

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 March 9, 2017.

Permit Number: **R30-06100033-2017**

Application Received: **June 5, 2018**

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: *August 24, 2018*

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.

The purpose of this modification is to add/revise the particulate matter controls on various packaging rooms, remove one fluid bed, and modify the removed fluid bed room into an additional packaging room. These changes were approved under R13-2068V

Emissions Summary

There are no changes in the facility's overall Potential to Emit (PTE).

Title V Program Applicability Basis

With the proposed changes associated with this modification, this facility maintains the potential to emit 147.0 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.

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

Federal and State:	45CSR7	Particulate matter air pollution from manufacturing processes
	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>)
R13-2068V	6/14/2018	

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 were made with this modification:

- The Control Device for Emission Point 575 was revised.
- Emission Point 537, previously Fluid Bed 1552, was revised. Emission Point 537 was reconfigured as the Room General Exhaust for packaging rooms. The rooms now listed under this emission point were previously listed under Emission Point 281.
- Emission Points, 325, 326, and 327 were added as the Room General Exhaust for packaging rooms.
- Emission Point 537 was removed from the emissions points listed in the heading for Section 5.0: Fluid Bed Granulators and condition 5.1.3. since this emission point is no longer a fluid bed.
- Emission Points 325, 326, 327, and 537 were added to the list in the heading for Section 6.0: Production Rooms.
- Emission Points 325, 326, 327, and 537 were added to Conditions 6.1.2. and 6.1.5., which address PM emissions.
- The PM emission limits in Condition 6.1.5. were increased to account for the additional production rooms added with this modification. This emissions increase will be offset by the reduction in emissions from the removal of the fluid bed, so there will be no net change in facility-wide potential emissions.

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.