

Fact Sheet



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

This Fact Sheet serves to address the changes specific to this Minor Modification, and shall be considered a supplement to the Fact Sheet corresponding with the Title V operating permit issued on January 10, 2012.

Permit Number: **R30-06100033-2012**

Application Received: **July 9, 2014**

Plant Identification Number: **03-54-061-00033**

Permittee: **Mylan Pharmaceuticals, Inc.**

Facility Name: **Morgantown**

Mailing Address: **781 Chestnut Ridge Road, Morgantown, WV 26505**

Permit Action Number: *MM03* Revised: *December 2, 2014*

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 modification is for the installation of a roof-mounted cartridge collector to control particulate matter emissions generated in fifteen (15) existing production rooms. These rooms currently are controlled with HEPA filters and vented back inside the building.

Emissions Summary

The PTE for PM Emissions will increase by 0.43 TPY.

Title V Program Applicability Basis

With the proposed changes associated with this modification, this facility maintains the potential to emit 141.7 TPY of VOCs. Due to this facility's potential to emit 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.

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

Federal and State:	45CSR7	Fugitive dust, particulate matter, and visible emissions
	45CSR13	NSR Permits
	45CSR30	Operating permit requirement.

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 (<i>if any</i>)
R13-2068Q	9/29/2014	

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

The following changes, which were approved under R13-2068Q, were made with this permit modification:

- The cartridge collector and corresponding production rooms were added to the emission units table as Emission Point 323.
- Condition 6.1.2 was revised to include Emission Point 323. This condition addressed streamlining of 45CSR§7-4.1 limit.

- Condition 6.1.5 was revised to include Emission Point 323. The PM emission rates were raised to 0.90 lb/hr and 2.19 TPY.

Non-Applicability Determinations

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

None

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: N/A
Ending Date: N/A

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.