



COMMONWEALTH OF
PUERTO RICO
Environmental Quality Board

STATEMENT OF BASIS -TITLE V PERMIT
ABBVIE LTD.
PFE-TV-2833-09-1096-0011-A

The Environmental Quality Board (EQB) is issuing a Title V permit pursuant to Title 40 of the Code of Federal Regulations (CFR), Part 70 and with Part VI of the Regulations for the Control of Atmospheric Pollution (RCAP) for AbbVie Ltd. (AbbVie). The facility is located in Road #2 Km. 58.0 Cruce Davila in Barceloneta, Puerto Rico. EQB received a Title V permit application on October 31, 1996 for Abbott Laboratories. On January 29, 2004 a public hearing was held with the intention to issue the operating permit for Abbott. However, a final permit was not issued. On January 1, 2013 Abbott completed the legal separation of its operations between two companies, Abbott Healthcare and AbbVie, Ltd. On January 2, 2013, we received an amended application on behalf of AbbVie, including only equipment belonging to AbbVie.

AbbVie Ltd. is a corporation organized according with the laws of Delaware State, with its main offices in North Chicago, Illinois. AbbVie Ltd. operates a pharmaceutical products manufacturing facility, and elaborates final dose pharmaceutical products such as capsules, tablets and granules. The company is divided into two subsidiaries, both under the common control of AbbVie: AbbVie Ltd. and AbbVie Biotechnology Ltd. AbbVie Ltd operates in the north and south facility of the complex, while AbbVie Biotechnology operates in the south facility. AbbVie, who is the owner of the facility, provides Abbott Healthcare with utilities services, such as steam, electricity, etc. The Volatile Organic Compound emissions (VOC) and particulate matter (PM) are controlled by gas scrubbers and dust collectors. AbbVie does not use or produces HAPs in their pharmaceutical processes, therefore it is not subject to the 40 CFR Part 63 Subpart GGG.

AbbVie is required to have an operating Title V permit because it is a major source of pollutants because the criteria pollutant emissions (PM, SO₂, NO_x, CO and VOC) exceed 100 ton/year. AbbVie is also a major source for greenhouse gases because the greenhouse gases, expressed as CO₂ equivalent exceed 100,000 tons per year. AbbVie is minor source for hazardous air pollutants (HAPs).

Emission Units

The Emission Units section lists the significant emission units, the associated control equipment, and fuel type. This section is an overview of the facility. The emission units are the following:

EU-5, EU-6 and EU-7: Mixing, Compounding and Tableting of Pharmaceuticals - Under these emission units are included the finished pharmaceutical products in Buildings 25, 14 and 14A. Actually AbbVie produces two products in the facility: Feno-Acid and Kaletra. The units use gas scrubbers and dust collectors to control VOC and particulate matter emissions.

EU-8: Utilities and support operations (S.F.) – Under this emission units are included two steam boilers: Boiler 101 and Boiler 102, of 50.8 MMBtu/hr. Both boilers are subject to the 40 CFR Part 60 Subpart Dc and to the 40 CFR Part 63 Subpart JJJJJJ. They use diesel fuel, LPG and comparable fuels.

EU-9: Cogeneration Unit– The cogeneration unit consists of a diesel engine of 28,463 hp. This engine uses a water injection system to control NOx emissions. It uses fuel num. 6, with a sulfur content of 1.0% or less. It is subject to the Prevention of Significant Deterioration (PSD) regulations, therefore it has a permit issued by the Environmental Protection Agency (EPA) that limits its emissions.

EU-10: Utilities and Support Operations (N.F.) - In this emission unit is Boiler #1. The 50 MMBtu/hr boiler uses diesel, fuel num. 6 and on-specification fuel (mixture of up to a maximum 20% used oil and minimum 80% diesel). This boiler is not subject to 40 CFR Part 60 Subpart Dc, but is subject to the 40 CFR Part 63 Subpart JJJJJJ. The PSD permit for the facility includes limitations for this boiler.

EU-10a: Steam production to support pharmaceutical process operations - The emission units consists of 3 boilers, Boiler 1a, 2a and 3a of 300 hp each one. They use diesel fuel and LPG. They are subject to the 40 CFR Part 60 Subpart Dc and by the 40 CFR Part 63 Subpart JJJJJJ.

EU-11: Boilers (UN/N.F.) – Includes Boiler 4. It has a capacity of 59 MMBtu/hr. It uses fuel no. 2. The boiler is subject to the 40 CFR Part 60 Subpart Dc and to the 40 CFR Part 63 Subpart JJJJJJ.

EU-12: Electric Generator (BSG) – Generator to support the Cogeneration Unit (EU-9) during electrical failures. It has a power of 2,319 hp and uses diesel. It is subject to the 40 CFR Part 63 Subpart ZZZZ.

EU-16: Loading, Unloading and Storage of Chemicals (MCP)(N.F.) – This emission units includes 3 ethanol storage tanks, one of 11,300 gallons, and two of 7,500 gallons, each one.

EU-24: Process Fugitive Emissions – This emission units come from the fugitive emissions from the combined use of 4,752,743 ton/yr of ethanol.

EU-26: Combustion units subject to the 40 CFR Part 63 Subpart ZZZZ – This emission unit includes 3 fire pumps and 12 electricity emergency generators. Four engines are authorized to operate 52 hours/year, one of the engines is authorized to operate 1,474 hours/year and the hours of operation for the others do not exceed 500 hours/year.

The Biotechnology plant in the emission unit EU-23, was not included as an emission unit, but was included in the insignificant activities list in section VIII of the permit, because the criteria pollutant emissions do not exceed 2 ton/year or 5 ton/year of a combination of pollutants.

Emission Limits

The emissions described in the following table represent the emission limits at the time of the permit application. According to RCAP Rule 610(a), when AbbVie requests a modification, administrative change or minor modification to its Title V permit, the source will pay only those charges related with any emission increase (if any) per ton, based on the change and not based on the previous total charges in accordance with RCAP Rule 610(a). The emission limits were based on the limitations contained in emission units construction permits.

Pollutants	Emissions (tons/year)
PM	169.12
SO ₂	927.50
NO _x	1,394.5
CO	203.51
VOC	400.96
Pb	1.745E-3
HAPs	0.47
CO ₂ e	167,949.2

Applicable Requirements

Prevention of Significant Deterioration– 40 CFR Part 52

The requirements of this regulations apply to the construction of any new major stationary source (as defined in §52.21(b)(1) or any project at an existing major stationary source in an area designated

as attainment or unclassifiable, under sections 107(d)(1)(A)(ii) or (iii) of the Clean Air Act. The cogeneration unit (EU-9) and Boiler 1 (EU-10) are subject to this regulation and they have a PSD permit issued by the Environmental Protection Agency. The PSD permit includes limitations for emissions and for fuel use for these equipment. The PSD permit conditions are considered applicable requirements, therefore they are included in the construction permit for the equipment and were included in the Title V permit prepared.

Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units, 40 CFR Part 60 Subpart Dc

This subpart applies to boilers constructed, modified or reconstructed after June 9, 1989, with a maximum heat input capacity of 100 MMBtu/hr, but greater than 10 MMBtu/hr. This regulation is applicable to all the boilers in AbbVie, except for Boiler 1 in the emission unit EU-10, because it was constructed before June 9, 1989. The requirements for this regulation for the boilers in AbbVie consist of opacity requirements and limitations in the sulfur content in the fuel burned.

Standards of Performance for Stationary Compression Ignition Internal Combustion Engines, (40 CFR Part 60 Subpart IIII)

Under this subpart, the engine EU26-P13 must comply with the emissions limitations for NMHC, NO_x, CO, and PM and opacity for the life of the engine. Also, the sulfur content is limited to 0.0015% weight and the cetane index to 40 minimum or the aromatic content is limited to 35% volume (maximum).

National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines - 40 CFR Part 63 Subpart ZZZZ

This subpart applies to any existing, new or reconstructed stationary reciprocal internal combustion engine located in area sources or major sources for hazardous air pollutants. AbbVie is a minor source of hazardous air pollutants. The requirements under this regulations vary from changes in oil and filter to inspections of hoses and belts through limits for carbon monoxide. This subpart applies to the engines in the units EU-9, EU-12 and EU-26 except the engine EU26-P13. Engine EU26-P13 shall comply with the requirements of Subpart ZZZZ by complying with the requirements of the 40 CFR, Part 60 Subpart IIII, therefore it does not have to comply with the specific requirements of Subpart ZZZZ.

National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers Area Sources (40 CFR Part 63 Subpart JJJJJ)

This subpart apply to boilers, new or existing, located in area sources for hazardous air pollutants. AbbVie is a minor source for hazardous air pollutants. The boilers in the units EU-8, EU-10, EU-11

are considered existing, while the boilers in the unit EU-10a are considered new. The requirements under this regulation for boilers with a capacity greater than 10 MMBtu/hr consist on minimizing startup and shutdown periods, for new equipment, and work practice standards for all the boilers, which require an initial tune-up and energy assessment for the boilers every 2 years, among other requirements.

Comparable Fuels Rule Vacatur

On June 27, 2014, the US Court of Appeals for the for the District of Columbia Circuit vacated the Comparable Fuels Exclusion included in the 40 CFR §§261.4(a)(16) and 261.38, in the case of Natural Resources Defense Council And Sierra Club, vs the Environmental Protection Agency (USCA Case 98-1379). In response, the EPA issued a final rule on April 8, 2015 removing from the CFR the RCRA exemptions applicable to hazardous materials that are reused for combustion. The facilities burning these materials will be subject to the Hazardous Waste Combustors regulations under 40 CFR Part 63 Subpart EEE, as well as applicable regulations under RCRA subtitle C.

Boilers 101 and 102 in the emission unit EU-8 were authorized to burn comparable fuels and the permit conditions were included in the draft Title V permit issued by the EQB¹. In response to the vacatur, the permittee shall cease to burn comparable fuels in the boilers at the facility, or shall comply with the regulations included in the 40 CFR Part 63 Subpart EEE, according to the itinerary in the Rule.

The following requirements are not applicable to AbbVie:

- 40 CFR Part 63 Subpart GGG (National Emission Standards for Hazardous Air Pollutants for Pharmaceutical Production) – Does not apply because AbbVie does not have pharmaceutical manufacturing operations, as defined in §63.1251 of the 40 CFR, that comply with the criteria in sections 60.1250(a)(1)(i) through (iii) of the 40 CFR.
- 40 CFR Part 63 Subpart VVVVV (National Emission Standards for Hazardous Air Pollutants for Chemical Manufacturing Area Sources) – Does not apply because the facility is not authorized to use any of the compounds listed in Table 1 of this Subpart.
- 40 CFR Part 63 Subpart DDDDD (National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters – Does not apply because the boilers are not located at a major source for HAPs according to §63.7485 of the 40 CFR.

¹ The public hearing for the draft Title V permit was held on May 30, 2014. The vacatur was ordered on June 27, 2014.

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- 40 CFR Part 60 Subparte IIII (Standards of Performance for Stationary Compression Ignition Internal Combustion Engines) – Does not apply to EU-9, EU-12 and EU26 because they are internal combustion engines that were constructed on or before July 11, 2005, except for the engine EU26-P13, which is affected by this regulation
- 40 CFR Part 60, Subparte JJJJ (Standards of Performance for Stationary Spark Ignition Internal Combustion Engines) – Does not apply to EU-9, EU-12 and EU26 because this internal engines are not spark ignition.
- Chemical Accident Prevention Provisions, 40 CFR Part 68 – Does not apply to AbbVie because they do not store any substance regulated by that part in excess of the threshold quantity (2,500 pounds for chlorine) established by the regulation.

The frequency of reporting for compliance certification for this source should be annual. However, AbbVie shall submit semiannual reports of any required monitoring. Unless specifically stated, all terms and conditions of the Title V permit, including provisions designed to limit the potential emission of the source, are enforceable by EPA and the citizens under the Federal Clean Air Act. The terms and conditions designated as state enforceable only, as indicated by the permit, are enforceable only by the EQB.

The EQB has determined that this Title V Operating Permit satisfies the requirements under RCAP Part VI.

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COMMONWEALTH OF
PUERTO RICO
Environmental Quality Board

TITLE V OPERATING PERMIT
AIR QUALITY AREA
ENVIRONMENTAL QUALITY BOARD



Permit Number:	PFE-TV-2833-09-1096-0011-A
Application Receipt Date:	October 31, 1996 ¹
Final or Effective Issue Date:	July 15, 2016
Expiration Date:	July 15, 2021

In accordance to the provisions of Part VI of the Regulation for Atmospheric Pollution Control (RCAP) and the provisions of the Code of Federal Regulations (CFR), Title 40, Part 70:

ABBVIE, LTD.
BARCELONETA, PUERTO RICO

hereinafter referred to as “the permittee” or **AbbVie**, is authorized to operate a stationary source of air pollutants consisting of the emission units described in this permit. Until such time as this permit expires, is modified or revoked, the permittee may emit air pollutants as a result of those processes and activities directly related to and associated with the emission sources, according to the requirements, limitations and conditions of this permit, until the expiration date or until it is modified or revoked.

The conditions of the permit are enforceable by the federal and state government. Those requirements that are enforceable only by the state government are identified as such in the permit. A copy of the permit must be kept in the aforementioned facility at all times.

¹ The initial application was made by Abbott Laboratories and included all sources of the Barceloneta Complex, including those that belong today to Abbott Healthcare. On January 1, 2013 the Barceloneta Complex was separated into two independent sources. On January 2, 2013, we received a Title V Permit application including only the sources that belong to AbbVie.

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Section I – General Information

A. Facility Information

Company Name:	AbbVie, Ltd.
Postal Address:	P.O. Box 278 Barceloneta, P.R. 00617
Facility Location:	Road No. 2 km. 58.0 Barceloneta, P.R. 00617
Responsible Officer	Barry J. Regan Site Director
Contact Person	Juan E. Forteza Chávez Environmental, Safety and Health Manager
Phone:	787-846-3500, ext. 5121
Fax:	787-846-5815
Primary SIC Code:	2833, 2834



B. Process Description

AbbVie, Inc. is a corporation organized according with the laws of Delaware State, with its main offices in North Chicago, Illinois. AbbVie Ltd. operates a pharmaceutical products manufacturing facility located in State Road PR-2, km. 58.0 in Barceloneta, Puerto Rico, and elaborates final dose pharmaceutical products such as capsules, tablets and granules. AbbVie Ltd. and AbbVie Biotechnology Ltd. are subsidiaries of AbbVie, Inc. Both operate in the Barceloneta plant.

Previously the sources that today are subsidiaries of Abbott Laboratories (Abbott Healthcare (AHL) and Abbott Diagnostics (ADI)), and the emission sources operated by AbbVie's Inc. subsidiaries (AbbVie, Ltd. and AbbVie Biotechnology, Ltd.) were grouped as one major stationary source for purposes of Title V permits program. On January 1, 2013, Abbott separated into two separate independent healthcare companies: a diversified medical products corporation, that retained the

Abbott name and a new, research based pharmaceutical company that owns the proprietary pharmaceutical business and was named AbbVie, Inc.

AbbVie Ltd. operates the utilities in the facility, including a cogeneration unit and the boilers, the pharmaceutical plant previously owned by Abbott (PF) and the North Chemical Plant in the north side of the Barceloneta plant. AbbVie also retains the PSD permit. AbbVie Biotechnology operates the plant that was previously known as Abbott Biotechnology Ltd. in the south side of the Barceloneta plant. For purposes of this Title V Permit, AbbVie Ltd. and AbbVie Biotechnology are considered as a single source under common control of its matrix company, AbbVie, Inc.

The emission source include mixing, compounding and tableting of pharmaceuticals (EU-5, EU-6 and EU-7), utilities and support operations (EU-8 and EU-10), the cogeneration unit (EU-9), steam production to support pharmaceutical processes (EU-10a), Boiler No. 4 (EU-11), an electricity generator to support the cogeneration unit (EU-12), emergency generations subject to the 40 CFR Parte 63 Subpart ZZZZ (EU-26), and the loading, unloading and storage (EU-16). As part of the agreements between AHL and AbbVie, Ltd, the last one offers utility services to AHL and ADI, which include water supply, vapor, and electricity, among others.

AbbVie, Ltd. is a major source of atmospheric air pollutants because it has the potential to emit more than 100 ton/yr of PM, SO₂, NO_x, CO, VOC and more than 100,000 ton/year of greenhouse gases, expressed as CO₂ equivalent. Is a minor source of hazardous air pollutants. The emission sources regulated by this permit are found next.

Section II - Emission Units Description and Control Equipment

The emission units regulated by this permit are the following:

Emission Unit	Description	Control Equipment
EU-5	<p>Mixing, Compounding and Tableting of Pharmaceuticals in Building 25-</p> <p>Finished pharmaceutical products are produced using batch chemical processing techniques. Typically, different unit operations are employed, such as mixing, drying, coating and compression steps. Solvents are typically used in these steps of the process.</p>	<p>SC-25-9, SC-25-2, DC-5, SC-25-3, DC-14C-48-01, DC-14C-49-01, DC-25-21-01</p>

Emission Unit	Description	Control Equipment
EU-6	<p>Mixing, Compounding and Tableting of Pharmaceuticals in Building 14 -</p> <p>Finished pharmaceutical products are produced using batch chemical processing techniques. Typically, different unit operations are employed, such as mixing, drying, coating and compression steps. Solvents are typically used in these steps of the process.</p>	DC-12, SC-8, SC-6, SC-48, DC-38, DC-39, DC-16, SC-16, SC-18, DC-18, DC-40, DC-41, DC-17, DC-17-1
EU-7	<p>Mixing, Compounding and Tableting of Pharmaceuticals in Building 14A -</p> <p>Finished pharmaceutical products are produced using batch chemical processing techniques. Typically, different unit operations are employed, such as mixing, drying, coating and compression steps. Solvents are typically used in these steps of the process.</p>	SC-20, SC-27, SC-28, SC-25 & 25B, SC-22 & 22B, DC-29, DC-44
EU-8	<p>Utilities and support operations (S.F.) - Production of steam, refrigeration, compressed air, drinking water and other utilities to support pharmaceutical manufacturing operations. The emission unit includes two steam boilers identified as Boiler 101 and Boiler 102, each one of 50.8 MMBtu/hr that use diesel (330 gal/hr), LPG (519.1 gal/hr) and comparable fuels (561.1 gal/hr). The boilers are subject to the 40 CFR Part 60 Subpart Dc and to the 40 CFR Part 63 Subpart JJJJJJ.</p>	None
EU-9	<p>Cogeneration (N.F) -The unit includes the operation of a cogeneration engine (28,463 hp) to produce electricity (20.2 MW), chill water and steam for internal consumption (20,000 lb/hr) and for manufacturing processes. It uses fuel #6, at a rate of 1,200 gal/hr with a sulfur content less than or equal to 1% weight. It uses water injection to control NOx emissions.</p>	Water Injection

Emission Unit	Description	Control Equipment
EU-10	Utilities and Support Operations (N.F.) – Production of steam, refrigeration, compressed air, process and drinking water, and other utilities and emergency power to support utilities operations during electrical interruptions. The unit is composed of Boiler #1, of 50 MMBtu/hr. The boiler uses diesel fuel, fuel oil no. 6 and on-spec fuel (mixture of a maximum of 20% used oil and minimum 80% diesel). This boiler is not subject to the 40 CFR Part 60 Subpart Dc and the 40 CFR Part 63 Subpart JJJJJJ.	None
EU-10a	Steam production to support pharmaceutical process operations – The emission unit consists of three boilers of 300 hp each one. They use diesel and LPG. The boilers are subject to the 40 CFR Part 60 Subpart Dc and by the 40 CFR Part 63 Subpart JJJJJJ	None
EU-11	Boilers (UN/N.F.) – Boiler #4. Capacity of 59 MMBtu/hr. Uses fuel no. 2. This boiler is subject to the 40 CFR Part 60 Subpart Dc.	None
EU-12	Electric Generator (BSG) – It has a power of 2319 hp. Uses diesel at a rate of 131 gal/hr. This generator is subject to the 40 CFR Part 63 Subpart ZZZZ (RICE).	None
EU-16	Loading, Unloading and Storage of Chemicals – (MCP) (N.F.) Loading, unloading and storage of virgin, waste and recovered chemicals to support pharmaceutical mixing, compounding and tableting manufacturing activities. (Include three ethanol storage tanks)	None
EU-24	Process Fugitive Emissions– Come from the combined use of 4,752,743 ton/yr of ethanol in the following equipment: Accelacotas (two PR-14, two PR-14-A, two PR-14 previously 48); accelacotas (two PR-14, two PR-14-A, two PR-14 previously 48) for codes 6212, 6214 and 6215; Gral 600 and Gral 1200, 48 solution tanks of 14, Tunnel Dryer, Particle Coater; 15 solution tanks in PR-14; Fluid Bed Dryer T-6; Fluid Bed Dryer T-8; Potent Drug Module and Day Mixer.	None

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Emission Unit	Description	Control Equipment
EU-26	Combustion units subject to the 40 CFR Part 63 Subpart ZZZZ (RICE) Operation of emergency electricity generators to support manufacturing operations during electrical failures. Includes 12 generators and 3 fire pumps.	None

Section III – General Permit Conditions

1. **Sanctions and Penalties:** The permittee must comply with all terms, conditions, requirements, limitations and restrictions established in this permit. Any violation to the terms of this permit is subject to administrative, civil or criminal measures, as established in Section 16 of the Environmental Public Policy Act (Law No. 416 of September 22, 2004, as amended).
2. **Right of Entry:** As specified under Rules 103 and 603(c)(2) of the RCAP, the permittee shall allow the Board or an authorized representative, upon presentation of credentials and other documents as may be required by law, to perform the following activities:
 - a. Enter upon the permittee’s premises where an emission source is located or where emissions related activities are conducted, or where records must be kept under the conditions of this permit, under the RCAP, or under the Clean Air Act;
 - b. Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit, under the RCAP, or under the Clean Air Act;
 - c. Inspect and examine any facility, equipment (including monitoring and air pollution control equipment), practices or operations (including QA/QC methods) regulated or required under this permit; as well as sampling emissions of air quality and fuels; and;
 - d. As authorized by the Clean Air Act and the RCAP, to sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with the permit or other applicable requirements.
3. **Sworn Statement:** All records and reports required pursuant to the Regulations for the Control of Atmospheric Pollutants shall be submitted on forms prescribed by the Board and shall be submitted together with a sworn statement or affidavit of the corporate president or vice

president reporting directly to the President, or the highest ranking corporate office in Puerto Rico or a duly authorized representative or of an equivalent responsible officer in the case of the organizations, governments agencies or any other political subdivision. Such sworn statement or affidavit shall attest to the truth, correctness and completeness of such records and reports [Rule 103(D) of the RCAP].

4. **Data Availability:** As specified under Rule 104 of the RCAP, all emission data obtained by or submitted to the EQB, including data reported pursuant to Rule 103 of the RCAP, as well as that obtained in any other way, shall be available for public inspection and may also be made available to the public in any additional manner that the EQB may deem appropriate.
5. **Emergency Plan:** As specified under Rule 107 of the RCAP, the permittee shall have available an Emergency Plan which must be consistent with adequate safety practices, and provides for the reduction or retention of the emissions from the plant during periods classified by the EQB as air pollution alerts, warnings or emergencies. These plans shall identify the emission sources, include the reduction to be accomplished for each source, and the means by which such reduction will be accomplished. These plans will be available for any authorized representative of the EQB at any time.
6. **Air Pollution Control Equipment:** The permittee shall comply with Rule 108 of the RCAP, as follows:
 - a. All air pollution control equipment or control measures shall provide for continuous compliance with applicable rules and regulations. Such equipment or measures shall be installed, maintained, and operated according to those conditions imposed by this Title V permit, within the specified operating limitations of the manufacturer.
 - b. The collected material from air pollution control equipment shall be disposed in accordance with applicable rules and regulations. The removal, manipulation, transportation, storage, treatment or disposal will be done in such or manner that shall not to produce environmental degradation, and in accordance with applicable rules and regulations.
 - c. The Board may require, when deemed appropriate to safeguard the health and welfare of human beings, the installation and maintenance of additional, complete and separate air pollution control equipment of a capacity equal to the capacity of the primary control equipment. Furthermore, the Board may require that such additional air



pollution control equipment be operated continuously and conjunctionally with the primary air pollution control equipment.

- d. All air pollution control equipment shall be operated at all times while the source being controlled is in operation.
- e. In the case of a shutdown of air pollution control equipment for the necessary scheduled maintenance, the intent to shutdown such equipment shall be reported to the Board at least three days prior to the planned shutdown. Such prior notice shall include, but is not limited to the following:
 - i. Identification of the specific source to be taken out of service with its location and permit number.
 - ii. The expected length of time that the air pollution control equipment will be out of service.
 - iii. The nature and quantity of emissions of air pollutants likely to be permitted during the shutdown period.
 - iv. Measures such as the use of off-shift labor and equipment that will be taken to minimize the length of the shutdown period.
 - v. The reasons why it will be impossible or impractical to shutdown the operating source during the maintenance period.

7. **Compliance Certification:** As specified under Rule 602(c)(2)(ix)(C) of the RCAP, the permittee shall submit each year a compliance certification. This certification must be submitted to both the EQB and the Environmental Protection Agency (EPA)² no later than April 1st, covering the previous calendar year, after the permit effective date. The compliance certification shall include, but is not limited to, the information required under Rule 603(c) of the RCAP as follows:

² The certification to the EQB shall be mailed to: Manager, Air Quality Area, P.O. Box 11488, San Juan, PR 00910. The certification to the EPA shall be mailed to: Chief, Enforcement and Superfund Branch CEPD, US Environmental Protection Agency, #48 Rd. 165 Suite 7000 Guaynabo, P.R. 00968-8069.

- a. The identification of each term or condition of the permit that is the basis of the certification; and
- b. The compliance status. Each deviation shall be identified and taken into account in the compliance certification; and
- c. A statement indicating whether the compliance was continuous or intermittent; and
- d. The methods or other means used for determining the compliance status with each term and condition, currently and over the reporting period consistent with sections (a)(3)-(5) of Rule 603 of the RCAP; and
- e. Identification of possible exceptions to compliance, any periods which compliance is required and in which an excursion or exceedance as defined under 40 CFR Part 64 (CAM) occurred; and
- f. Such other facts as the Board may require to determine the compliance status of a source.

 8. **Regulation Compliance:** As specified under Rule 115 of the RCAP, any violation to the RCAP, or to any other applicable rule or regulation, shall be grounds for the Board to suspend, modify, or revoke any relevant permit, approval, variance or other authorization issued by the Board.

9. **Location Approval:** As specified under Rule 201 of the RCAP, nothing in this permit shall be interpreted as authorizing the location or construction of a major stationary source, or the modification of a major stationary source, or a major modification of a significant source, without obtaining first a location approval from the Board and without first demonstrating compliance with the National Ambient Air Quality Standards (NAAQS). This permit does not allow the construction of new minor sources without the required permit under Rule 203 of the RCAP.

10. **Objectionable Odors:** As specified under Rule 420 of the RCAP, the permittee shall not cause or permit emissions to the atmosphere of any matter which produces an objectionable odor that can be perceived in an area other than that designated for industrial purposes. If objectionable odors are detectable beyond the premises designated for industrial purposes property perimeter, and complaints are received, the permittee shall investigate and take

measures to minimize and/or eliminate the objectionable odors, if necessary. [This condition is enforceable only by the State]

11. **Permit Renewal Applications:** As established under Rule 602 (a)(1)(iv) of the RCAP, the permittee shall submit a permit renewal application applications for permit renewal shall be submitted at least 12 months prior to the date of permit expiration. A responsible official must certify all required applications consistent with paragraph (c)(3) of Rule 602 of the RCAP.
12. **Permit Duration:** As specified under Rule 603 of the RCAP, the following terms will apply during the duration of this permit:
 - a. **Expiration:** This authorization shall have a fixed term of 5 years since the effective date. The expiration date will be automatically extended until the Board approves or denies a renewal application (Rule 605(c)(4)(ii) of the RCAP) but only in those cases where the permittee submits a complete renewal application at least twelve (12) months before the expiration date. [Rules 603 (a)(2), 605 (c)(2), and 605(c)(4) of the RCAP]
 - b. **Permit Shield:** As specified under Rule 605 (c)(4)(i) of the RCAP, the permit shield may be extended until the time the permit is renewed if a timely and complete renewal application is submitted.
 - c. In case that this permit is subject to any challenge by third parties, the permit shall remain in effect until the time it is revoked by a court of law with jurisdiction in the matter.
13. **Recordkeeping Requirement:** As established under Rule 603(a)(4)(ii) of the RCAP, the permittee shall retain records of all required monitoring data and support information for a period of 5 years from the date of the monitoring sample, measurement, report, or application.
14. **Semiannual Monitoring Reports/Samplings:** As established under Rule 603(a)(5)(i) of the RCAP, the permittee shall submit reports to the EQB of all required monitoring every 6 months, or more frequently if required by the Board or any other underlying applicable requirement. These reports cover two major elements. The first element is the summary of all periodic monitoring / sampling required in this permit. The second element requires that all deviations from permit conditions are clearly identified, summarized and reported to the



Board. All instances of deviations from permit requirements must be clearly identified in such reports. All required reports must be certified by a responsible official as established under Rule 602(c)(3) of the RCAP. The report covering the period from January through June shall be submitted no later than October 1st of the same year and the report covering the period from July through December shall be submitted no later than April 1st of the following year. The first semiannual report shall cover the period starting from the effective date of the permit. Once the guidelines are developed by the Board, the permittee must use them to complete these reports.

15. **Deviations Reporting due to Emergencies:** According to Rule 603(a)(5)(ii)(a) of the RCAP, any deviation resulting from an upset (such as sudden malfunction or break-down) or emergency conditions, as defined in Rule 603(e) of the RCAP, must be reported within the next 2 working days from the time the emission limits are exceeded due to the emergency, if the permittee wishes to assert the affirmative defense authorized under Rule 603 (e) of the RCAP. If the permittee raises the emergency defense upon an enforcement action, the permittee shall demonstrate that such deviation happens due to an emergency and that the Board was adequately notified. If such emergency deviation last for more than 24 hours, the affected units may be operated until the end of the cycle or 48 hours, what occurs first. The Board may only extend the operation of an emission source in excess of 48 hours, if the source demonstrates to the Board's satisfaction that the National Air Quality Standards have not been exceeded and that there is no risk to the public health.
16. **Deviation Reporting (Hazardous Air Pollutants):** The source shall act as specified in its Emergency Response Plan (established in Rule 107 (C) of the RCAP), when such Plan has shown no significant impact on an area other than those that have been designated for industrial purposes or will cease operations immediately if there is a significant impact on an area other than those that have been designated for industrial purposes (state-only enforceable condition). In accordance with Rule 603(a)(5)(ii)(b) of the RCAP, he shall notify the Board within the next 24 hours if a deviation that results in the release of emissions of hazardous air pollutants for more than occurs an hour in excess of the applicable limit. For the discharge of any regulated air pollutant that continues for more than 2 hours in excess of the applicable limit, the permittee shall notify the Board within 24 hours of the deviation. The permittee shall submit to the Board, within 7 days of the deviation, a detailed written report which includes probable causes, time and duration of the deviation, remedial action taken and the steps you are following to prevent recurrence.

17. **Severability Clause:** As specified under Rule 603(a)(6) of the RCAP, the clauses in this permit are severable. In the event of a successful challenge to any portion of the permit in an administrative or judicial forum, or in the event any of its clauses is held to be invalid, all other portions of the permit shall remain valid and effective, including those related to emission limits, terms and conditions, be they specific or general, as well as monitoring, record keeping and reporting requirements.
18. **Permit Noncompliance:** According to Rule 603(a)(7)(i) of the RCAP, the permittee must comply with all conditions of the permit. Permit noncompliance constitutes a violation of the Regulations and will be grounds for taking the appropriate enforcement action, impose sanctions, revoke, terminate, modify, and/or reissue the permit, or to deny a permit renewal application.
19. **Defense not Allowed:** As specified under Rule 603(a)(7)(ii) of the RCAP, the permittee shall not allege as a defense in an enforcement action, that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.
20. **Permit Modification and Revocation:** As specified under Rule 603(a)(7)(iii) of the RCAP, the permit may be modified, revoked, reopened, reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit condition.
21. **Property Rights:** As specified under Rule 603(a)(7)(iv) of the RCAP, this permit does not convey any property rights of any sort, nor does it grant any exclusive privilege.
22. **Obligation to Furnish Information:** As specified under Rule 603(a)(7)(v) of the RCAP, the permittee shall furnish to the EQB, within a reasonable time, any information that the EQB may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee shall also furnish to the EQB copies of documents related to this permit.
23. **Change in Operating Scenario:** As specified under Rule 603(a)(10)(i) of the RCAP, the permittee shall record in a logbook, contemporaneously with making a change from one operating scenario to another, the scenario under which it is operating. This logbook must be kept at the facility at all times.

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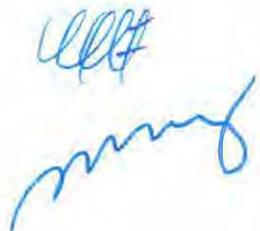
24. **Prohibition on Default Issuance:** As specified under Rule 605(d) of the RCAP, it shall never be considered that a permit has been issued by default as a result of the EQB's failure to take final action on a permit application within 18 months. The EQB's failure to issue a final permit within 18 months should be treated as a final action solely for the purpose of obtaining judicial review in a state court.
25. **Administrative Permit Amendments and Permit Modifications:** As specified under Rule 606 of the RCAP, the permit shall not be amended nor modified unless the permittee complies with the requirements for administrative permit amendments and permit modifications as described in the RCAP.
26. **Permit Reopening:** As specified under Rule 608(a)(1) of the RCAP, this permit shall be reopened and revised under the following circumstances:
- i. Whenever additional applicable requirements under any law or regulation become applicable to the permittee, when the remaining permit term is of 3 or more years. Such reopening shall be completed 18 months after promulgation of said applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which the permit is due to expire, unless the original permit or any of its terms and conditions have been extended pursuant to Rule 605(c)(4)(i) or Rule 605(c)(4)(ii) of the RCAP.
 - ii. Whenever the EQB or the EPA determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emission standards or other terms or conditions of the permit.
 - iii. Whenever the EQB or the EPA determines that the permit must be revised or revoked to assure compliance with the applicable requirements.
27. **Changes in Name or Responsible Official:** This permit is issued to **AbbVie, Ltd.** In the event that the company and/or facility change its name, the responsible official must submit an administrative amendment to this permit to reflect the change in name. If the event that the responsible official changes, the new responsible official must submit no later than 30 days after the change, an administrative amendment including a sworn statement in which he/she accepts and promises to comply with all the conditions of this permit.



28. **Changes in Ownership:** This permit is issued to **AbbVie, Ltd.** In the event that the company and/or facility is transferred to a different owner or change operational control and the Board determines that no other change in the permit is necessary, the new responsible official must submit an administrative amendment. The administrative amendment shall include a sworn statement in which the new responsible official accepts and promises to comply with all the conditions of this permit, and a written agreement containing a specific date for transfer of permit responsibility, coverage, and liability between the current and new permittee. This is not applicable if the Board determines that changes to the permit are necessary.
29. **Renovation Work/ Demolition:** The permittee shall comply with the provisions set forth in 40 CFR §61.145 and §61.150, and Rule 422 of the RCAP, and Regulations for the Processing of General Permits (General Permit for the Handling of Asbestos Containing Materials) when doing renovation or demolition activities of asbestos containing materials at the facility.
30. **Risk Management Plan:** If during the effectiveness of this permit, the permittee is subject to the 40 CFR part 68, the permittee shall submit a Risk Management Plan according with the compliance schedule in the 40 CFR part 68.10. If during the effectiveness of this permit, the permittee is subject to the 40 CFR part 68, the permittee shall submit a compliance certification with the requirements of part 68 as part of the annual compliance certification required under 40 CFR part 70, including the recordkeeping and the Risk Management Plan.
31. **General Duty:** The permittee has the general obligation of identifying hazards which may result from accidental releases of any controlled substance under section 112(r) of the Clean Air Act or any other extremely hazardous substance in a process, using appropriate hazard assessment techniques, designing, maintaining, and operating a safe facility and minimizing the consequences of accidental releases if they occur as required in section 112(r)(1) of the Act and Rule 107(D) of the RCAP.
32. **Requirements for Refrigerants (Climatologic and Stratospheric Ozone Protection):**
- a. In the event that the permittee has equipment or appliances, including air conditioning units, which use Class I or II refrigerants as defined in 40 CFR part 82, subpart A, Appendices A and B, the permittee shall take the necessary measures to ensure that all maintenance, service or repair services performed are done so according to the practices, certification and personnel requirements, disposition requirements, and recycling and/or recovery equipment certification requirements specified under 40 CFR part 82, subpart F.

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- b. Owners/ operators of appliances normally containing 50 or more pounds of refrigerant must keep records of refrigerant purchased and added to such appliances pursuant to 40 CFR §82.166.
- c. Service on Motor Vehicles: If the permittee performs a service on motor (fleet) vehicles when this service involves ozone-depleting substance refrigerant (or regulated substitute substance) in the motor vehicle air conditioner (MVAC), The permittee is subject to all the applicable requirements as specified in 40 CFR part 82, subpart B, Servicing of Motor Vehicle Air Conditioners. The term motor vehicle, as used in subpart B does not include the air-tight sealed refrigeration system used as refrigerated cargo or system used on passenger buses using HCFC-22 refrigerant.
33. **Labeling of Products Using Ozone-Depleting Substances:** The permittee shall comply with the standards for labeling of products using ozone-depleting substances pursuant to 40 CFR part 82, subpart E.
- a. All containers in which a class I or class II substance is stored or transported, all products containing a class I substance, and all products directly manufactured with a class I substance must bear the required warning statement if it is being introduced into interstate commerce pursuant to 40 CFR §82.106.
- b. The placement of the required warning statement must comply with the requirements pursuant to 40 CFR §82.108.
- c. The form of the label bearing the required warning statement must comply with the requirements pursuant to 40 CFR §82.110.
- d. No person may modify, remove, or interfere with the required warning statement except as described in 40 CFR §82.112.
34. **Roof Surface Coating:** The permittee shall not cause or permit the roof surface coating by applying hot tar or any other coating material containing organic compounds without previous notification to the Board. The use of used oil or hazardous waste for roof surface coating is prohibited.[This is a state-only enforceable requirement.]

35. **Open Burning:** Pursuant to Rule 402 of the RCAP, the permittee shall not cause or permit the open burning of refuse in their premises except as established under paragraph (E) of such rule which authorizes to conduct training or research of firefighting techniques, as previously approved by the Board.
36. **Fugitive Emissions:** Compliance with Rule 404 of the RCAP:
- a. The permittee shall use water or suitable chemicals for chemical stabilization and the control of dust in the demolition of a building or structures, construction operations, quarrying operations, the grading of roads, or the clearing of lands.
 - b. The permittee shall not cause or permit the discharge of visible emissions of fugitive dust beyond the boundary line of the property on which the emissions originate.
 - c. When air pollutants escape from a building or equipment and cause and nuisance or violate any regulations, the Board may order that building or equipment in which processing, handling, and storage are done, be tightly closed and/or ventilated so that all emissions from the building or equipment are controlled to remove or destroy such air pollutants before being discharged to the open air. The implementation of this measure should not create occupational health hazards.
37. **Compliance Clause:** Under no circumstances does compliance with this permit exempt the permittee from complying with all other applicable state or federal laws, regulations, permits, administrative orders or applicable court orders.
38. **Emissions Calculations:** The permittee shall submit, on or before **April 1st of each year**, the actual or permissible emissions calculations for the previous natural year. The emissions calculations shall be submitted on the forms prepared by the Board for this purpose and the responsible official must certify all the information submitted as true, correct and representative of the permitted activity.
39. **Annual Fee:** As specified under Rule 610 of the RCAP, the permittee must submit an annual payment based on the emissions calculations for each regulated pollutant. The payment will be based on their actual emissions at a rate of \$37.00 per ton, unless the Board decides otherwise as permitted under Rule 610(b)(2)(iv) of the RCAP. This payment for the previous year must be made on or before **June 30 of each year**.



40. **New or Amended Regulation:** Whether a federal or state regulation is promulgated or amended and the facility is affected by it, the owner or operator shall comply with the requirements of the new or amended regulation by the compliance date or granted extension of compliance date.
41. **Reports:** Any requirement of information submittal to the Board shall be addressed to: Manager, Air Quality Area, P.O. Box 11488, San Juan, P.R. 00910.
42. **Reservation of Rights:** Except as expressly provided in this Title V permit:
- a. Nothing herein shall prevent Board or the EPA from taking administrative enforcement measures or seeking legal or equitable relief to enforce the terms of the Title V permit, including but not limited to the right to seek injunctive relief, and imposition of statutory penalties and/or fines.
 - b. Nothing herein shall be construed to limit the rights of EPA or the Board to undertake any criminal enforcement activity against the permittee or any person.
 - c. Nothing herein shall be construed to limit the authority of EPA or the Board to undertake any actions in response to conditions that present an imminent and substantial endangerment to public health or welfare, or the environment.
 - d. Nothing herein shall be construed to limit the permittee's rights to administrative hearing and judicial appeal of termination/ revocation/ disputes over modification/ denial actions in accordance with regulations and the Environmental Public Policy Act.
43. Any conflict arising between a permit condition and or a requirement established in the law or the federal regulations and a provision incorporated to the same purpose in the Spanish permit, the language in the applicable federal norm shall prevail, except in cases where the



EQB according to the authority granted by law, establishes more stringent requirements than those included in the federal regulations.

Section IV – Emission Limits

1. The emissions described in the following table represent the allowable emission limits at the time of the permit application. According to Resolution RI-06-02³, the emissions calculations will be based on **AbbVie's** actual emissions, however calculations based on the facility's allowable emissions will be accepted. If **AbbVie** decides to perform the calculations based on allowable emissions, **AbbVie** shall pay the same charge per ton as the facilities that decide to do calculations based on their actual emissions. Also, when **AbbVie** requests a modification, administrative change or minor modification to its Title V permit, the source will pay only those charges related with any emission increase (if any) per ton, based on the change and not based on the previous total charges in accordance with Rule 610(a) of the RCAP.



Pollutants	Emissions (ton/yr)
PM	169.12
SO ₂	927.50
NO _x	1,394.5
CO	203.51
VOC	400.96
Pb	1.745E-3
HAPs	0.47
CO ₂ e	167,949.2

Section V – Specific Permit Conditions

A. Facility-Wide Specific Conditions (North and South Facilities)

1. The cogeneration unit (EU-9) and boiler 1 (EU-10) are subject to the provisions in the 40 CFR Part 52.21 and are subject to a PSD permit granted by the EPA. The PSD conditions

³EQB Resolution - Payment procedure for Title V operating charges and Title V permit renewal charges, issued on March 20, 2006.

applicable to the AbbVie facility are included next. The PSD permit conditions applicable to the emission units EU-9 and EU-10, are detailed in section V.B. of this permit.

- a. Nothing in this permit shall be interpreted as an authorization or amendment to the requirements and permit conditions or applicability of Prevention of Significant Deterioration (PSD) applicability or non-applicability determinations granted to AbbVie. [PFE-09-1110-0587-I-II-C, 5-29-12]
- b. The use of fuel #2 in the Barceloneta facility (north and south facility) shall be limited to a maximum of 27,000 gal/day and 6,281,951 gal/year, as computed on a rolling 365-day year.[PFE-09-1110-0587-I-II-C, 5-29-12]
- c. AbbVie shall keep records of the total amount of fuel #2 burned daily in the facility and based on a rolling 365-day year. [PFE-09-1110-0587-I-II-C, 5-29-12]
- d. The sulfur content in the fuel #2 shall not exceed 0.5% weight. [PFE-09-1110-0587-I-II-C, 5-29-12]
- e. The use of fuel #6 shall only be allowed on Boiler 1⁴ [PFE-09-1110-0587-I-II-C, 5-29-12] and in the cogeneration unit.
- f. Records demonstrating that AbbVie's compliance with all permit conditions (PSD) shall be maintained for at least 5 years and shall summarized in reports which shall be submitted to EPA quarterly (with a copy to EQB). Other records to be maintained shall include logs, reports, computer analysis, calibration charts for manual lube oil set point readings, and any other documentation necessary to demonstrate compliance with all permit conditions. [PFE-09-1110-0587-I-II-C, 5-29-12]
- g. AbbVie shall submit all reports required by the PSD permit to:

Chief, Permitting Section
Air Programs Branch
EPA Region 2
290 Broadway, NY, NY 10007

⁴ The condition specifies that it is in the three existing boilers. However, boilers 2 and 3 were eliminated from the facility, therefore boiler 1 is only subject.

- h. Effectiveness of the permit conditions computed on a rolling 365-day year
 - i. All limitation of the fuel maximum limit (CAP) computed based on a rolling 365-day period shall be effective 364 days after the startup of operations in the facility (cogeneration unit and boilers). [PFE-09-1110-0587-I-II-C, 5-29-12]
 - ii. A day consists of a calendar day (from midnight to midnight). [PFE-09-1110-0587-I-II-C, 5-29-12]

2. Appendix III contains a summary of the pollutants subject to PSD and BACT.

B. Requirements for each emission unit

- 1. EU-5, EU-6 and EU-7: Mixing, Compounding and Tableting of Pharmaceuticals, in Buildings 25, 14 and 14A [PFE-09-0496-0435-I-C]



Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Non process sources	PM	0.05	Pounds output/ pounds uncontrolled emissions	Pressure drop across the dust collector	Weekly (check pressure drop) Monthly (visual inspection of the filters)	Records	Semi-annual
Rule 419 of the RCAP	VOC	3 15	lbs/hr lbs/day	Emission Calculations	N/A	Keep records with the emission calculations	Semi-annual

- a. **Control equipment**
 - i. AbbVie shall use the control equipment, as included in Appendix II to control VOC and PM emissions from this emission unit.
 - ii. The control equipment shall comply with the operating conditions included in condition V.B.1.e of this permit.

b. **Non-process sources limit (Rule 409 of the RCAP)**

- i. According to Rule 409 of the RCAP, AbbVie shall not cause or permit the emission of particulate matter in any one hour in excess of 0.05 pounds per pound of uncontrolled emissions for any non-process source.
- ii. AbbVie shall demonstrate compliance with the previous condition by keeping and recording on a weekly basis the pressure drop across the dust collectors according with the parameters established by the manufacturer.
- iii. The permittee shall submit to the EQB a semiannual report of the pressure drop (monthly averages per unit, deviation per unit) in these units. The report that covers the period between January through June shall be submitted no later than October 1st of the same year and the report covering the period from July through December shall be submitted no later than April 1st of the following year.

c. **Rule 419 of the RCAP [state enforceable only]**

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- i. According to Rule 419 of the RCAP, AbbVie shall not permit the emission of 3 pounds per hour or 15 pounds per day of VOC in any article, machine, equipment or any other contrivance unless it is provided with a control system, pollution prevention, and reduction s mechanisms or programs or both, as approved or required by the Board.
 - ii. AbbVie must operate the dust collectors and gas scrubbers at all times while emissions of VOC are generated or could be generated during the manufacturing process in excess of the threshold established in Rule 419 of the RCAP, as included in Appendix II of this permit.

d. **Production Limits**

- i. The increase in emissions is limited to a total VOC limit of 72.19 ton/year. [PFE-09-0496-0435-I-II-C, 7-12-12]
- ii. The total emissions for the manufacturing processes of the pharmaceutical plant (EU-5, EU-6 and EU-7) shall be limited to 1.18 ton/year of particulate matter. [PFE-09-0496-0435-I-II-C, 7-12-12]

- iii. The following equipment are limited as follows, according to the permit PFE-09-0496-0435-I-II-C from July 12, 2012.

Equipment	Maximum raw material use (lbs/yr ethanol)
Accelacotas (two PR-14, two PR-14-A, two PR-14 previously 48")	1,375,470
Accelacotas (two PR-14, two PR-14-A, two PR-14 previously 48"), for the codes 6212, 6214 and 6215	170,346
Gral 600 and Gral 1200	203,470
48 solution tanks in PR-14	882,070
Tunnel Dryer	204,186
Particle Coater	447,346
15 solution tanks in PR-14A	1,056,275
Fluid Bed Dryer T-6	154,570
Fluid Bed Dryer T-8	46,420
Potent Drug Module	8,200
Day Mixer	204,390

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- iv. AbbVie shall prepare and maintain a record with the quarterly amount (in an annual rolling basis) of raw material used for each one of the units included in the previous condition. It shall be available for inspection by EQB's technical personnel. [PFE-09-0496-0435-I-C, 7-12-12]
- v. The amount of mixture per batch and the batches per year for the manufacturing steps of Feno-Acid and Kaletra shall not exceed the following quantities: [PFE-09-0496-0435-I-C, 7-12-12].

Process	Equipment	Batch size	Batches per year
Feno-Acid			
Feno Acid Drying Step	Fluid Bed Dryer T-8	456.4 kg	250
Feno Acid Milling & Sifting Step	Fitzmill & Sweeco	292.4kg	250

Process	Equipment	Batch size	Batches per year
Kaletra Metrex Manufacturing			
Kaletra Metrex Blending Step	V-Blender	1,350.2	697
	Bohle Blender		
Kaletra Meltrex Sieving Step	Comil Mill	1,346.1	697
	Gerteis Mill		
Kaletra Meltrex Milling Step	Fluid Air Mill	1,409.5	697
	Alpine Mill		
Kaletra Meltrex Coating Step	Two Accelacotas 60" (PR-14)	1,581.8	697
	Two Accelacotas 60"(PR-14A)		
	Two Accelacotas 60" (Previously 48")		
Kaletra Meltrex Compressing Step	Fette 3090	1,396.8	697

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- vi. AbbVie shall prepare and maintain a record with the quarterly amount (in an annual rolling basis) of mixture used for each one of the units included in the previous condition [PFE-09-0496-0435-I-C, 7-12-12]
 - vii. AbbVie shall prepare and maintain records with the quarterly amount (in an annual rolling basis) of raw material (ethanol and manufactured product) used and batches manufactured for each one of the units included in this permit. [PFE-09-0496-0435-I-C, 7-12-12]
- e. **Operating Conditions for the Control Equipment**
- i. **Gas Scrubbers**
 - a. The gas scrubbers shall be inspected and shall be maintained according to the manufacturer's recommendation. They will be provided with equipment to monitor the minimum flow of the caustic solutions or

water, as applicable, to ensure that the operational conditions are appropriate.

- b. The permittee shall maintain and operate a flow meter in each one of the gas scrubbers to corroborate the operating parameters of the units. The installed flow meter shall be certified by the manufacturer and shall be precise within $\pm 10\%$ of the gas scrubber design flow.
- c. The flow meter of each unit shall be calibrated every 12 months and you shall keep and calibration records or documents available at all times for review by EQB's technical personnel or to be submitted to EQB upon request.
- d. The permittee shall keep record of the maintenance given to each control equipment. Such record shall be kept in the facility at all times for review by EQB's technical personnel or to be submitted upon request.
- e. AbbVie shall operate an automatic control system to regulate the flow of water in the gas scrubbers as follows: [PFE-09-0496-0435-I-C, 7-12-12]

Unit	Gas Scrubber	Coating without acetone		Coating with acetone ⁵	
		Minimum Flow (gpm)	Ethanol removal efficiency	Minimum flow (gpm)	Ethanol removal efficiency
Accelacota 30	SC-16	90	95%	60	71%
Accelacota 36	SC-18	90	95%	60	71%
Accelacota 48	SC-48	90	95%	60	67%
Accelacota 55	SC-27	92	95%	60	67%
Accelacota 56	SC-28	92	95%	60	67%
Particle Coater	SC-25A/B ⁶	92	95%	50	83%

⁵ Only for the products with codes 65522, 56212, 6214 and 6215.

⁶ Gas scrubbers in series.

- f. The permittee shall monitor the gas scrubbers of the facility to ensure that they are operated and maintained to achieve their design control level. The minimum water flow shall be recorded in an hourly basis and daily average. You shall begin corrective measures immediately when the pre-established minimum daily average flow of water is not achieved. You shall keep a monthly record where the reading of the flow meters are recorded. It shall be available for inspection by EQB's technical personnel.

ii. **Dust Collectors**

- a. The permittee shall calibrate every six months the pressure drop meter of the dust collectors. The permittee shall prepare and maintain a record indicating the date, time, calibration results and methodology used for the calibration. It shall be available at all times for review by our technical personnel.
- b. The permittee shall inspect the clean side of the dust collectors at least once every six months or more frequent, as recommended by the manufacturer, for proper operation and to observe changes that signal the potential for malfunctions. This signals include, but are not limited to: dust deposits in the clean side of bags, loose clamps or in poor condition and spots in the interior shell of the dust collector. Also you shall verify the pressure drop indicator readings on a weekly basis during the operation of the dust collectors to ensure that they work within the range established by the manufacturer and that it guarantees the required control efficiency.
- c. If the permittee finds any defect or problem in the dust collectors during the weekly or monthly inspections, you must record in a logbook the nature of the problem as well as the corrective measures or preventive actions taken to correct the problem. The records must include also the time and date of the inspection.



2. EU-8: Utilities and Support Operations and - Boilers 101 and 102 [PFE-09-0392-0360-II-C]

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reporting Frequency
Sulfur limit in the fuel	Sulfur content	≤ 0.05 (Diesel) ≤ 0.03 (CC) ≤ 0.003 (LPG)	weight percent	Fuel Supplier Certification	With each fuel receipt	Daily records with the sulfur content and the fuel consumption	Monthly Summary in the semiannual reports
Emission Limits in the Boilers	See condition below	See condition below	ton/year	Emission calculations	Monthly	Records with the emission calculations	Semiannual
Visible emission limits	Opacity	20	percent (6-minute average)	Method 9	Once during the first year of the permit Weekly	With each reading	60 days after the readings Semiannual
Particulate matter emission limits (Rule 406 of the RCAP)	Particulate matter	0.3	pounds per million Btu	Method 5 In substitution: Fuel supplier certification with the type of fuel used	One test during the first year of the permit Each time the fuel is received in the facility	Final Test Report Daily records with the type of fuel and the sulfur content in the fuel burned	60 days after the test Semiannual
40 CFR Part 60 Subpart Dc	See condition V.B.2.b	---	---	---	---	---	---
40 CFR Part 63 Subpart JJJJJ	See Section V.C	---	---	---	---	---	---

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a. **Boilers Operation**

- i. Boilers 101 and 102 must not be operated simultaneously, except during the period necessary to put one of the boilers in service, while the other is being retired. [PFE-09-0392-0360-II-C, 5-29-12]

b. **40 CFR Part 60 Subpart Dc**

- i. The boilers are subject to the Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units included in the 40 CFR Part 60 Subpart Dc. AbbVie must operate in compliance with this regulation.
- ii. AbbVie must comply with the applicable recordkeeping and reporting requirements included in section 60.48c of the 40 CFR.

c. **Fuel sulfur limit**

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- i. Boilers 101 and 102 may use the following fuels individually, or any combination of these: [PFE-09-0392-0360-II-C, 5-29-12]
 - a. Diesel with a maximum sulfur content of 0.05% weight and 0.05% weight ash.
 - b. Comparable fuels (CC) with a maximum sulfur content of 0.03% weight and 0.05% weight ash.
 - c. Liquefied Gas (LPG) with a maximum sulfur content of 0.003% weight (30 ppm).
 - ii. The permittee shall keep monthly records for the last 12 calendar with the sulfur content percent analysis performed for each one of the fuels used in the boilers. [PFE-09-0392-0360-II-C, 5-29-12]
 - iii. According to Rule 410 of the RCAP, the permittee shall submit to the EQB a monthly report about boilers 101 and 102 indicating the monthly fuel use and the sulfur content of the fuel burned daily in weight percent. This report shall be sent to the Data Validation and Mathematical Modeling Division of the Air Quality Area no later than the next 15 days of the next month for which the report is representative. [PFE-09-0392-0360-II-C, 5-29-12]

- iv. AbbVie shall demonstrate compliance with the fuel sulfur emission limits using a fuel supplier certification. The certification must be obtained every time that the fuel is received in the facility and shall include the following information:
 - a. Name of the fuel supplier; [PFE-09-0392-0360-II-C, 5-29-12]
 - b. Statement by the diesel supplier indicating that it complies with distillate oil specifications, as defined by the American Society for Testing and Materials ASTM D396 (*Standard Specification for Fuel Oils*) and section 60.41c of the 40 CFR Part 60 Subpart Dc. [PFE-09-0392-0360-II-C, 5-29-12]
 - c. The sulfur content in the fuel in weight percent. [PFE-09-0392-0360-II-C, 5-29-12]
- v. Compliance with the fuel oil sulfur limits shall be determined on a 30-day rolling average basis. [40 CFR §60.42c(g)]
- vi. The fuel oil sulfur limits apply at all times, including periods of startup, shutdown and malfunction.[40 CFR §60.42c(i)]
- d. **Emission limits applicable to the boilers**
 - i. The criteria pollutant emissions generated from the actual use in an annual rolling basis, shall not exceed the following limits: [PFE-09-0392-0360-II-C, 5-29-12]



Maximum criteria pollutants emission levels authorized in the South Facility Boilers	
Pollutants	Emission levels (ton/year)
SO _x	5.31
PM	2.41
NO _x	24.07
VOC	0.619
CO	6.02

Maximum criteria pollutants emission levels authorized in the South Facility Boilers	
Pollutants	Emission levels (ton/year)
PM ₁₀	1.20
Pb	8.89E-04

- ii. The permittee shall record the volume of each fuel (diesel, CC, LPG) used in boilers 101 and 102 on a daily basis. The permittee shall keep a record with the fuel used each day added to the sum of the fuel used in the 364 previous day. [PFE-09-0392-0360-II-C, 5-29-12]
- iii. The emission calculations for each pollutant will be performed monthly according to the actual single use or any combination of them, by the corresponding emission factors, according to the following table: [PFE-09-0392-0360-II-C, 5-29-12]

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Pollutant	Emission factors (lbs/1000 gallons)		
	Low sulfur Limit	CC	LPG
SO _x	142*S	142*S	0.1*S
PM	2.0	2.0	0.7
NO _x	20	20	13
VOC	0.2	0.2	1.0
CO	5.0	5.0	7.5
PM ₁₀	1.0	1.0	---
Pb	9E-12 ⁷	---	---

- iv. The permittee shall keep a record itemizing the actual use of diesel, comparable fuels and LPG, and boilers 101 and 102 emissions corresponding to that use of fuel for the period of 12 previous months. [PFE-09-0392-0360-II-C, 5-29-12]

⁷ Lead emission limit in lbs/10¹² Btu.

- v. The limitations that are in an annual rolling basis become effective 365 days after May 29, 2012. [PFE-09-0392-0360-II-C, 5-29-12]
- vi. You shall keep and operate flow meters to record the flow of comparable fuels, LPG and diesel at the inlet of boilers 101 and 102. You shall calibrate the flow meters every six months to guarantee that the fuel use limit is not exceeded. The flow meters shall be operated and maintained according to the manufacturer's recommendation. [PFE-09-0392-0360-II-C, 5-29-12]
- vii. The permittee shall prepare and maintain records for the boilers indicating the date, time and results of the flow meters calibrations. The records shall be available at all times to be reviewed by EQB's technical personnel. [PFE-09-0392-0360-II-C, 5-29-12]
- viii. The permittee shall keep a daily record with the readings of the fuel flow meters and the fuel sulfur content in weight percent for the boilers. The record shall be available at all times at the facility to be reviewed by EQB's technical personnel. [PFE-09-0392-0360-II-C, 5-29-12]
- ix. The use of any comparable fuel shall only be allowed if it complies with all applicable requirements of the 40 CFR Part 63 Subpart EEE.
- x. On June 27, 2014, the US Court of Appeals for the for the District of Columbia Circuit vacated the Comparable Fuels Exclusion included in the 40 CFR §§261.4(a)(16) and 261.38, in the case of Natural Resources Defense Council And Sierra Club, vs the Environmental Protection Agency (USCA Case 98-1379). The permittee shall cease to burn comparable fuels in the boilers at the facility, or shall comply with the regulations included in the 40 CFR Part 63 Subpart EEE, according to the itinerary in the Rule.

e. **Visible emissions**

- i. As provided in section 60.43(c) of the 40 CFR, boilers 101 and 102 shall not exceed the opacity limit of 20% opacity in a 6-minute average except for one 6-minute period per hour of not more than 27% opacity. [PFE-09-0392-0360-II-C, 5-29-12]

- ii. AbbVie shall hire an independent opacity reader, certified in a school endorsed by the EPA to make one opacity reading on each boiler stack, or in a common stack, as applicable during the first year of the permit using Method 9 described in Appendix A of 40 CFR Part 60. The boilers shall be operating at the time of the opacity reading.
- iii. The permittee shall submit a testing protocol at least 30 days prior to the test for approval by the Board. This protocol must contain the information described in Rule 106(C) of the RCAP. AbbVie shall include a copy of the format that will be used to record the visible emissions readings.
- iv. The permittee shall notify in writing to the Board at least fifteen (15) days prior to the initial reading using Method 9, to allow the Board the opportunity to have an observer present. [Rule 106(D) of the RCAP]
- v. The permittee shall submit two (2) copies of the initial sampling results report under Method 9 within 60 days after the tests. This report shall contain the information required under Rule 106(E) of the RCAP.
- vi. AbbVie shall conduct weekly visible emissions tests according to the requirements listed below:
 - a. Abbvie shall conduct weekly visual opacity inspections of the units during daylight hours in the chimney stack of the equipment, or in a common stack using a Visible Emissions Reader certified by a program endorsed by the EPA or the Board. When the certified reader establishes that the opacity limit under Rule 403 of the RCAP is being exceeded, AbbVie shall verify that the equipment or equipments causing the visible emissions is/are operating in accordance with the manufacturer's specifications and permit conditions. If it is not working properly, the permittee shall take immediate corrective actions in order to eliminate the excess opacity and shall document the steps taken to correct any deficiencies.
 - (1) The weekly visible emission tests shall be performed according to Method 9 of the 40 CFR Part 60, Appendix A, for at least 6 minutes, and according to the following requirements:

CEP
[Signature]

- (a) The permittee shall conduct weekly opacity observations for a minimum of 8 consecutive weeks. If no emissions are observed above the established limit, then -
- (b) The permittee may perform the opacity readings once every two weeks, for a period of 8 consecutive weeks. If emissions are observed above what is established in Rule 403 of the RCAP, you shall revert the observations to a weekly frequency (according to the previous item (a)), If no emissions are observed above the limit established in Rule 203 of the RCAP, then-
- (c) The opacity observations may be performed once per month. If emissions are observed above what is established in Rule 403 of the RCAP, you shall revert the observations to a weekly frequency (according to the item (a) above).
- (d) If the facility reverts to a weekly frequency at any moment, the frequency of the tests shall progress in the same manner as the initial frequency. This means that, once step (a) is completed, you can continue to step (b) and subsequently to step (c), if no emissions are observed above what's established in Rule 403 of the RCAP and so on.

- (2) All the visible emissions observations must be recorded according to Method 9. The permittee shall prepare and maintain a record with the dates and results of the readings available at the facility at all times for review by the Board's technical personnel.
- (3) If the unit is not in operation or the conditions in Method 9 are not met on the day that the observation was going to be carried out, the permittee must document this situation in the observations records and must inform this situation in the

