

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

September 28, 2015

Joe Kessler, PE 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 Mr. Kessler:

Thank you for your time on September 23, 2015 to meet with Mylan EHS representatives and discuss the aforementioned Rule 13 application for modification. As requested during the meeting, Mylan hereby submits for your review and subsequent approval, revised pages to the "Modification Application for NSR Permit and Title V Permit Revision" that was submitted July 9, 2015 for the addition of a coating pan and associated dust collector to the facility. The modifications are being submitted to align the calculations for the new coating pan with previously permitted coating pans to maintain consistency within Mylan's Rule 13 and Title V permit.

Enclosed is the following revised information relating to said permit application modification:

- Attachment J Emission Points Data Summary Sheet
- Attachment N Supporting Emissions Calculations;
- Attachment S Title V Permit Revision Information;
- Appendix 2 Mylan Proposed Draft Permit Terms

Additionally, as discussed and agreed during the September 23 meeting, Mylan's coating pans are not regulated as a "Duplicate Source Operation" under 45CSR7 (Rule 7). Mylan's formulations and batch sizes are governed by the approvals of the United States Food and Drug Administration and other international health authorities. Additionally, the Morgantown facility manufactures hundreds of pharmaceutical products in batch operations. Based on these items, Mylan does not have the ability to utilize larger coating pans for processing larger batches in coating.

Therefore, maximum allowable emission rates from Table 45-7A should be applied to each coating pan as an individual source operation rather than as a duplicate source operation as currently reflected in Mylan's Title V permit emission limits.

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 Eric Hunsberger at the address provided by the letterhead, by telephoning (304) 554-7392 or by email at eric.hunsberger@mylan.com.

Sincerely,

Dale L. Stemple

Vice President, Global Environmental, Health and Safety

cc: Brian Tephabock, WV DEP Mylan Inc., Global EHS Eric Hunsberger Joe Losko



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

	VENDOR NAM				HECK DATE
		Dept of Environment			06/25/2015
RANSACTION NO.	DATE	INVOICE NO.	GROSS AMOUNT	DISC/WITHELD	NETAMOUNT
3200490473	06/18/2015	61815AIRPERMIT	1,000.00	0.00 / 0.00	1,000.00

On behalf of Mylan Pharmaceuticals Inc

TOTAL

********1,000.00

Mylan[®]
Seeing

is believing

MYLAN INC.

1000 MYLAN BOULEVARD

CANONSBURG, PA 15317-0000

CHECK DATE 06/25/2015

ORIGINAL CHECK IS PRINTED ON CHEMICAL REACTIVE PAPER WHICH CONTAINS A WATERMARK

PAY *EXACTLY *** ONE THOUSAND USD **

TO THE ORDER OF

West Virginia Dept of Environmental Protection-Division of Air Quality 601 57th Street CHARLESTON WV 25304-2943

62-20 311 CHECK NO.

527097
Citibank, N.A. One Penn's V
New Castle, DE 19720

.CHECK AMOUNT

VOID AFTER 180 DAYS



AUTHORIZED SIGNATURE

(ORIGINAL DOCUMENT)

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

PREPARED BY:

Mylan Pharmaceuticals Inc.

TABLE OF CONTENTS

\$1000 Application Fee (Modification)

<u>Appendix 1 – Application for Permit to Modify / Construct</u>

- 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

Appendix 1



WEST VIRGINIA DEPARTMENT OF **ENVIRONMENTAL PROTECTION**

DIVISION OF AIR QUALITY

601 57th Street, SE

APPLICATION FOR NSR PERMIT AND

Charleston, V (304) 926 www.dep.wy	TI		RMIT REVISIO TIONAL)	ON	
PLEASE CHECK ALL THAT APPLY TO NSR		PLEASE CHECK	TYPE OF 45C	SR30 (TITLE V) RE	VISION (IF ANY):
	☐ RELOCATION ☐ TEMPORARY	☐ ADMINISTRATE			MODIFICATION
CLASS II ADMINISTRATIVE UPDATE	AFTER-THE-FACT	IF ANY BOX ABO INFORMATION A	VE IS CHECKE S ATTACHMEN	D, INCLUDE TITLE \ IT S TO THIS APPLI	/ REVISION CATION
FOR TITLE V FACILITIES ONLY: Pleas (Appendix A, "Title V Permit Revision	e refer to "Title V Revis Flowchart") and ability	ion Guidance" in or to operate with the	der to determin changes reque	e your Title V Revis sted in this Permit A	ion options Application.
	Section	I. General			
Name of applicant (as registered with Mylan Pharmaceuticals Inc.	the WV Secretary of S	State's Office):	2. Federal E	Employer ID No. <i>(Fl</i> 5 5 0 4 5 5 4 2 3	•
3. Name of facility (if different from above	/e):		4. The applica	ant is the:	
4. Chestnut Ridge Facility			OWNER	OPERATOR	⊠ вотн
5A. Applicant's mailing address:		5B. Facility's prese	ent physical ad	ldress:	
P.O. Box 4310 Morgantown, WV 26504-4310		781 Chestnut Ridge Morgantown, WV 26			
 6. West Virginia Business Registration. If YES, provide a copy of the Certification change amendments or other Busine. If NO, provide a copy of the Certification amendments or other Business Certification. 	ate of Incorporation/ ss Registration Certific te of Authority/Autho	Organization/Limi cate as Attachmen prity of L.L.C./Req	ted Partnersh t A.	ip (one page) inclu	
7. If applicant is a subsidiary corporation,	please provide the na	me of parent corpo	ration: Mylan	Inc.	
8. Does the applicant own, lease, have ar	n option to buy or othe	rwise have control	of the <i>propose</i>	ed site? XYES	□NO
- If YES, please explain: Applica	nt owns the site.				
If NO, you are not eligible for a permi	it for this source.				
 Type of plant or facility (stationary sou administratively updated or tempor crusher, etc.): 	urce) to be constructe rarily permitted (e.g.,	ed, modified, reloc coal preparation pl	ated, ant, primary	10. North America Classification (NAICS) code	
Pharmaceutical Manufacturing Facility				325412	
11A. DAQ Plant ID No. (for existing faciliti 0 6 1 - 0 0 0 3 3	R13-2	List all current 45CS associated with this 068Q, issued Septe 6100033-2012 MM	process (for e ember 29, 201	existing facilities on	nit numbers ly):
All of the required forms and additional info	ormation can be found u	under the Permitting	Section of DA	O's website, or requ	ested by phone

12A.		
 For Modifications, Administrative Updates or Te present location of the facility from the nearest state 	mporary permits at an existing facility, e road;	please provide directions to the
 For Construction or Relocation permits, please proad. Include a MAP as Attachment B. 	provide directions to the proposed new s	site location from the nearest state
I-79 to exit 155 follow signs for W.V.U. Follow US Turn right to stay on SR 705 (Chestnut Ridge Road	Route 19 to Coliseum. Turn left onto Sd). Follow for approximately 0.6 miles to	R 705 for approximately 1.2 miles. plant on left.
12.B. New site address (if applicable):	12C. Nearest city or town:	12D. County:
N/A	Morgantown	Monongalia
12.E. UTM Northing (KM): 4390.1	12F. UTM Easting (KM): 589.6	12G. UTM Zone: 17
13. Briefly describe the proposed change(s) at the facilit Mylan proposes to add a new coating pan unit due installed to control particulate emissions. The coating control of solvent emissions.	to increases in production demand. Anng pan will tie into the existing regenera	associated dust collector will be tive thermal oxidizer at the site for
 14A. Provide the date of anticipated installation or change If this is an After-The-Fact permit application, provious change did happen: / / 		14B. Date of anticipated Start-Up if a permit is granted: 11/1/2015
14C. Provide a Schedule of the planned Installation of/ application as Attachment C (if more than one unit	Change to and Start-Up of each of the is involved).	units proposed in this permit
 Provide maximum projected Operating Schedule of Hours Per Day 24 Days Per Week 7 Weeks P 		ation:
16. Is demolition or physical renovation at an existing fac-	cility involved? XYES NO	
17. Risk Management Plans. If this facility is subject to	112(r) of the 1990 CAAA, or will become	e subject due to proposed
changes (for applicability help see www.epa.gov/cepp	o), submit your Risk Management Pla	n (RMP) to U. S. EPA Region III.
18. Regulatory Discussion. List all Federal and State a	ir pollution control regulations that you l	believe are applicable to the
proposed process (if known). A list of possible applica	ble requirements is also included in Atta	achment S of this application
(Title V Permit Revision Information). Discuss applical	oility and proposed demonstration(s) of	compliance (if known). Provide this
information as Attachment D.		
Section II. Additional atta	achments and supporting d	ocuments.
 Include a check payable to WVDEP – Division of Air 45CSR13). 	Quality with the appropriate application	fee (per 45CSR22 and
20. Include a Table of Contents as the first page of you	r application package.	
21. Provide a Plot Plan , e.g. scaled map(s) and/or sketc source(s) is or is to be located as Attachment E (Re	th(es) showing the location of the prope	rty on which the stationary
 Indicate the location of the nearest occupied structure 	(e.g. church, school, business, residen	ce)
 Provide a Detailed Process Flow Diagram(s) show device as Attachment F. 	ing each proposed or modified emission	ns unit, emission point and control
23. Provide a Process Description as Attachment G.		
 Also describe and quantify to the extent possible a 	all changes made to the facility since the	e last permit review (if applicable).
All of the required forms and additional information can be	found under the Permitting Section of DA	Q's website, or requested by phone.

[a, p,,,		
24. Provide Material Safety Data Sheets		
 For chemical processes, provide a MSD 		the air.
25. Fill out the Emission Units Table and		
26. Fill out the Emission Points Data Sur		
27. Fill out the Fugitive Emissions Data S	Summary Sheet and provide it a	s Attachment K.
28. Check all applicable Emissions Unit [Data Sheets listed below:	
Bulk Liquid Transfer Operations	☐ Haul Road Emissions	Quarry
☐ Chemical Processes	☐ Hot Mix Asphalt Plant	☐ Solid Materials Sizing, Handling and Storage
☐ Concrete Batch Plant	☐ Incinerator	Facilities
☐ Grey Iron and Steel Foundry	☐ Indirect Heat Exchanger	☐ Storage Tanks
General Emission Unit, specify: Coating	g Pan	
Fill out and provide the Emissions Unit Da	ta Sheet(s) as Attachment L.	
29. Check all applicable Air Pollution Cor	trol Device Sheets listed below	:
☐ Absorption Systems	Baghouse (Cartridge co	ollector)
☐ Adsorption Systems	☐ Condenser	☐ Mechanical Collector
Afterburner	☐ Electrostatic Precipitato	r ☐ Wet Collecting System
Other Collectors, specify:		
Fill out and provide the Air Pollution Conti	ol Device Sheet(s) as Attachm	ent M.
 Provide all Supporting Emissions Ca Items 28 through 31. 	Iculations as Attachment N, or	attach the calculations directly to the forms listed in
31. Monitoring, Recordkeeping, Reporti testing plans in order to demonstrate c application. Provide this information as	ompliance with the proposed em	roposed monitoring, recordkeeping, reporting and issions limits and operating parameters in this permit on is included in Attachment M.
Please be aware that all permits must i measures. Additionally, the DAQ may are proposed by the applicant, DAQ wi	not be able to accept all measure	er or not the applicant chooses to propose such es proposed by the applicant. If none of these plans e them in the permit.
32. Public Notice. At the time that the ap	plication is submitted, place a CI	ass I Legal Advertisement in a newspaper of general
circulation in the area where the source	e is or will be located (See 45CS)	R§13-8.3 through 45CSR§13-8.5 and Example Legal
		as Attachment P immediately upon receipt.
33. Business Confidentiality Claims. Do	es this application include confid	lential information (per 45CSR31)?
☐ YES	⊠ NO	
segment claimed confidential, including Notice – Claims of Confidentiality" g	the criteria under 45CSR§31-4. uidance found in the <i>General In</i>	
Sec	tion III. Certification of	Information
34. Authority/Delegation of Authority. C Check applicable Authority Form belo	only required when someone others:	er than the responsible official signs the application.
☐ Authority of Corporation or Other Busine	ss Entity	uthority of Partnership
☐ Authority of Governmental Agency	□ A	uthority of Limited Partnership
Submit completed and signed Authority Fo		
		rmitting Section of DAQ's website, or requested by phone.

35A. Certification of Information. To certify 2.28) or Authorized Representative shall chec	this permit application, a Responsible Off k the appropriate box and sign below.	icial (per 45CSR§13-2.22 and 45CSR§30-
Certification of Truth, Accuracy, and Comp	eleteness	
I, the undersigned Responsible Official / application and any supporting documents appreasonable inquiry I further agree to assume restationary source described herein in accordal Environmental Protection, Division of Air Quali and regulations of the West Virginia Division of business or agency changes its Responsible Contified in writing within 30 days of the official control of the control	pended hereto, is true, accurate, and compesponsibility for the construction, modificating with this application and any amendmentity permit issued in accordance with this application and with this application of 22-5-1 et sofficial or Authorized Representative, the Difficial or Authorized Representative, the Difficial or Authorized Representative.	plete based on information and belief after ion and/or relocation and operation of the ents thereto, as well as the Department of oplication, along with all applicable rules leg. (State Air Pollution Control Act) If the
Compliance Certification		
Except for requirements identified in the Title that, based on information and belief formed a compliance with all applicable requirements	/ Application for which compliance is not a fter reasonable inquiry, all air contaminant	sources identified in this application are in
SIGNATURE Se on C. 1		DATE: 8 JULY 2015
	use blue ink)	(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	36E. Phone: 304-599-2595	36F. FAX: 304-598-5471
36A. Printed name of contact person (if differe	nt 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 ATTACHMEN	ITS INCLUDED WITH THIS PERMIT APPLICAT	TION:
Attachment A: Business Certificate Attachment B: Map(s) Attachment C: Installation and Start Up Sche Attachment D: Regulatory Discussion Attachment E: Plot Plan Attachment F: Detailed Process Flow Diagrar Attachment G: Process Description Attachment H: Material Safety Data Sheets (N Attachment I: Emission Units Table Attachment J: Emission Points Data Summar Please mail an original and three (3) copies of the	Attachment L: Emission Attachment M: Air Pollu Attachment N: Supporti Attachment O: Monitoriu Attachment P: Public No Attachment Q: Business Attachment R: Authority Attachment S: Title V Poly Y Sheet Application Fee	tion Control Device Sheet(s) ng Emissions Calculations ng/Recordkeeping/Reporting/Testing Plans otice s Confidential Claims r Forms ermit Revision Information
address listed on the first	t page of this application. Please DO NOT fa	x permit applications.
FOR AGENCY USE ONLY — IF THIS IS A TITLE V Forward 1 copy of the application to the Title For Title V Administrative Amendments: NSR permit writer should notify Title V For Title V Minor Modifications: Title V permit writer should send application NSR permit writer should notify Title V For Title V Significant Modifications processes NSR permit writer should notify a Title Public notice should reference both 4 EPA has 45 day review period of a dra	e V Permitting Group and: V permit writer of draft permit, ropriate notification to EPA and affected stat V permit writer of draft permit. ed in parallel with NSR Permit revision: e V permit writer of draft permit, 5CSR13 and Title V permits,	es within 5 days of receipt,
All of the required forms and additional informat	ion can be found under the Permitting Secti	on of DAO's website, or requested by above

Attachment A

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.

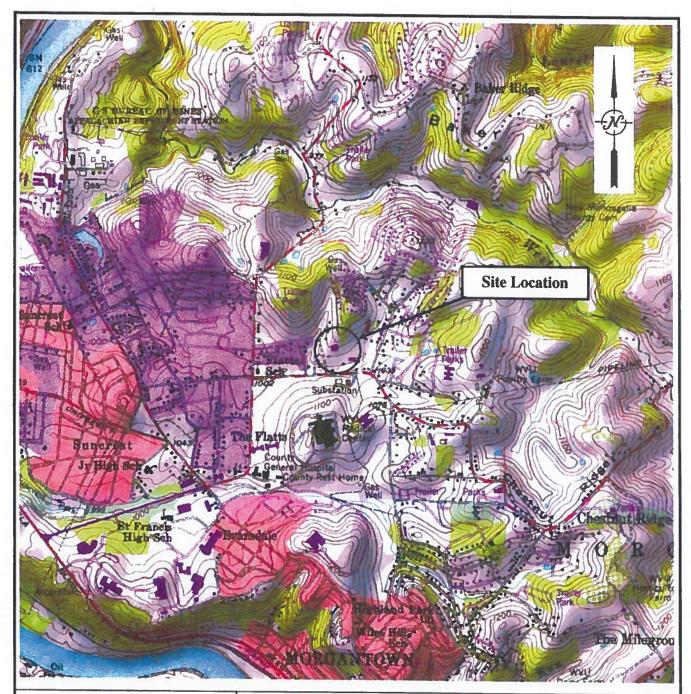
This certificate shall be permanent until cessation of the business for which the certificate of registration was granted or until it is suspended, revoked or cancelled by the Tax Commissioner.

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.

atL006 v.1 L2137111296

Attachment B



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

Attachment C

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

Attachment D

ATTACHMENT D - REGULATORY DISCUSSION

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

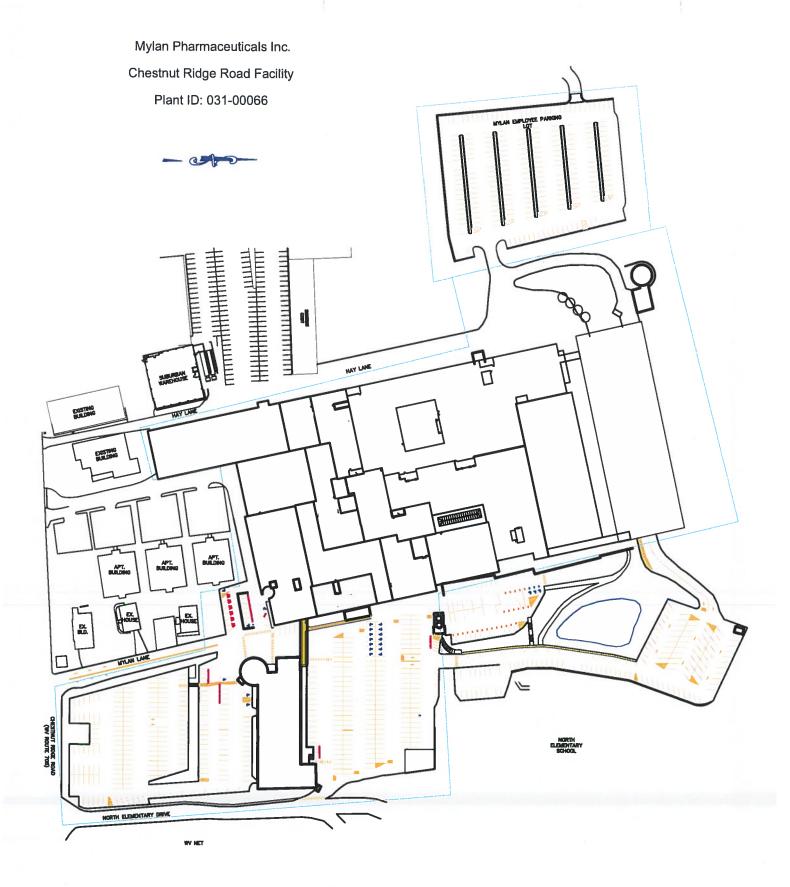
	Emission Source		
Regulatory Citation	Affected	Description of Applicability	Compliance Demonstration
45CSR7-3.1	Cartridge Collector:	20% max. opacity from all PM-	Quarterly visual observation and recordkeeping of
	DC246	emitting vent points other than the	visual observations.
		boilers vent points.	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

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	e Air Quality Requireme	ints	
	Emission Sources		
	Presumed to be Non-		
Regulatory Citation	Applicable	Basis of Non-Applicability	
7EC8937	All Sources in the	The proposed modification will not discharge any toxic air pollutant (as defined at	
45C3KZ/	proposed modification.	45CSR27-2.10.) into the open air in excess of the amounts shown in Table A of 45CSR27.	
ACCEDE1 All Cochagan	All Sources in the	Mylan does not believe that any 40CFR61 NESHAPS regulations apply to the proposed	
40CFR01 - All Subpairs	proposed modification.	modification.	
ACCEDES All Contracts	All Sources in the	Mylan does not believe that any 40CFR63 MACT regulations apply to the proposed	
40Crn83 – All subpairs	proposed modification.	modification.	
AECSB14	All Sources in the	The proposed modification is not a "significant modification" as defined in 45CSR14. A	
40C2NI4	proposed modification.	more detailed discussion on this topic is attached in Appendix 3.	

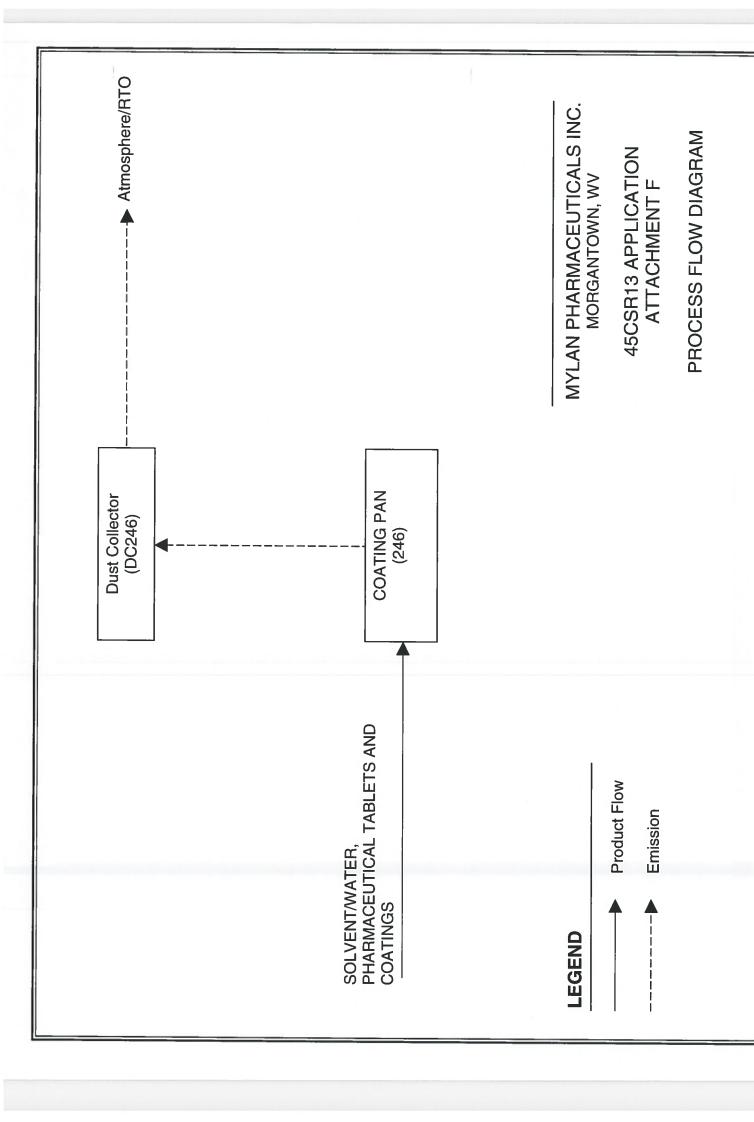
Attachment E

Attachment E - Plot Plan



DRAWING CREATED DN 08/26/2009

Attachment F



Attachment G

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.

Attachment I

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 ID ¹	Emission Point ID ²	Emission Unit Description	Year Installed/ Modified	Design Capacity	Type ³ and Date of Change	Control Device ⁴
246	246	Coating Pan	2015	750 lb/load maximum	New	Cartridge Dust Collector DC246

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 <u>C</u>ontrol Devices use the following numbering system: 1C, 2C, 3C,... or other appropriate designation.

Attachment J

Attachment J EMISSION POINTS DATA SUMMARY SHEET

Emission Concentration ⁷ (ppmv or mg/m ⁴)		N/A	N/A	
Est. Method Used ⁶		MB	MB	
Emission Form or Phase (At exit conditions,	sona, Liquid or Gas/Vapor)	Solid; Particulate	Gas	
num Potential led Emissions ⁵	ton/yr	6.25 is current limit in R13-2068Q and Title V for Emission Units 215, 241, 242, 244 and 245 (246 to be included)	5.0 tons/yr is current Coating Pan limit in R13- 2068Q and Title V	
Maxim	lb/hr	0.84	7.94	
n Potential ed Emissions	ton/yr	41.78	5.0 tons/yr is current Coating Pan limit in R13-2068Q and Title V	
Maximun Uncontrolle	lb/hr	16.88	396.9	
All Regulated Pollutants - Chemical Name/CAS ³	(Speciate VOCs & HAPS)	ρM	VOCs	
Time nission nit mical esses	Max (hr/yr)	N/A	N/A	
Vent for En Ul (cher proc	Short Term²	N/A	N/A	
ion Control evice t match its Table & Plot lan)	Device Type	Cartridge Dust Collector	Regenerative Thermal Oxidizer (RTO)	
Air Pollut De (Mus Emission Un	ID No.	DC246	RTO 10008085	
nit Vented This Point <i>imission Units</i> Yot Plan)	Source	Coating Pan 246		
Emission U Through 1 (Must match E Table & F	ID No.			
Emission Point Type ¹		Upward vertical stack/Tee 2 Damper to RTO		
Emission Point ID No. (Must match Emission Units Table	8	UJ ve st St R1		
	Emission Duit Vented Air Pollution Control Form Control Form Potential Maximum Potential Form or Method Form Point Through This Point Device Form On Type¹ (Must match Emission Units Table & Plot Plan) Fulsion Units Table & Plan	Emission Emission Unit Vented Air Pollution Control Formation Pollution Control Formation Formation	ission Emission Emission Emission Like Coating Pan Coating Pan	

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 rugitive emissions, plus all other emissions (e.g. uncaptured emissions). Please complete the FUGITIVE EMISSIONS DATA SUMMARY SHEET for fugitive emission activities.

 $^{^{}m 1}$ Please add descriptors such as upward vertical stack, downward vertical stack, horizontal stack, relief vent, rain cap, etc.

² 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).

³ 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, SO₃, all applicable Greenhouse Gases (including CO₂ and methane), etc. **DO NOT LIST** H₂, H₂O, N₂, O₂, and Noble Gases.

⁴ 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).

⁵ 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).

⁶ 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).

⁷ 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

	; (km)	Easting	Approx: Zone 17; 589.3285978 954759 (Long - 79.958659)	
	UTM Coordinates (km)	Northing	Approx: Zone 17; 4390.5540971422 5; 205 (Lat 39.660129)	
	vation (ft)	Stack Height ² (Release height of emissions above ground level)	~30 ft	
r Data	Emission Point Elevation (ft)	Ground Level (Height above mean sea level)	~1000	
Table 2: Release Parameter Data		Velocity (fps)	N/A	
Table 2: Rel	Exit Gas	Volumetric Flow ¹ (acfm) at operating conditions	4000 CFM	
		Temp. (°F)	45°C - 80°C	
	Inner Diameter (ft.)		N/A	
	Emission Point ID No. (Must match Emission Units Table)		246	

¹Give at operating conditions. Include inerts.
² Release height of emissions above ground level.

Attachment L

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

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.
 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 750 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 750 pounds per hour in Coating Pan 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 six pollution as a traditional state.

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

6.	Со	mbustion Da	ta (if applic	able):			
	(a)	Type and ar	nount in ap	propriate units of	fuel(s) to be bu	rned:	
N	ot A	pplicable					
	/h\	Chaminal au					
	(n)	and ash:	iaiysis oi pr	oposea iuei(s), e	xcluding coal, ir	iciuding maxim	um percent sulfur
N.I	4						
IN	ot A	pplicable					
	(c)	Theoretical	combustion	air requirement	(ACF/unit of fue	·l):	
		N/A	@		°F and		psia.
							'
	(d)	Percent exc	ess air: N	I/A			
	(e)	Type and B	ΓU/hr of bu	rners and all othe	er firing equipme	ent planned to b	pe used:
N	ot Δι	pplicable					
1 1	J. 7.1	pplicable					
	(f)	If coal is pro coal as it wil		source of fuel, ic	dentify supplier a	and seams and	give sizing of the
		coai as it wii	i be illea.				
Not Applicable							
	/a\	Droposed			NI - 1 A		106 DTII/
		***************************************		sign heat input:	ілот Ар	plicable	× 10 ⁶ BTU/hr.
7.	Pro	jected opera	ting schedu	ıle:		{	
Ηοι	urs/	Day	18	Days/Week	5.5	Weeks/Year	50

8.	8. Projected amount of pollutants that would be emitted from this affected source if no control devices were used:					
@	Varies	°F and	t	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.	со	N/A	lb/hr	N/A	grains/ACF	
d.	PM ₁₀	16.88	lb/hr	n/a	grains/ACF	
e.	Hydrocarbons	N/A	lb/hr	N/A	grains/ACF	
f.	VOCs	396.9	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.

 Proposed Monitoring, Recordkeeping, Report Please propose monitoring, recordkeeping, a with the proposed operating parameters. It compliance with the proposed emissions lim MONITORING Quarterly visible emission observations (conducted on external cartridge collector) 	and reporting in order to demonstrate compliance Please propose testing in order to demonstrate
REPORTING N/A	TESTING N/A
RECORDKEEPING. TESTING. PLEASE DESCRIBE ANY PROPOSED EMISPOLLUTION CONTROL DEVICE. 10. Describe all operating ranges and mainter	STRATE COMPLIANCE WITH THE OPERATION OF THIS CONTROL DEVICE. POSED RECORDKEEPING THAT WILL ACCOMPANY THE OPOSED FREQUENCY OF REPORTING OF THE SSIONS TESTING FOR THIS PROCESS EQUIPMENT/AIR
maintain warranty Not applicable	

Attachment M

Attachment M Air Pollution Control Device Sheet

(BAGHOUSE)

Control Device ID No. (must match Emission Units Table): DC246

Equipment Information and Filter Characteristics

1.	Manufacturer: Torit	Total number of compartments: 1					
	Model No. DFO 3-12 Note: These collectors are cartridge style collectors	Number of compartment online for norr operation: 1yes	mal				
4.	Provide diagram(s) of unit describing capture system with duct arrangement and size of duct, air volume, capacity, horsepower of movers. If applicable, state hood face velocity and hood collection efficiency.						
5.	Baghouse Configuration:						
6.	Filter Fabric Bag Material: Nomex nylon Wool Polyester Polypropylene Acrylics Ceramics Fiber Glass	7. Bag Dimension: Diameter n/a in. Length n/a ft. 8. Total cloth area: 1068 ft²					
	☐ Cotton Weight oz./sq.yd ☐ Teflon Thickness in	Number of bags: 12 cartridges					
	☐ Others, specify Ultra-Web	10. Operating air to cloth ratio: n/a ft/mir	า				
11.	Baghouse Operation: Continuous	☐ Automatic ☐ Intermittent					
12. Method used to clean bags: Mechanical Shaker Sonic Cleaning Reverse Air Jet Pneumatic Shaker Reverse Air Flow Other: Bag Collapse Pulse Jet Manual Cleaning Reverse Jet							
13. Cleaning initiated by: ☐ Timer ☐ Expected pressure drop range in. of water ☐ Other							
14.	Operation Hours: Max. per day: 24 Max. per yr: 8736	, 9	% %				
Gas Stream Characteristics							
16.	Gas flow rate into the collector: 4,000 ACFM ACFM: Design: PSIA Maximum:	1 at 70-100 °F and PSIA PSIA Average Expected: PSIA					
17. Water Vapor Content of Effluent Stream: lb. Water/lb. Dry Air							
18.	Gas Stream Temperature: 70-100 °F	19. Fan Requirements: 10 hp OR ft³/mi	in				
20.	Stabilized static pressure loss across baghouse. Pre		₂ O				
21.	Particulate Loading: Inlet: Varies	grain/scf Outlet: varies grain/scf					

22. Type of Pollutant(s) to be collected Particulate from pharmaceu	` •	• •	• • •			
23. Is there any SO ₃ in the emission s	stream?	No □\	es SC)₃ cont	ent:	ppmv
24. Emission rate of pollutant (specify				_		
, , , ,	,	Ì	N	Ū	_	UT
Pollutant		lb/hr	grains/	acf	lb/hr	grains/acf
PM		16.88	_		0.84	-
25. Complete the table:	Particle S	Size Distribution to Collector		Fra	ction Efficienc	y of Collector
Particulate Size Range (microns)	Weigl	ht % for Size R	ange		Weight % for S	
0 – 2	Va	ries by produ	ct		Varies by p	product
2 – 4	Va	ries by produ	ct		Varies by p	product
4 – 6	Va	ries by produ	ct		Varies by p	product
6 – 8		ries by produ			Varies by p	product
8 – 10		ries by produ			Varies by p	
10 – 12		ries by produ			Varies by p	
12 – 16		ries by produ			Varies by p	
16 – 20	Va	ries by produ	ct		Varies by p	product
20 – 30	Va	ries by produ	ct		Varies by p	product
30 – 40	Va	ries by produ	ct		Varies by p	product
40 – 50	Va	ries by produ	ct		Varies by p	product
50 – 60	Va	ries by produ	ct		Varies by p	product
60 – 70	Va	ries by produ	ct		Varies by p	product
70 – 80		ries by produ			Varies by p	
80 – 90	Va	ries by produ	ct		Varies by p	product
90 – 100	Va	ries by produ	ct		Varies by p	product
>100	Va	ries by produ	ct		Varies by p	roduct

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
20	Describe any filter acading being performed
20.	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
	Notice
20	
30.	Describe the collection material disposal system:
30.	
30.	Describe the collection material disposal system:
30.	Describe the collection material disposal system:
30.	Describe the collection material disposal system:
30.	Describe the collection material disposal system:
30.	Describe the collection material disposal system:
30.	Describe the collection material disposal system:
30.	Describe the collection material disposal system:
30.	Describe the collection material disposal system:
30.	Describe the collection material disposal system:
	Describe the collection material disposal system: Material is collected in drums and incinerated off site.
	Describe the collection material disposal system:

Please propose m proposed operating proposed emissions MONITORING:	g parameters. Please propose s limits.	and Testing eporting in order to demonstrate compliance with the testing in order to demonstrate compliance with the RECORDKEEPING: Maintain records of visual emission observations.
Quarterly visual emis	sion observations.	ivialntain records of visual emission observations.
REPORTING: None		TESTING: None
MONITORING: RECORDKEEPING:	monitored in order to demons equipment or air control device.	ocess parameters and ranges that are proposed to be strate compliance with the operation of this process cordkeeping that will accompany the monitoring.
REPORTING: TESTING:	pollution control device.	emissions testing for this process equipment on air emissions testing for this process equipment on air
100%	aranteed Capture Efficiency for ea	
99.9%	aranteed Control Efficiency for eac	
·	ng ranges and maintenance proce	edures 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)

Process/Equipment Affected: New Coating Pan 246 w/associated Dust Collector Reason for Application: New Coating Pan

ate Hours Annual Rate (ton/yr)	6.25 all coating pans	Total VOC limit for all applicable Coating	Pans is currently permitted at 5 tons/yr		
Hourly Rate with Control Device (Ib/hr)	0.84	N/A	7.94		
Hourly Rate without Control Device (Ib/hr)	16.88	396.9	396.9		
Emission Estimate Basis [2]	ЯW	MB	ЯW		
нар?	z	z	z		
Pollutant	Total PM	OOV	20/		
Control System Efficiency (%)	96	N/A	%86		
Control System ID No.	DC - 246	N/A	RTO 10008085		
Control System	Dust Collector	None; VOCs emitted to atmosphere	RTO for VOC Destruction		
Type of Release [1]	Ь	Ь	А		
	246	246	246		
Design Capacity	750 lb/hr dry raw materials	3000 g/min spray rate	3000 g/min spray rate		
Emission Unit Description	Coating Pan - Particulate Matter	Coating Pan - VOC emissions from processing with non-HAP solvents	Coating Pan - VOC emissions from processing with non-HAP solvents		
ID No.	246 F				

BASIS FOR EMISSION ESTIMATES:

1. PARTICULATE MATTER

- a. Maximum dry raw material load to coating pans is 310 kg/hr (682 lb/hr) per manufacturer's specifications.
 - An estimated 1.5% of dry material is lost from the coating pan due to tablet breakage and overspray.
 - Estimated upset factor: 1.5
- Maximum coating pan load is 750 lb.
- Material Loss = 750 lb/hr * 1.5% * 1.5 = 16.88 lb/hr
- Dust collector removes approximately 95% of total PM

2. VOLATILE ORGANIC COMPOUNDS (VOC) a. Assume 100% of VOC (IPA/Ethanol) added to

- 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 3000 g/min (3 kg/min) (spray application is not 100% VOC, but is assumed here for maximum emission estimates)

 Production maximum VOC emitted = 3 kg/min * 60 min/hr * 2.205 lb/kg = 396.9 lb/hr
- Uncontrolled Hourly limit = 396.9 lb/hr

VOC Emissions Controlled by RTO

- e. RTO control efficiency: 98% (per Permit R13-2068Q) f. RTO Controlled Hourly Limit = 396.9 lb/hr * (1-0.98) = 7.94 lb/hr

Overall Coating Pan Annual VOC Emissions

g. 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:					
☐ SIP	☐ FIP				
Minor source NSR (45CSR13)	☐ PSD (45CSR14)				
☐ NESHAP (45CSR15)	☐ Nonattainment NSR (45CSR19)				
Section 111 NSPS (Subpart(s))	Section 112(d) MACT standards (Subpart(s))				
Section 112(g) Case-by-case MACT	☐ 112(r) RMP				
Section 112(i) Early reduction of HAP	Consumer/commercial prod. reqts., section 183(e)				
Section 129 Standards/Reqts.	Stratospheric ozone (Title VI)				
☐ Tank vessel reqt., section 183(f)	☐ Emissions cap 45CSR§30-2.6.1				
☐ NAAQS, increments or visibility (temp. sources)	☐ 45CSR27 State enforceable only rule				
☐ 45CSR4 State enforceable only rule	☐ Acid Rain (Title IV, 45CSR33)				
☐ Emissions Trading and Banking (45CSR28)	Compliance Assurance Monitoring (40CFR64) (1)				
☐ NO _x Budget Trading Program Non-EGUs (45CSR1)	☐ NO _x Budget Trading Program EGUs (45CSR26)				
(1) If this box is checked, please include Compliance Assur Specific Emission Unit (PSEU) (See Attachment H to Title explain why Compliance Assurance Monitoring is not approximately approximately assurance in the compliance of the compliance	V Application). If this box is not checked, please				
Per 40 CFR 64.5, this application is not part of an initia not part of a significant Title V permit revision (40 CFR required until the renewal of Mylan's Title V permit as a renewal will be submitted by July 10, 2016 to comply w	64.5(a)(2)); therefore, CAM plan submittal is not stated in 40 CFR 64.5(a)(3). Mylan's Title V permit				
2. Non Applicability Determinations					
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. The regulatory discussion outlining non-applicable air quality requirements are contained in Attachment D of this permit application.					
Permit Shield Requested (not applicable to Mino	r Modifications)				
All of the required forms and additional information can be found und	er the Permitting Section of DAQ's website, or requested by phone.				
3. Suggested Title V Draft Permit Language					

Also, please provide Suggested T (including all applicable requirem /recordkeeping/ reporting requiren	ents associated w nents), OR attach nit or Consent Oro	mit langua ith the per a marked der number	age for the proposed Title V Permit revision rmit revision and any associated monitoring up pages of current Title V Permit. Please r, condition number and/or rule citation (e.g.	
4. Active NSR Permits/Permit Deter	minations/Conse	nt Orders	Associated With This Permit Revision	
Permit or Consent Order Number	Date of Issu	iance	Permit/Consent Order Condition Number	
R13-2068Q	09/29/2014			
R30-06100033-2012 MM03	12/02/2014			
	/ /			
		^ · · · · ·		
5. Inactive NSR Permits/Obsolete Pe			onditions Associated With This Revision	
Permit or Consent Order Number	Date of Issua	ance	Permit/Consent Order Condition Number	
	MM/DD/YYYY			
	/ /			
	/ /			
6. Change in Potential Emissions				
		CI	TDV	
Pollutant			ange in Potential Emissions (+ or -), TPY	
PM		+0.0 tpy (new coating pan will operate under existing 6.25 ton PM limit for all coating pans)		
VOCs		+0.0 tpy (new coating pan will operate under existing 5.0 ton VOC limit for all coating pans)		
All of the required forms and additional inform	nation can be found u	nder the Peri	nitting Section of DAQ's website, or requested by phone.	

Are there any changes involved with this Title V Permit revision outside of the scope of the NSR Permit

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;									
proc perm proc the S oper	withstanding subparagraph 45CSR§30-6.5.a.1.A. (items i through vi above), minor permit modification edures may be used for permit modifications involving the use of economic incentives, marketable nits, emissions trading, and other similar approaches, to the extent that such minor permit modification edures are explicitly provided for in rules of the Director which are approved by the U.S. EPA as a part of state Implementation Plan under the Clean Air Act, or which may be otherwise provided for in the Title V ating permit issued under 45CSR30. Suant to 45CSR§30-6.5.a.2.C., the proposed modification contained herein meets the criteria for use linor permit modification procedures as set forth in Section 45CSR§30-6.5.a.1.A. The use of Minor mit modification procedures are hereby requested for processing of this application.									
(Signed)	1 / 28 / 18									
Named	Named (typed): Dale L. Stemple Dale L. Stemple (Please use blue ink) Title: Vice President, Global Environmental, Health and Safety									
Note: P	lease check if the following included (if applicable):									
	Compliance Assurance Monitoring Form(s)									
\boxtimes	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

West Virginia Department of Environmental Protection

Earl Ray Tomblin Governor

Division of Air Quality

Randy C. Huffman Cabinet Secretary

Permit for Modification



R13-2068R

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: DRAFT

Permit R13-2068R Page 1 of 37

This permit will supersede and replace Permit R13-2068Q issued on September 29, 2014.

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: Installation of a new coating pan (246) and an associated cartridge collector (CC246).

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.

Table of Contents

1.0.	Emission Ur	nits	4
2.0.	General Co	nditions	9
	2.1.	Definitions	
	2.2.	Acronyms	9
	2.3.	Authority	10
	2.4.	Term and Renewal	10
	2.5.	Duty to Comply	
	2.6.	Duty to Provide Information.	
	2.7.	Duty to Supplement and Correct Information.	
	2.8.	Administrative Permit Update	
		1	
	2.9.	Permit Modification	
	2.10	Major Permit Modification	
	2.11.	Inspection and Entry	11
	2.12.	Emergency	
	2.13.	Need to Halt or Reduce Activity Not a Defense	12
	2.14.	Suspension of Activities	12
	2.15.	Property Rights	
	2.16.	Severability	
	2.17.		
	_,,,,	Transferability	
	2.18.	Notification Requirements	
	2.19.	Credible Evidence	13
3.0.	Facility-Wid	le Requirements	14
	3.1.	Limitations and Standards	14
	3.2.	Monitoring Requirements	14
	3.3.	Testing Requirements	
	3.4.	Recordkeeping Requirements	
	3.5.	Reporting Requirements	
	3.3.	Reporting Requirements	10
4.0.		ific Requirements (All Emission Units)	
	4.1.	Limitations and Standards	
	4.2.	Recordkeeping Requirements	18
5.0.	Source-Speci	ific Requirements (Boilers)	19
	5.1.	Limitations and Standards	
	5.2.	Monitoring Requirements.	
	5.3.	· · · · · · · · · · · · · · · · · · ·	
		Testing Requirements	
	5.4.	Recordkeeping Requirements	
	5.5.	Reporting Requirements	21
6.0.	Source-Speci	ific Requirements (Fluid Beds)	
	6.1.	Limitations and Standards	22
	6.2.	Monitoring Requirements	
	6.3.	Testing Requirements	
	6.4.	Recordkeeping Requirements.	
		1 & 1	
	6.5.	Reporting Requirements	23
7.0.		ific Requirements (Production Rooms)	
	7.1.	Limitations and Standards	
	7.2.	Monitoring Requirements	26
	7.3.	Testing Requirements	26
	7.4.	Recordkeeping Requirements	26
	7.5.	Reporting Requirements	
8.0.	Source Charles	rific Requirements (Cooting Pons)	27
0.0.	8.1.	ific Requirements (Coating Pans) Limitations and Standards	
	8.2.	Monitoring Requirements	
	8.3.	Testing Requirements	
	8.4.	Recordkeeping Requirements	29
	8.5.	Reporting Requirements	30
9.0.	Source Speci	rific Requirements (RTA)	20
9.0.	•	ific Requirements (RTO)	
	9.1.	Limitations and Standards	
	9.2.	Monitoring Requirements	
	9.3.	Testing Requirements	
	9.4.	Recordkeeping Requirements	33
	9.5.	Reporting Requirements	33

10.0.	Source-Spec	ific Requirements (Oven Dryers)	
	10.1.	Limitations and Standards	
	10.2.	Monitoring Requirements	
	10.3.	Testing Requirements	
	10.4.	Recordkeeping Requirements	
	10.5.	Reporting Requirements	
11.0.	Source-Spec	ific Requirements (Absorber)	34
	11.1.	Limitations and Standards	
	11.2.	Monitoring Requirements	
	11.3.	Testing Requirements	
	11.4.	Recordkeeping Requirements	
	11.5.	Reporting Requirements	35
12.0.	Source-Spec	ific Requirements (Coating Line)	35
	12.1.	Limitations and Standards	
	12.2.	Monitoring Requirements	
	12.3.	Testing Requirements	
	12.4.	Recordkeeping Requirements	
	12.5.	Reporting Requirements	
CERTI	FICATION OF	DATA ACCURACY	37

1.0. Emission Units

Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device ⁽¹⁾
007	007	Boiler 007: Natural Gas Boiler, Bryan Steam Corp.	1997	6.99 MMBtu/hr	None
008	008	Boiler 008: Natural Gas Boiler, Bryan Steam Corp.	1997	6.99 MMBtu/hr	None
010	010	Boiler 015: Natural Gas Boiler, Bryan Steam Corp.	2004	7.0 MMBtu/hr	None
011	011	Boiler 2343: Natural Gas Boiler	2005	21.0 MMBtu/hr	None
012	012	Boiler 2344: Natural Gas Boiler	2005	21.0 MMBtu/hr	None
013	013	Boiler 2345: Natural Gas Boiler	2005	21.0 MMBtu/hr	None
Rooms BL209, BL211, BL214, BL304, BL306, BL307, BL309 - BL314, BL316, BL402 - BL404, BL406 - BL414, BL416	287	Room General Exhaust	1996	Varies	Rotoclone 6
Rooms BB101 – BB103, BB106, BB108 - BB111, BB113 - BB118, BB201 - BB203, BB206 - BB208, BB210 - BB217, BB303, BB312	288	Room General Exhaust	1996	Varies	Rotoclone 5
Rooms 99-105, 99-114 - 99-122, 99- 209, 85-205A - 85- 208A, ORG201A- ORG204A	291	Room General Exhaust	1999	Varies	Rotoclone 7
Rooms BB112, 85- 106, 85-108, 85-114, 85- 115, 85-102, 85-104, 85-107, 85-110	294	Room General Exhaust	2003	Varies	Rotoclone 9
Rooms BL218, BL219	295	Room General Exhaust	2004	Varies	Rotoclone 10
Rooms NEX140, NEX142, NEX144, NEX146, NEX159 - NEX162	296	Room General Exhaust	2005	Varies	Rotoclone 2317

Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device ⁽¹⁾
Rooms NEX139, NEX141, NEX143, NEX145, NEX152 - NEX158, NEX163, NEX164	297	Room General Exhaust	2005	Varies	Rotoclone 2318
Rooms NEX131 - NEX136, NEX138, NEX147, NEX148	298	Room General Exhaust	2005	Varies	Rotoclone 2319
Rooms NEX175, NEX177, NEX179, NEX181, NEX183	299	Room General Exhaust	2005	Varies	Rotoclone 2320
Rooms NEX176, NEX178, NEX180, NEX182, NEX186 - NEX189	300	Room General Exhaust	2005	Varies	Rotoclone 2321
Rooms NEX231, NEX232, NEX234, NEX275- NEX283, NEX286- NEX289	305	Room General Exhaust	2005	Varies	Rotoclone 2322
Rooms NEX211A- NEX217A	306	Room General Exhaust	2005	Varies	Rotoclone 2323
Rooms NEX372, NEX374, NEX376, NEX378, NEX380	307	Room General Exhaust	2005	Varies	Rotoclone 2324
Rooms NEX349, NEX362, NEX364, NEX366, NEX368, NEX369	308	Room General Exhaust	2005	Varies	Rotoclone 2325
Rooms NEX346, NEX355, NEX357, NEX359 - NEX361	309	Room General Exhaust	2005	Varies	Rotoclone 2326
Rooms NEX375, NEX377, NEX379, NEX381	310	Room General Exhaust	2005	Varies	Rotoclone 2327
Rooms NEX 216A, NEX217A, NEX535- NEX538	311	Room General Exhaust	2005	Varies	Rotoclone 2328
Rooms NEX321 - NEX330, NEX421- NEX430	312	Room General Exhaust	2005	Varies	Rotoclone 2329
Rooms NEX303, NEX405 - NEX412	313	Room General Exhaust	2005	Varies	Rotoclone 2330
Rooms NEX468, NEX469, NEX472 - NEX480	314	Room General Exhaust	2005	Varies	Rotoclone 2331

Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device ⁽¹⁾
Rooms NEX435 - NEX438, NEX413 - NEX416, NEX419	315	Room General Exhaust	2005	Varies	Rotoclone 2332
Rooms NEX464 - NEX467, NEX481, NEX482, NEX484 - NEX492	316	Room General Exhaust	2005	Varies	Rotoclone 2333
Rooms NEX305- NEX312, NEX316	317	Room General Exhaust	2005	Varies	Rotoclone 2334
Rooms NEX445B, NEX445C, NEX445D, NEX445E, NEX445F, NEX445G	318	Room General Exhaust	2005	Varies	Rotoclone 2335
Rooms NEX514, NEX516A-D, NEX522 -NEX524, NEX526, NEX528, NEX530, NEX535 - NEX538	319	Room General Exhaust	2005	Varies	Rotoclone 2336
Rooms NEX503, NEX505, NEX507, NEX509, NEX511, NEX513	320	Room General Exhaust	2005	Varies	Rotoclone 2337
Rooms NEX506, NEX508, NEX510, NEX512, NEX 515	321	Room General Exhaust	2005	Varies	Rotoclone 2338
Rooms 74-174, 74- 175, 74-176, 74-177, 74-179, 74-179A, 74- 180, 74-180A	322	Room General Exhaust	2012	Varies	CC 17034
Rooms 74-150, 74- 152, 74-154, 74-159, 74-160, 74-161, 74- 162, 74-212, 91-232, 91-233	282	Room General Exhaust	2013	Varies	Rotoclone 3798
Rooms 87-103 to 87- 117	323	Room General Exhaust	2014	Varies	CC 10023125
533	533	Fluid Bed 527	1991	Up to 575 Kg/Load	CC EF527
534	534, 10008085 ⁽²⁾	Fluid Bed 473	1997	Up to 250 Kg/Load	CC EF473; RTO
535	535	Fluid Bed 1339	1997	Up to 575 Kg/Load	CC EF1339
536	536	Fluid Bed 1222	1997	Up to 250 Kg/Load	CC EF1222
537	537	Fluid Bed 1552	1997	Up to 575 Kg/Load	CC EF1552

Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device ⁽¹⁾
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	750 lbs/load	CC 246; RTO
260	260, 10008085 ⁽²⁾	Oven 19	<1973	Electric, Load Varies	RTO

Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device ⁽¹⁾
261	261, 10008085 ⁽²⁾	Oven 18	<1973	Electric, Load Varies	RTO
264	264, 10008085 ⁽²⁾	Oven 0021	2013	Electric, Load Varies	RTO
1911	1911, 10008085 ⁽²⁾	Coating Line 1911	2014	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.

2.0. General Conditions

2.1. Definitions

- 2.1.1. All references to the "West Virginia Air Pollution Control Act" or the "Air Pollution Control Act" mean those provisions contained in W.Va. Code §§ 22-5-1 to 22-5-18.
- 2.1.2. The "Clean Air Act" means those provisions contained in 42 U.S.C. §§ 7401 to 7671q, and regulations promulgated thereunder.
- 2.1.3. "Secretary" means the Secretary of the Department of Environmental Protection or such other person to whom the Secretary has delegated authority or duties pursuant to W.Va. Code §§ 22-1-6 or 22-1-8 (45CSR§30-2.12.). The Director of the Division of Air Quality is the Secretary's designated representative for the purposes of this permit.

2.2. Acronyms

CAAA CBI	Clean Air Act Amendments Confidential Business	NOx NSPS	Nitrogen Oxides New Source Performance
СЫ	Information	1431 3	Standards
CEM	Continuous Emission Monitor	PM	Particulate Matter
CES	Certified Emission Statement	PM _{2.5}	Particulate Matter less than 2.5
C.F.R. or CFR	Code of Federal Regulations		μm in diameter
CO	Carbon Monoxide	PM_{10}	Particulate Matter less than
C.S.R. or CSR	Codes of State Rules		10μm in diameter
DAQ	Division of Air Quality	Ppb	Pounds per Batch
DEP	Department of Environmental	Pph	Pounds per Hour
	Protection	Ppm	Parts per Million
dscm	Dry Standard Cubic Meter	Ppm _v or	Parts per Million by Volume
FOIA	Freedom of Information Act	ppmv	
HAP	Hazardous Air Pollutant	PSD	Prevention of Significant
HON	Hazardous Organic NESHAP		Deterioration
HP	Horsepower	Psi	Pounds per Square Inch
lbs/hr	Pounds per Hour	SIC	Standard Industrial
LDAR	Leak Detection and Repair		Classification
M	Thousand	SIP	State Implementation Plan Sulfur Dioxide
MACT	Maximum Achievable	SO_2	Toxic Air Pollutant
	Control Technology	TAP	
MDHI	Maximum Design Heat Input	TPY	Tons per Year
MM	Million	TRS	Total Reduced Sulfur
MMBtu/hr or	Million British Thermal Units	TSP	Total Suspended Particulate United States Environmental
mmbtu/hr	per Hour	USEPA	Protection Agency
MMCF/hr or	Million Cubic Feet per Hour		Universal Transverse Mercator
mmcf/hr	N. (A. 1' 11	UTM	Visual Emissions Evaluation
NA	Not Applicable	VEE	Volatile Organic Compounds
NAAQS	National Ambient Air Quality Standards	VOC	Volatile Organic Liquids
	National Emissions Standards	VOL	Volatile Organic Liquids
NESHAPS	for Hazardous Air Pollutants		

2.3. Authority

This permit is issued in accordance with West Virginia air pollution control law W.Va. Code §§ 22-5-1. et seq. and the following Legislative Rules promulgated thereunder:

2.3.1. 45CSR13 – Permits for Construction, Modification, Relocation and Operation of Stationary Sources of Air Pollutants, Notification Requirements, Temporary Permits, General Permits and Procedures for Evaluation;

2.4. Term and Renewal

2.4.1. This permit supersedes and replaces previously issued Permit R13-2068P. This Permit shall remain valid, continuous and in effect unless it is revised, suspended, revoked or otherwise changed under an applicable provision of 45CSR13 or any other applicable legislative rule;

2.5. Duty to Comply

2.5.1. The permitted facility shall be constructed and operated in accordance with the plans and specifications filed in Permit Application R13-2068 through R13-2068K, R13-2068M through R13-2068Q, and any modifications, administrative updates, or amendments thereto. The Secretary may suspend or revoke a permit if the plans and specifications upon which the approval was based are not adhered to;

[45CSR§§13-5.11 and -10.3.]

- 2.5.2. The permittee must comply with all conditions of this permit. Any permit noncompliance constitutes a violation of the West Virginia Code and the Clean Air Act and is grounds for enforcement action by the Secretary or USEPA;
- 2.5.3. Violations of any of the conditions contained in this permit, or incorporated herein by reference, may subject the permittee to civil and/or criminal penalties for each violation and further action or remedies as provided by West Virginia Code 22-5-6 and 22-5-7;
- 2.5.4. Approval of this permit does not relieve the permittee herein of the responsibility to apply for and obtain all other permits, licenses, and/or approvals from other agencies; i.e., local, state, and federal, which may have jurisdiction over the construction and/or operation of the source(s) and/or facility herein permitted.

2.6. Duty to Provide Information

The permittee shall furnish to the Secretary within a reasonable time any information the Secretary may request in writing to determine whether cause exists for administratively updating, modifying, revoking, or terminating the permit or to determine compliance with the permit. Upon request, the permittee shall also furnish to the Secretary copies of records to be kept by the permittee. For information claimed to be confidential, the permittee shall furnish such records to the Secretary along with a claim of confidentiality in accordance with 45CSR31. If confidential information is to be sent to USEPA, the permittee shall directly provide such information to USEPA along with a claim of confidentiality in accordance with 40 C.F.R. Part 2.

2.7. Duty to Supplement and Correct Information

Upon becoming aware of a failure to submit any relevant facts or a submittal of incorrect information in any permit application, the permittee shall promptly submit to the Secretary such supplemental facts or corrected information.

2.8. Administrative Update

The permittee may request an administrative update to this permit as defined in and according to the procedures specified in 45CSR13.

[45CSR§13-4.]

2.9. Permit Modification

The permittee may request a minor modification to this permit as defined in and according to the procedures specified in 45CSR13.

[45CSR§13-5.4.]

2.10 Major Permit Modification

The permittee may request a major modification as defined in and according to the procedures specified in 45CSR14 or 45CSR19, as appropriate.

[45CSR§13-5.1]

2.11. Inspection and Entry

The permittee shall allow any authorized representative of the Secretary, upon the presentation of credentials and other documents as may be required by law, to perform the following:

- a. At all reasonable times (including all times in which the facility is in operation) enter upon the permittee's premises where a source is located or emissions related activity is conducted, or where records must be kept under the conditions of this permit;
- b. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;
- Inspect at reasonable times (including all times in which the facility is in operation) any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under the permit;
- d. Sample or monitor at reasonable times substances or parameters to determine compliance with the permit or applicable requirements or ascertain the amounts and types of air pollutants discharged.

2.12. Emergency

2.12.1. An "emergency" means any situation arising from sudden and reasonable unforeseeable events beyond the control of the source, including acts of God, which situation requires immediate corrective action to restore normal operation, and that causes the source to exceed a technology-based emission limitation under the permit, due to unavoidable increases in emissions attributable to the emergency. An emergency shall not include noncompliance to the extent caused by improperly designed equipment, lack of preventative maintenance, careless or improper operation, or operator error.

- 2.12.2. Effect of any emergency. An emergency constitutes an affirmative defense to an action brought for noncompliance with such technology-based emission limitations if the conditions of Section 2.12.3 are met.
- 2.12.3. The affirmative defense of emergency shall be demonstrated through properly signed, contemporaneous operating logs, or other relevant evidence that:
 - a. An emergency occurred and that the permittee can identify the cause(s) of the emergency;
 - b. The permitted facility was at the time being properly operated;
 - c. During the period of the emergency the permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards, or other requirements in the permit; and
 - d. The permittee submitted notice of the emergency to the Secretary within one (1) working day of the time when emission limitations were exceeded due to the emergency and made a request for variance, and as applicable rules provide. This notice must contain a detailed description of the emergency, any steps taken to mitigate emissions, and corrective actions taken.
- 2.12.4. In any enforcement proceeding, the permittee seeking to establish the occurrence of an emergency has the burden of proof.
- 2.12.5 The provisions of this section are in addition to any emergency or upset provision contained in any applicable requirement.

2.13. Need to Halt or Reduce Activity Not a Defense

It shall not be a defense for a permittee in an enforcement action that it should have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit. However, nothing in this paragraph shall be construed as precluding consideration of a need to halt or reduce activity as a mitigating factor in determining penalties for noncompliance if the health, safety, or environmental impacts of halting or reducing operations would be more serious than the impacts of continued operations.

2.14. Suspension of Activities

In the event the permittee should deem it necessary to suspend, for a period in excess of sixty (60) consecutive calendar days, the operations authorized by this permit, the permittee shall notify the Secretary, in writing, within two (2) calendar weeks of the passing of the sixtieth (60) day of the suspension period.

2.15. Property Rights

This permit does not convey any property rights of any sort or any exclusive privilege.

2.16. Severability

The provisions of this permit are severable and should any provision(s) be declared by a court of competent jurisdiction to be invalid or unenforceable, all other provisions shall remain in full force and effect.

2.17. Transferability

This permit is transferable in accordance with the requirements outlined in Section 10.1 of 45CSR13. **[45CSR§13-10.1.]**

2.18. Notification Requirements

The permittee shall notify the Secretary, in writing, no later than thirty (30) calendar days after the actual startup of the operations authorized under this permit.

2.19. Credible Evidence

Nothing in this permit shall alter or affect the ability of any person to establish compliance with, or a violation of, any applicable requirement through the use of credible evidence to the extent authorized by law. Nothing in this permit shall be construed to waive any defense otherwise available to the permittee including, but not limited to, any challenge to the credible evidence rule in the context of any future proceeding.

3.0. Facility-Wide Requirements

3.1. Limitations and Standards

- 3.1.1. Open burning. The open burning of refuse by any person, firm, corporation, association or public agency is prohibited except as noted in 45CSR§6-3.1.
 [45CSR§6-3.1.]
- 3.1.2. **Open burning exemptions.** The exemptions listed in 45CSR§6-3.1 are subject to the following stipulation: Upon notification by the Secretary, no person shall cause, suffer, allow or permit any form of open burning during existing or predicted periods of atmospheric stagnation. Notification shall be made by such means as the Secretary may deem necessary and feasible. **[45CSR§6-3.2.]**
- 3.1.3. **Asbestos.** The permittee is responsible for thoroughly inspecting the facility, or part of the facility, prior to commencement of demolition or renovation for the presence of asbestos and complying with 40 C.F.R. § 61.145, 40 C.F.R. § 61.148, and 40 C.F.R. § 61.150. The permittee, owner, or operator must notify the Secretary at least ten (10) working days prior to the commencement of any asbestos removal on the forms prescribed by the Secretary if the permittee is subject to the notification requirements of 40 C.F.R. § 61.145(b)(3)(i). The USEPA, the Division of Waste Management, and the Bureau for Public Health Environmental Health require a copy of this notice to be sent to them.

[40CFR§61.145(b) and 45CSR§34]

- 3.1.4. **Odor.** No person shall cause, suffer, allow or permit the discharge of air pollutants which cause or contribute to an objectionable odor at any location occupied by the public. **[45CSR§4-3.1]** [State Enforceable Only]
- 3.1.5. **Permanent shutdown.** A source which has not operated at least 500 hours in one 12-month period within the previous five (5) year time period may be considered permanently shutdown, unless such source can provide to the Secretary, with reasonable specificity, information to the contrary. All permits may be modified or revoked and/or reapplication or application for new permits may be required for any source determined to be permanently shutdown. **[45CSR§13-10.5.]**
- 3.1.6. **Standby plan for reducing emissions.** When requested by the Secretary, the permittee shall prepare standby plans for reducing the emissions of air pollutants in accordance with the objectives set forth in Tables I, II, and III of 45CSR11.

 [45CSR\$11-5.2.]
- 3.1.7. Facility-wide emissions to the atmosphere of Hazardous Air Pollutants (HAPs) shall not exceed or equal 9.4 tons per year of any single HAP or 24.4 tons per year of any combination of HAPs. Yearly total HAPs will be determined using a 12-month rolling total.

3.2. Monitoring Requirements

3.2.1. The facility shall monitor on a monthly and yearly basis facility-wide HAP usage. Yearly HAP calculations shall be based on a 12-month rolling total.

3.3. Testing Requirements

- 3.3.1. **Stack testing.** As per provisions set forth in this permit or as otherwise required by the Secretary, in accordance with the West Virginia Code, underlying regulations, permits and orders, the permittee shall conduct test(s) to determine compliance with the emission limitations set forth in this permit and/or established or set forth in underlying documents. The Secretary, or his duly authorized representative, may at his option witness or conduct such test(s). Should the Secretary exercise his option to conduct such test(s), the operator shall provide all necessary sampling connections and sampling ports to be located in such manner as the Secretary may require, power for test equipment and the required safety equipment, such as scaffolding, railings and ladders, to comply with generally accepted good safety practices. Such tests shall be conducted in accordance with the methods and procedures set forth in this permit or as otherwise approved or specified by the Secretary in accordance with the following:
 - a. The Secretary may on a source-specific basis approve or specify additional testing or alternative testing to the test methods specified in the permit for demonstrating compliance with 40 C.F.R. Parts 60, 61, and 63 in accordance with the Secretary's delegated authority and any established equivalency determination methods which are applicable. If a testing method is specified or approved which effectively replaces a test method specified in the permit, the permit may be revised in accordance with 45CSR§13-4. or 45CSR§13-5.4 as applicable.
 - b. The Secretary may on a source-specific basis approve or specify additional testing or alternative testing to the test methods specified in the permit for demonstrating compliance with applicable requirements which do not involve federal delegation. In specifying or approving such alternative testing to the test methods, the Secretary, to the extent possible, shall utilize the same equivalency criteria as would be used in approving such changes under Section 3.3.1.a. of this permit. If a testing method is specified or approved which effectively replaces a test method specified in the permit, the permit may be revised in accordance with 45CSR§13-4. or 45CSR§13-5.4 as applicable.
 - c. All periodic tests to determine mass emission limits from or air pollutant concentrations in discharge stacks and such other tests as specified in this permit shall be conducted in accordance with an approved test protocol. Unless previously approved, such protocols shall be submitted to the Secretary in writing at least thirty (30) days prior to any testing and shall contain the information set forth by the Secretary. In addition, the permittee shall notify the Secretary at least fifteen (15) days prior to any testing so the Secretary may have the opportunity to observe such tests. This notification shall include the actual date and time during which the test will be conducted and, if appropriate, verification that the tests will fully conform to a referenced protocol previously approved by the Secretary.

[WV Code § 22-5-4(a)(15)]

3.4. Recordkeeping Requirements

3.4.1. **Retention of records.** The permittee shall maintain records of all information (including monitoring data, support information, reports, and notifications) required by this permit recorded in a form suitable and readily available for expeditious inspection and review. Support information includes all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation. The files shall be maintained for at least five (5) years following the date of each occurrence, measurement, maintenance, corrective action, report, or record. At a minimum, the most recent two (2) years of data shall be maintained on site. The remaining three (3) years of data may be maintained off site, but must remain accessible within a reasonable time. Where appropriate, the permittee may maintain records electronically (on a

computer, on computer floppy disks, CDs, DVDs, or magnetic tape disks), on microfilm, or on microfiche

3.4.2. **Odors.** For the purposes of 45CSR4, the permittee shall maintain a record of all odor complaints received, any investigation performed in response to such a complaint, and any responsive action(s) taken.

[45CSR§4. State Enforceable Only.]

3.4.3. To demonstrate compliance with the facility-wide HAP limits, the permittee shall maintain monthly and yearly records of facility-wide HAP usage. The facility shall prepare monthly facility-wide calculations of the amount of each individual HAP emitted and the amount of aggregated HAPs emitted. Yearly HAP calculations shall be based on a 12-month rolling total.

3.5. Reporting Requirements

- 3.5.1. **Responsible official.** Any application form, report, or compliance certification required by this permit to be submitted to the DAQ and/or USEPA shall contain a certification by the responsible official that states that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.
- 3.5.2. **Confidential information.** A permittee may request confidential treatment for the submission of reporting required by this permit pursuant to the limitations and procedures of W.Va. Code § 22-5-10 and 45CSR31.
- 3.5.3. **Correspondence.** All notices, requests, demands, submissions and other communications required or permitted to be made to the Secretary of DEP and/or USEPA shall be made in writing and shall be deemed to have been duly given when delivered by hand, or mailed first class with postage prepaid to the address(es) set forth below or to such other person or address as the Secretary of the Department of Environmental Protection may designate:

If to the DAQ:

Director WVDEP Division of Air Quality 601 57th Street Charleston, WV 25304-2345

If to the US EPA:

Associate Director
Office of Air Enforcement and Compliance
Assistance Review (3AP20)
U. S. Environmental Protection Agency
Region III
1650 Arch Street
Philadelphia, PA 19103-2029

3.5.4. **Operating Fee**

- 3.5.4.1. In accordance with 45CSR30 Operating Permit Program, the permittee shall submit a certified emissions statement and pay fees on an annual basis in accordance with the submittal requirements of the Division of Air Quality. A receipt for the appropriate fee shall be maintained on the premises for which the receipt has been issued, and shall be made immediately available for inspection by the Secretary or his/her duly authorized representative.
- 3.5.5. **Emission inventory.** At such time(s) as the Secretary may designate, the permittee herein shall prepare and submit an emission inventory for the previous year, addressing the emissions from the facility and/or process(es) authorized herein, in accordance with the emission inventory submittal requirements of the Division of Air Quality. After the initial submittal, the Secretary may, based

upon the type and quantity of the pollutants emitted, establish a frequency other than on an annual basis.

4.0. Source-Specific Requirements [All Emission Units listed in Section 1.0]

4.1. Limitations and Standards

4.1.1. **Operation and Maintenance of Air Pollution Control Equipment.** The permittee shall, to the extent practicable, install, maintain, and operate all pollution control equipment listed in Section 1.0 and associated monitoring equipment in a manner consistent with safety and good air pollution control practices for minimizing emissions, or comply with any more stringent limits set forth in this permit or as set forth by any State rule, Federal regulation, or alternative control plan approved by the Secretary.

[45CSR§13-5.11.]

4.2. Recordkeeping Requirements

- 4.2.1. **Record of Monitoring.** The permittee shall keep records of monitoring information that include the following:
 - a. The date, place as defined in this permit, and time of sampling or measurements;
 - b. The date(s) analyses were performed;
 - c. The company or entity that performed the analyses;
 - d. The analytical techniques or methods used;
 - e. The results of the analyses; and
 - f. The operating conditions existing at the time of sampling or measurement.
- 4.2.2. **Record of Maintenance of Air Pollution Control Equipment.** For all pollution control equipment listed in Section 1.0, the permittee shall maintain accurate records of all required pollution control equipment inspection and/or preventative maintenance procedures.
- 4.2.3. **Record of Malfunctions of Air Pollution Control Equipment.** For all air pollution control equipment listed in Section 1.0, the permittee shall maintain records of the occurrence and duration of any malfunction or operational shutdown of the air pollution control equipment during which excess emissions occur. For each such case, the following information shall be recorded:
 - a. The equipment involved.
 - b. Steps taken to minimize emissions during the event.
 - c. The duration of the event.
 - d. The estimated increase in emissions during the event.

For each such case associated with an equipment malfunction, the additional information shall also be recorded:

- e. The cause of the malfunction.
- f. Steps taken to correct the malfunction.

- g. Any changes or modifications to equipment or procedures that would help prevent future recurrences of the malfunction.
- 5.0. Source-Specific Requirements [Boilers 007, 008, 010, 011, 012, & 013]

5.1. Limitations and Standards

- 5.1.1. No person shall cause, suffer, allow or permit emission of smoke and/or particulate matter into the open air from any fuel burning unit which is greater than ten (10) percent opacity based on a six minute block average. [45CSR\$2-3.1] (007, 008, 010, 011, 012, 013)
- 5.1.2. Compliance with the visible emission requirements of 45CSR2 subsection 3.1 shall be determined in accordance with 40 CFR Part 60, Appendix A, Method 9 or by using measurements from continuous opacity monitoring systems approved by the Director. The Director may require the installation, calibration, maintenance and operation of continuous opacity monitoring systems and may establish policies for the evaluation of continuous opacity monitoring results and the determination of compliance with the visible emission requirements of subsection 3.1. Continuous opacity monitors shall not be required on fuel burning units which employ wet scrubbing systems for emission control. [45CSR§2-3.2] (007, 008, 010, 011, 012, 013)
- 5.1.3. No person shall cause, suffer, allow or permit the discharge of particulate matter into the open air from all fuel burning units located at one plant, measured in terms of pounds per hour in excess of the amount determined as follows:

Table 5.1.3.: Fuel Burning Unit 45CSR2 PM Limits

Emission Unit	PM Emission Limit (lb/hr)
011	1.89
012	1.89
013	1.89

Compliance with 45CSR§2-4.1.b shall be demonstrated through compliance with the more stringent particulate emission limit for Boiler 011, 012, & 013 listed in 5.1.8. **[45CSR§2-4.1.b]** (011, 012, 013)

5.1.4. No person shall cause, suffer, allow or permit the discharge of sulfur dioxide into the open air from all stacks located at one plant, measured in terms of pounds per hour, in excess of the amount determined as follows:

Table 5.1.4.: Fuel Burning Unit 45CSR10 SO₂ Limits

Emission Unit	SO ₂ Emission Limit (lb/hr)
011	67.2
012	67.2
013	67.2

Compliance with 45CSR§10-3.3.f. shall be demonstrated through compliance with the more stringent particulate emission limit for Boiler 011, 012, & 013 listed in 5.1.8. [45CSR§10-3.3.f.] (011, 012, 013)

5.1.5. Maximum emissions to the atmosphere from Emission Point ID# 007 (6.987 MMBtu/hr Bryan Steam Corporation Boiler) shall not exceed the following limits:

Table 5.1.5.: Boiler 007 Emission Limits

Pollutant	Maximum Hourly Emissions (lb/hr)	Maximum Annual Emissions (tpy)
СО	0.59	2.58
NO_x	0.70	3.07
PM _{2.5} /PM ₁₀ /PM ⁽¹⁾	0.10	0.30
SO_2	0.10	0.10
VOCs	0.10	0.20

⁽¹⁾ Including Condensables

5.1.6. Maximum emissions to the atmosphere from Emission Point ID# 008 (6.987 MMBtu/hr Bryan Steam Corporation Boiler) shall not exceed the following limits:

Table 5.1.6.: Boiler 008 Emission Limits

Pollutant	Maximum Hourly Emissions (lb/hr)	Maximum Annual Emissions (tpy)
СО	0.59	2.58
NO _x	0.70	3.07
$PM_{2.5}/PM_{10}/PM^{(1)}$	0.10	0.30
SO_2	0.10	0.10
VOCs	0.10	0.20

⁽¹⁾ Including Condensables

5.1.7. Maximum emissions to the atmosphere from Emission Point ID# 010 (7 MMBtu/hr Bryan Steam Corporation Boiler) shall not exceed the following limits:

Table 5.1.7.: Boiler 015 Emission Limits

Pollutant	Maximum Hourly Emissions (lb/hr)	Maximum Annual Emissions (tpy)
СО	0.59	2.58
NO_x	0.70	3.07
$PM_{2.5}/PM_{10}/PM^{(1)}$	0.10	0.30
SO_2	0.10	0.10
VOCs	0.10	0.20

⁽¹⁾ Including Condensables

5.1.8. Each of the three (3) 21.0 MMBtu/hr Bryan Steam Corporation boilers (Emission Points ID # 011, 012 & 013) shall not exceed the following emission rates:

Pollutant	Maximum Hourly Emissions per Boiler (lb/hr)	Maximum Annual Emissions per Boiler (tpy)
СО	4.07	17.84
NO_x	2.06	9.02
$PM_{2.5}/PM_{10}/PM^{(1)}$	0.20	0.86
SO_2	0.02	0.05
VOCs	0.21	0.92

Table 5.1.8.: Boiler 2343-2345 Emission Limits

- 5.1.9. The maximum amount of natural gas to be burned by a single boiler (Emission Points ID# 007, 008, 010) shall not exceed 7,000 cubic feet/hour or 61,320,000 cubic feet/year.
- 5.1.10. The three (3) Bryan Steam Corporation boilers (Emission Points ID # 011, 012 & 013) shall combust only natural gas fuel. The maximum amount of natural gas consumed by each boiler shall not exceed 20,590 cubic feet per hour (cfh) and 180.4 million cubic feet per year (mmcfy).

5.2. Monitoring Requirements

- 5.2.1. At such reasonable times as the Secretary may designate, the permittee shall conduct Method 9 emission observations for the purpose of demonstrating compliance with the opacity standards of 45CSR2-3.1. Method 9 shall be conducted in accordance with 40 CFR 60 Appendix A. (007, 008, 010, 011, 012, & 013)
- 5.2.2. The facility shall monitor the amount of natural gas used on a monthly and yearly basis for Boilers 007, 008, 010, 011, 012, &013.
- 5.2.3. The facility shall monitor the hours of operation on a monthly and yearly basis of the Boilers 007, 008, 010, 011, 012, & 013.

5.3. Testing Requirements

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

5.4. Recordkeeping Requirements

- 5.4.1. To demonstrate compliance with the emission limits and natural gas usage limits for the boilers, the permittee shall record for each boiler, the monthly hours of operation and the monthly fuel consumption. (007, 008, 010, 011, 012, 013)
- 5.4.2. A record of each visible emission check shall be maintained on site for five (5) years from the record creation date. Such record shall include, but not be limited to, the date, time, name of emission unit, the applicable visible emissions requirement, the results of the check, what actions(s), if any, was/were taken, and the name of the observer. (007, 008, 010, 011, 012, & 013)

5.5. Reporting Requirements

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

⁽¹⁾ Including Condensables

6.0. Source-Specific Requirements [Fluid Beds 533, 534, 535, 536, 537, 538, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, & 582]

6.1. Limitations and Standards

- 6.1.1. 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]
- 6.1.2. 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 6.1.2.:	Fluid Red	45CSR7	Individual	Emission	I imit
rable 0.1.2	riuia bea	431.311/	manyidua	i ciiiission	

Emission Unit	PM Emission Limit (lb/hr)	
<u>Size 60</u> 534, 536, 538, 572, 574, 575, 577, 581	0.46	
<u>Size 300</u> 533, 535, 537, 571, 573, 576, 578, 579, 580, 582	1.06	

Compliance with 45CSR§7-4.1 shall be demonstrated through compliance with the more stringent particulate emission limit set forth in 6.1.3. [45CSR§7-4.1.]

- 6.1.3. Maximum particulate matter emissions ($PM_{2.5}/PM_{10}/PM$) to the atmosphere from each Fluid Bed shall not exceed 0.1 lb/hr and 0.1 tons/year.
- 6.1.4. Maximum hourly volatile organic compound emissions to the atmosphere from the Fluid Beds shall not exceed:
 - a. 529.2 lb/hr for each fluid bed if not venting exhaust to the RTO or absorber for the purpose of controlling VOC emissions;
 - b. 10.59 lb/hr (as emitted from the RTO) each for Fluid Beds 534, 538, 572, 574 578, and 580 if venting exhaust to the RTO for the purpose of controlling VOC emissions; and
 - c. 26.46 lb/hr (as emitted from the absorber) each for Fluid Bed 573 and 579 if venting exhaust to the absorber for the purpose of controlling VOC emissions.
- 6.1.5. Maximum total combined annual volatile organic compound emissions to the atmosphere from the Fluid Beds shall not exceed 74.0 tons/year.
- 6.1.6. The fluid beds shall operate according to the following requirements:
 - a. The aggregate dry material loading of the fluid bed (excluding times of tablet/beads coating in a fluid bed) shall not exceed the following limits:
 - (1) Fluid Beds 534, 536, 538, 572, 574, 575, 577, 581: 250 kg/load
 - (2) Fluid Beds 533, 535, 537, 571, 573, 576, 578, 579, 580, 582: 575 kg/load

- b. The annual aggregate dry material loading of all fluid beds shall not exceed 99,000,000 pounds on a rolling yearly total basis;
- c. Cartridge collectors shall be used at all times on each fluid bed to control particulate matter emissions. Each collector shall, at a minimum, achieve a collection efficiency of 95%;
- d. The spray rate used in each fluid bed shall not exceed 4 kilograms-VOC/minute;
- e. Fluid Beds 534, 538, 572, 574 578, and 580 shall have the capability of directing exhaust to the RTO for control of VOCs or emitting directly to atmosphere;
- f. Fluid Beds 573 and 579 shall have the capability of directing exhaust to the absorber for control of VOCs or emitting directly to atmosphere; and
- g. No HAP-containing solvents shall be processed in any fluid bed.

6.2. Monitoring Requirements

6.2.1. 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 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.

- 6.2.2. For the purposes of demonstrating compliance with the minimum cartridge collection efficiency as given under 6.1.6(c), the permittee shall:
 - 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; and
 - 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%.
- 6.2.3. For the purposes of demonstrating compliance with maximum dry material loading set forth in 6.1.6(a), the permittee shall monitor and record the total dry material per load for each fluid bed. This requirement may be waived if the permittee is able to demonstrate that the maximum

- reasonable design capacity of each fluid bed is equal or less than the maximum load given under 6.1.6(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).
- 6.2.4. For the purposes of demonstrating compliance with maximum annual aggregate dry material loading set forth in 6.1.6(b), the permittee shall monitor and record the aggregate monthly and rolling twelve month total amount of dry material into the fluid beds.
- 6.2.5. For the purposes of demonstrating compliance with maximum annual VOC emission limit set forth in 6.1.5, the permittee shall:
 - a. Monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in each fluid bed with the exception of Fluid Beds 534, 538, and 572 580.
 - b. Monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in Fluid Beds 534, 538, and 572 580 when each bed is and is not venting exhaust to the RTO/Absorber (as applicable) for the purpose of controlling VOCs.
 - c. Calculate and record the monthly and rolling twelve month aggregate VOC emissions from all fluid beds by summing the following:
 - (1) The total amount of VOCs in pounds used in each fluid bed with the exception of Fluid Beds 534, 538, and 572 580.
 - (2) The total amount of VOCs in pounds used in Fluid Beds 534, 538, and 572 580 when not venting exhaust to the RTO/Absorber (as applicable) for the purpose of controlling VOCs.
 - (3) The total amount of VOCs used in Fluid Beds 534, 538, 572, 574 578, and 580 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 Fluid Beds 534, 538, 572, 574 578, and 580 when venting exhaust to the RTO for the purpose of controlling VOCs.
 - (4) The total amount of VOCs used in Fluid Beds 573 and 579 when venting exhaust to the Absorber for the purpose of controlling VOCs. Based on compliance with Requirement 11.1.2 of this permit, the permittee may apply a VOC destruction efficiency of 95% to the amount of VOCs used in Fluid Beds 573 and 579 when venting exhaust to the Absorber for the purpose of controlling VOCs.

6.3. Testing Requirements

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

6.4. Recordkeeping Requirements

- 6.4.1. 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.
- 6.4.2. The permittee shall maintain a record of all solvents used in the fluid beds and keep a copy of the associated MSDS/SDS to verify that the solvents did not contain any constituent HAPs.

6.5. Reporting Requirements

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

7.0. Source-Specific Requirements [Production Rooms]

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]
- 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 for each of the following emission points:

Table 7.1.2.: Production Room Emission Points 45CSR7 Emission Limits

Emission Point	PM Emission Limit (lb/hr)
287, 288, 291, 294, & 295	1.20 ⁽¹⁾
282, 296-300, 305-322	2.12(2)
323	1.16(3)

- (1) Based on a PWR of 1,000 lb/hr for a Type "a" source operation.
- (2) Based on a PWR of 1,764 lb/hr for a Type "a" source operation.
- (3) Based on a PWR of 964 lb/hr for a Type "a" source operation.

Compliance with 45CSR§7-4.1 shall be demonstrated through compliance with the more stringent particulate emission limit set forth in 7.1.3 and 7.1.6. [45CSR§7-4.1.]

7.1.3. Maximum particulate matter emissions to the atmosphere shall not exceed the following:

Table 7.1.3.: Rotoclone Emission Limits

Source	Maximum Hourly Emissions (lb/hr)
Rotoclone (294)	0.4
Rotoclone (295)	0.4
Rotoclone (287)	0.4
Rotoclone (288)	0.4
Rotoclone (291)	0.4

- 7.1.4. The Rotoclone control devices and cartridge collector servicing production rooms shall be designed to achieve a collection efficiency of 98% for particulate matter emissions.
- 7.1.5. At all times the production rooms listed under Table 1.0 are in operation, exhaust from these shall be vented to the applicable control devices as listed under Table 1.0.
- 7.1.6. Maximum particulate matter (PM) emissions to the atmosphere from Emission Points 282, 296-300, and 305-323, as emitted through the applicable control devices listed under Table 1.0, shall not exceed a maximum hourly emission rate of 0.90 pounds per hour (lb/hr) and 2.19 tons per year (tpy).

7.1.7. The permittee shall maintain and operate low water supply pressure sensors with control panel alarms for each Rotoclone to ensure adequate water supply and flow rate to the Rotoclones at each emission point specified, in order to ensure proper operation of the Rotoclone.

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 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.

- 7.2.2. For the purposes of demonstrating compliance with the minimum cartridge collection efficiency as given under 7.1.4., the permittee shall:
 - 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; and
 - 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 98%.

7.3. Testing Requirements

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

7.4. Recordkeeping Requirements

- 7.4.1. A record of each visible emission check shall be maintained on site for five (5) years from the record creation date. Such record shall include, but not be limited to, the date, time, name of emission unit, the applicable visible emissions requirement, the results of the check, what action(s), if any, was/were taken, and the name of the observer
- 7.4.2. Records of Rotoclone low water supply pressure sensor alarm shall be maintained on site for five (5) years from the record creation date. Records shall state the date and time of each Rotoclone low water supply pressure sensor alarm.

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	0.90
241	0.90
242	0.29
244	0.90
245	0.90
246	0 <mark>.90</mark>

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, and 246) at Emission Point ID Numbers 215, 241, 242, 244, 245, and 246 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 I	Emission Limit
Emission Unit	Pound/hour	ton/year
215	0.84	
241	0.84	
242	0.28	6.25
244	0.84	6.25
245	0.84	
246	0.84	

8.1.4. 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, 245, 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:
 - 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; and
 - (6) Coating Pan 246: 750 pound/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, 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, 245, and 246 shall have the capability of directing exhaust to RTO for control of VOCs or emitting directly to atmosphere; and
 - g. 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 reading s 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
 - d. 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;
 - e. 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; and
 - f. 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, 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, 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, 245, and 246.
 - (2) The total amount of VOCs in pounds used in Coating Pans 244, 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, 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, 245, and 246 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/SDS 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:

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

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

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

Incinerator Capacity	Factor F
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 more than eight (8) minutes per start-up, or six (6) minutes in any sixty (60)-minute period for stoking operations.

[45CSR§6-4.3 and 4.4]

9.1.3. Maximum emissions to the atmosphere from the RTO shall not exceed the values given in the following table:

Table 9.1.3(a): RTO Emission Limits

Pollutant	Maximum Hourly Emissions (lb/hr)	Maximum Annual Emissions (tpy)
СО	28.76	10.44
NO_x	49.11	14.90
PM	2.68	0.96
PM_{10}	2.68	0.96
PM _{2.5}	2.68	0.96
SO_2	0.08	0.05

Pollutant	Maximum Hourly Emissions (lb/hr)	Maximum Annual Emissions (tpy)	
VOCs	61.49	6.59	

- 9.1.4. The RTO shall be operated according to the following requirements:
 - a. The aggregate MDHI of the natural gas burner(s) shall not exceed 16.00 mmBtu/hr;
 - b. The aggregate annual amount of natural gas consumed by the RTO(s) shall not exceed 140.16 million cubic feet per rolling twelve month total; and
 - c. The aggregate maximum amount of solvent combusted by the RTO(s) shall not exceed 3,070 lb/hour or 1,019,240 pounds per rolling twelve month period.
- 9.1.5. The RTO shall, at all times when Fluid Beds 534, 538, 572, 574 578, and 580; Coating Pans 244, 245, and 246; Oven Dryers 260, 261, and 264; and the Coating Line are venting exhaust to the RTO for the purpose of controlling VOCs, achieve a minimum VOC destruction efficiency of 98%.
- 9.1.6. The permittee shall, within 60 days of the date of the performance test required under 9.3.2, determine the optimal operating ranges of the RTO parameters listed under 9.1.6(a) and (b) so as to monitor the effective operation of the RTO. The determination of operating ranges shall be based on data obtained from performance testing, manufacturing recommendations, or operational experience. The permittee shall maintain on-site, and update as necessary, a certified report listing the operating ranges. Any changes to the operating ranges shall be accompanied by the date of the change and reason for the change.
 - a. Minimum RTO Combustion Chamber Temperature; and
 - b. RTO Exhaust Flow Rate.
- 9.1.7 The permittee shall, to the extent reasonably possible, operate the RTO within the operating ranges as established under 9.1.6 at all times Fluid Beds 534, 538, 572, 574 578, and 580; Coating Pans 244, 245, and 246; Oven Dryers 260, 261, and 264; and the Coating Line are venting exhaust to the RTO for the purpose of controlling VOCs. If an excursion from the operating ranges occurs, the permittee shall attempt to immediately correct the problem and follow the record-keeping procedures under 9.4.1. If the permittee is unable to correct the excursion in a timely fashion, for the purposes of emissions calculations under 6.2.5(c)(3), a VOC destruction efficiency of 98% may not be assumed for the duration of the venting of VOC from Fluid Beds 534, 538, 572, 574 578, and 580; Coating Pans 244, 245, and 246; Oven Dryers 260, 261, and 264; and the Coating Line.
- 9.1.8. The permittee shall conduct, at a minimum, an annual inspection of the RTO to ensure proper operation of the control device. The inspection shall include the burner assemblies, blowers, fans, dampers, refractory lining, oxidizer shell, fuel lines, and ductwork.

9.2. Monitoring Requirements

9.2.1. Visible emissions monitoring shall be conducted initially at least once per month for all emission points subject to opacity limitations. After three consecutive monthly reading s 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 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.

- 9.2.2. For the purposes of demonstrating compliance with maximum annual natural gas combustion rates set forth in 9.1.4(b), the permittee shall monitor and record the rolling twelve month total of natural gas combusted by the RTO.
- 9.2.3. For the purposes of demonstrating compliance with maximum solvent combustion rates set forth in 9.1.4(c), the permittee shall monitor and record the amount of solvent, in pounds, sent to the RTO from Fluid Beds 534, 538, 572, 574 – 578, and 580; Coating Pans 244, 245, and 246; Oven Dryers 260, 261, and 264; and the Coating Line. The monthly and rolling twelve month total of solvent sent to RTO from Fluid Beds 534, 538, 572, 574 - 578, and 580; Coating Pans 244, 245, and 246; Oven Dryers 260, 261, and 264; and the Coating Line shall be summed and recorded.
- For the purposes of demonstrating compliance with the requirements set forth in 9.1.5, the 9.2.4. permittee shall continuously monitor and record the RTO Combustion Chamber Temperature (as measured at the outlet of the combustion chamber) and the RTO Exhaust Flow Rate (as measured at the RTO outlet or based on fan instrumentation). Monitoring shall be effected by use of the following:
 - Combustion Chamber Temperature: Thermocouples, RTDs, or alternative methods/instrumentation as appropriate for gas stream; and
 - RTO Exhaust Flow Rate: Differential pressure flow device, fan motor ammeter, or other type of device that measures gas velocity or flow rate.
- 9.2.5. The permittee shall install, maintain, and operate all monitoring equipment required by this section in accordance with all manufacture's recommendations.

9.3. **Testing Requirements**

- 9.3.1. Within 60 days after achieving the maximum solvent combustion rate at which the RTO(s) are permitted to operated at, but not later than 180 days after initial startup, and at such times thereafter as may be required by the Secretary, the permittee shall conduct, or have conducted, a performance test on the RTO(s) to determine compliance with the CO and NO_x emission limits listed in Table 9.1.3. The permittee shall use EPA approved test methods unless granted approval in writing by the Director to use an alternative test method in a protocol submitted pursuant to 3.3.1.c.
- 9.3.2. Within 60 days after achieving the maximum solvent combustion rate at which the RTO is permitted to operated at, but not later than 180 days after the initial use of the RTO to control of VOCs during a Fluid Bed production run, and at such times thereafter as may be required by the Secretary, the permittee shall conduct, or have conducted, a performance test on the RTO to determine compliance with the minimum VOC destruction efficiency as given under 9.1.5. The permittee shall use EPA approved test methods unless granted approval in writing by the Director to use an alternative test method in a protocol submitted pursuant to 3.3.1.c.

9.4. Recordkeeping Requirements

- 9.4.1. The permittee shall record the date, duration, and any corrective action taken in the occurrence of an excursion of RTO operating parameters outside the ranges as established under 9.1.6. If corrective action was not successful in a timely fashion, the permittee shall record the amount of solvent sent to the RTO while the excursion occurred.
- 9.4.2. The permittee shall meet all record-keeping requirements as applicable to the RTO and given under section 3.4 and 4.2 of this permit.

9.5 Reporting Requirements

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

10.0. Source-Specific Requirements [Oven Dryers 260, 261, 264]

10.1. Limitations and Standards

- 10.1.1. Maximum hourly volatile organic compound emissions to the atmosphere from Oven Dryers 260, 261, and 264 shall not exceed:
 - a. 529.2 lb/hr for each Oven Dryer if not venting exhaust to the RTO for the purpose of controlling VOC emissions; and
 - b. 10.59 lb/hr (as emitted from the RTO) for each Oven Dryer if venting exhaust to the RTO for the purpose of controlling VOC emissions.
- 10.1.2. The maximum total combined annual volatile organic compound emissions to the atmosphere from Oven Dryers 260, 261, and 264 shall not exceed 5.0 tons/year.
- 10.1.3. Oven Dryers 260, 261, and 264 shall operate according to the following requirements:
 - a. Each Oven Dryer shall have the capability of directing exhaust to RTO for control of VOCs or emitting directly to atmosphere; and
 - b. No HAP-containing solvents shall be processed in any Oven Dryer.

10.2. Monitoring Requirements

- 10.2.1. For the purposes of demonstrating compliance with maximum annual VOC emission limit set forth in 10.1.2., the permittee shall:
 - a. Monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in Oven Dryers 260, 261, and 264 when each Oven Dryer is and is not venting exhaust to the RTO for the purpose of controlling VOCs; and
 - b. Calculate and record the monthly and rolling twelve month aggregate VOC emissions from Oven Dryers 260, 261, and 264 by summing the following:
 - (1) The total amount of VOCs in pounds used in Oven Dryers 260, 261, and 264 when not venting exhaust to the RTO for the purpose of controlling VOCs; and
 - (2) The total amount of VOCs used in Oven Dryers 260, 261, and 264 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 Oven Dryers 260, 261, and 264 when venting exhaust to the RTO for the purpose of controlling VOCs.

10.3. Testing Requirements

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

10.4. Recordkeeping Requirements

10.4.1. The permittee shall maintain a record of all solvents used in Oven Dryers 260, 261, and 264 and keep a copy of the associated MSDS to verify that the solvents did not contain any constituent HAPs.

10.5. Reporting Requirements

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

11.0. Source-Specific Requirements [Absorber]

11.1. Limitations and Standards

- 11.1.1. The absorber shall, at all times when Fluid Beds 573 and 579 are venting exhaust to the absorber for the purpose of controlling VOCs, achieve a minimum VOC destruction efficiency of 95%.
- 11.1.2. The permittee shall, within 60 days of the date of the performance test required under 11.3.1, determine the optimal operating ranges of the absorber parameters listed under 11.1.2(a) so as to monitor the effective operation of the Absorber. The determination of operating ranges shall be based on data obtained from performance testing, manufacturing recommendations, or operational experience. The permittee shall maintain on-site, and update as necessary, a certified report listing the operating ranges. Any changes to the operating ranges shall be accompanied by the date of the change and reason for the change.
 - a. Minimum Water Flow
- 11.1.3. The permittee shall maintain and operate low water flow rate sensors with control panel alarms for the absorber to ensure adequate water flow rate to the absorber in order to ensure proper operation of the absorber.
- 11.1.4. The permittee shall, to the extent reasonably possible, operate the absorber within the operating ranges as established under 11.1.2. at all times Fluid Beds 573 and 579 are venting exhaust to the absorber for the purpose of controlling VOCs. If an excursion from the operating ranges occurs, the permittee shall attempt to immediately correct the problem and follow the record-keeping procedures under 11.4.1. If the permittee is unable to correct the excursion in a timely fashion, for the purposes of emissions calculations under 6.2.5(c), a VOC destruction efficiency of 95% may not be assumed for the duration of the venting of VOC from Fluid Beds 573 and 579.
- 11.1.5. The permittee shall conduct, at a minimum, an annual inspection of the absorber to ensure proper operation of the control device. The inspection shall include the spray nozzles, fans, dampers, absorber shell, packing, and ductwork.

11.2. Monitoring Requirements

11.2.1. For the purposes of demonstrating compliance with the requirements set forth in 11.1.2., the permittee shall continuously monitor and record the absorber water flow rate

11.2.2. The permittee shall install, maintain, and operate all monitoring equipment required by this section in accordance with all manufacture's recommendations.

11.3. Testing Requirements

11.3.1. Within 60 days after achieving the maximum solvent exhaust rate at which the absorber is permitted to operate at, but not later than 180 days after the initial use of the absorber to control of VOCs during a Fluid Bed production run, and at such times thereafter as may be required by the Secretary, the permittee shall conduct, or have conducted, a performance test on the absorber to determine compliance with the minimum VOC removal efficiency as given under 11.1.4. The permittee shall use EPA approved test methods unless granted approval in writing by the Director to use an alternative test method in a protocol submitted pursuant to 3.3.1.c.

11.4. Recordkeeping Requirements

- 11.4.1. The permittee shall record the date, duration, and any corrective action taken in the occurrence of an excursion of absorber operating parameters outside the ranges as established under 11.1.2. If corrective action was not successful in a timely fashion, the permittee shall record the amount of solvent sent to the absorber while the excursion occurred.
- 11.4.2. The permittee shall maintain records of Absorber low water flow rate alarms on site for five (5) years form the record creation date. The records shall state the date and time of each Absorber low water flow rate alarm and any corrective action taken.
- 11.4.3. The permittee shall meet all record-keeping requirements as applicable to the Absorber and given under section 3.4 and 4.2 of this permit.

11.5. Reporting Requirements

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

12.0. Source-Specific Requirements [Coating Line]

12.1. Limitations and Standards

- 12.1.1. Maximum hourly VOC/HAP emissions to the atmosphere from the Coating Line shall not exceed:
 - a. 7.0 lb/hr for the Coating Line if not venting exhaust to the RTO for the purpose of controlling VOC/HAP emissions; and
 - b. 0.14 lb/hr (as emitted from the RTO) for the Coating Line if venting exhaust to the RTO for the purpose of controlling VOC/HAP emissions.
- 12.1.2. The maximum annual VOC/HAP emissions to the atmosphere from Coating Line shall not exceed 3.0 tons/year.
- 12.1.3. The Coating Line shall have the capability of directing exhaust to RTO for control of VOC/HAPs or emitting directly to atmosphere.

12.2. Monitoring Requirements

12.2.1. For the purposes of demonstrating compliance with maximum annual VOC/HAP emission limit set forth in 10.1.2., the permittee shall:

- a. Monitor and record the aggregate monthly and rolling twelve month total amount of VOC/HAPs in pounds used in the Coating Line when it is and is not venting exhaust to the RTO for the purpose of controlling VOC/HAPs; and
- b. Calculate and record the monthly and rolling twelve month aggregate VOC/HAPs emissions from the Coating Line by summing the following:
 - (1) The total amount of VOC/HAPs in pounds used in the Coating Line when not venting exhaust to the RTO for the purpose of controlling VOCs; and
 - (2) The total amount of VOC/HAPs used in the Coating Line 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/HAPs destruction efficiency of 98% to the amount of VOC/HAPs used in the Coating Line when venting exhaust to the RTO for the purpose of controlling VOC/HAPs.

12.3. Testing Requirements

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

12.4. Recordkeeping Requirements

12.4.1. The permittee shall maintain a record of all solvents used in the Coating Line and keep a copy of the associated MSDS/SDS.

12.5. Reporting Requirements

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

CERTIFICATION OF DATA ACCURACY

	I, the undersigned, hereby cer	tify that, based	on information ar	d belief formed afte	r reasonable
inquiry, all info	ormation contained in the attack	hed		, repr	esenting the
period beginning and ending			, and any	supporting	
documents appe	nded hereto, is true, accurate, and	d complete.			
Signature ¹ (please use blue ink)	Responsible Official or Authorized Representative			Date	
Name & Title (please print or type)	Name		Title		
Telephone No.			Fax No		

- This form shall be signed by a "Responsible Official." "Responsible Official" means one of the following:
 - a. For a corporation: The president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:
 - (i) the facilities employ more than 250 persons or have a gross annual sales or expenditures exceeding \$25 million (in second quarter 1980 dollars), or
 - (ii) the delegation of authority to such representative is approved in advance by the Director;
 - b. For a partnership or sole proprietorship: a general partner or the proprietor, respectively;
 - c. For a municipality, State, Federal, or other public entity: either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a Federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., a Regional Administrator of U.S. EPA); or
 - d. The designated representative delegated with such authority and approved in advance by the Director.

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

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
<u>246</u>	CC246; RTO	<u>246</u>	Coating Pan 246	682750 lbs/load	<u>2015</u>

Emission Point ID	Control Device	Emission Unit ID	Mylan ID & Emission Unit Description	Design Capacity	Year Installed/ Modified
260; 10008085 ⁽²⁾	RTO*	260	Oven 19	Varies	Prior to 1973
261; 10008085 ⁽²⁾	RTO*	261	Oven 18	Varies	Prior to 1973
264; 10008085 ⁽²⁾	RTO*	264	Oven-0021_0021	Electric, Load Varies	2013
1911; 10008085 ⁽²⁾	RTO*	1911	Coating Line <u>1911</u> 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*	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*	Rooms BL209, BL211, BL214, BL304, BL306, BL307, BL309- BL314, BL316, BL402 – BL404, BL406-BL414, BL416	Room General Exhaust	Varies	1996
288	Rotoclone 5*	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*	Rooms 85-205A – 85- 208A, 99-105, 99-114 – 99-122, 99-209, ORG201A – ORG204A	Room General Exhaust	Varies	1999
294	Rotoclone 9*	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*	Rooms BL218, BL219	Room General Exhaust	Varies	2004
296	Rotoclone 2317*	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	Rooms 87-103 to 87- 117	Room General Exhaust	<u>Varies</u>	<u>2014</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

- d. The analytical techniques or methods used;
- e. The results of the analyses; and
- f. The operating conditions existing at the time of sampling or measurement.

[45CSR§30-5.1.c.2.A.; 45CSR13, Permit No. R13-2068 (Condition 4.2.1.)]

3.4.2. **Retention of records.** The permittee shall retain records of all required monitoring data and support information for a period of at least five (5) years from the date of monitoring sample, measurement, report, application, or record creation date. Support information includes all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by the permit. Where appropriate, records may be maintained in computerized form in lieu of the above records.

[45CSR§30-5.1.c.2.B.]

- 3.4.3. **Odors.** For the purposes of 45CSR4, the permittee shall maintain a record of all odor complaints received, any investigation performed in response to such a complaint, and any responsive action(s) taken. **[45CSR§30-5.1.c. State-Enforceable only.]**
- 3.4.4. **Fugitive Dust Control Systems.** The permittee shall maintain records indicating the use of any dust suppressants or any other suitable dust control measures applied at the facility. The permittee shall also inspect all fugitive dust control systems monthly to ensure that they are operated and maintained in conformance with their designs. The permittee shall maintain records of such inspections and of all scheduled and non-scheduled maintenance of such systems. These records shall be maintained on site for five (5) years from the record creation date, stating any maintenance or corrective actions taken as a result of the monthly inspections, and the times the fugitive dust control system(s) are inoperable and any corrective actions taken. **[45CSR§30-5.1.c.]**
- 3.4.5. To demonstrate compliance with the facility-wide HAP limits, the permittee shall maintain monthly and yearly records of facility-wide HAP usage. The facility shall prepare monthly facility-wide calculations of the amount of each individual HAP emitted and the amount of aggregated HAPs emitted. Yearly HAP calculations shall be based on a 12-month rolling total.

 [45CSR13, Permit No. R13-2068 (Condition 3.4.3.)]
- 3.4.6. **Record of Maintenance of Air Pollution Control Equipment.** For all pollution control equipment identified with an asterisk in Section 1.1., the permittee shall maintain accurate records of all required pollution control equipment inspection and/or preventative maintenance procedures.

 [45CSR13, Permit No. R13-2068 (Condition 4.2.2.)]
- 3.4.7. **Record of Malfunctions of Air Pollution Control Equipment.** For all air pollution control equipment identified with an asterisk in Section 1.1., the permittee shall maintain records of the occurrence and duration of any malfunction or operational shutdown of the air pollution control equipment during which excess emissions occur. For each such case, the following information shall be recorded:
 - a. The equipment involved.
 - b. Steps taken to minimize emissions during the event.

- c. The duration of the event.
- d. The estimated increase in emissions during the event.

For each such case associated with an equipment malfunction, the additional information shall also be recorded.

- e. The cause of the malfunction.
- f. Steps taken to correct the malfunction.
- g. Any changes or modifications to equipment or procedures that would help prevent future recurrences of the malfunction.

[45CSR13, Permit No. R13-2068 (Condition 4.2.3.)]

3.5. Reporting Requirements

3.5.1. **Responsible official.** Any application form, report, or compliance certification required by this permit to be submitted to the DAQ and/or USEPA shall contain a certification by the responsible official that states that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate and complete.

[45CSR§§30-4.4. and 5.1.c.3.D.]

- 3.5.2. A permittee may request confidential treatment for the submission of reporting required under 45CSR§30-5.1.c.3. pursuant to the limitations and procedures of W.Va. Code § 22-5-10 and 45CSR31. [45CSR§30-5.1.c.3.E.]
- 3.5.3. Except for the electronic submittal of the annual certification to the USEPA as required in 3.5.5 below, all notices, requests, demands, submissions and other communications required or permitted to be made to the Secretary of DEP and/or USEPA shall be made in writing and shall be deemed to have been duly given when delivered by hand, mailed first class or by private carrier with postage prepaid to the address(es) set forth below or to such other person or address as the Secretary of the Department of Environmental Protection may designate:

If to the DAQ:

If to the US EPA:

Director Associate Director

WVDEP Office of Enforcement and Permits Review

Division of Air Quality (3AP12)

601 57th Street SE U. S. Environmental Protection Agency

Charleston, WV 25304 Region III

1650 Arch Street

Phone: 304/926-0475 Philadelphia, PA 19103-2029

FAX: 304/926-0478

- 3.5.4. Certified emissions statement. The permittee shall submit a certified emissions statement and pay fees on an annual basis in accordance with the submittal requirements of the Division of Air Quality.

 [45CSR§30-8.]
- 3.5.5. **Compliance certification.** The permittee shall certify compliance with the conditions of this permit on the forms provided by the DAQ. In addition to the annual compliance certification, the permittee may be required to submit certifications more frequently under an applicable requirement of this permit. The annual certification shall be submitted to the DAQ and USEPA on or before March 15 of each year, and shall certify compliance for the period ending December 31. The annual certification to the USEPA shall be submitted in electronic format only. It shall be submitted by e-mail to the following address: R3_APD_Permits@epa.gov. The permittee shall maintain a copy of the certification on site for five (5) years from submittal of the certification.

[45CSR§30-5.3.e.]

3.5.6. **Semi-annual monitoring reports.** The permittee shall submit reports of any required monitoring on or before September 15 for the reporting period January 1 to June 30 and on or before March 15 for the reporting period July 1 to December 31. All instances of deviation from permit requirements must be clearly identified in such reports. All required reports must be certified by a responsible official consistent with 45CSR§30-44

[45CSR§30-5.1.c.3.A.]

- 3.5.7. **Emergencies.** For reporting emergency situations, refer to Section 2.17 of this permit.
- 3.5.8. **Deviations.**
 - a. In addition to monitoring reports required by this permit, the permittee shall promptly submit supplemental reports and notices in accordance with the following:
 - 1. Any deviation resulting from an emergency or upset condition, as defined in 45CSR§30-5.7., shall be reported by telephone or telefax within one (1) working day of the date on which the permittee becomes aware of the deviation, if the permittee desires to assert the affirmative defense in accordance with 45CSR§30-5.7. A written report of such deviation, which shall include the probable cause of such deviations, and any corrective actions or preventative measures taken, shall be submitted and certified by a responsible official within ten (10) days of the deviation.
 - 2. Any deviation that poses an imminent and substantial danger to public health, safety, or the environment shall be reported to the Secretary immediately by telephone or telefax. A written report of such deviation, which shall include the probable cause of such deviation, and any corrective actions or preventative measures taken, shall be submitted by the responsible official within ten (10) days of the deviation.
 - 3. Deviations for which more frequent reporting is required under this permit shall be reported on the more frequent basis.
 - 4. All reports of deviations shall identify the probable cause of the deviation and any corrective actions or preventative measures taken.

[45CSR§30-5.1.c.3.C.]

b. The permittee shall, in the reporting of deviations from permit requirements, including those attributable to upset conditions as defined in this permit, report the probable cause of such deviations and any corrective actions or preventive measures taken in accordance with any rules of the Secretary.

[45CSR§30-5.1.c.3.B.]

the maximum loading based on product formulations is equal or less than the maximum load given under 5.1.3.a.

[45CSR13, Permit No. R13-2068 (Conditions 6.2.3.)]

5.2.4. For the purposes of demonstrating compliance with maximum annual aggregate dry material loading set forth in 5.1.3.b., the permittee shall monitor and record the aggregate monthly and rolling twelve month total amount of dry material into the fluid beds.

[45CSR13, Permit No. R13-2068 (Conditions 6.2.4.)]

- 5.2.5. For the purposes of demonstrating compliance with maximum annual VOC emission limit set forth in 5.1.5, the permittee shall:
 - a. Monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in each fluid bed with the exception of Fluid Beds 534, 538, and 572 580.
 - b. Monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in Fluid Beds 534, 538, and 572 580 when each bed is and is not venting exhaust to the RTO/Absorber (as applicable) for the purpose of controlling VOCs.
 - c. Calculate and record the monthly and rolling twelve month aggregate VOC emissions from all fluid beds by summing the following:
 - (1) The total amount of VOCs in pounds used in each fluid bed with the exception of Fluid Beds 534, 538, and 572 580.
 - (2) The total amount of VOCs in pounds used in Fluid Beds 534, 538, and 572 580 when not venting exhaust to the RTO/Absorber (as applicable) for the purpose of controlling VOCs.
 - (3) The total amount of VOCs used in Fluid Beds 534, 538, 572, 574 578, and 580 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 Fluid Beds 534, 538, 572, 574 578, and 580 when venting exhaust to the RTO for the purpose of controlling VOCs.
 - (4) The total amount of VOCs used in Fluid Beds 573 and 579 when venting exhaust to the Absorber for the purpose of controlling VOCs. Based on compliance with Requirement 11.1.2 of this permit, the permittee may apply a VOC destruction efficiency of 95% to the amount of VOCs used in Fluid Beds 573 and 579 when venting exhaust to the Absorber for the purpose of controlling VOCs.

[45CSR13, Permit No. R13-2068 (Conditions 6.2.5.)]

5.3. Testing Requirements

5.3.1. See Section 3.3.1.

5.4. Recordkeeping Requirements

5.4.1. The permittee shall maintain a record of all solvents used in the fluid beds and keep a copy of the associated MSDS/SDS to verify that the solvents did not contain any constituent HAPs.

[45CSR13, Permit No. R13-2068 (Condition 6.4.2.)]

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		
241	0.84		
242	0.28	<u>6.25</u> -8.32	
244	0.84		
245	0.84]	
246	0.84		

[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 pound/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, 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 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 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/SDS 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

c. The aggregate maximum amount of solvent combusted by the RTO(s) shall not exceed 3,070 lb/hour or 1,019,240 pounds per rolling twelve month period.

[45CSR13, Permit No. R13-2068 (Condition 9.1.4.)]

8.1.5. The RTO shall, at all times when Fluid Beds 534, 538, 572, 574 – 578, and 580; Coating Pans 244, and 245, and 246; Oven Dryers 260, 261, and 264; and the coating line are venting exhaust to the RTO for the purpose of controlling VOCs, achieve a minimum VOC destruction efficiency of 98%.

[45CSR13, Permit No. R13-2068 (Condition 9.1.5.)]

- 8.1.6. The permittee shall, within 60 days of the date of the performance test required under 8.3.2, determine the optimal operating ranges of the RTO parameters listed under 8.1.6(a) and (b) so as to monitor the effective operation of the RTO. The determination of operating ranges shall be based on data obtained from performance testing, manufacturing recommendations, or operational experience. The permittee shall maintain on-site, and update as necessary, a certified report listing the operating ranges. Any changes to the operating ranges shall be accompanied by the date of the change and reason for the change.
 - a. Minimum RTO Combustion Chamber Temperature; and
 - b. RTO Exhaust Flow Rate.

[45CSR13, Permit No. R13-2068 (Condition 9.1.6.)]

8.1.7. The permittee shall, to the extent reasonably possible, operate the RTO within the operating ranges as established under 8.1.6 at all times Fluid Beds 534, 538, 572, 574 – 578, and 580; Coating Pans 244, and 245, and 246; Oven Dryers 260, 261, and 264; and the coating line are venting exhaust to the RTO for the purpose of controlling VOCs. If an excursion from the operating ranges occurs, the permittee shall attempt to immediately correct the problem and follow the record-keeping procedures under 8.4.1. If the permittee is unable to correct the excursion in a timely fashion, for the purposes of emissions calculations under 5.2.5(c)(3), a VOC destruction efficiency of 98% may not be assumed for the duration of the venting of VOC from Fluid Beds 534, 538, 572, 574 – 578, and 580; Coating Pans 244, and 245, and 246; Oven Dryers 260, 261, and 264; and the coating line.

[45CSR13, Permit No. R13-2068 (Condition 9.1.7.)]

8.1.8. The permittee shall conduct, at a minimum, an annual inspection of the RTO to ensure proper operation of the control device. The inspection shall include the burner assemblies, blowers, fans, dampers, refractory lining, oxidizer shell, fuel lines, and ductwork.

[45CSR13, Permit No. R13-2068 (Condition 9.1.8.)]

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 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 9.2.1.)]

8.2.2. For the purposes of demonstrating compliance with maximum annual natural gas combustion rates set forth in 8.1.4(b), the permittee shall monitor and record the rolling twelve month total of natural gas combusted by the RTO.

[45CSR13, Permit No. R13-2068 (Condition 9.2.2.)]

8.2.3. For the purposes of demonstrating compliance with maximum solvent combustion rates set forth in 8.1.4(c), the permittee shall monitor and record the amount of solvent, in pounds, sent to the RTO from Fluid Beds 534, 538, 572, 574 – 578, and 580; Coating Pans 244, and 245, and 246; Oven Dryers 260, 261 and 264; and the coating line. The monthly and rolling twelve month total of solvent sent to RTO from Fluid Beds 534, 538, 572, 574 – 578, and 580; Coating Pans 244, and 245, and 246; Oven Dryers 260, 261, and 264; and the coating line-shall be summed and recorded.

[45CSR13, Permit No. R13-2068 (Condition 9.2.3.)]

- 8.2.4. For the purposes of demonstrating compliance with the requirements set forth in 8.1.5, the permittee shall continuously monitor and record the RTO Combustion Chamber Temperature (as measured at the outlet of the combustion chamber) and the RTO Exhaust Flow Rate (as measured at the RTO outlet or based on fan instrumentation). Monitoring shall be effected by use of the following:
 - a. RTO Combustion Chamber Temperature: Thermocouples, RTDs, or alternative methods/instrumentation as appropriate for gas stream;
 - b. RTO Exhaust Flow Rate: Differential pressure flow device, fan motor ammeter, or other type of device that measures gas velocity or flow rate.

[45CSR13, Permit No. R13-2068 (Condition 9.2.4.)]

8.2.5. The permittee shall install, maintain, and operate all monitoring equipment required by this section in accordance with all manufacture's recommendations.

[45CSR13, Permit No. R13-2068 (Condition 9.2.5.)]

8.3. Testing Requirements

8.3.1. Within 60 days after achieving the maximum solvent combustion rate at which the RTO(s) are permitted to operate at, but not later than 180 days after initial startup, and at such times thereafter as may be required by the Secretary, the permittee shall conduct, or have conducted, a performance test on the RTO(s) to determine compliance with the CO and NO_x emission limits listed in 8.1.3. The permittee shall use EPA approved test methods unless granted approval in writing by the Director to use an alternative test method in a protocol submitted pursuant to 3.3.1.c.

[45CSR13, Permit No. R13-2068 (Condition 9.3.1.)]

10.0 Oven Dryers [emission point ID(s): 260, 261, 264]

10.1. Limitations and Standards

- 10.1.1. Maximum hourly volatile organic compound (VOC) emissions to the atmosphere from Oven Dryers 260, 261 and 264 shall not exceed:
 - a. 529.2 lb/hr for each Oven Dryer if not venting exhaust to the RTO for the purpose of controlling VOC emissions.
 - b. 10.59 lb/hr (as emitted from the RTO) for each Oven Dryers if venting exhaust to the RTO for the purpose of controlling VOC emissions.

[45CSR13, Permit No. R13-2068 (Condition 10.1.1.)]

10.1.2. The maximum total combined annual volatile organic compound (VOC) emissions to the atmosphere from the Oven Dryers 260, 261, and 264 shall not exceed 5.0 tons/year.

[45CSR13, Permit No. R13-2068 (Condition 10.1.2.)]

- 10.1.3. Oven Dryers 260, 261, and 264 shall operate according to the following requirements:
 - a. Each Oven Dryers shall have the capability of directing exhaust to RTO for control of VOCs or emitting directly to atmosphere; and
 - b. No HAP-containing solvents shall be processed in any Oven Dryer.

[45CSR13, Permit No. R13-2068 (Condition 10.1.3.)]

10.2. Monitoring Requirements

- 10.2.1. For the purposes of demonstrating compliance with maximum annual VOC emission limit set forth in 10.1.2., the permittee shall:
 - a. Monitor and record the aggregate monthly and rolling twelve month total amount of VOCs in pounds used in Oven Dryers 260, 261, and 264 when each Oven Dryer is and is not venting exhaust to the RTO for the purpose of controlling VOCs; and
 - b. Calculate and record the monthly and rolling twelve month aggregate VOC emissions from Oven Dryers 260, 261, and 264 by summing the following:
 - (1) The total amount of VOCs in pounds used in Oven Dryers 260, 261, and 264 when not venting exhaust to the RTO for the purpose of controlling VOCs; and
 - (2) The total amount of VOCs used in Oven Dryers 260, 261, and 264 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 Oven Dryers 260, 261, and 264 when venting exhaust to the RTO for the purpose of controlling VOCs.

[45CSR13, Permit No. R13-2068 (Condition 10.2.1.)]

10.3. Testing Requirements

10.3.1. See Section 3.3.1.

10.4. Recordkeeping Requirements

10.4.1. The permittee shall maintain a record of all solvents used in the Oven Dryers 260, 261, and 264 and keep a copy of the associated MSDS/SDS to verify that the solvents did not contain any constituent HAPs. [45CSR13, Permit No. R13-2068 (Condition 10.4.1.)]

10.5. Reporting Requirements

10.5.1. See Section 3.5 Facility - Wide Reporting Requirements

10.6. Compliance Plan

10.6.1. None

12.0. Coating Line [emission point ID(s): TBD 10008085)

12.1. Limitations and Standards

- 12.1.1. Maximum hourly VOC/HAP emissions to the atmosphere from the Coating Line shall not exceed:
 - a. 7.0 lb/hr for the Coating Line if not venting exhaust to the RTO for the purpose of —controlling VOC/HAP emissions; and
 - b. 0.14 lb/hr (as emitted from the RTO) for the Coating Line if venting -exhaust to the RTO for -the purpose of controlling VOC/HAP emissions.

[45CSR13, Permit No. R13-2068 (Condition 12.1.1.)]

12.1.2. The maximum annual VOC/HAP emissions to the atmosphere from Coating Line -shall not exceed 3.0 tons/year.

[45CSR13, Permit No. R13-2068 (Condition 12.1.2.)]

12.1.3. The Coating Line shall have the capability of directing exhaust to RTO for control of VOC/HAPs or emitting directly to atmosphere.

[45CSR13, Permit No. R13-2068 (Condition 12.1.3.)]

12.2. Monitoring Requirements

- 12.2.1. For the purposes of demonstrating compliance with maximum annual VOC/HAP emission limit set forth in 10.1.2., the permittee shall:
 - Monitor and record the aggregate monthly and rolling twelve month total amount of VOC/HAPs in pounds used in the Coating Line when it is and is not venting exhaust to the RTO for the purpose of controlling VOC/HAPs; and
 - b. Calculate and record the monthly and rolling twelve month aggregate VOC/HAPs emissions from the Coating Line by summing the following:
 - (1) The total amount of VOC/HAPs in pounds used in the Coating Line when not venting exhaust to the RTO for the purpose of controlling VOCs; and
 - (2) The total amount of VOC/HAPs used in the Coating Line 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/HAPs destruction efficiency of 98% to the amount of VOC/HAPs used in the Coating Line when venting exhaust to the RTO for the purpose of controlling VOC/HAPs.

[45CSR13, Permit No. R13-2068 (Condition 12.2.1.)]

12.3. Testing Requirements

12.3.1. See Section 3.3 Facility - Wide Testing Requirements

12.4. Recordkeeping Requirements

12.4.1. The permittee shall maintain a record of all solvents used in the Coating Line and keep a copy of the associated MSDS/SDS.

[45CSR13, Permit No. R13-2068 (Condition 12.4.1.)]

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	 Modifications to RTO, Absorber, and Fluid Bed maximum load information
R13-2068P	July 2013	-0.31 tons	 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	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, revised September 2015	0 tons	The addition of a coating pan and associated dust collector to the facility.

Based on no 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.