

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 13, 2015**

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: *MM04* Revised: *March 22, 2016*

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 additional coating pan 23581 (Emission Unit ID 246) with an associated cartridge-type dust collector (CC 246) to control particulate matter emissions. The new coating pan shall have the capability to route VOC emissions from the unit to the Thermal Oxidizer (RTO).

Emissions Summary

The PTE for PM10 Emissions will increase by 0.17 TPY (facility-wide PM10 PTE will be 76.83 TPY after increase). VOC emissions will not increase, because the new coating pan 23581 (Emission Unit ID 246) will operate under existing 5 TPY VOC limit for all coating pans (requirement 7.1.5).

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>)
R13-2068R	11/03/2015	

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, as per permit R13-2068R, were made with this permit modification:

- Emission Units Table 1.0 – new coating pan 23581 (Emission Unit ID 246) was added; TBDs (to be determined) were updated; and a typo was corrected by changing Emission Point ID “10008583” to “10008538”.
- Equipment (Mylan) ID numbers were included throughout the permit requirements (in addition to Emission Unit ID numbers) for clarity;
- Requirement 3.7.2.j – a typo was corrected: Emergency Generator ID “EG01” was changed to “10007530”;
- Requirement 7.1.3 – new coating pan 23581 (Emission Unit ID 246) PM hourly emission limit was added;
- Requirement 7.1.6(a)(6) - new coating pan 23581 (Emission Unit ID 246) dry loading limit was added;
- Coating pan 23581 (Emission Unit ID 246) with existing coating pans 7552 and 8421 (Emission Unit IDs 244 and 245) was referenced in various requirements related to use of the Thermal Oxidizer (RTO) on these pans – 7.1.4, 7.1.6(d) and (f), 7.2.5, 8.1.5, 8.1.7 and 8.2.3.
- Requirements 7.1.2 and 7.2.1 – added reference to the new coating pan 23581 (Emission Unit ID 246) related to the 45CSR§7-4.1 applicability and visible emission checks per 45CSR§7-3.1.
- Requirement 7.1.3 - 45CSR§7-4.1 requires that each manufacturing process meet a particulate matter stack emission limit based on the weight of material processed through the source operation (PWR). The emission limits are given under Table 45-7A and are based on the type of source operation as defined in the Rule. Coating pans are defined, pursuant to §45-7-2.39(a), as type ‘a’ source operation types. The maximum amount of material charged through the new coating pan is 682 pounds per hour (lb/hr). Based on Table 45-7A, the aggregate particulate matter limit for the new coating pan would be 0.84 lb/hr. The maximum particulate matter emission rate from the new coating pan is calculated to be 0.77 lbs/hr, which is below the 45CSR§7-4.1 limit.
- Requirements 5.4.1, 7.4.2 and 12.4.1 – added “SDS” (safety data sheet).

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:

Natalya V. Chertkovsky-Veselova
West Virginia Department of Environmental Protection
Division of Air Quality
601 57th Street SE
Charleston, WV 25304
Phone: 304/926-0499 ext. 1220 • Fax: 304/926-0478
Natalya.V.Chertkovsky@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.