Stationary compression ignition IC engines
	40CFR60, Subpart JJJJ	Stationary spark ignition IC engines
	40CFR63, Subpart ZZZZ	RICE MACT
	40 C.F.R. Part 61	Asbestos inspection and removal
	40 C.F.R. Part 82, Subpart F	Ozone depleting substances
State Only:	45CSR4	No objectionable odors

Each State and Federally-enforceable condition of the 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 (if any)
R13-2068S	October 27, 2016	
G60-C035A	December 28, 2011	

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," which may be downloaded from DAQ's website.

Determinations and Justifications

Equipment Changes

As requested in the minor modification application, the following equipment changes were made to the Emission Units Table:

- A new 6.0 MMBtu/hr natural gas boiler (Emission Unit ID: 016) was added.
- Fluid Bed 24410 (Emission Unit ID: 583) was added in addition to its control device (Cartridge Collector 10024247).
- Existing Cartridge Collector EF527, which serves as a control device for Fluid Bed 527, was replaced with new Cartridge Collector 10024047.
- Existing Cartridge Collector EF7674, which serves as a control device for Coating Pan 7552, was replaced with new Cartridge Collector 10024526.
- Existing Cartridge Collector 8421, which serves as a control device for Coating Pan 8421, was replaced with new Cartridge Collector 10024525.
- The control device for Coating Pan 23581 (Emission Unit ID: 246) was changed from cartridge collector 246 to Cartridge Collector 23583.

R13-2068S

The following changes were made to this Title V permit as a result of revisions in R13-2068S:

- Emission Point 016 (Natural Gas Boiler 24524) was added to the emission point list in the heading for section 4.0.
- The regulatory citation for condition 4.1.3 was revised to reference condition 5.1.11 of R13-2068S.
- The regulatory citation for condition 4.1.6 was revised to reference conditions 5.1.3, 5.1.4, and 5.1.9 of R13-2068S.
- Condition 4.1.7 was added listing emission limits for Emission Point 016 (Natural Gas Boiler 24524). This condition references condition 5.1.8 of R13-2068S.
- Condition 4.1.8 was added specifying natural gas usage limits for Emission Point 016. This condition references condition 5.1.10 of R13-2068S.
- Conditions 4.2.1 was updated to include a reference to Emission Point 016.
- Emission Unit 583 (Fluid Bed 24410) was added to the emission point list in the heading for section 5.0.
- References to Emission Unit 583 (Fluid Bed 24410) were added to conditions 5.1.3.a and 5.1.4.

References to Class II General Permit G60-C

Section 9.0, which addresses emergency generators, was revised to included references to the applicable conditions in G60-C.

Streamlining in Condition 9.1.4.

General Permit Registration G60-C035 limits the fuel oil sulfur content to 0.05% for Emergency Generator 1053. However, condition 7.1.11 of G60-C, which references 40CFR§60.4207(b), specifies the sulfur limit for nonroad diesel fuel found in 40CFR§80.510(b). 40CFR§80.510(b) has a stricter fuel oil sulfur content limit of 0.0015%. This condition was revised for the stricter limit with appropriate streamlining language included.

40 C.F.R. 63, Subpart ZZZZ: RICE MACT

The engines at this facility are subject to either 40 C.F.R. 60, Subpart IIII or Subpart JJJJ. Per 40 C.F.R. §63.6590(c), for a new stationary ICE at an area source, compliance with the RICE MACT is achieved through compliance with these subparts.

Non-Applicability Determinations

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

- a. 45CSR27 – *To Prevent and Control the Emissions of Toxic Air Pollutants*. This rule does not apply to the facility because the facility currently does not have the potential to emit any such air pollutant in quantities equal to or greater than those set forth in this rule.
- b. 40 C.F.R. 60, Subpart Ka – *Standards of Performance for Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978 and Prior to July 23, 1984*. This subpart does not apply to the storage tanks at the facility because the tanks do not contain a petroleum liquid and the tanks have a capacity (8,200 gallons each) less than those tanks defined as an affected facility.
- c. 40 C.F.R. 60, Subpart Kb – *Standard of Performance for Volatile Organic Liquid Storage Vessels (including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced after July 23, 1984*. There are no tanks at this facility that have a capacity of 75 cubic meters or greater, therefore, per 40 C.F.R. §60.110b(a), this subpart does not apply.
- d. 40 C.F.R. 63, Subpart F – *National Emissions Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry*. The facility does not manufacture any of the chemicals listed in Table I of Subpart F as a primary product.
- e. 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*. The facility is not subject to Subpart F, therefore, it is not subject to Subpart G of Part 63.
- f. 40 C.F.R. 63, Subpart FFFF – *National Standards for Miscellaneous Organic Chemical Manufacturing*. The facility does not emit hazardous air pollutants at major levels and is therefore not subject to this subpart.
- g. 40 C.F.R. 63, Subpart GGG – *National Standards for Pharmaceuticals Production*. The facility does not emit hazardous air pollutants at major levels and is therefore not subject to this subpart.
- h. 40 C.F.R. 63, Subpart DDDDD – *National Standards for Industrial, Commercial, and Institutional Boilers and Process Heaters*. The facility is not a major source of hazardous air pollutants and is therefore not subject to this subpart.
- i. 40 C.F.R. 63, Subpart VVVVVV – *National Emission Standards for Hazardous Air Pollutants for Chemical Manufacturing Area Sources*. Mylan has stated that all HAP emissions are from the quality control laboratories, which are exempt from this subpart according to 40 C.F.R. § 63.11494(c)(4).
- j. 40 C.F.R. 64 - *Compliance Assurance Monitoring*. This is the third permit renewal for this facility. At the time of the second renewal, CAM was determined not to be applicable to the sources currently in use at the facility. Since the second renewal, several new pieces of equipment were installed at this facility. Any units installed since the second renewal either do not use control devices or, the pre-control device PTE of any unit being routed to a control device is less than major source thresholds, therefore CAM still does not apply.
- k. 45CSR§2-5.1 – The facility burns natural gas only; therefore this section of 45CSR2 does not apply.
- l. 45CSR§10-4 – The facility’s manufacturing process source operations do not emit sulfur dioxide with the exception of trace amounts from natural gas combustion.
- m. 45CSR§10-5 & 45CSR§10-8 – The facility’s boilers burn only natural gas; therefore, they are exempt from the requirements of these sections of 45CSR10.
- n. 45CSR10A – *Testing, Monitoring, Recordkeeping and Reporting Requirements Under 45CSR10*. The facility’s boilers combust natural gas only; therefore, the facility is exempt from the requirements of this rule.

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: Tuesday, January 31, 2017

Ending Date: Thursday, March 2, 2017

Point of Contact

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

Rex Compston, P.E.
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
Rex.E.Compston@wv.gov

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.

Response to Comments (Statement of Basis)

Not applicable.