

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: **June 3, 2013**

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: *November 5, 2013*

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 minor modification covers the following changes in recently issued permit R13-2068P:

- The addition of a new oven dryer (264) to replace two (2) existing dryers (262 and 263);
- The replacement of an existing rotoclone (Emission Point ID 282) with a smaller rotoclone (3798);
- The addition of a cartridge collector CC 17034 (Emission Point ID 322) to control particulate matter emissions from production rooms 74-174, 74-175, 74-176, 74-177, 74-179, 74-179A, 74-180, 74-180A;
- The addition of a pilot coating line (TBD 10008085) for research and development purposes;
- The decrease of aggregate annual PM emissions from the coating pans, and the decrease of aggregate annual VOC emissions from the fluid beds.

Emissions Summary

Change in Plantwide Emissions [Tons per Year]	
Regulated Pollutants	Change in Potential Emissions
Particulate Matter (PM _{2.5})	-2.07 TPY
Particulate Matter (PM ₁₀)	-2.07 TPY
Total Particulate Matter (TSP)	-2.07 TPY
Volatile Organic Compounds (VOC)	-17.0 TPY

PM_{2.5} is a component of TSP.

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 (if any)
R13-2068P	August 12, 2013	

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

Determinations and Justifications

As a result of the modification, the following changes have been made to this Title V permit based on the permit R13-2068P:

1. Emission Units Table 1.1 - revised: added a new oven dryer (264) to replace two (2) existing dryers (262 and 263), added a rotoclone (3798) to replace an existing rotoclone (Emission Point ID 282), added a cartridge collector (CC 17034) and a pilot coating line (TBD 10008085); revised control device IDs and emission unit descriptions for rotoclones 2 through 2338; renamed the cartridge collector (CC TBD) for Fluid Bed 15982 to "CC 15982" (Emission Point 581); renamed the cartridge collector (CC TBD) and the Fluid Bed TBD to "CC 16117" and "Fluid Bed 16117" (Emission Point 582), and fixed a typo in the Emission Unit ID for the Absorber from 10008085 to 10008538.
2. Requirement 3.3.1 – added citation from R13-2068P (requirement 3.3.1);
3. Requirement 5.1.5 - lowered the annual aggregate VOC limit for the fluid beds to 74.0 TPY;
4. Section 6.0 - restructured and re-named from "Rotoclones" to "Production Rooms" to identify the Production Rooms as the emission units instead of the rotoclones;
5. Requirement 6.1.1 – 20% opacity limit (45CSR§7-3.1) is applicable to Room General Exhausts (Emission Points 282 and 322), but they are controlled by the new rotoclone and new cartridge collector, therefore opacity from these sources is expected to be minimal. Compliance will be demonstrated by existing monthly monitoring for the rotoclones (condition 6.2.1) and the new monitoring for the cartridge collectors (condition 6.2.2);
6. Requirement 6.1.2 - Room General Exhausts (Emission Points 282 and 322) are subject to the PM stack emission limit based on the weight of material processed through the source operation (45CSR§7-4.1), but there has been no increase in the aggregate hourly PM emission limit for the multiple emission points listed in condition 6.1.5, and this condition demonstrates compliance with the less stringent 45CSR§7-4.1 limit.

Requirement 6.1.2 was revised to make it correspond better with the underlying requirement 7.1.2 of R13-2068P;
7. Added cartridge collector language to production room control requirements (requirements 6.1.4 through 6.1.6) and to the Production Rooms monitoring section (new requirement 6.2.2);
8. Requirement 7.1.3 - lowered the annual aggregate PM limit for the coating pans to 6.25 TPY (7.1.3);
9. Section 8.0 and 10.0 – updated the Oven Dryer ID numbers and added the coating line to the listing of equipment controlled by the RTO in conditions 8.1.5, 8.1.7, and 8.2.3;

10. Requirement 11.3.1 – word “destruction” was replaced with “removal”;
11. Requirement 11.4.3 - “RTO” (Regenerative Thermal Oxidizer) was replaced with “Absorber”;
12. Section 12.0 - added to address the addition of the new Pilot Coating Line (TBD 10008085);

Non-Applicability Determinations

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

1. Compliance Assurance Monitoring (CAM) Plan – there were no PSEUs added during this modification that satisfied the CAM applicability criteria under 40CFR§64.2(a), therefore CAM is not applicable.

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:

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Division of Air Quality
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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.