

# 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: **July 27, 2017**

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: *MM02*      Revised: *December 27, 2017*

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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.

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### 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 authorize the use of VOC-containing solvents in an additional fluid bed (583) and an increase in the solvent use in various coating pans (241, 242, 244, 245, 246, 247).

## Emissions Summary

With the proposed changes in this Modification, this facility's PTE will increase by 5.00 TPY of VOC.

## 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:	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> )
R13-2068U	10/24/2017	

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

Mylan has requested the use of VOC-containing solvents in an additional fluid bed (583) and an increase in the existing solvent use in various coating pans (241, 242, 244, 245, 246, 247). Previously, fluid bed 583 was not authorized to use VOC-containing solvents and the coating pans were limited to an aggregate limit of 5.0 tons-VOC/year. Mylan has requested the coating pan VOC limit be increased to 10.0 tons-VOC/year. Mylan is not requesting an increase in the aggregate VOC emissions limit from the fluid beds. Fluid bed 583 will not have the capability to exhaust to the RTO and will vent emissions directly to the atmosphere.

Additionally, Mylan has requested alternate visible emissions monitoring language for the fluid beds and coating pans to account for months when specific units do not operate.

Due to the changes requested, the following changes were made with this modification:

- Minor updates were made to the emission units table:
  - CC10024526 was changed to 10031225 (Emission Point 244).
  - CC23583 was changed to CC10023583 (Emission Point 246).
  - The emission unit ID was revised for Emission Point 281.
  - The emission unit ID was revised for Emission Point 324.
- Rotoclone 4 (Emission Point 280) has been removed. This emission point was removed from the emission units table, the heading for Section 6.0, and condition 6.1.2.
- The exclusion of Emission Point 583 was removed from condition 5.1.4.a.
- The visible emissions monitoring language in conditions 5.2.2 and 7.2.1 were revised, as requested.
- The VOC emission limit from the coating pans in condition 7.1.5 was increased from 5.0 to 10.0 TPY.
- Condition 7.1.6.h, which stated that no more than 5 coating pans could use VOC-containing solvents in the production process, was removed.

### **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 57<sup>th</sup> Street SE  
Charleston, WV 25304  
Phone: 304/926-0499 ext. 1209 • Fax: 304/926-0478  
[Rex.E.Compston@wv.gov](mailto: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.