New York State Department of Environmental Conservation

Permit Review Report

Permit ID: 3-3926-00134/00054
Renewal Number: 1
Modification Number: 2 08/06/2013

Facility Identification Data
Name: PAR PHARMACEUTICAL INC
Address: 1 RAM RIDGE RD
SPRING VALLEY, NY 10977

Owner/Firm
Name: PAR PHARMACEUTICAL INC
Address: 1 RAM RIDGE RD
SPRING VALLEY, NY 10977-6714, USA
Owner Classification: Corporation/Partnership

Permit Contacts
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Permit Description

Introduction

The Title V operating air permit is intended to be a document containing only enforceable terms and conditions as well as any additional information, such as the identification of emission units, emission points, emission sources and processes, that makes the terms meaningful. 40 CFR Part 70.7(a)(5) requires that each Title V permit have an accompanying "...statement that sets forth the legal and factual basis for the draft permit conditions". The purpose for this permit review report is to satisfy the above requirement by providing pertinent details regarding the permit/application data and permit conditions in a more easily understandable format. This report will also include background narrative and explanations of regulatory decisions made by the reviewer. It should be emphasized that this permit review report, while based on information contained in the permit, is a separate document and is not itself an enforceable term and condition of the permit.

Summary Description of Proposed Project
Minor permit modification

Attainment Status
PAR PHARMACEUTICAL INC is located in the town of RAMAPO in the county of ROCKLAND. The attainment status for this location is provided below. (Areas classified as attainment are those that meet all ambient air quality standards for a designated criteria air pollutant.)

Criteria Pollutant	Attainment Status
Particulate Matter (PM)	ATTAINMENT
Particulate Matter< 10µ in diameter (PM10)	ATTAINMENT
Sulfur Dioxide (SO2)	ATTAINMENT
Ozone*	SEVERE NON-ATTAINMENT
Oxides of Nitrogen (NOx)**	ATTAINMENT
Carbon Monoxide (CO)	ATTAINMENT

* Ozone is regulated in terms of the emissions of volatile organic compounds (VOC) and/or oxides of nitrogen (NOx) which are ozone precursors.
** NOx has a separate ambient air quality standard in addition to being an ozone precursor.

Facility Description:
Par Pharmaceutical, Inc. is a manufacturer as well as a research and development facility of pharmaceutical products. The facility is located in Chestnut Ridge, Rockland County, New York. Potential emissions of Volatile Organic Compounds exceed major source thresholds subjecting the facility to Title V permitting. The facility emissions of individual and total Hazardous Air Pollutants (HAPs) are limited below major source thresholds. The facility is subject to monitoring and recordkeeping requirement under 6NYCRR Parts 201, 212 and 228. The Standard Industrial Code (SIC) is 2834 - Pharmaceutical Preparations.

Permit Structure and Description of Operations
The Title V permit for PAR PHARMACEUTICAL INC is structured in terms of the following hierarchy: facility, emission unit, emission point, emission source and process. A facility is defined as all emission sources located at one or more adjacent or contiguous properties owned or operated by the same person or persons under common control. The facility is subdivided into one or more emission units (EU). Emission units are defined as any part or activity of a stationary facility that emits or has the potential to emit any federal or state regulated air pollutant. An emission unit is represented as a grouping of processes (defined as any activity involving one or more emission sources (ES) that emits or has the potential to emit any federal or state regulated air pollutant). An emission source is defined as any apparatus, contrivance or machine capable of causing emissions of any air contaminant to the outdoor atmosphere, including any appurtenant exhaust system or air cleaning device. [NOTE: Indirect sources of air contamination as defined in 6 NYCRR Part 203 (i.e. parking lots) are excluded from this definition]. The applicant is required to identify the principal piece of equipment (i.e., emission source) that directly results in or controls the emission of federal or state regulated air

pollutants from an activity (i.e., process). Emission sources are categorized by the following types:
combustion - devices which burn fuel to generate heat, steam or power
incinerator - devices which burn waste material for disposal
control - emission control devices
process - any device or contrivance which may emit air contaminants that is not included in the above categories.

PAR PHARMACEUTICAL INC is defined by the following emission unit(s):

Emission unit 00000E - Aqueous coating of pharmaceutical tablets. Particulate emissions are controlled by a dust collector exhausted to emission point 00020.

Emission unit 00000E is associated with the following emission points (EP):
00020
Process: P01 is located at GROUND - Aqueous coating of pharmaceutical tablets.

Emission unit 00000M - This emission unit is comprised of the Compression Area (Rooms 23, 27 and 28) and relocated Pharmacy Dispensing Area (Rooms 1, 2 and 3). Negative pressure is maintained on emission sources consisting of each Pharmacy Dispensing Area room and three Compression Area tablet presses; (2) Fette 3090 tablet presses and one (1) Fette 2090 tablet press.

Particulate emissions are controlled by a DFT 2-4 PulseJet Cartridge Dust Collector (control ID DC16) and exhausted through Emission Point 00034.

Emission unit 00000M is associated with the following emission points (EP):
00034
Process: P06 is located at Ground - Combined process consisting of the pharmacy dispensing area and compression area activities.

Emission unit 00000C - Chemical storage room.

Emission unit 00000C is associated with the following emission points (EP):
00004
Process: S01 Chemical Storage.

Emission unit 00000D - Removal of isopropyl alcohol from pharmaceutical products utilizing drying ovens No. 6, No. 7 and No. 8. Three scrubbers are used to control VOC emissions identified as Scrubber No. 1, No. 2 and No. 3.

Process flow as follows:

Drying oven No. 6 vents to scrubber No. 2 which exhausts to emission point 00006 for the first 6 hours of the drying cycle. Then scrubber will be turned off and emissions from the remaining portion of the drying

cycle exhausted through emission point 00008.

Drying oven No. 7 vents to scrubber No. 1 which exhausts to emission point 00005 for the first 6 hours of the drying cycle. Then scrubber will be turned off and emissions from the remaining portion of the drying cycle exhausted through emission point 00009.

Drying oven No. 8 vents to scrubber No. 3 which exhausts to emission point 00007 for the first 6 hours of the drying cycle. Then scrubber will be turned off and emissions from the remaining portion of the drying cycle exhausted through emission point 00010.

Emission unit 00000D is associated with the following emission points (EP):
00005, 00006, 00007, 00008, 00009, 00010
Process: D03 Removal of isopropyl alcohol from pharmaceutical products.

Emission unit 00000I - Operations associated with the compression area. Particulate emissions are controlled by a dust collector (DC04) exhausted to emission point 00024.

Emission unit 00000I is associated with the following emission points (EP):
00024
Process: P04 is located at GROUND - Operations associated with the compression area.

Emission unit 00000Q - This emission unit consists of a 48" Tablet Coater(Accela-Coater) and two Glatt GPCG-60 coater/granulation/dryer units. There are three fume hoods HOOD01, HOOD02 and HOOD03 which collect emissions from the devices. Particulate emissions from the 48 inch tablet coater is controlled by dust collector DC-11. Particulate emissions from the Glatt units are controlled by internal dust collectors DC-12 and DC-13. A carbon absorption system CA-1RR serves to control volatile organic compound emissions while production is utilizing solvent materials which is exhausted to EP00040.

Operating system components using solvent (P07) and aqueous based materials (P08, P09, P10) are defined under separate process descriptions.

Emission unit 00000Q is associated with the following emission points (EP):
00040, 00041, 00042
Process: P07 is located at Ground, Building 01 - All pharmaceutical components associated with this emission unit operated utilizing solvent materials vented to EP00040.

Process: P08 Aqueous materials used in the unit components Glatt GPCG-60 No. 1, Dust collector No. 12 and Hood No. 2 exhausted through EP00026.

Process: P09 is located at Building 01 - Aqueous materials used in the unit components 48 inch tablet coater, Dust collector No. 11 and Hood No. 1 exhausted through EP00041.

Process: P10 is located at Building 01 - Aqueous materials used in the unit components Glatt GPCG-60 No. 2, Dust collector No. 13 and Hood No. 3 exhausted through EP00042.

Emission unit 00000B - Drying aqueous based pharmaceutical products using an aeromatic fluidized bed dryer. Emissions are exhausted through emission point 00003.

Emission unit 00000B is associated with the following emission points (EP):
00003
Process: D02 is located at GROUND - Drying aqueous based pharmaceutical products.

Emission unit 00000A - Drying pharmaceutical products using oven No.4 and oven No.5 (each lydon brothers model 3469-5-t2wm). Products are aqueous based only.

Emission unit 00000A is associated with the following emission points (EP):
00001, 00002
Process: D01 is located at GROUND - Drying of aqueous based pharmaceutical products.

Emission unit 00000J - Operations associated with the granulation area. Particulate emissions are controlled by a dust collector (DC05) exhausted to emission point 00025.

Emission unit 00000J is associated with the following emission points (EP):
00025
Process: P05 is located at GROUND - Operations associated with the granulation area.

Emission unit 00000G - Aqueous based compu-lab tablet coater. Particulate emissions are controlled by a dust collector exhausted to emission point 00022.

Emission unit 00000G is associated with the following emission points (EP):
00022
Process: P03 is located at GROUND - Aqueous based compu-lab tablet coater.

Emission unit 00000R - Activities associated with granulation rooms No. 2, No. 4 and No. 6A. Emission sources are a portable Fitzmill, a granulator, a blender and a sifter. Air is collected from each room, routed to separate in line HEPA filters, combined, and vented to a common dust collector to control particulate emissions prior to exiting through emission point 00043.

Emission unit 00000R is associated with the following emission points (EP):
00026, 00043
Process: P11 is located at Building 01 - Process associated with granulation.

Emission unit 00000H - This emission unit defines overall facility fugitive volatile organic compound (VOC) emissions associated with sanitizing solvents used and batch production of pharmaceutical products. Fugitive VOC emissions are assumed exhausting through emission point 00023.

Emission unit 00000H is associated with the following emission points (EP):
00023
Process: F01 is located at GROUND - Fugitive volatile organic compound (VOC) emissions associated with sanitizing solvents used and batch production of pharmaceutical products.

Emission unit 00000L - Operations associated with the storage of hazardous waste.

Emission unit 00000L is associated with the following emission points (EP):
00032
Process: S03 Storage of hazardous wastes.

Emission unit 00000K - Chemical storage building.

Emission unit 00000K is associated with the following emission points (EP):
00031
Process: S02 Chemical storage.

Emission unit 00000F - Aqueous coating of pharmaceutical tablets. Particulate emissions are controlled by a dust collector exhausted to emission point 00021.

Emission unit 00000F is associated with the following emission points (EP):
00021
Process: P02 is located at GROUND - Aqueous coating of pharmaceutical tablets.

Emission unit 00000N - Packaging lines lines A, D, E and F. Particulate emissions are controlled by dust collector DC-07 vented to EP00035.

Emission unit 00000N is associated with the following emission points (EP):
00035, 00036
Process: PLA is located at Ground, Building 01 - Packaging of pharmaceutical products Lines A, D, E and F in support of equipment used in pharmaceutical production and or R & D. Dust collector DC07 is

utilized to control particulate emissions exhausted through emission point 35.

Emission unit 00000O - Two Packaging lines B and C and one blister packaging line. Particulate emissions are controlled by dust collector DC-8 vented to EP00036.

Process: PLB is located at Building 01 - Packaging of pharmaceutical products Lines B, C and Blister.

Title V/Major Source Status
PAR PHARMACEUTICAL INC is subject to Title V requirements. This determination is based on the following information:
Facility is a major source of volatile organic compounds.

Program Applicability
The following chart summarizes the applicability of PAR PHARMACEUTICAL INC with regards to the principal air pollution
regulatory programs:

Regulatory Program	Applicability
PSD	NO
NSR (non-attainment)	NO
NESHAP (40 CFR Part 61)	NO
NESHAP (MACT - 40 CFR Part 63)	NO
NSPS	NO
TITLE IV	NO
TITLE V	YES
TITLE VI	NO
RACT	NO
SIP	YES

NOTES:
PSD Prevention of Significant Deterioration (40 CFR 52) - requirements which pertain to major stationary sources located in areas which are in attainment of National Ambient Air Quality Standards (NAAQS) for specified pollutants.

NSR New Source Review (6 NYCRR Part 231) - requirements which pertain to major stationary sources located in areas which are in non-attainment of National Ambient Air Quality Standards (NAAQS)
for specified pollutants.

NESHAP National Emission Standards for Hazardous Air Pollutants (40 CFR 61) - contaminant and source specific emission standards established prior to the Clean Air Act Amendments of 1990 (CAAA)

which were developed for 9 air contaminants (inorganic arsenic, radon, benzene, vinyl chloride, asbestos, mercury, beryllium, radionuclides, and volatile HAP's).

MACT Maximum Achievable Control Technology (40 CFR 63) - contaminant and source specific emission standards established by the 1990 CAAA. Under Section 112 of the CAAA, the US EPA is required to develop and promulgate emissions standards for new and existing sources. The standards are to
be based on the best demonstrated control technology and practices in the regulated industry, otherwise known as MACT. The corresponding regulations apply to specific source types and contaminants.

NSPS New Source Performance Standards (40 CFR 60) - standards of performance for specific stationary source categories developed by the US EPA under Section 111 of the CAAA. The standards apply only to those stationary sources which have been constructed or modified after the regulations have been proposed by publication in the Federal Register and only to the specific contaminant(s) listed in the regulation.

Title IV Acid Rain Control Program (40 CFR 72 thru 78) - regulations which mandate the implementation of the acid rain control program for large stationary combustion facilities.

Title VI Stratospheric Ozone Protection (40 CFR 82, Subparts A thru G) - federal requirements that apply to sources which use a minimum quantity of CFC's (chlorofluorocarbons), HCFC's (hydrofluorocarbons) or other ozone depleting substances or regulated substitute substances in equipment such as air conditioners, refrigeration equipment or motor vehicle air conditioners or appliances.

RACT Reasonably Available Control Technology (6 NYCRR Parts 212.10, 226, 227-2, 228, 229, 230, 232, 233, 234, 235, 236) - the lowest emission limit that a specific source is capable of meeting by application of control technology that is reasonably available, considering technological and economic feasibility. RACT is a control strategy used to limit emissions of VOC's and NOx for the purpose of attaining the air quality standard for ozone. The term as it is used in the above table refers to those state air pollution control regulations which specifically regulate VOC and NOx emissions.

SIP State Implementation Plan (40 CFR 52, Subpart HH) - as per the CAAA, all states are empowered and required to devise the specific combination of controls that, when implemented, will bring about attainment of ambient air quality standards established by the federal government and the individual state. This specific combination of measures is referred to as the SIP. The term here refers to those state regulations that are approved to be included in the SIP and thus are considered federally enforceable.

Compliance Status
Facility is in compliance with all requirements.

SIC Codes
SIC or Standard Industrial Classification code is an industrial code developed by the federal Office of Management and Budget for use, among other things, in the classification of establishments by the type of activity in which they are engaged. Each operating establishment is assigned an industry code on the basis
of its primary activity, which is determined by its principal product or group of products produced or distributed, or services rendered. Larger facilities typically have more than one SIC code.

SIC Code	Description
2834	PHARMACEUTICAL PREPARATIONS

SCC Codes

SCC or Source Classification Code is a code developed and used" by the USEPA to categorize processes which result in air emissions for the purpose of assessing emission factor information.Each SCC represents
a unique process or function within a source category logically associated with a point of air pollution emissions. Any operation that causes air pollution can be represented by one or more SCC's.

SCC Code	Description
3-01-060-09	CHEMICAL MANUFACTURING CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS Air Dryers
3-01-060-10	CHEMICAL MANUFACTURING CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS Storage/Transfer
3-01-060-11	CHEMICAL MANUFACTURING CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS Coating Process
3-01-060-12	CHEMICAL MANUFACTURING CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS Granulation Process
3-01-060-22	CHEMICAL MANUFACTURING CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS CHEMICAL MFG:PHARMACEUTICAL PRODUCTION:MISCELLANEOUS FUGITIVES
3-01-060-99	CHEMICAL MANUFACTURING CHEMICAL MANUFACTURING - PHARMACEUTICAL PREPARATIONS Other Not Classified

Facility Emissions Summary

In the following table, the CAS No. or Chemical Abstract Service code is an identifier assigned to every chemical compound. [NOTE: Certain CAS No.'s contain a 'NY' designation within them. These are not true CAS No.'s but rather an identification which has been developed by the department to identify groups of contaminants which ordinary CAS No.'s do not do. As an example, volatile organic compounds or VOC's are identified collectively by the NY CAS No. 0NY998-00-0.] The PTE refers to the Potential to Emit. This is defined as the maximum capacity of a facility or air contaminant source to emit any air contaminant under its physical and operational design. Any physical or operational limitation on the capacity of the facility or air contamination source to emit any air contaminant , including air pollution control equipment and/or restrictions on the hours of operation, or on the type or amount or material combusted, stored, or processed, shall be treated as part of the design only if the limitation is contained in federally enforceable permit conditions. The PTE Range represents an emission range for a contaminant. Any PTE quantity that is displayed represents a facility-wide emission cap or limitation for that contaminant. If no PTE quantity is displayed, the PTE Range is provided to indicate the approximate magnitude of facility-wide emissions for the specified contaminant in terms of tons per year (tpy). The term 'HAP' refers to any of the hazardous air pollutants listed in section 112(b) of the Clean Air Act Amendments of 1990. Total emissions of all hazardous air pollutants are listed under the special NY CAS No. 0NY100-00-0. In addition, each individual hazardous air pollutant is also listed under its own

specific CAS No. and is identified in the list below by the (HAP) designation.

Cas No.	Contaminant Name	PTE lbs/yr	Range
000067-56-1	METHYL ALCOHOL		> 0 but < 10 tpy
0NY075-00-0	PARTICULATES		> 0 but < 2.5 tpy
0NY075-00-5	PM-10		> 0 but < 2.5 tpy
0NY100-00-0	TOTAL HAP	49000	
0NY998-00-0	VOC		>= 25 tpy but < 40 tpy

NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS

Item A: Emergency Defense - 6 NYCRR 201-1.5

An emergency, as defined by subpart 201-2, constitutes an affirmative defense to penalties sought in an enforcement action brought by the Department for noncompliance with emissions limitations or permit conditions for all facilities in New York State.

(a) The affirmative defense of emergency shall be demonstrated through properly signed, contemporaneous operating logs, or other relevant evidence that:

(1) An emergency occurred and that the facility owner or operator can identify the cause(s) of the emergency;
(2) The equipment at the permitted facility causing the emergency was at the time being properly operated and maintained;
(3) During the period of the emergency the facility owner or operator took all reasonable steps to minimize levels of emissions that exceeded the emission standards, or other requirements in the permit; and
(4) The facility owner or operator notified the Department within two working days after the event occurred. This notice must contain a description of the emergency, any steps taken to mitigate emissions, and corrective actions taken.

(b) In any enforcement proceeding, the facility owner or operator seeking to establish the occurrence of an emergency has the burden of proof.

(c) This provision is in addition to any emergency or upset provision contained in any applicable requirement.

Item B: Public Access to Recordkeeping for Title V Facilities - 6 NYCRR 201-1.10(b)
The Department will make available to the public any permit application, compliance plan, permit, and monitoring and compliance certification report pursuant to Section 503(e) of the Act, except for information entitled to confidential treatment pursuant to 6 NYCRR Part 616 - Public Access to records and Section 114(c) of the Act.

Item C: Timely Application for the Renewal of Title V Permits -6 NYCRR Part 201-6.2(a)(4)

Owners and/or operators of facilities having an issued Title V permit shall submit a complete application at least 180 days, but not more than eighteen months, prior to the date of permit expiration for permit renewal purposes.

Item D: Certification by a Responsible Official - 6 NYCRR Part 201-6.2(d)(12)
Any application, form, report or compliance certification required to be submitted pursuant to the federally enforceable portions of this permit shall contain a certification of truth, accuracy and completeness by a responsible official.This certification shall state that based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

Item E: Requirement to Comply With All Conditions - 6 NYCRR Part 201-6.4(a)(2)
The permittee must comply with all conditions of the Title V facility permit. Any permit non-compliance constitutes a violation of the Act and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application.

Item F: Permit Revocation, Modification, Reopening, Reissuance or Termination, and Associated Information Submission Requirements - 6 NYCRR Part 201-6.4(a)(3)
This permit may be modified, revoked, reopened and 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.

Item G: Cessation or Reduction of Permitted Activity Not a Defense - 6 NYCRR 201-6.4(a)(5)
It shall not be a defense for a permittee in an enforcement action to claim that a cessation or reduction in the permitted activity would have been necessary in order to maintain compliance with the conditions of this permit.

Item H: Property Rights - 6 NYCRR 201-6.4(a)(6)
This permit does not convey any property rights of any sort or any exclusive privilege.

Item I: Severability - 6 NYCRR Part 201-6.4(a)(9)
If any provisions, parts or conditions of this permit are found to be invalid or are the subject of a challenge, the remainder of this permit shall continue to be valid.

Item J: Permit Shield - 6 NYCRR Part 201-6.4(g)
All permittees granted a Title V facility permit shall be covered under the protection of a permit shield, except as provided under 6 NYCRR Subpart 201-6. Compliance with the conditions of the permit shall be deemed compliance with any applicable requirements as of the date of permit issuance, provided that such applicable requirements are included and are specifically identified in the permit, or the Department, in acting on the permit application or revision, determines in writing that other requirements specifically identified

are not applicable to the major stationary source, and the permit includes the determination or a concise summary thereof. Nothing herein shall preclude the Department from revising or revoking the permit pursuant to 6 NYCRR Part 621 or from exercising its summary abatement authority. Nothing in this permit shall alter or affect the following:

i. The ability of the Department to seek to bring suit on behalf of the State of New York, or the Administrator to seek to bring suit on behalf of the United States, to immediately restrain any person causing or contributing to pollution presenting an imminent and substantial endangerment to public health, welfare or the environment to stop the emission of air pollutants causing or contributing to such pollution;

ii. The liability of a permittee of the Title V facility for any violation of applicable requirements prior to or at the time of permit issuance;

iii. The applicable requirements of Title IV of the Act;

iv. The ability of the Department or the Administrator to obtain information from the permittee concerning the ability to enter, inspect and monitor the facility.

Item K: Reopening for Cause - 6 NYCRR Part 201-6.4(i)

This Title V permit shall be reopened and revised under any of the following circumstances:

i. If additional applicable requirements under the Act become applicable where this permit's remaining term is three or more years, a reopening shall be completed not later than 18 months after promulgation of the applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which this permit is due to expire, unless the original permit or any of its terms and conditions has been extended by the Department pursuant to the provisions of Part 2 01-6.7 and Part 621.

ii. The Department or the Administrator determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or conditions of the permit.

iii. The Department or the Administrator determines that the Title V permit must be revised or reopened to assure compliance with applicable requirements.

iv. If the permitted facility is an "affected source" subject to the requirements of Title IV of the Act, and additional requirements (including excess emissions requirements) become applicable. Upon approval by the Administrator, excess emissions offset plans shall be deemed to be incorporated into the permit.

Proceedings to reopen and issue Title V facility permits shall follow the same procedures as apply to initial permit issuance but shall affect only those parts of the permit for which cause to reopen exists.

Reopenings shall not be initiated before a notice of such intent is provided to the facility by the Department at least thirty days in advance of the date that the permit is to be reopened, except that the Department may provide a shorter time period in the case of an emergency.

Item L: Permit Exclusion - ECL 19-0305

The issuance of this permit by the Department and the receipt thereof by the Applicant does not and shall not be construed as barring, diminishing, adjudicating or in any way affecting any legal, administrative or equitable rights or claims, actions, suits, causes of action or demands whatsoever that the Department may have against the Applicant for violations based on facts and circumstances alleged to have occurred or existed prior to the effective date of this permit, including, but not limited to, any enforcement action authorized pursuant to the provisions of applicable federal law, the Environmental Conservation Law of the State of New York (ECL) and Chapter III of the Official Compilation of the Codes, Rules and Regulations of the State of New York (NYCRR). The issuance of this permit also shall not in any way affect pending or future enforcement actions under the Clean Air Act brought by the United States or any person.

Item M: Federally Enforceable Requirements - 40 CFR 70.6(b)

All terms and conditions in this permit required by the Act or any applicable requirement, including any provisions designed to limit a facility's potential to emit, are enforceable by the Administrator and citizens under the Act. The Department has, in this permit, specifically designated any terms and conditions that are not required under the Act or under any of its applicable requirements as being enforceable under only state regulations.

NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS

Item A: General Provisions for State Enforceable Permit Terms and Condition - 6 NYCRR Part 201-5

Any person who owns and/or operates stationary sources shall operate and maintain all emission units and any required emission control devices in compliance with all applicable Parts of this Chapter and existing laws, and shall operate the facility in accordance with all criteria, emission limits, terms, conditions, and standards in this permit. Failure of such person to properly operate and maintain the effectiveness of such emission units and emission control devices may be sufficient reason for the Department to revoke or deny a permit.

The owner or operator of the permitted facility must maintain all required records on-site for a period of five years and make them available to representatives of the Department upon request. Department representatives must be granted access to any facility regulated by this Subpart, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations or law.

Regulatory Analysis

Location Facility/EU/EP/Process/ES	Regulation	Condition	Short Description
FACILITY	ECL 19-0301	35	Powers and Duties of the Department with respect to air pollution control
FACILITY	40CFR 63-GGG.1250(c)	1 -7	Pharmaceutical MACT - Applicability
FACILITY	40CFR 68	21	Chemical accident

			prevention provisions
FACILITY	40CFR 82-F	22	Protection of Stratospheric Ozone - recycling and emissions reduction
FACILITY	6NYCRR 200.6	2	Acceptable ambient air quality.
FACILITY	6NYCRR 200.7	10	Maintenance of equipment.
FACILITY	6NYCRR 201-1.4	36, 2 -18	Unavoidable noncompliance and violations
FACILITY	6NYCRR 201-1.7	2 -6	Recycling and Salvage
FACILITY	6NYCRR 201-1.8	12	Prohibition of reintroduction of collected contaminants to the air
FACILITY	6NYCRR 201-3.2(a)	2 -7, 2 -8	Exempt Activities - Proof of eligibility
FACILITY	6NYCRR 201-3.3(a)	2 -9	Trivial Activities - proof of eligibility
FACILITY	6NYCRR 201-6	23, 28, 29	Title V Permits and the Associated Permit Conditions
FACILITY	6NYCRR 201-6.4(a)(4)	2 -10	General Conditions - Requirement to Provide Information
FACILITY	6NYCRR 201-6.4(a)(7)	2 -1	General Conditions - Fees
FACILITY	6NYCRR 201-6.4(a)(8)	2 -11	General Conditions - Right to Inspect
FACILITY	6NYCRR 201-6.4(c)	2 -2	Recordkeeping and Reporting of Compliance Monitoring
FACILITY	6NYCRR 201-6.4(c)(2)	2 -3	Records of Monitoring, Sampling and Measurement
FACILITY	6NYCRR 201-6.4(c)(3)(ii	2 -4	Reporting Requirements - Deviations and Noncompliance
FACILITY	6NYCRR 201-6.4(d)(4)	2 -13	Compliance Schedules - Progress Reports
FACILITY	6NYCRR 201-6.4(e)	2 -5	Compliance Certification
FACILITY	6NYCRR 201-6.4(f)(6)	2 -12	Off Permit Changes
FACILITY	6NYCRR 201-6.5(g)	24	Permit shield
FACILITY	6NYCRR 201-7	1 -5, 1 -6, 1 -7	Federally Enforceable Emissions Caps
FACILITY	6NYCRR 202-1.1	19	Required emissions tests.
FACILITY	6NYCRR 202-2.1	1 -4	Emission Statements - Applicability
FACILITY	6NYCRR 202-2.5	9	Emission Statements - record keeping requirements.
FACILITY	6NYCRR 211.1	1 -8	General Prohibitions - air pollution prohibited
FACILITY	6NYCRR 211.2	1 -14	General Prohibitions - visible emissions limited.
FACILITY	6NYCRR	2 -16, 2 -17	NOx and VOC RACT

	212.10(c)(4)(i)			required at major facilities
FACILITY	6NYCRR 212.11(b)(3)	1	-13	Sampling and monitoring
FACILITY	6NYCRR 212.4(c)	2	-14	General Process Emission Sources - emissions from new processes and/or modifications
FACILITY	6NYCRR 212.6(a)	2	-15	General Process Emission Sources - opacity of emissions limited
FACILITY	6NYCRR 215.2	1		Open Fires - Prohibitions
FACILITY	6NYCRR 231-2.2(a)	1	-6	Applicability to emission increases in any nonattainment area and attainment portions of the ozone transport region.

Applicability Discussion:
Mandatory Requirements: The following facility-wide regulations are included in all Title V permits:

ECL 19-0301
This section of the Environmental Conservation Law establishes the powers and duties assigned to the Department with regard to administering the air pollution control program for New York State.

6 NYCRR 200.6
Acceptable ambient air quality - prohibits contravention of ambient air quality standards without mitigating measures

6 NYCRR 200.7
Anyone owning or operating an air contamination source which is equipped with an emission control device must operate the control consistent with ordinary and necessary practices, standards and procedures, as per manufacturer's specifications and keep it in a satisfactory state of maintenance and repair so that it operates effectively

6 NYCRR 201-1.4
This regulation specifies the actions and recordkeeping and reporting requirements for any violation of an applicable state enforceable emission standard that results from a necessary scheduled equipment maintenance, start-up, shutdown, malfunction or upset in the event that these are unavoidable.

6 NYCRR 201-1.7
Requires the recycle and salvage of collected air contaminants where practical

6 NYCRR 201-1.8
Prohibits the reintroduction of collected air contaminants to the outside air

6 NYCRR 201-3.2 (a)
An owner and/or operator of an exempt emission source or unit may be required to certify that it operates within the specific criteria described in this Subpart. All required records must be maintained on-site for a period of 5 years and made available to department representatives upon request. In addition, department representatives must be granted access to any facility which contains exempt emission sources

or units, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations, or law.

6 NYCRR 201-3.3 (a)
The owner and/or operator of a trivial emission source or unit may be required to certify that it operates within the specific criteria described in this Subpart. All required records must be maintained on-site for a period of 5 years and made available to department representatives upon request. In addition, department representatives must be granted access to any facility which contains trivial emission sources or units subject to this Subpart, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations, or law.

6 NYCRR Subpart 201-6
This regulation applies to those terms and conditions which are subject to Title V permitting. It establishes the applicability criteria for Title V permits, the information to be included in all Title V permit applications as well as the permit content and terms of permit issuance. This rule also specifies the compliance, monitoring, recordkeeping, reporting, fee, and procedural requirements that need to be met to obtain a Title V permit, modify the permit and demonstrate conformity with applicable requirements as listed in the Title V permit. For permitting purposes, this rule specifies the need to identify and describe all emission units, processes and products in the permit application as well as providing the Department the authority to include this and any other information that it deems necessary to determine the compliance status of the facility.

6 NYCRR 201-6.4 (a) (4)
This mandatory requirement applies to all Title V facilities. It requires the permittee to provide information that the Department may request in writing, within a reasonable time, in order to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. The request may include copies of records required to be kept by the permit.

6 NYCRR 201-6.4 (a) (7)
This is a mandatory condition that requires the owner or operator of a facility subject to Title V requirements to pay all applicable fees associated with the emissions from their facility.

6 NYCRR 201-6.4 (a) (8)
This is a mandatory condition for all facilities subject to Title V requirements. It allows the Department to inspect the facility to determine compliance with this permit, including copying records, sampling and monitoring, as necessary.

6 NYCRR 201-6.4 (c)
This requirement specifies, in general terms, what information must be contained in any required compliance monitoring records and reports. This includes the date, time and place of any sampling, measurements and analyses; who performed the analyses; analytical techniques and methods used as well as any required QA/QC procedures; results of the analyses; the operating conditions at the time of sampling or measurement and the identification of any permit deviations. All such reports must also be certified by the designated responsible official of the facility.

6 NYCRR 201-6.4 (c) (2)
This requirement specifies that all compliance monitoring and recordkeeping is to be conducted according to the terms and conditions of the permit and follow all QA requirements found in applicable regulations. It also requires monitoring records and supporting information to be retained for at least 5 years from the time of sampling, measurement, report or application. Support information is defined as including all calibration and maintenance records and all original strip-chart recordings for continuous monitoring

instrumentation, and copies of all reports required by the permit.

6 NYCRR 201-6.4 (c) (3) (ii)
This regulation specifies any reporting requirements incorporated into the permit must include provisions regarding the notification and reporting of permit deviations and incidences of noncompliance stating the probable cause of such deviations, and any corrective actions or preventive measures taken.

6 NYCRR 201-6.4 (d) (5)
This condition applies to every Title V facility subject to a compliance schedule. It requires that reports, detailing the status of progress on achieving compliance with emission standards, be submitted semiannually.

6 NYCRR 201-6.4 (e)
Sets forth the general requirements for compliance certification content; specifies an annual submittal frequency; and identifies the EPA and appropriate regional office address where the reports are to be sent.

6 NYCRR 201-6.4 (f) (6)
This condition allows changes to be made at the facility, without modifying the permit, provided the changes do not cause an emission limit contained in this permit to be exceeded. The owner or operator of the facility must notify the Department of the change. It is applicable to all Title V permits which may be subject to an off permit change.

6 NYCRR 201-6.4 (g)
Permit Exclusion Provisions - specifies those actions, such as administrative orders, suits, claims for natural resource damages, etc that are not affected by the federally enforceable portion of the permit, unless they are specifically addressed by it.

6 NYCRR 202-1.1
This regulation allows the department the discretion to require an emission test for the purpose of determining compliance. Furthermore, the cost of the test, including the preparation of the report are to be borne by the owner/operator of the source.

6 NYCRR 202-2.1
Requires that emission statements shall be submitted on or before April 15th each year for emissions of the previous calENDar year.

6 NYCRR 202-2.5
This rule specifies that each facility required to submit an emission statement must retain a copy of the statement and supporting documentation for at least 5 years and must make the information available to department representatives.

6 NYCRR 211.2
This regulation limits opacity from sources to less than or equal to 20 percent (six minute average) except for one continuous six-minute period per hour of not more than 57 percent opacity.

6 NYCRR 215.2
Except as allowed by section 215.3 of 6 NYCRR Part 215, no person shall burn, cause, suffer, allow or permit the burning of any materials in an open fire.

40 CFR Part 68
This Part lists the regulated substances and there applicability thresholds and sets the requirements for

stationary sources concerning the prevention of accidental releases of these substances.

40 CFR Part 82, Subpart F
Subpart F requires the reduction of emissions of class I and class II refrigerants to the lowest achievable level during the service, maintenance, repair, and disposal of appliances in accordance with section 608 of the Clean Air Act AmENDments of 1990. This subpart applies to any person servicing, maintaining, or repairing appliances except for motor vehicle air conditioners. It also applies to persons disposing of appliances, including motor vehicle air conditioners, refrigerant reclaimers, appliance owners, and manufacturers of appliances and recycling and recovery equipment. Those individuals, operations, or activities affected by this rule, may be required to comply with specified disposal, recycling, or recovery practices, leak repair practices, recordkeeping and/or technician certification requirements.

Facility Specific Requirements
In addition to Title V, PAR PHARMACEUTICAL INC has been determined to be subject to the following regulations:
40 CFR 63.1250 (c)

6 NYCRR 211.1
This regulation requires that no person shall cause or allow emissions of air contaminants to the outdoor atmosphere of such quantity, characteristic or duration which are injurious to human, plant or animal life or to property, or which unreasonably interfere with the comfortable enjoyment of life or property.

6 NYCRR 212.10 (c) (4) (i)
VOC removal efficiency greater than 81% is considered RACT.

6 NYCRR 212.11 (b) (3)
VOC concentration must be monitored and recorded exiting the carbon carbon adsorption unit.

6 NYCRR 212.4 (c)
This rule requires existing sources (in operation after July 1, 1973) of solid particulates with environmental rating of B or C which are not subject to Table 5 "Processes for which Permissible Emission Rate is Based on Process Weight, to be limited to an particulate emission rate not to exceed 0.05 grains per dry standard cubic foot.

6 NYCRR 212.6 (a)
This rule specifies an opacity limitation of less than 20% for any six consecutive minute period for all process emission sources.

6 NYCRR 231-2.2 (a)

6 NYCRR Subpart 201-7
This regulation sets forth an emission cap that cannot be exceeded by the facility. In this permit that cap is

Non Applicability Analysis
List of non-applicable rules and regulations:

Location Facility/EU/EP/Process/ES	Regulation	Short Description
FACILITY	40 CFR Part 63, Subpart GGG	Pharmaceutical MACT

Reason: An existing facility that does not emit greater than 10 tpy of individual Hazardous Air Pollutant and greater than 25 tpy total Hazardous Air Pollutants. Facility is therefore not subject to 40 CFR Part 63.GGG, National Emission Standards for Pharmaceutical Production, see 40CFR 63.GGG.1250(a)(2).

FACILITY	6 NYCRR Part 233	Pharmaceutical and Cosmetic Manufacturing Processes

Reason: Facility does not engage in chemical synthesis and therefore is not subject to Part 233. Packaging and formulation only is not considered to be synthesized pharamaceutical manufacturing per 233.2 (13).

NOTE: Non-applicability determinations are cited as a permit condition under 6 NYCRR Part 201-6.4(g). This information is optional and provided only if the applicant is seeking to obtain formal confirmation, within an issued Title V permit, that specified activities are not subject to the listed federal applicable or state only requirement. The applicant is seeking to obtain verification that a requirement does not apply for the stated reason(s) and the Department has agreed to include the non-applicability determination in the issued Title V permit which in turn provides a shield against any potential enforcement action.

Compliance Certification
Summary of monitoring activities at PAR PHARMACEUTICAL INC:

Location Facility/EU/EP/Process/ES	Cond No.	Type of Monitoring
FACILITY	2-8	work practice involving specific operations
FACILITY	2-4	record keeping/maintenance procedures
FACILITY	2-5	record keeping/maintenance procedures

FACILITY	1-6	work practice involving specific operations
FACILITY	1-7	work practice involving specific operations
FACILITY	1-4	record keeping/maintenance procedures
FACILITY	2-16	intermittent emission testing
FACILITY	2-17	intermittent emission testing
FACILITY	1-13	monitoring of process or control device parameters as surrogate
FACILITY	2-14	intermittent emission testing
FACILITY	2-15	monitoring of process or control device parameters as surrogate

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Basis for Monitoring
Facility is subject to 212 and 228 monitoring requirements.