



ESTADO LIBRE ASOCIADO DE
PUERTO RICO
ENVIRONMENTAL QUALITY BOARD

**TITLE V OPERATING PERMIT
AIR QUALITY AREA
ENVIRONMENTAL QUALITY BOARD**



Permit Number:	PFE-TV-2834-44-0507-0596
Application Receipt Date:	May 14, 2007
Final or Effective Issue Date:	September 15, 2016
Expiration Date:	September 15, 2021

In conformity with the provisions of Part VI of the Regulation for Atmospheric Pollution Control (RCAP) and the provisions of the Code of Federal Regulations (CFR), Volume 40, Part 70 we authorize:

**McNEIL HEALTHCARE, LLC
LAS PIEDRAS, PUERTO RICO**

hereinafter **McNeil** or **the permittee**, is authorized to operate a stationary source of air pollutants emissions consisting of the units and conditions described in this permit. Until this permit expires, is modified or revoked, McNeil shall be able to emit atmospheric pollutants as a result of those processes and activities directly related and associated with the emission sources, in compliance with the requirements, limitations and conditions of this permit, until its expiration date or until such is modified or revoked.

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

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Section I - General Information

A. Facility Information

Facility Name: McNeil Healthcare, LLC

Postal Address: P.O. Box 2009

City: Las Piedras

State: Puerto Rico

Postal Code: 00771-2009

Company Name: Johnson & Johnson

Plant Location: Road 183 Km 19.7
Las Piedras, Puerto Rico

Responsible Officer: Debbie Vázquez Castillo
Vice-President & General Manager

Contact Person: Anabel Ortiz
Senior EHS Specialist

Phone: (787) 733-1000

Fax: (787) 716-5027

SIC Primary Code: 2834



B. Process Description

McNeil Healthcare, LLC. is located at Road 183 km 19.7 in Las Piedras and manufactures pharmaceutical products.

The emission units included are: manufacturing areas, cleaning of process equipment, tanks, boilers and electricity generators. Some of these units are subject by the federal regulation for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP).

The manufacturing area consists of all the equipment used in manufacturing processes that emit particulate matter. These operations include granulation, compression, coating, roto-granulation, packaging and related processes. Emissions are controlled by the collectors at 95% or more of efficiency for the removal of particulate matter.

ROTO granulator unit consists of batch processing of pharmaceuticals in aqueous base. Emissions of volatile organic compounds (VOC) are controlled by a thermal oxidizer and an auxiliary filter with 30% efficiency.

Processes tanks are located in the area of ROTO Granulation. These tanks are used to store a mixture of acetone and methanol. These are equipped by a nitrogen blanketing system.

In the cleaning operations of the equipment, isopropyl alcohol 70% and 99%, *Quick Solve* solvent and thinner are used. The emissions of these operations are fugitive.

McNeil uses 5 steam boilers, identified as B-1, B-2, B-3, B-4, and B-5, which burn diesel fuel with a maximum sulfur content of 0.5 percent by weight. The use of biodiesel fuel is permitted as an alternate scenario for these boilers. The units identified as B-4 and B-5 are subject to the New Source Performance Standards contained in 40 CFR Part 60, Subpart Dc. In addition, the 5 boilers are subject to the National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial and Institutional Boilers Area Sources under 40 CFR Part 63, Subpart JJJJJ. 

There are three boilers in Building 3 to generate steam identified as SB-001, SB-004 and SB-005 and one electric generator for emergencies *Wartsila*. These units are authorized to burn residual #6 fuel or lighter grade fuel with a maximum sulfur content of 2% by weight. In addition, the three boilers are subject to the National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial and Institutional Boilers Area Sources under 40 CFR Part 63 Subpart JJJJJ.

McNeil uses internal combustion engines for 13 electric generators and 3 for emergency fire pumps, which burn diesel fuel with a maximum sulfur content limit of 0.5% by weight. All engines are subject to the National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines of Maximum Achievable Control Technology (RICE MACT) under 40 CFR Part 63, Subpart ZZZZ. The permit specifies those engines affected by the requirements of 40 CFR Part 60 Subpart IIII: New Source Performance Standards for Stationary Compression Ignition Internal Combustion Engines.

The ICENG PE-1 unit, include portable units such as welding machines, pressure washing machines, transfer pumps, compressors and electric generators, burn diesel fuel with a maximum sulfur content of 0.5 percent by weight.

McNeil is a major source for atmospheric pollutants because it has the potential to emit SO₂, NO_x and PM₁₀ in excess of 100 tons per year. McNeil is a minor source of hazardous air pollutants and greenhouse gases (GHGs) expressed as CO₂e.

Section II - Emission Units Description

The emission units regulated by this permit are the following:

Emission Units	Description	Control Equipment
PHARMFG	<p align="center">Pharmaceutical Products Manufacturing Area</p> <p>It consists of all equipment used in pharmaceutical manufacturing that emits particulate matter (PM). The processes are not necessarily restricted to a particular equipment. Emissions of particulate matter are controlled by dust collectors with an efficiency of 95% or greater.</p>	<p>DC-1, DC-2, DC-3, DC-4, DC-6, DC-7-DC-27, DC-30, DC-35</p> <p>(See descriptions in Appendices II and III)</p>
EQUIPCLN-1	Process Equipment Cleaning	None
GLATTS	Six fluidized bed dryers and granulators	None
Chewables	Weight and material transfer rooms	<p>DC-5, EF-211, Vacuum system (Discharge volume 175 SCFM)</p> <ul style="list-style-type: none"> • Efficiency- 95% (See descriptions in Appendices II and III)
Process Tanks	<p>Emission units representing the VOC process tanks installed in the ROTOR area. Units SPT-1 and SPT-2 have a storage capacity of 250 gallons each. SFT-unit 1 has a capacity of 35 gallons. These tanks are used to prepare mixtures of acetone and methanol. A maximum of 85,237.48 gallons per year of methanol are processed. Tanks are equipped with a nitrogen blanketing system.</p>	None

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Emission Units	Description	Control Equipment
ROTOR	ROTO-Granulation Unit. The unit is used in the manufacture of 627 annual batches of pharmaceutical products: Tylenol, Motrin, Pepcid, Imodium and Benadryl. A solution containing 90% solvent (methanol and acetone) and 10% cellulose is used.	Thermal Oxidizer TOS1/TO-1 Design efficiency for methanol and acetone removal-99.91% <ul style="list-style-type: none"> • Discharge volume: 5,000 SCFM for gas flow • Auxiliary fuel: propane • Fuel Consumption: 35.4 gallons per year • Sulfur Percentage: 0.1% (See descriptions in Appendices II and III)
Cleaning of Roto-Granulation Equipment	Cleaning of processes equipment. Fugitive emissions	None
ROTOR-Granulation Room and Sieving Area	3,322 batches per year of pharmaceutical products are handled. Rooms are equipped with a dust collection system for particulate matter.	DC-31 (See descriptions in Appendices II and III)
PHARMFG 2	Continuous operation of packaging for pharmaceuticals. The pharmaceutical area is controlled by a particulate control unit.	DC-33 (See descriptions in Appendices II and III)
B-1	Boiler with a heat input rate of 6.3 MMBtu/hr. Burns diesel fuel at a rate of 45 gallons per hour with a maximum sulfur content of 0.5% by weight. It can be used biodiesel B(20) as established in the alternate operating scenario.	None
B-2	Boiler with a heat input rate of 6.3 MMBtu/hr. Burns diesel fuel at a rate of 45 gallons per hour with a maximum sulfur content of 0.5% by weight. It can be used biodiesel B(20) as established in the alternate operating scenario.	None

Emission Units	Description	Control Equipment
B-3	Boiler with a heat input rate of 6.3 MMBtu/hr. Burns diesel fuel at a rate of 45 gallons per hour with a maximum sulfur content of 0.5% by weight. It can be used biodiesel B(20) as established in the alternate operating scenario.	None
B-4	Boiler with a heat input rate of 16.8 MMBtu/hr. Burns diesel fuel at a rate of 120 gallons per hour with a maximum sulfur content of 0.5% by weight. It can be used biodiesel B(20) as established in the alternate operating scenario.	None
B-5	Boiler with a heat input rate of 25.13 MMBtu/hr. Burns diesel fuel at a rate of 179.5 gallons per hour with a maximum sulfur content of 0.5% by weight. It can be used biodiesel B(20) as established in the alternate operating scenario.	None
SB-001	Boiler with a heat input rate of 28.8 MMBtu/hr. The unit is limited to consume 691,320 gallons of diesel per year with a maximum sulfur content of 2.0% by weight.	None
SB-004	Boiler with a heat input rate of 8.4 MMBtu/hr. The unit is limited to consume 375,290 gallons of diesel per year with a maximum sulfur content of 2.0% by weight.	None
SB-005	Boiler with a heat input rate of 6.7 MMBtu/hr. The unit is limited to consume 316,030 gallons of diesel per year with a maximum sulfur content of 2.0% by weight.	None
ICENG PE-1	Internal combustion portable units with capacity of 10 hp to 200 hp. Include portable units such as welding, pressure washing machines, transfer pumps, compressors or electricity generators. These portable units consume up to 5,624 gallons of diesel fuel per year.	None

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Emission Units	Description	Control Equipment
INENGS EG-1	Internal combustion engine for emergency electricity Generator, <i>Cummins</i> Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-2	Internal combustion engine for emergency electricity generator, <i>Cummins</i> Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-3	Internal combustion engine for emergency electricity generator, <i>Cummins</i> Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-4	Internal combustion engine for emergency electricity generator, <i>Cummins</i> Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-5	Internal combustion engine for emergency electricity generator, <i>Cummins</i> Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-6	Internal combustion engine for emergency electricity generator, <i>Cummins</i> Brand, Model DQKC, engine with a capacity of 2,680 hp. Diesel fuel consumed at a rate of 135 gallons per hour with a maximum sulfur content of 0.5% by weight.	None

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Emission Units	Description	Control Equipment
INENGS EG-7	Internal combustion engine for emergency electricity generator, with engine capacity of 470 hp (350 kW). Consumes diesel fuel at a rate of 23.7 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-8	Internal combustion engine for an emergency electricity generator, with engine capacity of 1,135 hp. Consumes diesel fuel at a rate of 58.5 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-9	Internal combustion engine for and emergency electricity generator, with engine capacity of 200 hp (150 kW). Consumes diesel fuel at a rate of 10.1 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-10	Internal combustion engine for emergency electricity generator, with engine capacity of 100 hp. Consumes diesel fuel at a rate of 5.1 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-11	Internal combustion engine for emergency electricity generator, with engine capacity of 277 hp (750 kW). Consumes diesel fuel at a rate of 11.3 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
INENGS EG-12	Internal combustion engine for an emergency electricity generator, with engine capable of 1,300 hp (970 kW). Consumes diesel fuel at a rate of 65 gallons per hour with a maximum sulfur content of 0.5% by weight.	None

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Emission Units	Description	Control Equipment
EG-03	Internal combustion engine for emergency electricity generator <i>Wartsila</i> with a capacity of 20.4 MMBtu/hr. The generator is limited to consume 787,600 gallons annually of residual oil #6 or lighter oil with a maximum sulfur content of 2.0% by weight.	None
EG-2H	Internal combustion engine for an emergency electricity generator with capacity of 1,040 kW. Consumes residual oil #6 or lighter oil at a rate of 81.0 gallons per hour with a maximum sulfur content of 0.3% by weight.	None
FIRE 1	Internal combustion engine for a pump with a capacity of 187 hp. Consumes diesel fuel at a rate of 9.4 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
FIRE 2	Internal combustion engine for a pump with a capacity of 187 hp. Consumes diesel fuel at a rate of 9.4 gallons per hour with a maximum sulfur content of 0.5% by weight.	None
FP-002	Internal combustion engine for a pump with a capacity of 157 hp. Consumes diesel fuel at a rate of 8.8 gallons per hour with a maximum sulfur content of 0.5% by weight.	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 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 or Affidavit:** All reports required pursuant Rule 103(D) of the RCAP (i.e., semiannual monitoring reports and annual compliance certification) should be submitted together with a sworn statement or affidavit by the Responsible Official or a duly authorized representative. Such sworn statement or affidavit shall attest to the truth, correctness and completeness of such records and reports.
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.
- f. The permittee shall, to the extent possible, maintain and operate at all times, including periods of start-up, shutdown and malfunction, any affected source and the associated air pollution control equipment, in a manner consistent with the original manufacturers design specifications and in compliance with applicable rules and regulations and permit conditions.
- g. The permittee shall keep copies of monthly calibrations and inspections reports of the control equipment such as dust collectors. The permittee shall keep records of all incidents control equipment shutdown if the process continues its operation. All the records shall be available to EQB personnel.



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)¹ no later than **April 1st of each year**, covering the previous calendar year. The compliance certification shall include, but is not limited to, the information required under Rule 603(c) of the RCAP as follows:
- 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.

¹ 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: U.S. Environmental Protection Agency, 48 Carr. 165 Suite 7000, Guaynabo, P.R. 00968-8073.

10. **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.
11. **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. [This condition is enforceable only by the State]
12. **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.
13. **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.
14. **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. The permittee shall keep available in the facility, copies of all records of required monitoring information including the following :
- i . Date, place - as defined in the permit-and time of sampling;
- ii . Date analyzes were performed;
- iii . The company or entity that performed the analyzes;
- iv . Analytical methods or techniques used;
- v . The results of these analyzes; and
- vi . The operating conditions at the time of sampling or measurement.



15. **Semiannual Monitoring Reports/Samplings²:** 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. 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 1 of the same year and the report covering the period from July through December shall be submitted no later than April 1 of the following year. Once the guidelines are developed by the Board, the permittee must use them to complete these reports.
16. **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, whichever 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.
17. **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, the Board shall be notified within the next 24 hours if a deviation that results in the release of emissions of hazardous air pollutants for more than an hour in excess of the applicable limit occurs. 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.
18. **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

² These reports include two major elements. The first element is the summary of all monitoring / periodical sampling required in this permit. The second element requires that all deviations from permit conditions are clearly identified, summarized and reported to the Board.

emission limits, terms and conditions, be they specific or general, as well as monitoring, record keeping and reporting requirements.

19. **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 RCAP 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.
20. **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.
21. **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.
22. **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.
23. **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.
24. **Changes in Operating Scenarios:** As specified in Rule 603(a)(10) 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.
25. **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.
26. **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.

27. **Permit Reopening:** As specified under Rule 608(a)(1), this permit shall be reopened and revised under the following circumstances:
- a. 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.
 - b. 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.
 - c. Whenever the EQB or the EPA determines that the permit must be revised or revoked to assure compliance with the applicable requirements.
-  28. **Changes in Name or Responsible Official:** This permit is issued to **McNeil Healthcare, LLC**. 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.
29. **Changes in Ownership:** This permit is issued to **McNeil Healthcare, LLC**. 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.
30. **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.
31. **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.

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.
- b. Owners/ operators of appliances normally containing 50 or more pounds of refrigerant³ 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 a vehicle in which final assembly of the vehicle has not been completed. The term MVAC 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. **Risk Management Plan (RMP):** 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

³ As defined in the 40 CFR 82.152.

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.

35. **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.

 36. **Roof Surface Coating:** Pursuant to Rule 424 of the RCAP, McNeil 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 rule will not apply to activities where tar or sealing material is applied without heat and such material is asbestos-free. [State enforceable only]

37. **Ozone Generating Machines:**

- a. The operation of each ozone generator machine⁴ identified as insignificant activity is limited to 240 hours per year.
- b. The permittee shall keep a monthly record of hours and days of operation of each machine. This record shall be available at all times for inspection by EQB and EPA.

38. **Fugitive Emissions:** Compliance with Rule 404 of the RCAP:

- a. The permittee shall use, as much as possible, 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.

39. **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

⁴Emission discharge volume = 8.5 grams / hr

purpose and the responsible official must certify all the information submitted as true, correct and representative of the permitted activity.

40. **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.**
41. **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.
42. **Reports:** Unless a permit condition establishes otherwise, any requirement of information submittal to the Board shall be addressed to: Manager, Air Quality Area, PO Box 11488, San Juan, P.R. 00910.
43. **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 permits, 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 the Board or the EPA to undertake any criminal enforcement activity against the permittee or any person.
 - c. Nothing herein shall be construed to limit the authority the Board or the EPA 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.

Section IV - Allowable Emissions

The emissions described in the following table represent the allowable emissions at the time of the permit application and will be used for payment purposes only. According to Resolution RI-06-02⁵, the emissions calculations will be based on actual emissions of **McNeil**, however calculations based on allowable emissions of the installation will be accepted. If **McNeil** going to perform the calculations based on allowable emissions, **McNeil** shall pay the same charge

⁵EQB Resolution - Payment procedure for Title V operating charges and Title V permit renewal charges, issued on March 20, 2006.

per ton as the facilities that decide to do the calculations based on actual emissions. Also, when **McNeil** 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).

Pollutant	Emissions Cap (ton/year)
PM	118.25
SO ₂	450.96
NO _x	411.52
CO	93.49
VOC	22.34
Pb	0.02
Ozone	0.07
HAP (methanol)	2.67
HAP (combustion)	0.43
CO _{2e}	55,630.51

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Section V - Specific Permit Conditions

A. Normal Operating Scenario

The tables presented below contain a summary of the applicable requirements and test methods required to demonstrate compliance with the emission units identified in Section II of this permit.

1. **PHARMFG, CHEWABLES, ROTO-GRANULATION ROOM and SIEVING AREA, GLATTS, PHARMFG 2**

Condition	Parameter	Value	Units	Test Method	Method Frequency	Recordkeeping Requirements	Reports Frequency
Production limit	Annual production of Tylenol, Motrin, Pepcid Imodium and Benadryl (Sieving Room)	3,322	lots per year	Records	Monthly	Logbook	Semiannual
Particulate Matter emission limit for non-process sources	PM	≤0.05	lbs/lbs of uncontrolled emissions	Emission calculations using emission factor 0.0085 grains/dscf Stack test using method 5 of Appendix A of 40 CFR Part 60, during the first year of duration of the permit	Monthly During the first year of duration of the Permit	Record of the readings of pressure drops and calibrations	Semiannual Sixty days (60) after the Stack test.

a. **Production limit:**

- (i) Production is limited to a maximum of 3,322 lots per year (Tylenol, Motrin, Pepcid, Imodium and Benadryl). Shall keep a monthly record with the following information about lots processed in the Sieving Room:
 - a. Product name and its components,
 - b. Lot size,
 - c. Start date and
 - d. Date completed.

b. **Particulate Matter emission limit for non-process sources:**

- (i) McNeil shall not cause the emission of particulate matter at any time in excess of 0.05 pounds per pound of uncontrolled emissions from any non-process source. [Rule 409(B) of the RCAP]
- (ii) Actual emissions of particulate matter of the emission units will be calculated monthly based on the emission factor of particulate matter **and the actual performance rate of the production data**. The emission factor equivalent to the