



PERMIT
Under the Environmental Conservation Law (ECL)

IDENTIFICATION INFORMATION

Permit Type: Air State Facility
Permit ID: 3-3922-00062/02002
Mod 0 Effective Date: 04/05/2005 Expiration Date: No expiration date.
Mod 1 Effective Date: 06/07/2006 Expiration Date: No expiration date.
Mod 2 Effective Date: 10/26/2009 Expiration Date: No expiration date.

Permit Issued To: BARR LABORATORIES INC
223 QUAKER RD
POMONA, NY 10970-2930

Contact: BARR LABORATORIES INC
223 QUAKER RD
POMONA, NY 10970-2930

Facility: BARR LABORATORIES
223 QUAKER RD
POMONA, NY 10970

Contact: JEFFREY GERBER
BARR LABORATORIES
223 QUAKER RD
POMONA, NY 10970
(201) 930-3798

Description:

Barr Laboratories, Inc. is located in the Town of Pomona. The facility manufactures pharmaceutical products and also participates in Research and Development. Heating and process needs are met by the operation of ten exempt (< 10 mmBTU/hr) boilers firing natural gas. The facility also operates an exempt (operated < 500 hrs annually) 3,017 hp diesel CAT generator for emergency power backup. A log is kept on site recording date and hours of generator run times for compliance purposes.

Facilities potential to emit (PTE) is below major stationary source threshold as defined under 6NYCRR Part 201 for all criteria pollutants.

The facility is subject to monitoring and reporting requirements under 6NYCRR Part 212. VOC potential emissions (PTE) are below 25 tons per year, therefore in accordance with 6 NYCRR Subpart 233.1(b)(3), Barr Laboratories is not subject to 6 NYCRR Subpart 233: Pharmaceutical and Cosmetic Manufacturing Processes, and under 40 CFR § 63.1250(a)(ii) is not subject to 40 CFR 63



Subpart GGG—National Emission Standards for Pharmaceuticals Production.

The Standard Industrial Classification representative of this facility is 2834
– Pharmaceutical Preparations.

Modification 2

Minor administrative modifications to more accurately represent applicable regulations.

By acceptance of this permit, the permittee agrees that the permit is contingent upon strict compliance with the ECL, all applicable regulations, the General Conditions specified and any Special Conditions included as part of this permit.

Permit Administrator: KENNETH R GRZYB
 NYSDEC REGION 3
 21 S PUTT CORNERS RD
 NEW PALTZ, NY 12561

Authorized Signature: _____ Date: ____ / ____ / ____



Notification of Other State Permittee Obligations

Item A: Permittee Accepts Legal Responsibility and Agrees to Indemnification

The permittee expressly agrees to indemnify and hold harmless the Department of Environmental Conservation of the State of New York, its representatives, employees and agents ("DEC") for all claims, suits, actions, and damages, to the extent attributable to the permittee's acts or omissions in connection with the compliance permittee's undertaking of activities in connection with, or operation and maintenance of, the facility or facilities authorized by the permit whether in compliance or not in any compliance with the terms and conditions of the permit. This indemnification does not extend to any claims, suits, actions, or damages to the extent attributable to DEC's own negligent or intentional acts or omissions, or to any claims, suits, or actions naming the DEC and arising under article 78 of the New York Civil Practice Laws and Rules or any citizen suit or civil rights provision under federal or state laws.

Item B: Permittee's Contractors to Comply with Permit

The permittee is responsible for informing its independent contractors, employees, agents and assigns of their responsibility to comply with this permit, including all special conditions while acting as the permittee's agent with respect to the permitted activities, and such persons shall be subject to the same sanctions for violations of the Environmental Conservation Law as those prescribed for the permittee.

Item C: Permittee Responsible for Obtaining Other Required Permits

The permittee is responsible for obtaining any other permits, approvals, lands, easements and rights-of-way that may be required to carry out the activities that are authorized by this permit.

Item D: No Right to Trespass or Interfere with Riparian Rights

This permit does not convey to the permittee any right to trespass upon the lands or interfere with the riparian rights of others in order to perform the permitted work nor does it authorize the impairment of any rights, title, or interest in real or personal property held or vested in a person not a party to the permit.



LIST OF CONDITIONS

DEC GENERAL CONDITIONS

General Provisions

Facility Inspection by the Department
Relationship of this Permit to Other Department Orders and
Determinations
Applications for permit renewals, modifications and transfers
Permit modifications, suspensions or revocations by the Department

Facility Level

Submission of application for permit modification or renewal-REGION 3
HEADQUARTERS



DEC GENERAL CONDITIONS
****** General Provisions ******
GENERAL CONDITIONS - Apply to ALL Authorized Permits.

Condition 1: Facility Inspection by the Department
Applicable State Requirement: ECL 19-0305

Item 1.1:

The permitted site or facility, including relevant records, is subject to inspection at reasonable hours and intervals by an authorized representative of the Department of Environmental Conservation (the Department) to determine whether the permittee is complying with this permit and the ECL. Such representative may order the work suspended pursuant to ECL 71-0301 and SAPA 401(3).

Item 1.2:

The permittee shall provide a person to accompany the Department's representative during an inspection to the permit area when requested by the Department.

Item 1.3:

A copy of this permit, including all referenced maps, drawings and special conditions, must be available for inspection by the Department at all times at the project site or facility. Failure to produce a copy of the permit upon request by a Department representative is a violation of this permit.

Condition 2: Relationship of this Permit to Other Department Orders and Determinations
Applicable State Requirement: ECL 3-0301 (2) (m)

Item 2.1:

Unless expressly provided for by the Department, issuance of this permit does not modify, supersede or rescind any order or determination previously issued by the Department or any of the terms, conditions or requirements contained in such order or determination.

Condition 2-1: Applications for permit renewals, modifications and transfers
Applicable State Requirement: 6 NYCRR 621.11

Item 2-1.1:

The permittee must submit a separate written application to the Department for renewal, modification or transfer of this permit. Such application must include any forms or supplemental information the Department requires. Any renewal, modification or transfer granted by the Department must be in writing.

Item 2-1.2:

The permittee must submit a renewal application at least 180 days before expiration of permits for Title V Facility Permits, or at least 30 days before expiration of permits for State Facility Permits.

Item 2-1.3:

Permits are transferrable with the approval of the department unless specifically prohibited by the statute, regulation or another permit condition. Applications for permit transfer should be submitted prior to actual transfer of ownership.

Condition 2-2: Permit modifications, suspensions or revocations by the



Applicable State Requirement: 6 NYCRR 621.13

Item 2-2.1:

The Department reserves the right to modify, suspend, or revoke this permit in accordance with 6NYCRR Part 621. The grounds for modification, suspension or revocation include:

- a) materially false or inaccurate statements in the permit application or supporting papers;
- b) failure by the permittee to comply with any terms or conditions of the permit;
- c) exceeding the scope of the project as described in the permit application;
- d) newly discovered material information or a material change in environmental conditions, relevant technology or applicable law or regulations since the issuance of the existing permit;
- e) noncompliance with previously issued permit conditions, orders of the commissioner, any provisions of the Environmental Conservation Law or regulations of the Department related to the permitted activity.

****** Facility Level ******

Condition 2-3: Submission of application for permit modification or renewal-REGION 3

HEADQUARTERS

Applicable State Requirement: 6 NYCRR 621.6 (a)

Item 2-3.1:

Submission of applications for permit modification or renewal are to be submitted to:

NYSDEC Regional Permit Administrator
Region 3 Headquarters
Division of Environmental Permits
21 South Putt Corners Road
New Paltz, NY 12561-1696
(845) 256-3054



Permit Under the Environmental Conservation Law (ECL)

**ARTICLE 19: AIR POLLUTION CONTROL - AIR STATE FACILITY
PERMIT**

IDENTIFICATION INFORMATION

Permit Issued To: BARR LABORATORIES INC
223 QUAKER RD
POMONA, NY 10970-2930

Facility: BARR LABORATORIES
223 QUAKER RD
POMONA, NY 10970

Authorized Activity By Standard Industrial Classification Code:
2834 - PHARMACEUTICAL PREPARATIONS

Mod 0 Permit Effective Date: 04/05/2005
date.

Permit Expiration Date: No expiration

Mod 1 Permit Effective Date: 06/07/2006
date.

Permit Expiration Date: No expiration

Mod 2 Permit Effective Date: 10/26/2009
date.

Permit Expiration Date: No expiration



LIST OF CONDITIONS

FEDERALLY ENFORCEABLE CONDITIONS

Facility Level

- 1-2 40CFR 82, Subpart F: Recycling and Emissions Reduction
- 2-1 6 NYCRR 212.4: Compliance Demonstration
- 2-2 6 NYCRR 212.6: Compliance Demonstration
- 2-3 6 NYCRR 212.11 (b): Compliance Demonstration

STATE ONLY ENFORCEABLE CONDITIONS

Facility Level

- 5 ECL 19-0301: Contaminant List
- 2-4 6 NYCRR 201-1.4: Unavoidable noncompliance and violations
- 7 6 NYCRR Subpart 201-5: Emission Unit Definition
- 2-5 6 NYCRR 211.2: Air pollution prohibited

Emission Unit Level

- 9 6 NYCRR Subpart 201-5: Emission Point Definition By Emission Unit
- 10 6 NYCRR Subpart 201-5: Process Definition By Emission Unit



FEDERALLY ENFORCEABLE CONDITIONS

****** Facility Level ******

NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS

This section contains terms and conditions which are federally enforceable. Permittees may also have other obligations under regulations of general applicability

Item A: Sealing - 6 NYCRR 200.5

The Commissioner may seal an air contamination source to prevent its operation if compliance with 6 NYCRR Chapter III is not met within the time provided by an order of the Commissioner issued in the case of the violation.

Sealing means labeling or tagging a source to notify any person that operation of the source is prohibited, and also includes physical means of preventing the operation of an air contamination source without resulting in destruction of any equipment associated with such source, and includes, but is not limited to, bolting, chaining or wiring shut control panels, apertures or conduits associated with such source.

No person shall operate any air contamination source sealed by the Commissioner in accordance with this section unless a modification has been made which enables such source to comply with all requirements applicable to such modification.

Unless authorized by the Commissioner, no person shall remove or alter any seal affixed to any contamination source in accordance with this section.

Item B: Acceptable Ambient Air Quality - 6 NYCRR 200.6

Notwithstanding the provisions of 6 NYCRR Chapter III, Subchapter A, no person shall allow or permit any air contamination source to emit air contaminants in quantities which alone or in combination with emissions from other air contamination sources would contravene any applicable ambient air quality standard and/or cause air pollution. In such cases where contravention occurs or may occur, the Commissioner shall specify the degree and/or method of emission control required.

Item C: Maintenance of Equipment - 6 NYCRR 200.7

Any person who owns or operates an air contamination source which is equipped with an emission control device shall operate such device and keep it in a satisfactory state of maintenance and repair in accordance with ordinary and necessary practices, standards and procedures, inclusive of manufacturer's specifications, required to operate such device effectively.



Item D: Unpermitted Emission Sources - 6 NYCRR 201-1.2

If an existing emission source was subject to the permitting requirements of 6 NYCRR Part 201 at the time of construction or modification, and the owner and/or operator failed to apply for a permit for such emission source then the following provisions apply:

- (a) The owner and/or operator must apply for a permit for such emission source or register the facility in accordance with the provisions of Part 201.
- (b) The emission source or facility is subject to all regulations that were applicable to it at the time of construction or modification and any subsequent requirements applicable to existing sources or facilities.

Item E: Emergency Defense - 6 NYCRR 201-1.5

An emergency constitutes an affirmative defense to an action brought 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 and/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;
- (3) During the period of the emergency the facility owner and/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 and/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 and/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 F: Recycling and Salvage - 6 NYCRR 201-1.7

Where practical, any person who owns or operates an air contamination source shall recycle or salvage air contaminants collected in an air cleaning device according to the requirements of 6 NYCRR.

Item G: Prohibition of Reintroduction of Collected Contaminants to the Air - 6 NYCRR 201-1.8

No person shall unnecessarily remove, handle, or cause to be handled, collected air contaminants from an air cleaning device for recycling, salvage or disposal in a manner that would reintroduce them to the outdoor atmosphere.

Item H: Proof of Eligibility for Sources Defined as Exempt Activities - 6 NYCRR 201-3.2 (a)

The owner and/or operator of an emission source or unit that is eligible to be exempt, may be required to certify that it operates within the specific criteria described in 6 NYCRR Subpart 201-3. The owner or operator of any such emission source 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 which contains emission sources or units subject to 6 NYCRR Subpart 201-3, 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.

Item I: Proof of Eligibility for Sources Defined as Trivial Activities - 6 NYCRR 201-3.3 (a)

The owner and/or operator of an emission source or unit that is listed as being trivial in 6 NYCRR Part 201 may be required to certify that it operates within the specific criteria described in 6 NYCRR Subpart 201-3. The owner or operator of any such emission source 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 which contains emission sources or units subject to 6 NYCRR Subpart 201-3, 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.

Item J: Required Emission Tests - 6 NYCRR 202-1.1

An acceptable report of measured emissions shall be submitted, as may be required by the Commissioner, to ascertain compliance or noncompliance with any air



pollution code, rule, or regulation. Failure to submit a report acceptable to the Commissioner within the time stated shall be sufficient reason for the Commissioner to suspend or deny an operating permit. Notification and acceptable procedures are specified in 6 NYCRR Subpart 202-1.

Item K: Visible Emissions Limited - 6 NYCRR 211.3

Except as permitted by a specific part of this Subchapter and for open fires for which a restricted burning permit has been issued, no person shall cause or allow any air contamination source to emit any material having an opacity equal to or greater than 20 percent (six minute average) except for one continuous six-minute period per hour of not more than 57 percent opacity.

Item L: Open Fires - 6 NYCRR Part 215

No person shall burn, cause, suffer, allow or permit the burning in an open fire of garbage, rubbish for salvage, or rubbish generated by industrial or commercial activities.

Item M: 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 N: 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.



FEDERAL APPLICABLE REQUIREMENTS
The following conditions are federally enforceable.

Condition 1-2: Recycling and Emissions Reduction
Effective between the dates of 06/07/2006 and Permit Expiration Date

Applicable Federal Requirement: 40CFR 82, Subpart F

Item 1-2.1:

The permittee shall comply with all applicable provisions of 40 CFR Part 82.

Condition 2-1: Compliance Demonstration
Effective between the dates of 10/26/2009 and Permit Expiration Date

Applicable Federal Requirement: 6 NYCRR 212.4

Replaces Condition(s) 1-3

Item 2-1.1:

The Compliance Demonstration activity will be performed for the facility:
The Compliance Demonstration applies to:

Emission Unit: A-00001	Emission Point: 00001
Emission Unit: A-00001	Emission Point: 00002
Emission Unit: A-00001	Emission Point: 00006
Emission Unit: A-00001	Emission Point: 00010
Emission Unit: A-00001	Emission Point: 00011
Emission Unit: A-00001	Emission Point: 00042
Emission Unit: A-00002	Emission Point: 00003
Emission Unit: A-00002	Emission Point: 00007
Emission Unit: A-00002	Emission Point: 00014
Emission Unit: A-00002	Emission Point: 00033
Emission Unit: A-00002	Emission Point: 00035
Emission Unit: A-00002	Emission Point: 00036
Emission Unit: A-00002	Emission Point: 00037
Emission Unit: A-00002	Emission Point: 00038
Emission Unit: A-00002	Emission Point: 00039



Emission Unit: A-00002

Emission Point: 00040

Emission Unit: A-00002

Emission Point: 00041

Emission Unit: A-00002

Emission Point: 00044

Regulated Contaminant(s):

CAS No: 0NY998-00-0

VOC

CAS No: 0NY075-00-0

PARTICULATES

Item 2-1.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Barr Laboratories shall not cause or allow emissions that violate the following degree of air cleaning requirements as applicable;

Gases and Liquid Particulate Emissions (Environmental Rating A,B,C or D) and Solid Particulate Emissions (Environmental Rating A or D) specified in Table 2.

Process Emission Sources Emitting Volatile Organic Compounds specified in Table 3.

For an environmental rating of B or C, the facility will not cause or allow emissions of solid particulates that exceed 0.050 grains of particulates per cubic foot of exhaust gas, expressed at standard conditions on a dry gas basis.

Barr Laboratories shall maintain a comprehensive inventory record of emission points subject to this requirement as well as documentation of compliance as appropriate. All records shall be available to the Department upon request.

The Department reserves the right to request the facility conduct future performance testing to verify compliance.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Averaging Method: AVERAGING METHOD - SEE MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 2-2: Compliance Demonstration

Effective between the dates of 10/26/2009 and Permit Expiration Date

**Applicable Federal Requirement:6 NYCRR 212.6****Item 2-2.1:**

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: A-00001	Emission Point: 00001
Emission Unit: A-00001	Emission Point: 00002
Emission Unit: A-00001	Emission Point: 00006
Emission Unit: A-00001	Emission Point: 00010
Emission Unit: A-00001	Emission Point: 00011
Emission Unit: A-00001	Emission Point: 00042
Emission Unit: A-00002	Emission Point: 00003
Emission Unit: A-00002	Emission Point: 00007
Emission Unit: A-00002	Emission Point: 00014
Emission Unit: A-00002	Emission Point: 00033
Emission Unit: A-00002	Emission Point: 00035
Emission Unit: A-00002	Emission Point: 00036
Emission Unit: A-00002	Emission Point: 00037
Emission Unit: A-00002	Emission Point: 00038
Emission Unit: A-00002	Emission Point: 00039
Emission Unit: A-00002	Emission Point: 00040
Emission Unit: A-00002	Emission Point: 00041
Emission Unit: A-00002	Emission Point: 00044

Item 2-2.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Barr Laboratories shall not cause or allow emissions having an average opacity during any six consecutive minutes of 20 percent or greater from any process emission source, except only the emission of uncombined water.

A daily visible emissions survey is not required, however



the Department reserves the right to conduct or request EPA Method 9 visible emissions performance testing to determine compliance.

Reference Test Method: EPA Method 9

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Averaging Method: 6-MINUTE AVERAGE (METHOD 9)

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 2-3: Compliance Demonstration

Effective between the dates of 10/26/2009 and Permit Expiration Date

Applicable Federal Requirement: 6 NYCRR 212.11 (b)

Item 2-3.1:

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: A-00002

Process: CTO

Emission Source: 40COA

Regulated Contaminant(s):

CAS No: 0NY998-00-0 VOC

Item 2-3.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL DEVICE PARAMETERS AS SURROGATE

Monitoring Description:

Barr Laboratories shall operate the Catalytic Oxidizer at a minimum bed temperature of 600 F.

Continuous monitors and data recorders are required to measure combustion and outlet temperatures. Continuous monitors must be operated at all times when the associated process equipment is operating a batch except during any quality assurance and routine maintenance activities. The facility shall maintain recorded data on site for a period of five years, available to the Department upon request, and be able to provide a correlation between batch run time (Date, start time, end time, and duration), batch identification, and temperature reading as recorded continuously during process operation.

The oxidizer shall be operated in a satisfactory state of maintenance and repair in accordance with ordinary and necessary practices, standards, and procedures, inclusive of manufacturer's specifications. The Department reserves the right to require Barr Laboratories conduct future performance testing to verify VOC capture and destruction efficiencies.



Unavoidable noncompliance and violations shall require notification to the Department as specified in additional permit conditions.

Parameter Monitored: TEMPERATURE

Lower Permit Limit: 600 degrees Fahrenheit

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING

DESCRIPTION

Averaging Method: MINIMUM - NOT TO FALL BELOW STATED

VALUE AT ANY TIME

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY



STATE ONLY ENFORCEABLE CONDITIONS

****** Facility Level ******

NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS

This section contains terms and conditions which are not federally enforceable. Permittees may also have other obligations under regulations of general applicability

Item A: Public Access to Recordkeeping for Facilities With State Facility Permits - 6 NYCRR 201-1.10 (a)

Where emission source owners and/or operators keep records pursuant to compliance with the operational flexibility requirements of 6 NYCRR Subpart 201-5.4(b)(1), and/or the emission capping requirements of 6 NYCRR Subparts 201-7.2(d), 201-7.3(f), 201-7.3(g), 201-7.3(h)(5), 201-7.3(i) and 201-7.3(j), the Department will make such records available to the public upon request in accordance with 6 NYCRR Part 616 - Public Access to Records. Emission source owners and/or operators must submit the records required to comply with the request within sixty working days of written notification by the Department of receipt of the request.

Item B: 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.

STATE ONLY APPLICABLE REQUIREMENTS

The following conditions are state only enforceable.



Condition 5: Contaminant List
Effective between the dates of 04/05/2005 and Permit Expiration Date

Applicable State Requirement:ECL 19-0301

Item 5.1:

Emissions of the following contaminants are subject to contaminant specific requirements in this permit(emission limits, control requirements or compliance monitoring conditions).

CAS No: 0NY075-00-0
Name: PARTICULATES

CAS No: 0NY998-00-0
Name: VOC

Condition 2-4: Unavoidable noncompliance and violations
Effective between the dates of 10/26/2009 and Permit Expiration Date

Applicable State Requirement:6 NYCRR 201-1.4

Item 2-4.1:

At the discretion of the commissioner a violation of any applicable emission standard for necessary scheduled equipment maintenance, start-up/shutdown conditions and malfunctions or upsets may be excused if such violations are unavoidable. The following actions and recordkeeping and reporting requirements must be adhered to in such circumstances.

(a) The facility owner and/or operator shall compile and maintain records of all equipment maintenance or start-up/shutdown activities when they can be expected to result in an exceedance of any applicable emission standard, and shall submit a report of such activities to the commissioner's representative when requested to do so in writing or when so required by a condition of a permit issued for the corresponding air contamination source except where conditions elsewhere in this permit which contain more stringent reporting and notification provisions for an applicable requirement, in which case they supercede those stated here. Such reports shall describe why the violation was unavoidable and shall include the time, frequency and duration of the maintenance and/or start-up/shutdown activities and the identification of air contaminants, and the estimated emission rates. If a facility owner and/or operator is subject to continuous stack monitoring and quarterly reporting requirements, he need not submit reports for equipment maintenance or start-up/shutdown for the facility to the commissioner's representative.

(b) In the event that emissions of air contaminants in excess of any emission standard in 6 NYCRR Chapter III Subchapter A occur due to a malfunction, the facility owner and/or operator shall report such malfunction by telephone to the commissioner's representative as soon as possible during normal working hours, but in any event not later than two working days after becoming aware that the malfunction occurred. Within 30 days thereafter, when requested in writing by the commissioner's representative, the facility owner and/or operator shall submit a written report to the commissioner's representative describing the malfunction, the corrective action taken, identification of air contaminants, and an estimate of the emission rates. These reporting requirements are superceded by conditions elsewhere in this permit which contain reporting and notification provisions for applicable requirements more stringent than those above.



(c) The Department may also require the owner and/or operator to include in reports described under (a) and (b) above an estimate of the maximum ground level concentration of each air contaminant emitted and the effect of such emissions depending on the deviation of the malfunction and the air contaminants emitted.

(d) In the event of maintenance, start-up/shutdown or malfunction conditions which result in emissions exceeding any applicable emission standard, the facility owner and/or operator shall take appropriate action to prevent emissions which will result in contravention of any applicable ambient air quality standard. Reasonably available control technology, as determined by the commissioner, shall be applied during any maintenance, start-up/shutdown or malfunction condition subject to this paragraph.

(e) In order to have a violation of a federal regulation (such as a new source performance standard or national emissions standard for hazardous air pollutants) excused, the specific federal regulation must provide for an affirmative defense during start-up, shutdowns, malfunctions or upsets.

Condition 7: Emission Unit Definition

Effective between the dates of 04/05/2005 and Permit Expiration Date

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 7.1(From Mod 2):

The facility is authorized to perform regulated processes under this permit for:

Emission Unit: A-00001

Emission Unit Description:

Manufacturing and Research & Development in Building 01.

Building(s): 01

Item 7.2(From Mod 2):

The facility is authorized to perform regulated processes under this permit for:

Emission Unit: A-00002

Emission Unit Description:

Manufacturing of pharmaceutical products in Building 02.

Building(s): 02

Condition 2-5: Air pollution prohibited

Effective between the dates of 10/26/2009 and Permit Expiration Date

Applicable State Requirement:6 NYCRR 211.2

Item 2-5.1:

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. Notwithstanding the existence of specific air quality standards or emission limits, this prohibition applies, but is not limited to, any particulate, fume, gas, mist, odor, smoke, vapor, pollen, toxic or deleterious emission, either alone or in combination with others.



****** Emission Unit Level ******

Condition 9: Emission Point Definition By Emission Unit
Effective between the dates of 04/05/2005 and Permit Expiration Date

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 9.1(From Mod 2):

The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: A-00001

Emission Point: 00001

Height (ft.): 29	Diameter (in.): 10	
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 01

Emission Point: 00002

Height (ft.): 31	Diameter (in.): 12	
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 01

Emission Point: 00006

Height (ft.): 31	Diameter (in.): 30	
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 01

Emission Point: 00010

Height (ft.): 29	Length (in.): 14	Width (in.): 20
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 01

Emission Point: 00011

Height (ft.): 29	Length (in.): 10	Width (in.): 14
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 01

Emission Point: 00042

Height (ft.): 31	Diameter (in.): 8	
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 01

Item 9.2(From Mod 2):

The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: A-00002

Emission Point: 00003

Height (ft.): 39	Diameter (in.): 16	
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 02

Emission Point: 00007

Height (ft.): 34	Diameter (in.): 16	
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 02

Emission Point: 00014

Height (ft.): 34	Length (in.): 24	Width (in.): 24
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 02

Emission Point: 00033			
Height (ft.): 31	Length (in.): 18	Width (in.): 18	
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 02	
Emission Point: 00035			
Height (ft.): 43	Length (in.): 14	Width (in.): 16	
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 02	
Emission Point: 00036			
Height (ft.): 43	Length (in.): 14	Width (in.): 16	
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 02	
Emission Point: 00037			
Height (ft.): 37	Diameter (in.): 20		
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 02	
Emission Point: 00038			
Height (ft.): 37	Diameter (in.): 10		
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 02	
Emission Point: 00039			
Height (ft.): 37	Diameter (in.): 10		
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 02	
Emission Point: 00040			
Height (ft.): 39	Diameter (in.): 24		
NYTMN (km.): 4560.7	NYTME (km.): 580.4	Building: 02	
Emission Point: 00041			
Height (ft.): 38	Diameter (in.): 28		
NYTMN (km.): 4560.7	NYTME (km.): 580.6	Building: 02	
Emission Point: 00044			
Height (ft.): 42	Diameter (in.): 12		
NYTMN (km.): 4560.7	NYTME (km.): 580.6	Building: 02	

Condition 10: Process Definition By Emission Unit
Effective between the dates of 04/05/2005 and Permit Expiration Date

Applicable State Requirement:6 NYCRR Subpart 201-5

Item 10.1(From Mod 2):

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: A-00001
Process: FPB
Process Description: FLUID BED PROCESSOR

Emission Source/Control: 42FAA - Control
Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 00042 - Process



Item 10.2(From Mod 2):

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: A-00001

Process: PCK

Source Classification Code: 3-01-060-11

Process Description: COATING

Emission Source/Control: 02DCA - Control

Control Type: FABRIC FILTER

Emission Source/Control: 02HFA - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 00002 - Process

Item 10.3(From Mod 2):

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: A-00001

Process: PHM

Process Description:

PHARMACEUTICAL FORMULATION OPERATIONS
INCLUDING WEIGHING, MIXING, GRANULATING,
MILLING, TABLETING, AND ENCAPSULATION OF
PHARMACEUTICAL PRODUCTS.

Emission Source/Control: 01ADC - Control

Control Type: FABRIC FILTER

Emission Source/Control: 01AHF - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 06DCA - Control

Control Type: FABRIC FILTER

Emission Source/Control: 06HFA - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 10HFA - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 11HFA - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 00001 - Process

Emission Source/Control: 00006 - Process

Emission Source/Control: 00010 - Process

Emission Source/Control: 00011 - Process

Item 10.4(From Mod 2):



This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: A-00002
Process: CTG
Process Description: COATING

Emission Source/Control: 38DCA - Control
Control Type: FABRIC FILTER

Emission Source/Control: 38HFA - Control
Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 39DCA - Control
Control Type: FABRIC FILTER

Emission Source/Control: 39HFA - Control
Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 00038 - Process

Emission Source/Control: 00039 - Process

Item 10.5(From Mod 2):

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: A-00002
Process: CTO
Process Description: CATALYTIC OXIDATION FOR VOC CONTROL

Emission Source/Control: 40COA - Control
Control Type: CATALYTIC OXIDATION

Emission Source/Control: 40HFA - Control
Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 00040 - Process

Item 10.6(From Mod 2):

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: A-00002
Process: DR2
Process Description: DRYING

Emission Source/Control: 37HFA - Control
Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 00037 - Process

Item 10.7(From Mod 2):

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: A-00002



Process: PH2

Process Description:

PHARMACEUTICAL MANUFACTURING FORMULATION
OPERATIONS INCLUDING WEIGHING, MIXING,
GRANULATING, MILLING, TABLETING, AND
ENCAPSULATION OF PHARMACEUTICAL PRODUCTS.

Emission Source/Control: 14DCA - Control

Control Type: FABRIC FILTER

Emission Source/Control: 14HFA - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 33DCA - Control

Control Type: FABRIC FILTER

Emission Source/Control: 35DCA - Control

Control Type: FABRIC FILTER

Emission Source/Control: 35HFA - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 36DCA - Control

Control Type: FABRIC FILTER

Emission Source/Control: 36HFA - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 41DCA - Control

Control Type: FABRIC FILTER

Emission Source/Control: 41HFA - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 00014 - Process

Emission Source/Control: 00033 - Process

Emission Source/Control: 00035 - Process

Emission Source/Control: 00036 - Process

Emission Source/Control: 00041 - Process

Item 10.8(From Mod 2):

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: A-00002

Process: SB2

Process Description: SPIRAFLOW UTILIZING AQUEOUS SOLUTION

Emission Source/Control: 03DFA - Control

Control Type: FABRIC FILTER



Emission Source/Control: 03WSA - Control
Control Type: WET SCRUBBER

Emission Source/Control: 07DFA - Control
Control Type: FABRIC FILTER

Emission Source/Control: 14DCA - Control
Control Type: FABRIC FILTER

Emission Source/Control: 14HFA - Control
Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 33DCA - Control
Control Type: FABRIC FILTER

Emission Source/Control: 44CFA - Control
Control Type: FABRIC FILTER

Emission Source/Control: 00003 - Process

Emission Source/Control: 00007 - Process

Emission Source/Control: 00014 - Process

Emission Source/Control: 00033 - Process

Emission Source/Control: 00044 - Process

Item 10.9(From Mod 2):

This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: A-00002
Process: SPF
Process Description: SPIRAFLOW UTILIZING SOLVENT.

Emission Source/Control: 03DFA - Control
Control Type: FABRIC FILTER

Emission Source/Control: 03WSA - Control
Control Type: WET SCRUBBER

Emission Source/Control: 14DCA - Control
Control Type: FABRIC FILTER

Emission Source/Control: 14HFA - Control
Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 00003 - Process

Emission Source/Control: 00014 - Process



