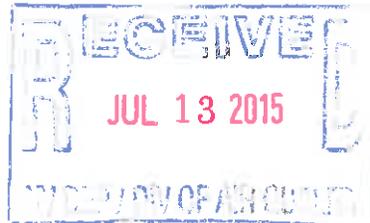


**APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION
(COPY #2)**

**MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA**



PREPARED BY:

Mylan Pharmaceuticals

*Mylan Pharmaceuticals Inc
Morgantown
061-00033
R13-2068R
Joe Kessler*



781 Chestnut Ridge Road
Morgantown, WV 26505 USA
Phone 304.599.2595
Web www.mylan.com

July 9, 2015

NSR Permitting Manager
WV Department of Environmental Protection
Division of Air Quality
601 57th Street SE
Charleston, WV 25304

RE: Mylan Pharmaceuticals Inc., Chestnut Ridge Manufacturing Facility
DAQ Plant ID# 061-00033
Application for NSR Permit (R13-2068R) and Title V Permit (R30-06100033-2012) Modifications

Dear Sir or Madam:

Mylan Pharmaceuticals Inc. (Mylan) hereby submits for your review and subsequent approval, a "Modification Application for NSR Permit and Title V Permit Revision" regarding changes of operation at Mylan's Chestnut Ridge Road manufacturing facility in Morgantown, WV. The application includes the following:

- The addition of a coating pan and associated dust collector to the facility.

Enclosed is the following information completing said permit application:

- Original "Permit Application";
- Three signed copies of the "Permit Application";
- The check for the \$1000 application fee

The attached Class I Legal Advertisement will be published in the Dominion Post within five (5) days of your office's receipt of this permit application. An "Affidavit of Publication" will be provided to the Division of Air Quality upon the completion of said publication.

Mylan has always strived to maintain a proactive role in assuring environmental compliance and appreciates your assistance with this permit application. Should you require any additional information, please contact me directly at the address provided by the letterhead or by telephoning (304) 554-5751.

Sincerely,

Justin Hartshorn
Senior Manager, North America Environmental Compliance

cc: Brian Tephabock, WV DEP
Mylan Inc., Global EHS

TABLE OF CONTENTS

\$1000 Application Fee (Modification)

Appendix 1 – Application for Permit to Modify / Construct

1. Application for NSR Permit
2. Application Attachments
 - A) Business Certificate
 - B) Site Location Map
 - C) Installation and Startup Schedule
 - D) Regulatory Discussion
 - E) Plot Plan
 - F) Process Flow Diagrams
 - G) Process Description
 - H) *Not Required: MSDS Sheets*
 - I) Emissions Unit Table
 - J) Emission Points Data Summary Sheet
 - K) *Not Required: Fugitive Emissions Data Sheet*
 - L) Emissions Unit Data Sheet
 - M) Air Pollution Control Device Sheet
 - Dust Collector
 - N) Supporting Calculations
 - Coating Pan
 - O) *Not Required: Monitoring/Recordkeeping/Reporting/Testing Plans*
 - P) Public Notice
 - Q) *Not Required: Business Confidential Claims*
 - R) *Not Required: Authority Forms*
 - S) Title V Permit Revision Information

Appendix 2 – Mylan Proposed Draft Permit Terms

1. R13/Title V Proposed Terms

Appendix 3 – PSD Review

1. PSD Review Summary

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Appendix 1

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA



WEST VIRGINIA DEPARTMENT OF ENVIRONMENTAL PROTECTION
DIVISION OF AIR QUALITY

601 57th Street, SE
Charleston, WV 25304
(304) 926-0475
www.dep.wv.gov/dag

**APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION
(OPTIONAL)**

PLEASE CHECK ALL THAT APPLY TO NSR (45CSR13) (IF KNOWN):

- CONSTRUCTION MODIFICATION RELOCATION
 CLASS I ADMINISTRATIVE UPDATE TEMPORARY
 CLASS II ADMINISTRATIVE UPDATE AFTER-THE-FACT

PLEASE CHECK TYPE OF 45CSR30 (TITLE V) REVISION (IF ANY):

- ADMINISTRATIVE AMENDMENT MINOR MODIFICATION
 SIGNIFICANT MODIFICATION

IF ANY BOX ABOVE IS CHECKED, INCLUDE TITLE V REVISION INFORMATION AS ATTACHMENT S TO THIS APPLICATION

FOR TITLE V FACILITIES ONLY: Please refer to "Title V Revision Guidance" in order to determine your Title V Revision options (Appendix A, "Title V Permit Revision Flowchart") and ability to operate with the changes requested in this Permit Application.

Section I. General

1. Name of applicant (as registered with the WV Secretary of State's Office): Mylan Pharmaceuticals Inc.		2. Federal Employer ID No. (FEIN): 5 5 0 4 5 5 4 2 3	
3. Name of facility (if different from above): 4. Chestnut Ridge Facility		4. The applicant is the: <input type="checkbox"/> OWNER <input type="checkbox"/> OPERATOR <input checked="" type="checkbox"/> BOTH	
5A. Applicant's mailing address: P.O. Box 4310 Morgantown, WV 26504-4310		5B. Facility's present physical address: 781 Chestnut Ridge Road Morgantown, WV 26505	
6. West Virginia Business Registration. Is the applicant a resident of the State of West Virginia? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO - If YES, provide a copy of the Certificate of Incorporation/Organization/Limited Partnership (one page) including any name change amendments or other Business Registration Certificate as Attachment A . - If NO, provide a copy of the Certificate of Authority/Authority of L.L.C./Registration (one page) including any name change amendments or other Business Certificate as Attachment A .			
7. If applicant is a subsidiary corporation, please provide the name of parent corporation: Mylan Inc.			
8. Does the applicant own, lease, have an option to buy or otherwise have control of the <i>proposed site</i> ? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO - If YES, please explain: Applicant owns the site. - If NO, you are not eligible for a permit for this source.			
9. Type of plant or facility (stationary source) to be constructed, modified, relocated, administratively updated or temporarily permitted (e.g., coal preparation plant, primary crusher, etc.): Pharmaceutical Manufacturing Facility		10. North American Industry Classification System (NAICS) code for the facility: 325412	
11A. DAQ Plant ID No. (for existing facilities only): 0 6 1 - 0 0 0 3 3		11B. List all current 45CSR13 and 45CSR30 (Title V) permit numbers associated with this process (for existing facilities only): R13-2068Q, issued September 29, 2014 R30-06100033-2012 MM03, issued December 2, 2014	
All of the required forms and additional information can be found under the Permitting Section of DAQ's website, or requested by phone.			

<p>12A.</p> <ul style="list-style-type: none"> For Modifications, Administrative Updates or Temporary permits at an existing facility, please provide directions to the <i>present location</i> of the facility from the nearest state road; For Construction or Relocation permits, please provide directions to the <i>proposed new site location</i> from the nearest state road. Include a MAP as Attachment B. <p>I-79 to exit 155 follow signs for W.V.U. 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.</p>		
12.B. New site address (if applicable): N/A	12C. Nearest city or town: Morgantown	12D. County: Monongalia
12.E. UTM Northing (KM): 4390.1	12F. UTM Easting (KM): 589.6	12G. UTM Zone: 17
<p>13. Briefly describe the proposed change(s) at the facility: Mylan proposes to add a new coating pan unit due to increases in production demand. An associated dust collector will be installed to control particulate emissions. The coating pan will tie into the existing regenerative thermal oxidizer at the site for control of solvent emissions.</p>		
<p>14A. Provide the date of anticipated installation or change: Modification: 9/30/2015</p> <ul style="list-style-type: none"> If this is an After-The-Fact permit application, provide the date upon which the proposed change did happen: / / 		<p>14B. Date of anticipated Start-Up if a permit is granted: 11/1/2015</p>
<p>14C. Provide a Schedule of the planned Installation of/Change to and Start-Up of each of the units proposed in this permit application as Attachment C (if more than one unit is involved).</p>		
<p>15. Provide maximum projected Operating Schedule of activity/activities outlined in this application: Hours Per Day 24 Days Per Week 7 Weeks Per Year 52</p>		
<p>16. Is demolition or physical renovation at an existing facility involved? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p>		
<p>17. Risk Management Plans. If this facility is subject to 112(r) of the 1990 CAAA, or will become subject due to proposed changes (for applicability help see www.epa.gov/ceppo), submit your Risk Management Plan (RMP) to U. S. EPA Region III.</p>		
<p>18. Regulatory Discussion. List all Federal and State air pollution control regulations that you believe are applicable to the proposed process (<i>if known</i>). A list of possible applicable requirements is also included in Attachment S of this application (Title V Permit Revision Information). Discuss applicability and proposed demonstration(s) of compliance (<i>if known</i>). Provide this information as Attachment D.</p>		

Section II. Additional attachments and supporting documents.

<p>19. Include a check payable to WVDEP – Division of Air Quality with the appropriate application fee (per 45CSR22 and 45CSR13).</p>
<p>20. Include a Table of Contents as the first page of your application package.</p>
<p>21. Provide a Plot Plan, e.g. scaled map(s) and/or sketch(es) showing the location of the property on which the stationary source(s) is or is to be located as Attachment E (Refer to Plot Plan Guidance).</p> <ul style="list-style-type: none"> Indicate the location of the nearest occupied structure (e.g. church, school, business, residence).
<p>22. Provide a Detailed Process Flow Diagram(s) showing each proposed or modified emissions unit, emission point and control device as Attachment F.</p>
<p>23. Provide a Process Description as Attachment G.</p> <ul style="list-style-type: none"> Also describe and quantify to the extent possible all changes made to the facility since the last permit review (<i>if applicable</i>).
<p>All of the required forms and additional information can be found under the Permitting Section of DAQ's website, or requested by phone.</p>

24. Provide **Material Safety Data Sheets (MSDS)** for all materials processed, used or produced as **Attachment H**.
 -- For chemical processes, provide a MSDS for each compound emitted to the air.

25. Fill out the **Emission Units Table** and provide it as **Attachment I**.

26. Fill out the **Emission Points Data Summary Sheet (Table 1 and Table 2)** and provide it as **Attachment J**.

27. Fill out the **Fugitive Emissions Data Summary Sheet** and provide it as **Attachment K**.

28. Check all applicable **Emissions Unit Data Sheets** listed below:

<input type="checkbox"/> Bulk Liquid Transfer Operations	<input type="checkbox"/> Haul Road Emissions	<input type="checkbox"/> Quarry
<input type="checkbox"/> Chemical Processes	<input type="checkbox"/> Hot Mix Asphalt Plant	<input type="checkbox"/> Solid Materials Sizing, Handling and Storage Facilities
<input type="checkbox"/> Concrete Batch Plant	<input type="checkbox"/> Incinerator	<input type="checkbox"/> Storage Tanks
<input type="checkbox"/> Grey Iron and Steel Foundry	<input type="checkbox"/> Indirect Heat Exchanger	
<input type="checkbox"/> General Emission Unit, specify: Coating Pan		

Fill out and provide the **Emissions Unit Data Sheet(s)** as **Attachment L**.

29. Check all applicable **Air Pollution Control Device Sheets** listed below:

<input type="checkbox"/> Absorption Systems	<input checked="" type="checkbox"/> Baghouse (Cartridge collector)	<input type="checkbox"/> Flare
<input type="checkbox"/> Adsorption Systems	<input type="checkbox"/> Condenser	<input type="checkbox"/> Mechanical Collector
<input type="checkbox"/> Afterburner	<input type="checkbox"/> Electrostatic Precipitator	<input type="checkbox"/> Wet Collecting System
<input type="checkbox"/> Other Collectors, specify:		

Fill out and provide the **Air Pollution Control Device Sheet(s)** as **Attachment M**.

30. Provide all **Supporting Emissions Calculations** as **Attachment N**, or attach the calculations directly to the forms listed in Items 28 through 31.

31. **Monitoring, Recordkeeping, Reporting and Testing Plans.** Attach proposed monitoring, recordkeeping, reporting and testing plans in order to demonstrate compliance with the proposed emissions limits and operating parameters in this permit application. Provide this information as **Attachment O**. This information is included in Attachment M.

➤ Please be aware that all permits must be practically enforceable whether or not the applicant chooses to propose such measures. Additionally, the DAQ may not be able to accept all measures proposed by the applicant. If none of these plans are proposed by the applicant, DAQ will develop such plans and include them in the permit.

32. **Public Notice.** At the time that the application is submitted, place a **Class I Legal Advertisement** in a newspaper of general circulation in the area where the source is or will be located (See 45CSR§13-8.3 through 45CSR§13-8.5 and **Example Legal Advertisement** for details). Please submit the **Affidavit of Publication** as **Attachment P** immediately upon receipt.

33. **Business Confidentiality Claims.** Does this application include confidential information (per 45CSR31)?

YES NO

➤ If YES, identify each segment of information on each page that is submitted as confidential and provide justification for each segment claimed confidential, including the criteria under 45CSR§31-4.1, and in accordance with the DAQ's "**Precautionary Notice – Claims of Confidentiality**" guidance found in the **General Instructions** as **Attachment Q**.

Section III. Certification of Information

34. **Authority/Delegation of Authority.** Only required when someone other than the responsible official signs the application. Check applicable **Authority Form** below:

<input type="checkbox"/> Authority of Corporation or Other Business Entity	<input type="checkbox"/> Authority of Partnership
<input type="checkbox"/> Authority of Governmental Agency	<input type="checkbox"/> Authority of Limited Partnership

Submit completed and signed **Authority Form** as **Attachment R**.

All of the required forms and additional information can be found under the Permitting Section of DAQ's website, or requested by phone.

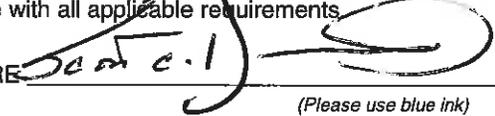
35A. **Certification of Information.** To certify this permit application, a Responsible Official (per 45CSR§13-2.22 and 45CSR§30-2.28) or Authorized Representative shall check the appropriate box and sign below.

Certification of Truth, Accuracy, and Completeness

I, the undersigned **Responsible Official** / **Authorized Representative**, hereby certify that all information contained in this application and any supporting documents appended hereto, is true, accurate, and complete based on information and belief after reasonable inquiry I further agree to assume responsibility for the construction, modification and/or relocation and operation of the stationary source described herein in accordance with this application and any amendments thereto, as well as the Department of Environmental Protection, Division of Air Quality permit issued in accordance with this application, along with all applicable rules and regulations of the West Virginia Division of Air Quality and W.Va. Code § 22-5-1 et seq. (State Air Pollution Control Act). If the business or agency changes its Responsible Official or Authorized Representative, the Director of the Division of Air Quality will be notified in writing within 30 days of the official change.

Compliance Certification

Except for requirements identified in the Title V Application for which compliance is not achieved, I, the undersigned hereby certify that, based on information and belief formed after reasonable inquiry, all air contaminant sources identified in this application are in compliance with all applicable requirements.

SIGNATURE 
(Please use blue ink)

DATE: 8 JULY 2015
(Please use blue ink)

35B. Printed name of signee: Scott Denicourt

35C. Title: General Manager and Vice President, Morgantown Operations

35D. E-mail: scott.denicourt@mylan.com

35E. Phone: 304-599-2595

35F. FAX: 304-598-5471

36A. Printed name of contact person (if different from above): Justin Hartshorn

36B. Title: Senior Manager, NA Environmental Compliance

36C. E-mail: justin.hartshorn@mylan.com

36D. Phone: 304-554-5751

36E. FAX: 304-598-5471

PLEASE CHECK ALL APPLICABLE ATTACHMENTS INCLUDED WITH THIS PERMIT APPLICATION:

- | | |
|--|---|
| <input checked="" type="checkbox"/> Attachment A: Business Certificate | <input type="checkbox"/> Attachment K: Fugitive Emissions Data Summary Sheet |
| <input checked="" type="checkbox"/> Attachment B: Map(s) | <input type="checkbox"/> Attachment L: Emissions Unit Data Sheet(s) |
| <input checked="" type="checkbox"/> Attachment C: Installation and Start Up Schedule | <input checked="" type="checkbox"/> Attachment M: Air Pollution Control Device Sheet(s) |
| <input checked="" type="checkbox"/> Attachment D: Regulatory Discussion | <input checked="" type="checkbox"/> Attachment N: Supporting Emissions Calculations |
| <input checked="" type="checkbox"/> Attachment E: Plot Plan | <input type="checkbox"/> Attachment O: Monitoring/Recordkeeping/Reporting/Testing Plans |
| <input checked="" type="checkbox"/> Attachment F: Detailed Process Flow Diagram(s) | <input type="checkbox"/> Attachment P: Public Notice |
| <input checked="" type="checkbox"/> Attachment G: Process Description | <input type="checkbox"/> Attachment Q: Business Confidential Claims |
| <input type="checkbox"/> Attachment H: Material Safety Data Sheets (MSDS) | <input type="checkbox"/> Attachment R: Authority Forms |
| <input checked="" type="checkbox"/> Attachment I: Emission Units Table | <input checked="" type="checkbox"/> Attachment S: Title V Permit Revision Information |
| <input checked="" type="checkbox"/> Attachment J: Emission Points Data Summary Sheet | <input checked="" type="checkbox"/> Application Fee |

Please mail an original and three (3) copies of the complete permit application with the signature(s) to the DAQ, Permitting Section, at the address listed on the first page of this application. Please DO NOT fax permit applications.

FOR AGENCY USE ONLY – IF THIS IS A TITLE V SOURCE:

- Forward 1 copy of the application to the Title V Permitting Group and:
- For Title V Administrative Amendments:
 - NSR permit writer should notify Title V permit writer of draft permit,
- For Title V Minor Modifications:
 - Title V permit writer should send appropriate notification to EPA and affected states within 5 days of receipt,
 - NSR permit writer should notify Title V permit writer of draft permit.
- For Title V Significant Modifications processed in parallel with NSR Permit revision:
 - NSR permit writer should notify a Title V permit writer of draft permit,
 - Public notice should reference both 45CSR13 and Title V permits,
 - EPA has 45 day review period of a draft permit.

All of the required forms and additional information can be found under the Permitting Section of DAQ's website, or requested by phone.

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment A

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

**WEST VIRGINIA
STATE TAX DEPARTMENT
BUSINESS REGISTRATION
CERTIFICATE**

ISSUED TO:
**MYLAN PHARMACEUTICALS INC
DBA MYLAN PHARMACEUTICALS
781 CHESTNUT RIDGE RD
MORGANTOWN, WV 26505-2730**

BUSINESS REGISTRATION ACCOUNT NUMBER: 1034-8407

This certificate is issued on: 06/24/2010

*This certificate is issued by
the West Virginia State Tax Commissioner
in accordance with W.Va. Code § 11-12.*

*The person or organization identified on this certificate is registered
to conduct business in the State of West Virginia at the location above.*

This certificate is not transferrable and must be displayed at the location for which issued.

This certificate shall be permanent until cessation of the business for which the certificate of registration was granted or until it is suspended, revoked or cancelled by the Tax Commissioner.

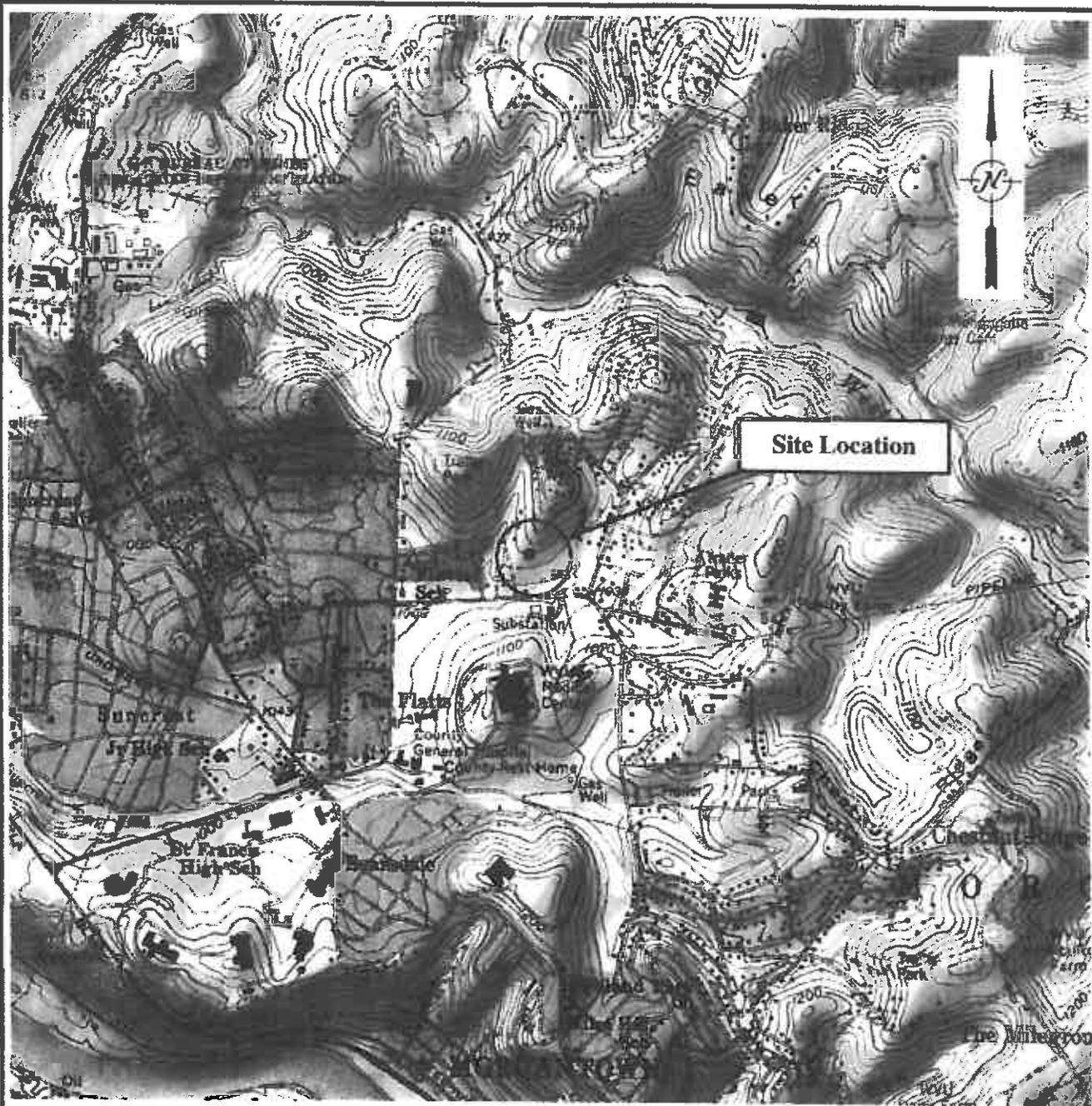
Change in name or change of location shall be considered a cessation of the business and a new certificate shall be required.

TRAVELING/STREET VENDORS: Must carry a copy of this certificate in every vehicle operated by them.
CONTRACTORS, DRILLING OPERATORS, TIMBER/LOGGING OPERATIONS: Must have a copy of this certificate displayed at every job site within West Virginia.

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment B

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA



Site Location

Reference:
 3-D TopoQuads © DeLorme,
 Yarmouth, Me 04096
 Source Data:
 7.5 Minute USGS
 Topographic Quadrangle

 Morgantown North, WV

Vicinity Map

 Scale 1" = 2000'

**Mylan
 Pharmaceuticals**

Air Permit Application

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment C

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

ATTACHMENT C – CURRENT INSTALLATION & START UP SCHEDULE

Equipment	Proposed Installation Date	Proposed Start Up Date
New Coating Pan and associated dust collector	September 30, 2015	November 1, 2015

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment D

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

ATTACHMENT D – REGULATORY DISCUSSION

The following tables discuss the most significant air quality regulatory requirements that Mylan believes apply to the proposed changes.

Presumed Applicable Air Quality Requirements			
Regulatory Citation	Emission Source Affected	Description of Applicability	Compliance Demonstration
45CSR7-3.1	Cartridge Collector: DC246	20% max. opacity from all PM-emitting vent points other than the boilers vent points.	Quarterly visual observation and recordkeeping of visual observations.
45CSR7-4.1	Cartridge Collector: DC246	PM emission limits from all PM-emitting vent points other than the boilers vent points.	Proper operation and maintenance of cartridge collectors.

The following table discusses the most significant air quality regulatory requirements that Mylan believes do not apply to the affected permit application.

Presumed Non-Applicable Air Quality Requirements		
Regulatory Citation	Emission Sources Presumed to be Non-Applicable	Basis of Non-Applicability
45CSR27	All Sources in the proposed modification.	The proposed modification will not discharge any toxic air pollutant (as defined at 45CSR27-2.10.) into the open air in excess of the amounts shown in Table A of 45CSR27.
40CFR61 – All Subparts	All Sources in the proposed modification.	Mylan does not believe that any 40CFR61 NESHAPS regulations apply to the proposed modification.
40CFR63 – All Subparts	All Sources in the proposed modification.	Mylan does not believe that any 40CFR63 MACT regulations apply to the proposed modification.
45CSR14	All Sources in the proposed modification.	The proposed modification is not a “significant modification” as defined in 45CSR14. A more detailed discussion on this topic is attached in Appendix 3.

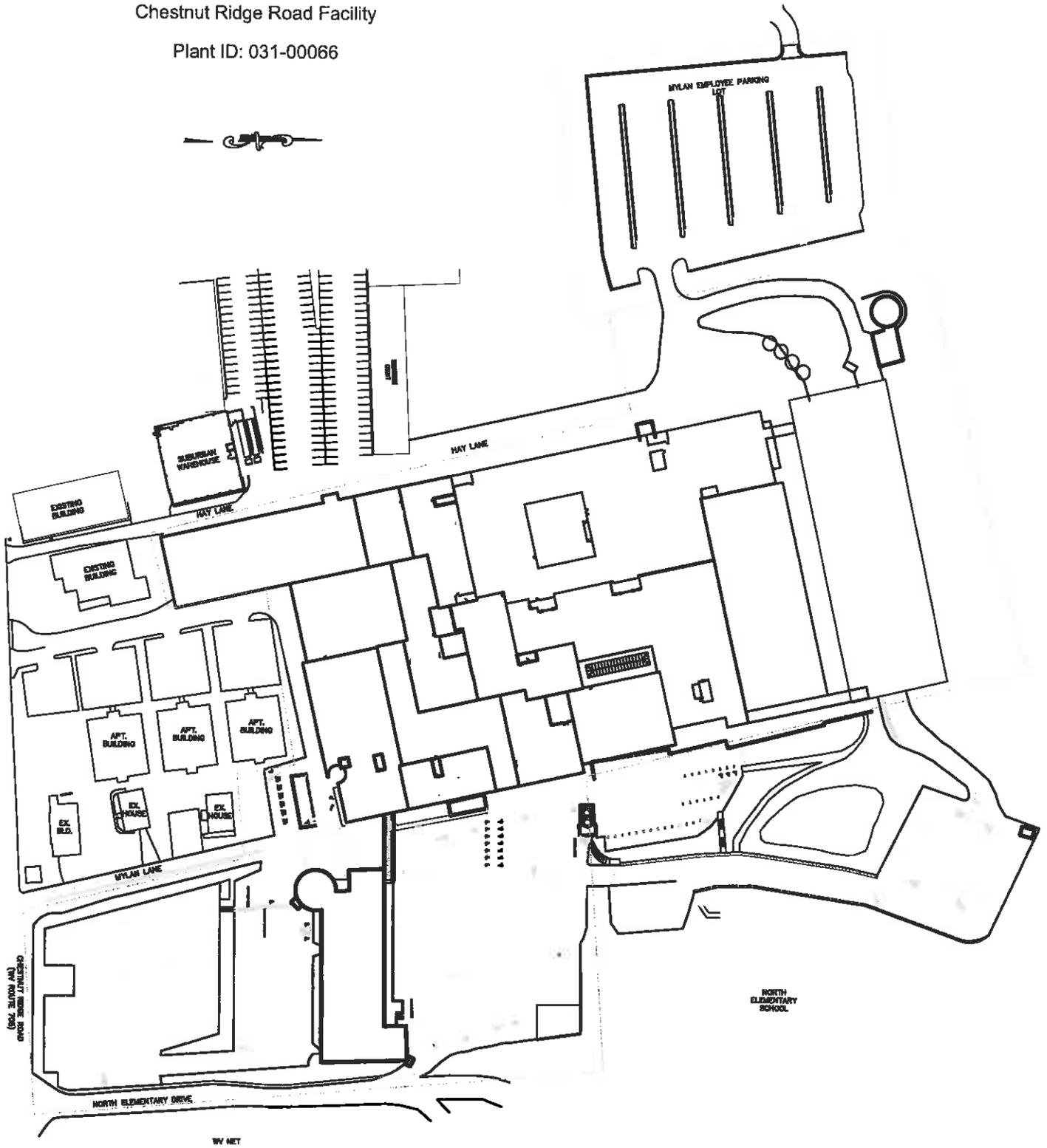
APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment E

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

Attachment E - Plot Plan

Mylan Pharmaceuticals Inc.
Chestnut Ridge Road Facility
Plant ID: 031-00066

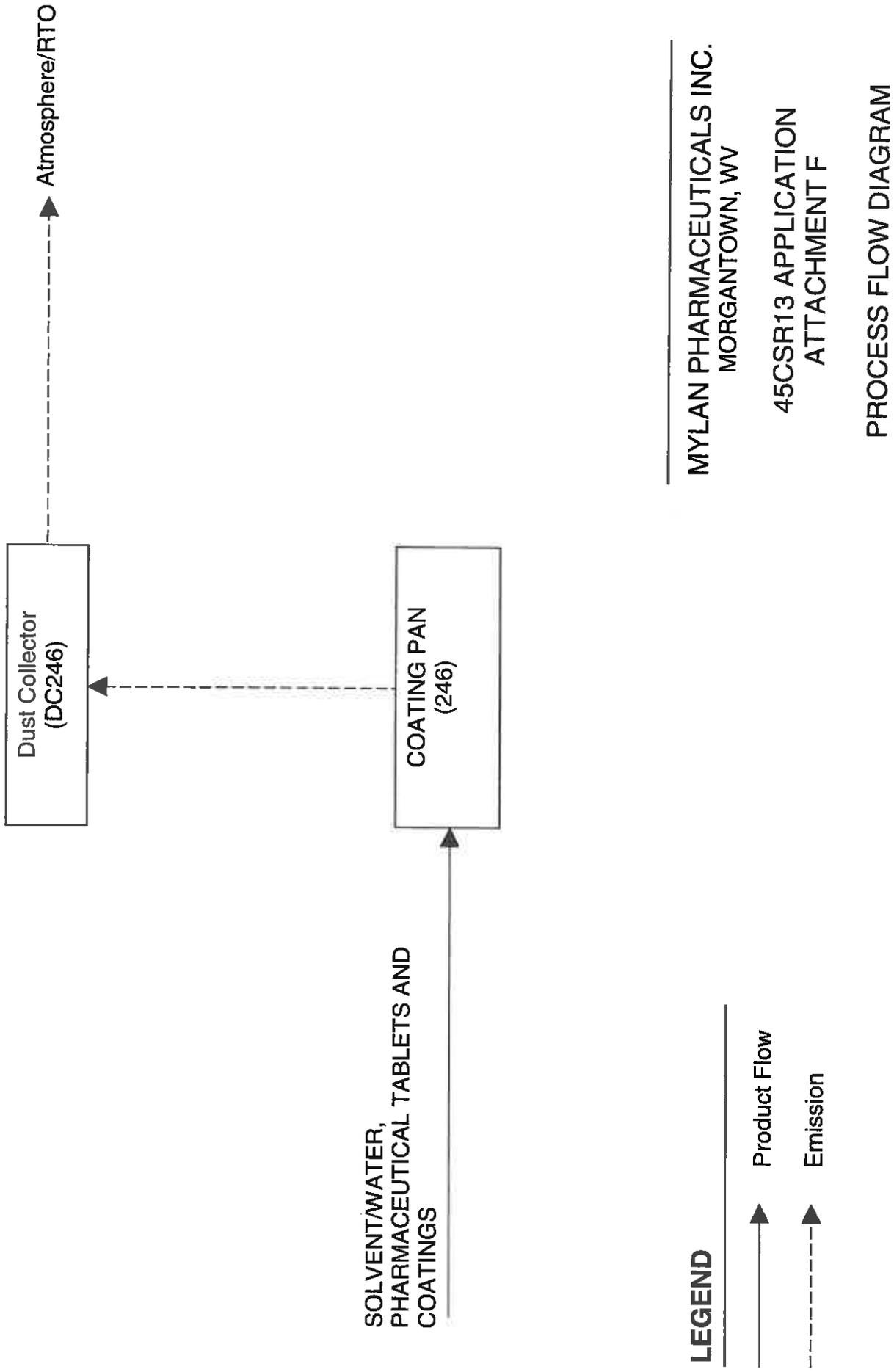


DRAWING CREATED ON 08/26/2009

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment F

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA



LEGEND

- ▶ Product Flow
- - -▶ Emission

MYLAN PHARMACEUTICALS INC.
MORGANTOWN, WV

45CSR13 APPLICATION
ATTACHMENT F

PROCESS FLOW DIAGRAM

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment G

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

ATTACHMENT G – PROCESS DESCRIPTION

Chestnut Ridge Road Facility Overview

Mylan Pharmaceuticals Inc. (Mylan) is a batch pharmaceutical manufacturing company. Mylan purchases raw materials from various suppliers. Once the material is cleared by quality control, it is weighed, blended, granulated, formulated, and packaged. The final products from the Chestnut Ridge facility are solid dose pharmaceuticals. The facility incorporates a quality control laboratory.

All of the processes at the Chestnut Ridge Facility are in accordance with the rules and regulations of the United States Food and Drug Administration (FDA). The FDA (along with Mylan's quality control) limits the release/loss of pharmaceutical ingredients during manufacturing processes. This includes the release/loss of pharmaceutical ingredients to the atmosphere as air emissions of particulate matter.

Coating Pan

Mylan currently operates several, permitted coating pan units at the Chestnut Ridge location. The purpose of this application is to install a new coating pan at the site. This installation is part of a new project and is only related to business demand and an increase in production rates. A cartridge style dust collector will be installed downstream of the coating pan in the same setup that currently exists at the Chestnut Ridge facility.

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment I

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

Attachment I

Emission Units Table

(includes all emission units and air pollution control devices that will be part of this permit application review, regardless of permitting status)

Emission Unit ID¹	Emission Point ID²	Emission Unit Description	Year Installed/ Modified	Design Capacity	Type³ and Date of Change	Control Device⁴
246	246	<i>Coating Pan</i>	2015	<i>682 lb/load maximum</i>	<i>New</i>	<i>Cartridge Dust Collector DC246</i>

¹ For Emission Units (or Sources) use the following numbering system: 1S, 2S, 3S,... or other appropriate designation

² For Emission Points use the following numbering system: 1E, 2E, 3E, ... or other appropriate designation

³ New, modification, removal

⁴ For Control Devices use the following numbering system: 1C, 2C, 3C,... or other appropriate designation.

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment J

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

**Attachment J
EMISSION POINTS DATA SUMMARY SHEET**

Table 1: Emissions Data

Emission Point ID No. (Must match Emission Units Table & Plot Plan)	Emission Point Type ¹	Emission Unit Vented Through This Point (Must match Emission Units Table & Plot Plan)		Air Pollution Control Device (Must match Emission Units Table & Plot Plan)		Vent Time for Emission Unit (chemical processes only)		All Regulated Pollutants - Chemical Name/CAS ³	Maximum Potential Uncontrolled Emissions ⁴		Maximum Potential Controlled Emissions ⁵		Emission Form or Phase (At exit conditions, Solid, Liquid or Gas/Vapor)	Est. Method Used ⁶	Emission Concentration ⁷ (ppmv or mg/m ³)
		ID No.	Source	ID No.	Device Type	Short Term ² (hr/yr)	Max (hr/yr)		lb/hr	ton/yr	lb/hr	ton/yr			
246	Upward vertical stack	246	Coating Pan 246	DC246	Cartridge Dust Collector	C	4950	PM	68.2	168.8	0.07	0.17	Solid; Particulate	MB	N/A
246	Upward vertical stack	246	Coating Pan 246	RTO 10008085	Regenerative Thermal Oxidizer (RTO)	C	4950	VOCs	132.3	5 tons/yr is current Coating Pan limit in R13-2068Q	2.65	5 tons/yr is current Coating Pan limit in R13-2068Q	Gas	MB	N/A

The EMISSION POINTS DATA SUMMARY SHEET provides a summation of emissions by emission unit. Note that uncaptured process emission unit emissions are not typically considered to be fugitive and must be accounted for on the appropriate EMISSIONS UNIT DATA SHEET and on the EMISSION POINTS DATA SUMMARY SHEET. Please note that total emissions from the source are equal to all vented emissions, all fugitive emissions, plus all other emissions (e.g. uncaptured emissions). Please complete the FUGITIVE EMISSIONS DATA SUMMARY SHEET for fugitive emission activities.

- Please add descriptors such as upward vertical stack, downward vertical stack, horizontal stack, relief vent, rain cap, etc.
- Indicate by "C" if venting is continuous. Otherwise, specify the average short-term venting rate with units, for intermittent venting (ie., 15 min/hr). Indicate as many rates as needed to clarify frequency of venting (e.g., 5 min/day, 2 days/wk).
- List all regulated air pollutants. Speciate VOCs, including all HAPs. Follow chemical name with Chemical Abstracts Service (CAS) number. LIST Acids, CO, CS₂, VOCs, H₂S, Inorganics, Lead, Organics, O₃, NO, NO₂, SO₂, SO_x, all applicable Greenhouse Gases (including CO₂ and methane), etc. **DO NOT LIST** H₂, H₂O, N₂, O₂, and Noble Gases.
- Give maximum potential emission rate with no control equipment operating. If emissions occur for less than 1 hr, then record emissions per batch in minutes (e.g. 5 lb VOC/20 minute batch).
- Give maximum potential emission rate with proposed control equipment operating. If emissions occur for less than 1 hr, then record emissions per batch in minutes (e.g. 5 lb VOC/20 minute batch).
- Indicate method used to determine emission rate as follows: MB = material balance; ST = stack test (give date of test); EE = engineering estimate; O = other (specify).
- Provide for all pollutant emissions. Typically, the units of parts per million by volume (ppmv) are used. If the emission is a mineral acid (sulfuric, nitric, hydrochloric or phosphoric) use units of milligram per dry cubic meter (mg/m³) at standard conditions (68 °F and 29.92 inches Hg) (see 45CSR7). If the pollutant is SO₂, use units of ppmv (See 45CSR10).

Attachment J
EMISSION POINTS DATA SUMMARY SHEET

Table 2: Release Parameter Data

Emission Point ID No. <i>(Must match Emission Units Table)</i>	Inner Diameter (ft.)	Exit Gas			Emission Point Elevation (ft)		UTM Coordinates (km)	
		Temp. (°F)	Volumetric Flow ¹ (acfm) <i>at operating conditions</i>	Velocity (fps)	Ground Level <i>(Height above mean sea level)</i>	Stack Height ² <i>(Release height of emissions above ground level)</i>	Northing	Easting
246	N/A	45°C - 80°C	4000 CFM	N/A	~1000	~30 ft	Approx: Zone 17; 4390.5540971422 205 (Lat 39.6660129)	Approx: Zone 17; 589.3285978 954759 (Long - 79.958659)

¹ Give at operating conditions. Include inerts.

² Release height of emissions above ground level.

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment L

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

Attachment L
EMISSIONS UNIT DATA SHEET
GENERAL

To be used for affected sources other than asphalt plants, foundries, incinerators, indirect heat exchangers, and quarries.

Identification Number (as assigned on *Equipment List Form*): Coating Pan 246

1. Name or type and model of proposed affected source:

Coating Pans manufactured by O'Hara Technologies and similar in design to the coating pans already installed at the facility. Specification sheet available upon request.

2. On a separate sheet(s), furnish a sketch(es) of this affected source. If a modification is to be made to this source, clearly indicated the change(s). Provide a narrative description of all features of the affected source which may affect the production of air pollutants.

3. Name(s) and maximum amount of proposed process material(s) charged per hour:

Dry powder raw pharmaceutical materials will be mixed and formulated in quantities up to 682 pounds per hour in Coating Pan 246. Certain products may be mixed with water and/or non-HAP solvents.

4. Name(s) and maximum amount of proposed material(s) produced per hour:

Dry powder raw pharmaceutical materials will be mixed and formulated in quantities up to 682 pounds per hour in Coating Pans 246.

5. Give chemical reactions, if applicable, that will be involved in the generation of air pollutants:

None

* The identification number which appears here must correspond to the air pollution control device identification number appearing on the *List Form*.

6. Combustion Data (if applicable):			
(a) Type and amount in appropriate units of fuel(s) to be burned:			
Not Applicable			
(b) Chemical analysis of proposed fuel(s), excluding coal, including maximum percent sulfur and ash:			
Not Applicable			
(c) Theoretical combustion air requirement (ACF/unit of fuel):			
N/A	@	°F and	psia.
(d) Percent excess air: N/A			
(e) Type and BTU/hr of burners and all other firing equipment planned to be used:			
Not Applicable			
(f) If coal is proposed as a source of fuel, identify supplier and seams and give sizing of the coal as it will be fired:			
Not Applicable			
(g) Proposed maximum design heat input:		Not Applicable	× 10 ⁶ BTU/hr.
7. Projected operating schedule:			
Hours/Day	18	Days/Week	5.5
		Weeks/Year	50

8. Projected amount of pollutants that would be emitted from this affected source if no control devices were used:

@	Varies	°F and	Ambient	psia	
a.	NO _x	N/A	lb/hr	N/A	grains/ACF
b.	SO ₂	N/A	lb/hr	N/A	grains/ACF
c.	CO	N/A	lb/hr	N/A	grains/ACF
d.	PM ₁₀	68.2	lb/hr	n/a	grains/ACF
e.	Hydrocarbons	N/A	lb/hr	N/A	grains/ACF
f.	VOCs	132.3	lb/hr		grains/ACF
g.	Pb	N/A	lb/hr	N/A	grains/ACF
h.	Specify other(s)				
	None	N/A	lb/hr	N/A	grains/ACF
			lb/hr		grains/ACF
			lb/hr		grains/ACF
			lb/hr		grains/ACF

NOTE: (1) An Air Pollution Control Device Sheet must be completed for any air pollution device(s) used to control emissions from this affected source.

(2) Complete the Emission Points Data Sheet.

<p>9. Proposed Monitoring, Recordkeeping, Reporting, and Testing Please propose monitoring, recordkeeping, and reporting in order to demonstrate compliance with the proposed operating parameters. Please propose testing in order to demonstrate compliance with the proposed emissions limits.</p>	
<p>MONITORING Quarterly visible emission observations (conducted on external cartridge collector)</p>	<p>RECORDKEEPING Keep monthly records of non-HAP alcohol used, number of batches in which non-HAP alcohol was used, the number of hours for each batch.</p>
<p>REPORTING N/A</p>	<p>TESTING N/A</p>
<p>MONITORING. PLEASE LIST AND DESCRIBE THE PROCESS PARAMETERS AND RANGES THAT ARE PROPOSED TO BE MONITORED IN ORDER TO DEMONSTRATE COMPLIANCE WITH THE OPERATION OF THIS PROCESS EQUIPMENT OPERATION/AIR POLLUTION CONTROL DEVICE.</p> <p>RECORDKEEPING. PLEASE DESCRIBE THE PROPOSED RECORDKEEPING THAT WILL ACCOMPANY THE MONITORING.</p> <p>REPORTING. PLEASE DESCRIBE THE PROPOSED FREQUENCY OF REPORTING OF THE RECORDKEEPING.</p> <p>TESTING. PLEASE DESCRIBE ANY PROPOSED EMISSIONS TESTING FOR THIS PROCESS EQUIPMENT/AIR POLLUTION CONTROL DEVICE.</p>	
<p>10. Describe all operating ranges and maintenance procedures required by Manufacturer to maintain warranty</p> <p>Not applicable</p>	

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment M

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

22. Type of Pollutant(s) to be collected (if particulate give specific type):
 Particulate from pharmaceutical powder processing operations

23. Is there any SO₃ in the emission stream? No Yes SO₃ content: ppmv

24. Emission rate of pollutant (specify) into and out of collector at maximum design operating conditions:

Pollutant	IN		OUT	
	lb/hr	grains/acf	lb/hr	grains/acf
PM	68.2	-	0.07	-

25. Complete the table:

Particulate Size Range (microns)	Particle Size Distribution at Inlet to Collector	Fraction Efficiency of Collector
	Weight % for Size Range	Weight % for Size Range
0 – 2	Varies by product	Varies by product
2 – 4	Varies by product	Varies by product
4 – 6	Varies by product	Varies by product
6 – 8	Varies by product	Varies by product
8 – 10	Varies by product	Varies by product
10 – 12	Varies by product	Varies by product
12 – 16	Varies by product	Varies by product
16 – 20	Varies by product	Varies by product
20 – 30	Varies by product	Varies by product
30 – 40	Varies by product	Varies by product
40 – 50	Varies by product	Varies by product
50 – 60	Varies by product	Varies by product
60 – 70	Varies by product	Varies by product
70 – 80	Varies by product	Varies by product
80 – 90	Varies by product	Varies by product
90 – 100	Varies by product	Varies by product
>100	Varies by product	Varies by product

26. How is filter monitored for indications of deterioration (e.g., broken bags)?

- Continuous Opacity
- Pressure Drop
- Alarms-Audible to Process Operator
- Visual opacity readings, Frequency: Quarterly
- Other, specify:

27. Describe any recording device and frequency of log entries:

None

28. Describe any filter seeding being performed:

None

29. Describe any air pollution control device inlet and outlet gas conditioning processes (e.g., gas cooling, gas reheating, gas humidification):

None

30. Describe the collection material disposal system:

Material is collected in drums and incinerated off site.

31. Have you included **Baghouse Control Device** in the Emissions Points Data Summary Sheet?

As Cartridge Collector

32. Proposed Monitoring, Recordkeeping, Reporting, and Testing

Please propose monitoring, recordkeeping, and reporting in order to demonstrate compliance with the proposed operating parameters. Please propose testing in order to demonstrate compliance with the proposed emissions limits.

MONITORING:
Quarterly visual emission observations.

RECORDKEEPING:
Maintain records of visual emission observations.

REPORTING:
None

TESTING:
None

MONITORING: Please list and describe the process parameters and ranges that are proposed to be monitored in order to demonstrate compliance with the operation of this process equipment or air control device.
RECORDKEEPING: Please describe the proposed recordkeeping that will accompany the monitoring.
REPORTING: Please describe any proposed emissions testing for this process equipment on air pollution control device.
TESTING: Please describe any proposed emissions testing for this process equipment on air pollution control device.

33. Manufacturer's Guaranteed Capture Efficiency for each air pollutant.
100%

34. Manufacturer's Guaranteed Control Efficiency for each air pollutant.
99.9%

35. Describe all operating ranges and maintenance procedures required by Manufacturer to maintain warranty.
TBD when unit arrives

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment N

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

ATTACHMENT N – SUPPORTING EMISSIONS CALCULATIONS

The attached spreadsheets contain the estimated maximum hourly and annual emission rates for the new coating pan and the new dust collector associated with the coating pan. A new coating pan is being installed due to new product forecasts and production requirements. The coating pan will be capable of applying both aqueous and solvent based solutions to tablets. The associated dust collector will be installed to capture particulate emissions from tablet breakage or solution overspray. The coating pan will be connected to the Regenerative Thermal Oxidizer (RTO) system to control VOC emissions. The coating pan will have permitted flexibility to emit to atmosphere or to the RTO as long as emission limits are met.

Plant: Mylan Pharmaceuticals Inc. - Morgantown, WV (WVDAQ ID# 06100033)
 Reason for Application: New Coating Pan
 Process/Equipment Affected: New Coating Pan 246 w/associated Dust Collector

ID No	Emission Unit Description	Design Capacity	Vent/Stack ID No.	Type of Release [1]	Control System	Control System ID No.	Control System Efficiency (%)	Pollutant	HAP?	Emission Estimate Basis [2]	Hourly Rate without Control Device (lb/hr)	Hourly Rate with Control Device (lb/hr)	Hours Oper (hr/yr)	Annual Rate (tons/yr)
246	Coating Pan - Particulate Matter	682 lb/hr dry raw materials	246	P	Dust Collector	DC - 246	99.9	Total PM	N	MB	68.20	0.068	4,950	0.17
	Coating Pan - VOC emissions from processing with non-HAP solvents	1000 g/min spray rate	246	P	None; VOCs emitted to atmosphere	N/A	N/A	VOC	N	MB	132.3	N/A	4,950	Total VOC limit for all applicable Coating Pans is currently permitted at 5 tons/yr
	Coating Pan - VOC emissions from processing with non-HAP solvents	1000 g/min spray rate	246	P	RTO for VOC Destruction	RTO 10008085	98%	VOC	N	MB	132.3	2.65		

BASIS FOR EMISSION ESTIMATES:

1. PARTICULATE MATTER

- Maximum dry raw material load to coating pans is 310 kg/hr (682 lb/hr) per manufacturer's specifications.
- An estimated 10% of material is lost from the coating pan due to tablet breakage and overspray.
- Material Loss = 682 lb/hr * 0.1 = 68.2 lb/hr
- Max. Annual Operating Time = 4950 hr/yr for each coating pan due to batch operating schedule
- Dust collector removes approximately 99.9% of total PM per manufacturer's specifications
- Maximum coating pan load is 682 lb.

2. VOLATILE ORGANIC COMPOUNDS (VOC)

- Assume 100% of VOC (IPA/Ethanol) added to coating pans is emitted to atmosphere, except VOC exhausted to RTO.
- Maximum alcohol production feed rate to a coating pan is 1000 g/min (1 kg/min) as outlined in manufacturer's specifications (spray application is not 100% VOC, but is assumed here for maximum emission estimates)
- Production maximum VOC emitted = 1 kg/min * 60 min/hr * 2.05 lb/kg = 132.3 lb/hr
- Uncontrolled Hourly limit = 132.3 lb/hr

VOC Emissions Controlled by RTO

- RTO control efficiency: 98% (per Permit R13-2068Q)
- RTO Controlled Hourly Limit = 132.3 lb/hr * (1-0.98) = 2.65 lb/hr

Overall Coating Pan Annual VOC Emissions

- Annual limit = 5.0 tpy (As currently stated in R13-2068Q. Value based on product type and forecast, and use of RTO. Value is not dependent on hourly rates.)

Note: Coating Pans are authorized to emit to the RTO and to the atmosphere.

NOTES:

- [1] P=Point, F=Fugitive, S=Secondary
- [2] EF=Emission Factor, MB=Material Balance, EN=Engineering Calculation, MO=Monitoring/Measurement

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment P

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

ATTACHMENT P – PUBLIC NOTICE

Mylan will submit the required Class I legal advertisement to a local newspaper and will forward the original affidavit of publication to DAQ within 30 days of submittal of this construction application.

The anticipated text of the legal ad to be placed in the *Morgantown Dominion-Post* is as follows:

AIR QUALITY PERMIT NOTICE Notice of Application

Notice is given that Mylan Pharmaceuticals Inc. has applied to the West Virginia Department of Environmental Protection, Division of Air Quality, for a Permit Modification for a pharmaceutical manufacturing facility located on 781 Chestnut Ridge Road, Morgantown, in Monongalia County, West Virginia. The latitude and longitude coordinates are: 39.65923, -79.95824

The applicant estimates an increase of potential to discharge the following Regulated Air Pollutants will be: 0.17 tons per year of particulate emissions.

Startup of operation is planned to begin on or about the 1st day of November, 2015. Written comments will be received by the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street, SE, Charleston, WV 25304, for at least 30 calendar days from the date of publication of this notice.

Any questions regarding this permit application should be directed to the DAQ at (304) 926-0499, extension 1227, during normal business hours.

Dated this the 9th day of July, 2014.

By: Mylan Pharmaceuticals Inc.
Scott Denicourt
General Manager and Vice President, Morgantown Operations
P.O. Box 4310
Morgantown, WV 26504-4310

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Attachment S

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

Attachment S

Title V Permit Revision Information

1. New Applicable Requirements Summary	
Mark all applicable requirements associated with the changes involved with this permit revision:	
<input type="checkbox"/> SIP	<input type="checkbox"/> FIP
<input checked="" type="checkbox"/> Minor source NSR (45CSR13)	<input type="checkbox"/> PSD (45CSR14)
<input type="checkbox"/> NESHAP (45CSR15)	<input type="checkbox"/> Nonattainment NSR (45CSR19)
<input type="checkbox"/> Section 111 NSPS (Subpart(s) _____)	<input type="checkbox"/> Section 112(d) MACT standards (Subpart(s) _____)
<input type="checkbox"/> Section 112(g) Case-by-case MACT	<input type="checkbox"/> 112(r) RMP
<input type="checkbox"/> Section 112(i) Early reduction of HAP	<input type="checkbox"/> Consumer/commercial prod. reqts., section 183(e)
<input type="checkbox"/> Section 129 Standards/Reqts.	<input type="checkbox"/> Stratospheric ozone (Title VI)
<input type="checkbox"/> Tank vessel reqt., section 183(f)	<input type="checkbox"/> Emissions cap 45CSR§30-2.6.1
<input type="checkbox"/> NAAQS, increments or visibility (temp. sources)	<input type="checkbox"/> 45CSR27 State enforceable only rule
<input type="checkbox"/> 45CSR4 State enforceable only rule	<input type="checkbox"/> Acid Rain (Title IV, 45CSR33)
<input type="checkbox"/> Emissions Trading and Banking (45CSR28)	<input type="checkbox"/> Compliance Assurance Monitoring (40CFR64) ⁽¹⁾
<input type="checkbox"/> NO _x Budget Trading Program Non-EGUs (45CSR1)	<input type="checkbox"/> NO _x Budget Trading Program EGUs (45CSR26)
<p>⁽¹⁾ If this box is checked, please include Compliance Assurance Monitoring (CAM) Form(s) for each Pollutants Specific Emission Unit (PSEU) (See Attachment H to Title V Application). If this box is not checked, please explain why Compliance Assurance Monitoring is not applicable:</p> <p style="margin-left: 40px;">Per 40 CFR 64.5, this application is not part of an initial Title V permit application (40 CFR 64.5(a)(1)) and not part of a significant Title V permit revision (40 CFR 64.5(a)(2)); therefore, CAM plan submittal is not required until the renewal of Mylan's Title V permit as stated in 40 CFR 64.5(a)(3). Mylan's Title V permit renewal will be submitted by July 10, 2016 to comply with an expiration date of January 10, 2017.</p>	

2. Non Applicability Determinations
<p>List all requirements, which the source has determined not applicable to this permit revision and for which a permit shield is requested. The listing shall also include the rule citation and a rationale for the determination.</p> <p>The regulatory discussion outlining non-applicable air quality requirements are contained in Attachment D of this permit application.</p>
<p><input type="checkbox"/> Permit Shield Requested <i>(not applicable to Minor Modifications)</i></p>
<p><i>All of the required forms and additional information can be found under the Permitting Section of DAQ's website, or requested by phone.</i></p>
3. Suggested Title V Draft Permit Language

Are there any changes involved with this Title V Permit revision outside of the scope of the NSR Permit revision? Yes No If Yes, describe the changes below.

Also, please provide **Suggested Title V Draft Permit language** for the proposed Title V Permit revision (including all applicable requirements associated with the permit revision and any associated monitoring /recordkeeping/ reporting requirements), OR attach a marked up pages of current Title V Permit. Please include appropriate citations (Permit or Consent Order number, condition number and/or rule citation (e.g. 45CSR§7-4.1)) for those requirements being added / revised.

4. Active NSR Permits/Permit Determinations/Consent Orders Associated With This Permit Revision

Permit or Consent Order Number	Date of Issuance	Permit/Consent Order Condition Number
R13-2068Q	09/29/2014	
R30-06100033-2012 MM03	12/02/2014	
	/ /	

5. Inactive NSR Permits/Obsolete Permit or Consent Orders Conditions Associated With This Revision

Permit or Consent Order Number	Date of Issuance	Permit/Consent Order Condition Number
	MM/DD/YYYY	
	/ /	
	/ /	

6. Change in Potential Emissions

Pollutant	Change in Potential Emissions (+ or -), TPY
PM	+0.17 tpy
VOCs	+0.0 tpy (new coating pan will operate under existing 5 ton VOC limit for all coating pans)

All of the required forms and additional information can be found under the Permitting Section of DAQ's website, or requested by phone.

7. Certification For Use Of Minor Modification Procedures (Required Only for Minor Modification Requests)

Note: This certification must be signed by a responsible official. Applications without a signed certification will be returned as incomplete. The criteria for allowing the use of Minor Modification Procedures are as follows:

- i. Proposed changes do not violate any applicable requirement;
- ii. Proposed changes do not involve significant changes to existing monitoring, reporting, or recordkeeping requirements in the permit;
- iii. Proposed changes do not require or change a case-by-case determination of an emission limitation or other standard, or a source-specific determination for temporary sources of ambient air quality impacts, or a visibility increment analysis;
- iv. Proposed changes do not seek to establish or change a permit term or condition for which there is no underlying applicable requirement and which permit or condition has been used to avoid an applicable requirement to which the source would otherwise be subject (synthetic minor). Such terms and conditions include, but are not limited to a federally enforceable emissions cap used to avoid classification as a modification under any provision of Title I or any alternative emissions limit approved pursuant to regulations promulgated under § 112(j)(5) of the Clean Air Act;
- v. Proposed changes do not involve preconstruction review under Title I of the Clean Air Act or 45CSR14 and 45CSR19;
- vi. Proposed changes are not required under any rule of the Director to be processed as a significant modification;

Notwithstanding subparagraph 45CSR§30-6.5.a.1.A. (items i through vi above), minor permit modification procedures may be used for permit modifications involving the use of economic incentives, marketable permits, emissions trading, and other similar approaches, to the extent that such minor permit modification procedures are explicitly provided for in rules of the Director which are approved by the U.S. EPA as a part of the State Implementation Plan under the Clean Air Act, or which may be otherwise provided for in the Title V operating permit issued under 45CSR30.

Pursuant to 45CSR§30-6.5.a.2.C., the proposed modification contained herein meets the criteria for use of Minor permit modification procedures as set forth in Section 45CSR§30-6.5.a.1.A. The use of Minor permit modification procedures are hereby requested for processing of this application.

(Signed):

(Please use blue ink)

Date:

July 18, 15
(Please use blue ink)

Named (typed):

Scott Denicourt

Title:

General Manager and Vice
President, Morgantown
Operations

Note: Please check if the following included (if applicable):

- Compliance Assurance Monitoring Form(s)
- Suggested Title V Draft Permit Language

All of the required forms and additional information can be found under the Permitting Section of DAQ's website, or requested by phone.

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Appendix 2

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

Earl Ray Tomblin
Governor

Division of Air Quality

Randy C. Huffman
Cabinet Secretary

Permit for Modification



R13-2068Q2068R

This permit is issued in accordance with the West Virginia Air Pollution Control Act (West Virginia Code §§22-5-1 et seq.) and 45 C.S.R. 13 – Permits for Construction, Modification, Relocation and Operation of Stationary Sources of Air Pollutants, Notification Requirements, Temporary Permits, General Permits and Procedures for Evaluation. The permittee identified at the above-referenced facility is authorized to construct the stationary sources of air pollutants identified herein in accordance with all terms and conditions of this permit.

Issued to:
Mylan Pharmaceuticals Inc.
Chestnut Ridge Facility
061-00033

William F. Durham
Director

Issued: September 29, 2014 • Effective: September 29, 2014

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Revision 3/29/05 Revision 3/29/05

This permit will supersede and replace Permit R13-2068P issued on August 12, 2013.

Facility Location: Morgantown, Monongalia County, West Virginia
Mailing Address: 781 Chestnut Ridge Road, Morgantown, WV 26504
Facility Description: Pharmaceutical Manufacturing Facility
NAICS Codes: 325412
UTM Coordinates: 589.6 km Easting • 4,390.1 km Northing • Zone 17
Latitude/Longitude: 39.65913/-79.95824
Permit Type: Modification
Description of Change: ~~Class II Administrative Update for installation of a new 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.~~ This modification include the addition of a new coating pan and associated dust collection control device.

Any person whose interest may be affected, including, but not necessarily limited to, the applicant and any person who participated in the public comment process, by a permit issued, modified or denied by the Secretary may appeal such action of the Secretary to the Air Quality Board pursuant to article one [§§22B-1-1 et seq.], Chapter 22B of the Code of West Virginia. West Virginia Code §§22-5-14.

The source is subject to 45CSR30. Changes authorized by this permit must also be incorporated into the facility's Title V operating permit. Commencement of the operations authorized by this permit shall be determined by the appropriate timing limitations associated with Title V permit revisions per 45CSR30.

Mylan Pharmaceuticals Inc. • Chestnut Ridge Facility

Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device ⁽¹⁾
537	537	Fluid Bed 1552	1997	Up to 575 Kg/Load	CC EF1552
538	538, 10008085 ⁽²⁾	Fluid Bed 1855	2002	Up to 250 Kg/Load	CC EF2113; RTO
571	571	Fluid Bed 2113	2004	Up to 575 Kg/Load	CC EF2113
572	572, 10008085 ⁽²⁾	Fluid Bed 2181	2004	Up to 250 Kg/Load	CC EF2181; RTO
573	573, 10008538 ⁽²⁾	Fluid Bed 2811	2006	Up to 575 Kg/Load	CC 3340; Absorber
574	574, 10008085 ⁽²⁾	Fluid Bed 3287	2006	Up to 250 Kg/Load	CC 3416; RTO
575	575, 10008085 ⁽²⁾	Fluid Bed 3620	2007	Up to 250 Kg/Load	CC 3643; RTO
576	576, 10008085 ⁽²⁾	Fluid Bed 3426	2007	Up to 575 Kg/Load	CC 3407; RTO
577	577, 10008085 ⁽²⁾	Fluid Bed 3704	2008	Up to 250 Kg/Load	CC 3881; RTO
578	578, 10008085 ⁽²⁾	Fluid Bed 3705	2008	Up to 575 Kg/Load	CC 3879; RTO
579	579, 10008538 ⁽²⁾	Fluid Bed 4001	2008	Up to 575 Kg/Load	CC 4287; Absorber
580	580, 10008085 ⁽²⁾	Fluid Bed 7560	2010	Up to 575 Kg/Load	CC 10007482; RTO
581	581	Fluid Bed 15982	2011	Up to 250 Kg/Load	CC 15982
582	582	Fluid Bed 16117	2011	Up to 575 Kg/Load	CC 16117
215	215	Coating Pan 1390	1999	750 lbs/load	CC EF1390
241	241	Coating Pan 4549	2009	750 lbs/load	CC EF4553
242	242	Coating Pan 4027	2008	245 lbs/load	CC EF4101
244	244, 10008085 ⁽²⁾	Coating Pan 7552	2010	750 lbs/load	CC EF7674; RTO
245	245, 10008085 ⁽²⁾	Coating Pan 8421	2010	750 lbs/load	CC 8422; RTO
246	246, 10008085 ⁽²⁾	Coating Pan 246	2015	682 lbs/load	CC 246; RTO

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Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device ⁽¹⁾
260	260, 10008085 ⁽²⁾	Oven 19	<1973	Electric. Load Varies	RTO
261	261, 10008085 ⁽²⁾	Oven 18	<1973	Electric. Load Varies	RTO
264	264, 10008085 ⁽²⁾	Oven FBD0021	2013	Electric. Load Varies	RTO
FBD1911	1911 (FBD 10008085 ⁽²⁾)	Coating Line FBD1911	FBD201 4	10.77 lb/hr	RTO
10008085	10008085	Regenerative Thermal Oxidation	2010	16.0 mmBtu/hr 3,070 lbs/hr	None
10008538	10008538	Absorber	2010	4,000 cfm	None

(1) CC = Cartridge Collector; WS = Wet Scrubber; RTO = Regenerative Thermal Oxidizer

(2) Noted Emissions Units/Sources are authorized to exhaust (after the Cartridge Collector) to the RTO/Absorber (as applicable) and to atmosphere.

- a. Install, maintain, and operate the cartridge collectors consistent with safety and good air pollution control practices for minimizing emissions, and shall follow all manufacturer's recommendations concerning control device maintenance and performance.
- b. Conduct a weekly visual inspection of the cartridge collector housing, cartridge connections, and dust hoppers of each cartridge collector, in order to ensure proper operation of cartridge collectors. Records shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any.
- c. Either conduct representative performance testing, pursuant to the performance testing procedures as outlined under 3.3.1. of this permit, on the cartridge collectors to determine a minimum collection efficiency or produce a vendor guarantee stating that the cartridge collectors (or associated filters) will meet a minimum collection efficiency of 95%.

7.5. Reporting Requirements

N/A - See Section 3.5 Facility - Wide Reporting Requirements

8.0. Source-Specific Requirements [Coating Pans 215, 241, 242, 244, 245, 246]

8.1. Limitations and Standards

- 8.1.1. No person shall cause, suffer, allow or permit emission of smoke and/or particulate matter into the open air from any process source operation which is greater than twenty (20) percent opacity. [45CSR§7-3.1]
- 8.1.2. No person shall cause, suffer, allow or permit particulate matter to be vented into the open air from any type source operation or duplicate source operation, or from all air pollution control equipment installed on any type source operation or duplicate source operation in excess of the quantity specified as follows:

Table 8.1.2.: Coating Pans 45CSR7 Emission Limits

Emission Unit	PM Emission Limit (lb/hr)
215	0.84
241	0.84
242	0.28
244	0.84
245	0.84
246	0.84

Compliance with 45CSR§7-4.1 shall be demonstrated through compliance with the more stringent particulate emission limit set forth in 8.1.3. [45CSR§7-4.1.]

- 8.1.3. Particulate matter emissions from the Coating Pans, venting through a cartridge collector (215, 241, 242, 244, 245, 246) at Emission Point ID Numbers 215, 241, 242, 244, and 245 shall not exceed the following:

Table 8.1.3.: Coating Pans PM_{2.5}/PM₁₀/PM Emission Limits

Emission Unit	PM _{2.5} /PM ₁₀ /PM Emission Limit	
	Pound/hour	ton/year
215	0.84	6.25
241	0.84	
242	0.28	
244	0.84	
245	0.84	
<u>246</u>	<u>0.84</u>	

- 8.1.4. Maximum hourly volatile organic compound emissions to the atmosphere from the Coating Pans shall not exceed:
- 396.9 lb/hr for each coating pan unit if not venting exhaust to the RTO for the purpose of controlling VOC emissions.
 - 7.94 lb/hr (as emitted from the RTO) each for Coating Pans ~~244, and 245, and 246~~ 244, and 246 if venting exhaust to the RTO for the purpose of controlling VOC emissions.
- 8.1.5. Maximum total combined annual volatile organic compound emissions to the atmosphere from the Coating Pans shall not exceed 5.0 tons/year.
- 8.1.6. The coating pans shall operate according to the following requirements:
- The aggregate dry material loading of each coating pan shall not exceed the following values:
 - Coating Pan 215: 750 pound/load;
 - Coating Pan 241: 750 pound/load;
 - Coating Pan 242: 245 pound/load;
 - Coating Pan 244: 750 pound/load.
 - Coating Pan 245: 750 pound/load.
 - ~~(5)~~(6) Coating Pan 246: 750 pound/load
 - The annual aggregate dry material loading of all coating pans shall not exceed 11,000,000 pounds on a rolling yearly total basis.
 - Cartridge collectors shall be used at all times on each coating pan to control particulate matter emissions. Each collector shall, at a minimum, achieve a collection efficiency of 95%.
 - The solvent spray rate processed in coating pans 241, 242, 244, ~~and 245, and 246~~ shall not exceed 3,000 grams-VOC/minute in each coating pan.
 - No VOC-containing solvents shall be processed in coating pan 215.
 - Coating Pans ~~244 and, 245, and 246~~ 244, and 246 shall have the capability of directing exhaust to RTO for control of VOCs or emitting directly to atmosphere.
 - No HAP-containing solvents shall be processed in any coating pan.

8.2. Monitoring Requirements

- 8.2.1. Visible emissions monitoring shall be conducted initially at least once per month for all emission points subject to opacity limitations. After three consecutive monthly readings in which no visible emissions are observed from any of the subject emission points, those emission points will be allowed to conduct visible emissions checks once per calendar quarter. If visible emissions are observed during a quarterly monitoring from an emission point(s), then that emission point(s) with observed emissions or opacity shall be required to revert to monthly monitoring. Any emission point that has reverted to monthly monitoring shall be allowed to again conduct quarterly visible emissions checks only after three consecutive monthly readings in which no visible emissions are observed from the subject emission point.

These visible emission checks shall be conducted in accordance with 40 CFR , Appendix A, Method 22 during periods of normal facility operation for a sufficient time interval to determine if the unit has visible emissions. If sources of visible emissions are identified during the survey, or at any other time, the permittee shall conduct a 40 CFR 60, Appendix A, Method 9 evaluation within twenty four (24) hours. A Method 9 evaluation shall not be required if the visible emissions condition is corrected within twenty four (24) hours from the time the visible emission condition was identified and the unit is operated at normal operating conditions.

- 8.2.2 For the purposes of demonstrating compliance with the minimum cartridge collection efficiency as given under 8.1.6(c), the permittee shall
- a. Install, maintain, and operate the cartridge collectors consistent with safety and good air pollution control practices for minimizing emissions, and shall follow all manufacture's recommendations concerning control device maintenance and performance.
 - b. Conduct a weekly visual inspection of the cartridge collector housing, cartridge connections, and dust hoppers of each cartridge collector, in order to ensure proper operation of cartridge collectors. Records shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any.
 - c. Either conduct representative performance testing, pursuant to the performance testing procedures as outlined under 3.3.1. of this permit, on the cartridge collectors to determine a minimum collection efficiency or produce a vendor guarantee stating that the cartridge collectors (or associated filters) will meet a minimum collection efficiency of 95%.
- 8.2.3 For the purposes of demonstrating compliance with maximum dry material loading set forth in 8.1.6(a), the permittee shall monitor and record the total dry material per load for each coating pan. This requirement may be waived if the permittee is able to demonstrate that the maximum reasonable design capacity of each coating pan is equal or less than the maximum load given under 8.1.6(a) or if the permittee is able to demonstrate that the maximum loading based on product formulations is equal or less than the maximum load given under 6.1.6(a).
- 8.2.4 For the purposes of demonstrating compliance with maximum annual aggregate dry material loading set forth in 8.1.6(b), the permittee shall monitor and record the aggregate monthly and rolling twelve month total amount of dry material loaded into the coating pans.
- 8.2.5 For the purposes of demonstrating compliance with maximum annual VOC emission limit set forth in 8.1.5, the permittee shall:
- a. Monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in each coating pan with the exception of Coating Pans 244 and 245, and 246.
 - b. Monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in Coating Pans 244 ~~and~~, 245, and 246 when each coating pan is and is not venting exhaust to the RTO for the purpose of controlling VOCs.

- c. Calculate and record the monthly and rolling twelve month aggregate VOC emissions from all coating pans by summing the following:
- (1) The total amount of VOCs in pounds used in each coating pan with the exception of Coating Pans 244 ~~and~~, 245, ~~and~~ 246.
 - (2) The total amount of VOCs in pounds used in Coating Pans 244, ~~and~~ 245, ~~and~~ 246 when not venting exhaust to the RTO for the purpose of controlling VOCs.
 - (3) The total amount of VOCs used in Coating Pans 244, ~~and~~ 245, ~~and~~ 246 when venting exhaust to the —RTO for the purpose of controlling VOCs. Based on compliance with Requirement —9.1.7 of this permit, the permittee may apply a VOC destruction efficiency of 98% to —the amount of VOCs used in Coating Pans 244 and 245 when venting exhaust to the RTO —for the purpose of controlling VOCs.

8.3. Testing Requirements

N/A - See Section 3.3 Facility - Wide Testing Requirements

8.4. Recordkeeping Requirements

- 8.4.1. Records of weekly inspections conducted on the cartridge collector shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any.
- 8.4.2. The permittee shall maintain a record of all solvents used in the coating pans and keep a copy of the associated MSDS to verify that the solvents did not contain any constituent HAPs.

8.5. Reporting Requirements

N/A - See Section 3.5 Facility - Wide Reporting Requirements

9.0. Source-Specific Requirements [Regenerative Thermal Oxidizer (RTO)]

9.1. Limitations and Standards

- 9.1.1. The permittee shall not cause, suffer, allow or permit particulate matter to be discharged from the RTO into the open air in excess of the quantity determined by use of the following formula:

$$\text{Emissions (lb/hr)} = F \times \text{Incinerator Capacity (tons/hr)}$$

Where, the factor, F, is as indicated in Table I below:

Table I: Factor, F, for Determining Maximum Allowable Particulate Emissions

<u>Incinerator Capacity</u>	<u>Factor F</u>
A. Less than 15,000 lbs/hr	5.43
B. 15,000 lbs/hr or greater	2.72

[45CSR§6-4.1]

- 9.1.2. The permittee shall not cause or allow emission of smoke into the atmosphere from the RTO which is twenty percent (20%) opacity or greater. The provisions of 45CSR§6-4.3 shall not apply to smoke which is less than forty percent (40%) opacity, for a period or periods aggregating no

*West Virginia Department of Environmental Protection
Division of Air Quality*

*Earl Ray Tomblin
Governor*

*Randy C. Huffman
Cabinet Secretary*

Permit to

Operate



*Pursuant to
Title V
of the Clean Air Act*

Issued to:
Mylan Pharmaceuticals
Morgantown
R30-06100033-2012

*John A. Benedict
Director*

*Issued: January 10, 2012 • Effective: January 24, 2012
Expiration: January 10, 2017 • Renewal Application Due: July 10, 2016*

Permit Number: **R30-06100033-2012**
Permittee: **Mylan Pharmaceuticals Inc.**
Facility Name: **Morgantown**
Mailing Address: 781 Chestnut Ridge Road, Morgantown, WV 26505

This permit is issued in accordance with the West Virginia Air Pollution Control Act (West Virginia Code §§ 22-5-1 et seq.) and 45CSR30 C Requirements for Operating Permits. The permittee identified at the above-referenced facility is authorized to operate the stationary sources of air pollutants identified herein in accordance with all terms and conditions of this permit.

Facility Location:	Morgantown, Monongalia County, West Virginia
Mailing Address:	PO Box 4310, Morgantown, WV 26504-4310
Telephone Number:	(304) 599-2595
Type of Business Entity:	Corporation
Facility Description:	Pharmaceutical Compounding and Formulating
SIC Codes:	2834
UTM Coordinates:	589.6 km Easting \$ 4390.1 km Northing \$ Zone 17

Permit Writer: Rex Compston

Any person whose interest may be affected, including, but not necessarily limited to, the applicant and any person who participated in the public comment process, by a permit issued, modified or denied by the Secretary may appeal such action of the Secretary to the Air Quality Board pursuant to article one [§§ 22B-1-1 et seq.], Chapter 22B of the Code of West Virginia. West Virginia Code §22-5-14.

Issuance of this Title V Operating Permit does not supersede or invalidate any existing permits under 45CSR13, 14 or 19, although all applicable requirements from such permits governing the facility's operation and compliance have been incorporated into the Title V Operating Permit.

1.0 Emission Units and Active R13, R14, and R19 Permits

1.1 Emission Units

Emission Point ID	Control Device	Emission Unit ID	Mylan ID & Emission Unit Description	Design Capacity	Year Installed/Modified
001	None	001	Boiler 3: Natural gas boiler	6.27 MMBtu/hr	1987
002	None	002	Boiler 4: Natural gas boiler	1.5 MMBtu/hr	1987
003	None	003	Boiler 5: Natural gas boiler	6.00 MMBtu/hr	1991
004	None	004	Boiler 2: Natural gas boiler	1.18 MMBtu/hr	1974
006	None	006	Boiler 1: Natural gas boiler	3.34 MMBtu/hr	1968
007	None	007	Boiler 7: Natural gas boiler	6.99 MMBtu/hr	1997
008	None	008	Boiler 8: Natural gas boiler	6.99 MMBtu/hr	1997
009	None	009	Boiler 11: Natural gas boiler	2.07 MMBtu/hr	2000
009	None	009A	Boiler 12: Natural gas boiler	2.07 MMBtu/hr	2000
010	None	010	Boiler 15: Natural gas boiler	7 MMBtu/hr	2004
011	None	011	Boiler 2343: Natural gas boiler	21.0 MMBtu/hr	2005
012	None	012	Boiler 2344: Natural gas boiler	21.0 MMBtu/hr	2005
013	None	013	Boiler 2345: Natural gas boiler	21.0 MMBtu/hr	2005
014	None	014	Boiler 2674: Natural gas boiler	0.65 MMBtu/hr	2005
015	None	015	Boiler 2675: Natural gas boiler	0.65 MMBtu/hr	2005
210	210	210	Coating Pan 169: Coating pan controlled by cartridge collector EF169	500 lb/load	1985
215	CC EF1390*	215	Coating Pan 1390	750 lb/load	1999
220	220	220	Coating Pan 186: Coating pan controlled by cartridge collector EF186	500 lb/load	1986
230	230	230	Coating Pan 217: Coating pan controlled by cartridge collector EF217	500 lb/load	1987
240	240	240	Coating Pan 99: Coating pan controlled by cartridge collector EF99	500 lb/load	1983
241	CC EF 4553*	241	Coating Pan 4549	750 lb/load	2009
242	CC EF4101*	242	Coating Pan 4027	245 lb/load	2008
243	243	243	Coating Pan 3853: Coating Pan controlled by cartridge collector 4164	750 lbs/load	2008
244; 10008085 ⁽²⁾	CC EF7674*; RTO	244	Coating Pan 7552	750 lb/load	2010
245; 10008085 ⁽²⁾	CC 8421*; RTO	245	Coating Pan 8421	750 lb/load	2010
246	CC246: RTO	246	Coating Pan 246	682 lbs/load	2015

Emission Point ID	Control Device	Emission Unit ID	Mylan ID & Emission Unit Description	Design Capacity	Year Installed/Modified
260; 10008085 ⁽²⁾	RTO ³	260	Oven 19	Varies	Prior to 1973
261; 10008085 ⁽²⁾	RTO ³	261	Oven 18	Varies	Prior to 1973
264; 10008085 ⁽²⁾	RTO ³	264	Oven- 0021 0021	Electric, Load Varies	2013
1911; 10008085 ⁽²⁾	RTO ³	1911	Coating Line 1911 1911	10.77 lb/hr	2014
280	Rotoclone 4	Rooms 74-101 – 74-122, 74-129	Room General Exhaust	Varies	1992 (Rotoclone)
281	Rotoclone 3	Rooms 74-151, 74-153, 91-129, 91-130, 91-132, 91-134 – 91-137, 91-139, 91-229, 91-230, 91-232, 91-329, 91-330, 91-332, 91-334 – 91-337	Room General Exhaust	Varies	1991 (Rotoclone)
282	Rotoclone 3798 ³	Rooms 74-150, 74-152, 74-154, 74-159, 74-160, 74-161, 74-162, 74-212, 91-232, 91-233	Room General Exhaust	Varies	2013
283	Rotoclone 2	Rooms 74-205 – 74-209, 99-217 – 99-219	Room General Exhaust-equipment serviced by Rotoclone	Varies	1982 (Rotoclone)
287	Rotoclone 6 ³	Rooms BL209, BL211, BL214, BL304, BL306, BL307, BL309- BL314, BL316, BL402 – BL404, BL406-BL414, BL416	Room General Exhaust	Varies	1996
288	Rotoclone 5 ³	Rooms BB101-BB103, BB 106, BB108- BB111, BB113-BB118, BB201- BB203, BB206- BB208, BB210-BB217, BB303, BB312	Room General Exhaust	Varies	1996
291	Rotoclone 7 ³	Rooms 85-205A – 85-208A, 99-105, 99-114 – 99-122, 99-209, ORG201A – ORG204A	Room General Exhaust	Varies	1999
294	Rotoclone 9 ³	Rooms BB112, 85-106, 85-108, 85-114, 85-115, 85-102, 85-104, 85-107, 85-110	Room General Exhaust	Varies	2003
295	Rotoclone 10 ³	Rooms BL218, BL219	Room General Exhaust	Varies	2004
296	Rotoclone 2317 ³	Rooms NEX140, NEX142, NEX144, NEX146, NEX159 - NEX162	Room General Exhaust	Varies	2005

Emission Point ID	Control Device	Emission Unit ID	Mylan ID & Emission Unit Description	Design Capacity	Year Installed/ Modified
575; 10008085 ⁽²⁾	CC 3643; RTO*	575	Fluid Bed 3620	Up to 250 Kg/Load	2007
576; 10008085 ⁽²⁾	CC 3407; RTO*	576	Fluid Bed 3426	Up to 575 Kg/Load	2007
577; 10008085 ⁽²⁾	CC 3881; RTO*	577	Fluid Bed 3704	Up to 250 Kg/Load	2008
578; 10008085 ⁽²⁾	CC 3879; RTO*	578	Fluid Bed 3705	Up to 575 Kg/Load	2008
579; 10008583 ⁽²⁾	CC 4287*; Absorber	579	Fluid Bed 4001	Up to 575 Kg/Load	2008
580; 10008085 ⁽²⁾	CC 10007482; RTO*	580	Fluid Bed 7560	Up to 575 Kg/Load	2010
581	CC 15982*	581	Fluid Bed 15982	Up to 250 Kg/Load	2011
582	CC 16117*	582	Fluid Bed 16117	Up to 575 Kg/Load	2011
N/A	None	N/A	Class I or Class II CFC-containing Equipment Subject to 40 CFR Part 82 Subpart F	Varies	Varies
10008085	None	10008085	Regenerative Thermal Oxidation	16.0 mmBtu/hr 3,070 lbs/hr	2010
10008538	None	10008538	Absorber	Up to 4,000 cfm	2010
10007530	None	10007530	Kohler 100 REZG Natural Gas Fired Emergency Generator	162 bph/1,800 rpm	2010
10008594	None	10008594	Kohler 100 REZG Natural Gas Fired Emergency Generator	162 bph/1,800 rpm	2011
1053	None	1053	750 kW Detroit Diesel/MTU	1,006 bhp/1800 rpm	2011
1053	None	1053	Diesel Fuel Tank	2,100 Gallons	2011
323	CC 10023125	<u>Rooms 87-103 to 87- 117</u>	<u>Room General Exhaust</u>	<u>Varies</u>	<u>2011</u>

*Identifies pollution control equipment included in R13-2068PQ.

⁽¹⁾CC = Cartridge Collector; WS = Wet Scrubber; RTO = Regenerative Thermal Oxidizer

⁽²⁾Noted Emissions Units/Sources are authorized to exhaust (after the Cartridge Collector) to the RTO/Absorber (as applicable) and to atmosphere

7.0 Coating Pans [emission point ID(s): 210, 215, 220, 230, 240, 241, 242, 243, 244, 245, 246]

7.1. Limitations and Standards

7.1.1 No person shall cause, suffer, allow or permit emission of smoke and/or particulate matter into the open air from any process source operation, which is greater than twenty (20) percent opacity.
[45CSR§7-3.1. and 45CSR13, Permit No. R13-2068 Condition 8.1.1.)]

7.1.2. No person shall cause, suffer, allow or permit particulate matter to be vented into the open air from any type source operation or duplicate source operation, or from all air pollution control equipment installed on any type source operation or duplicate source operation in excess of the quantity specified under the appropriate source operation type in Table 45-7A found at the end of 45CSR7. Based on the process weight rates for the Coating Pans (excluding Emission Unit ID No. 215, 241, 242, 243, 244, and 245), 333 pounds per hour each, the corresponding allowable particulate matter emission rate is 0.4 pounds per hour each. Based on the process weight rates for Coating Pans 243, 750 pounds per hour, the corresponding allowable particulate matter emission rate is 0.9 pounds per hour.
[45CSR§7-4.1] (210, 220, 230, 240, 243)

7.1.3. Particulate matter emissions from the Coating Pan, venting through a cartridge collector (215, 241, 242, 244, 245) at Emission Point ID No. 215, 241, 242, 244, and 245, shall not exceed the following:

Emission Unit	PM _{2.5} /PM ₁₀ /PM Emission Limit	
	Pounds per Hour	Tons per Year
215	0.84	<u>6.25-8.32</u>
241	0.84	
242	0.28	
244	0.84	
245	0.84	
<u>246</u>	<u>0.84</u>	

[45CSR§7-4.1 and 45CSR13, Permit No. R13-2068 (Condition 8.1.3)] (215, 241, 242, 244, 245, 246)
 Compliance with this streamlined limit will assure compliance with 45CSR§7-4.1 and R13-2068 (Condition 8.1.2.).

7.1.4. Maximum hourly volatile organic compound emissions to the atmosphere from the Coating Pans shall not exceed:

- a. 396.9 lb/hr for each coating pan unit if not venting exhaust to the RTO for the purpose of controlling VOC emissions.
- b. 7.94 lb/hr (as emitted from the RTO) each for Coating Pans 244 and 245 and 246 if venting exhaust to the RTO for the purpose of controlling VOC emissions.

[45CSR13, Permit No. R13-2068 (Condition 8.1.4.)]

7.1.5. Maximum total combined annual volatile organic compound emissions to the atmosphere from the Coating Pans shall not exceed 5.0 tons/year.

[45CSR13, Permit No. R13-2068 (Condition 8.1.5.)]

- 7.1.6. The coating pans shall operate according to the following requirements:
- a. The aggregate dry material loading of each coating pan shall not exceed the following values:
 - (1) Coating Pan 215: 750 pound/load;
 - (2) Coating Pan 241: 750 pound/load;
 - (3) Coating Pan 242: 245 pound/load;
 - (4) Coating Pan 244: 750 pound/load;
 - (5) Coating Pan 245: 750 pound/load.
 - ~~(5)~~(6) Coating Pan 246: 750 lbs/load
 - b. The annual aggregate dry material loading of all coating pans shall not exceed 11,000,000 pounds on a rolling yearly total basis.
 - c. Cartridge collectors shall be used at all times on each coating pan to control particulate matter emissions. Each collector shall, at a minimum, achieve a collection efficiency of 95%.
 - d. The solvent spray rate processed in coating pans 241, 242, 244, and 245 and 246 shall not exceed 3,000 grams-VOC/minute in each coating pan.
 - e. No VOC-containing solvents shall be processed in coating pan 215.
 - f. Coating Pans 244 and 245 and 246 shall have the capability of directing exhaust to RTO for control of VOCs or emitting directly to atmosphere.
 - g. No HAP-containing solvents shall be processed in any coating pan.

[45CSR13, Permit No. R13-2068 (Condition 8.1.6.)]

7.2. Monitoring Requirements

- 7.2.1. Visible emissions monitoring shall be conducted initially at least once per month for all emission points subject to opacity limitations. After three consecutive monthly readings in which no visible emissions are observed from any of the subject emission points, those emission points will be allowed to conduct visible emissions checks once per calendar quarter. If visible emissions are observed during a quarterly monitoring from an emission point(s), then that emission point(s) with observed emissions or opacity shall be required to revert to monthly monitoring. Any emission point that has reverted to monthly monitoring shall be allowed to again conduct quarterly visible emissions checks only after three consecutive monthly readings in which no visible emissions are observed from the subject emission point.

These visible emission checks shall be conducted in accordance with 40 CFR 60, Appendix A, Method 22 during periods of facility operation for a sufficient time interval to determine if the unit has visible emissions. If sources of visible emissions are identified during the survey, or at any other time, the permittee shall conduct a 40 CFR 60, Appendix A, Method 9 evaluation within twenty four (24) hours. A Method 9 evaluation shall not be required if the visible emissions condition is corrected within twenty four (24) hours from the time the visible emission condition was identified and the unit is operated at normal operating conditions.

[45CSR13, Permit No. R13-2068 (Condition 8.2.1.)] (215, 241, 242, 244, 245, 246)

- 7.2.2. For the purposes of demonstrating compliance with the minimum cartridge collection efficiency as given under 7.1.6.c, the permittee shall:

- a. Install, maintain, and operate the cartridge collectors consistent with safety and good air pollution control practices for minimizing emissions, and shall follow all manufacture's recommendations concerning control device maintenance and performance.
- b. Conduct a weekly visual inspection of the cartridge, cartridge connections, and dust hoppers of each cartridge collector, in order to ensure proper operation of cartridge collectors. Records shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any.
- c. Either conduct representative performance testing, pursuant to the performance testing procedures as outlined under 3.3.1. of this permit, on the cartridge collectors to determine a minimum collection efficiency or produce a vendor guarantee stating that the cartridge collectors (or associated filters) will meet a minimum collection efficiency of 95%.

[45CSR13, Permit No. R13-2068 (Condition 8.2.2.)]

- 7.2.3. For the purposes of demonstrating compliance with maximum dry material loading set forth in 7.1.6.a., the permittee shall monitor and record the total dry material per load for each coating pan. This requirement may be waived if the permittee is able to demonstrate that the maximum reasonable design capacity of each coating pan is equal or less than the maximum load given under 7.1.6.a. or if the permittee is able to demonstrate that the maximum loading based on product formulations is equal or less than the maximum load given under 7.1.6.a.

[45CSR13, Permit No. R13-2068 (Condition 8.2.3.)]

- 7.2.4. For the purposes of demonstrating compliance with maximum annual aggregate dry material loading set forth in 7.1.6.b., the permittee shall monitor and record the aggregate monthly and rolling twelve month total amount of dry material loaded into the coating pans.

[45CSR13, Permit No. R13-2068 (Condition 8.2.4.)]

- 7.2.5. For the purposes of demonstrating compliance with maximum annual VOC emission limit set forth in 7.1.5, the permittee shall:

- a. Monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in each coating pan with the exception of Coating Pans 244 and 245 and 246.
- b. Monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in Coating Pans 244 and 245 and 246 when each coating pan is and is not venting exhaust to the RTO for the purpose of controlling VOCs.
- c. Calculate and record the monthly and rolling twelve month aggregate VOC emissions from all coating pans by summing the following:
 - (1) The total amount of VOCs in pounds used in each coating pan with the exception of Coating Pans 244 and 245 and 246.
 - (2) The total amount of VOCs in pounds used in Coating Pans 244 and 245 when not venting exhaust to the RTO for the purpose of controlling VOCs.
 - (3) The total amount of VOCs used in Coating Pans 244 and 245 and 246 when venting exhaust to the RTO for the purpose of controlling VOCs. Based on compliance with Requirement 8.1.7 of this permit, the permittee may apply a VOC destruction efficiency of 98% to the amount of VOCs used in Coating Pans 244 and 245 and 246 when venting exhaust to the RTO for the purpose of controlling VOCs.

[45CSR13, Permit No. R13-2068 (Condition 8.2.5.)]

7.3. Testing Requirements

7.3.1. See Section 3.3.1.

7.4. Recordkeeping Requirements

7.4.1. Records of weekly inspections conducted on the cartridge collector shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each cartridge collector inspection, the inspection results, and corrective actions taken, if any.
[45CSR13, Permit No. R13-2068 (Condition 8.4.1.)]

7.4.2. The permittee shall maintain a record of all solvents used in the coating pans and keep a copy of the associated MSDS to verify that the solvents did not contain any constituent HAPs.
[45CSR13, Permit No. R13-2068 (Condition 8.4.2.)]

7.5. Reporting Requirements

7.5.1. See Section 3.5 Facility - Wide Reporting Requirements

7.6. Compliance Plan

7.6.1. None

APPLICATION FOR NSR PERMIT
AND
TITLE V PERMIT REVISION

Appendix 3

MYLAN PHARMACEUTICALS INC.
PLANT ID# 061-00033
MORGANTOWN, WEST VIRGINIA

Appendix 3 – PSD Applicability Review

R14 PSD Applicability Review

Mylan Pharmaceuticals Inc. (Mylan) is adding a new coating pan unit as part of this permit application. This coating pan is a stand-alone project and is being added due to current production demand and future forecasting. The following table outlines increases in Particulate Matter emissions based on the past 4 years of permit applications:

Permit Name	Application Date	Increase in PM	Description of Changes
R13-2068O	June 2011	0 tons	<ul style="list-style-type: none"> • Modifications to RTO, Absorber, and Fluid Bed maximum load information
R13-2068P	July 2013	-0.31 tons	<ul style="list-style-type: none"> • The addition of a cartridge collector to control particulate matter emissions from production rooms, • The replacement of an existing rotoclone with a new rotoclone, • The addition of a pilot coating line for research and development, • PM limit decrease for coating pans, • VOC limit decrease for fluid beds, and • The addition of a new oven dryer (replaces an existing oven dryer).
R13-2068Q	July 2014	0.43 tons	<ul style="list-style-type: none"> • The addition of a cartridge collector to control particulate matter emissions from production room general exhaust. This replaces existing HEPA filter units inside the room.
R13-2068R	Pending July 2015	0.17 tons	<ul style="list-style-type: none"> • The addition of a coating pan and associated dust collector to the facility.

Based on the small emissions increase of particulate matter, this permit application would not be a significant emissions increase or a significant net emissions increase per 45CSR14; therefore, 45CSR14 would not be applicable to this permit application.