

**New York State Department of Environmental Conservation  
Facility DEC ID: 3372000073**



**PERMIT  
Under the Environmental Conservation Law (ECL)**

**IDENTIFICATION INFORMATION**

Permit Type: Air State Facility  
Permit ID: 3-3720-00073/00025  
Mod 0 Effective Date: 08/30/2001 Expiration Date: No expiration date.  
Mod 1 Effective Date: 03/25/2003 Expiration Date: No expiration date.  
Mod 2 Effective Date: 05/14/2004 Expiration Date: No expiration date.  
Mod 3 Effective Date: 03/20/2007 Expiration Date: No expiration date.

Permit Issued To: WATSON PHARMA INC  
311 BONNIE CIRCLE  
CORONA, CA 92878

Contact: THOMAS A STROHL  
WATSON LABORATORIES INC  
1033 STONELEIGH AVE  
CARMEL, NY 10512  
(914) 767-2162

Facility: WATSON LABORATORIES INC  
1033 STONELEIGH AVE  
CARMEL, NY 10512

Contact: ADRIENNE SCIVOLETTE  
WATSON LABORATORIES INC  
39 MT EBO RD S  
BREWSTER, NY 10509  
(845) 278-3725

**Description:**

The facility manufactures solid dosage generic pharmaceutical compounds. Pharmaceutical tablets and capsules are formulated from dry, powdered products. Manufacturing operations include pharmacy, compounding, compression, encapsulation, coating, packaging, and laboratory operations. Emissions are generated from some of these processes and from boilers on site.

Modification #2 involves the removal of emission source BS002, a 12.6 million BTU per hour boiler, and the deletion of 40 CFR 60 Subpart Dc requirements. It also involves the addition of new emission sources, including an aqueous fluid bed dryer and an aqueous coater.

Modification #3 is for a new coating process and associated emission control devices. The facility will

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utilize the emission control devices to comply with 6 NYCRR Part 212 and achieve a minimum emission reduction of 75 percent.

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 SOUTH 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 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 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  
Applications for Permit Renewals and Modifications  
Permit modifications, suspensions or revocations by the Department  
Applications for Permit Renewals and Modifications  
Permit Modifications, Suspensions and Revocations by the Department  
Permit Modifications, Suspensions, and Revocations by the Department

**Facility Level**

Submission of Applications for Permit Modification or Renewal-REGION 3  
HEADQUARTERS  
Submission of Applications for Permit Modification or Renewal-REGION 3  
HEADQUARTERS  
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 3-1: Applications for permit renewals, modifications and transfers**  
**Applicable State Requirement: 6NYCRR 621.11**

**Item 3-1.1:**

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 3-1.2:**

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 3-1.3:**

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



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actual transfer of ownership.

**Condition 1-1: Applications for Permit Renewals and Modifications**  
**Applicable State Requirement: 6NYCRR 621.13**

**Expired by Mod No: 3**

**Item 1-1.1:**

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 1-1.2:**

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 1-1.3:**

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 3-2: Permit modifications, suspensions or revocations by the Department**  
**Applicable State Requirement: 6NYCRR 621.13**

**Item 3-2.1:**

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.

**Condition 3: Applications for Permit Renewals and Modifications**  
**Applicable State Requirement: 6NYCRR 621.13(a)**

**Expired by Mod No: 1**

**Item 3.1:**

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.



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**Item 3.2:**

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.

**Condition 1-2: Permit Modifications, Suspensions and Revocations by the Department**  
**Applicable State Requirement: 6NYCRR 621.14**

**Item 1-2.1:**

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.

**Condition 4: Permit Modifications, Suspensions, and Revocations by the Department**  
**Applicable State Requirement: 6NYCRR 621.14**

**Expired by Mod No: 1**

**Item 4.1:**

The Department reserves the right to modify, suspend, or revoke this permit. The grounds for modification, suspension or revocation include:

- a) the scope of the permitted activity is exceeded or a violation of any condition of the permit or provisions of the ECL and pertinent regulations is found;
- b) the permit was obtained by misrepresentation or failure to disclose relevant facts;
- c) new material information is discovered; or
- d) environmental conditions, relevant technology, or applicable law or regulation have materially changed since the permit was issued.

**\*\*\*\* Facility Level \*\*\*\***

**Condition 1-3: Submission of Applications for Permit Modification or Renewal-REGION 3 HEADQUARTERS**  
**Applicable State Requirement: 6NYCRR 621.5(a)**

**Expired by Mod No: 3**

**Item 1-3.1:**

Submission of applications for permit modification or renewal are to be submitted to:  
NYSDEC Regional Permit Administrator

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

**Condition 5: Submission of Applications for Permit Modification or Renewal-REGION 3 HEADQUARTERS**  
**Applicable State Requirement: 6NYCRR 621.5(a)**

**Expired by Mod No: 3**

**Item 5.1:**

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

**Condition 3-3: Submission of application for permit modification or renewal-REGION 3 HEADQUARTERS**  
**Applicable State Requirement: 6NYCRR 621.6(a)**

**Item 3-3.1:**

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

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**Permit Under the Environmental Conservation Law (ECL)**

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

**IDENTIFICATION INFORMATION**

Permit Issued To: WATSON PHARMA INC  
311 BONNIE CIRCLE  
CORONA, CA 92878

Facility: WATSON LABORATORIES INC  
1033 STONELEIGH AVE  
CARMEL, NY 10512

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

Mod 0 Permit Effective Date: 08/30/2001

Permit Expiration Date: No expiration date.

Mod 1 Permit Effective Date: 03/25/2003

Permit Expiration Date: No expiration date.

Mod 2 Permit Effective Date: 05/14/2004

Permit Expiration Date: No expiration date.

Mod 3 Permit Effective Date: 03/20/2007

Permit Expiration Date: No expiration date.



**LIST OF CONDITIONS**

**FEDERALLY ENFORCEABLE CONDITIONS**

**Facility Level**

2-1 6NYCRR 212.4(c): Compliance Demonstration

**Emission Unit Level**

**EU=A-00001**

- 3-1 6NYCRR 212.9(b): Compliance Demonstration
- 3-2 6NYCRR 212.9(b): Compliance Demonstration
- 3-3 6NYCRR 212.11(b): Compliance Demonstration
- 3-4 6NYCRR 212.11(b)(1): Compliance Demonstration

**EU=B-00001**

1-1 6NYCRR 227-1.3(a): Compliance Demonstration

**EU=M-00001**

1-14 6NYCRR 212.6(a): Compliance Demonstration

**STATE ONLY ENFORCEABLE CONDITIONS**

**Facility Level**

- 1-15 ECL 19-0301: Contaminant List
- 1-16 6NYCRR 201-1.4: Unavoidable noncompliance and violations
- 19 6NYCRR 201-5: Emission Unit Definition
- 2-2 6NYCRR 201-5.3(b): Compliance Demonstration
- 22 6NYCRR 211.2: Air pollution prohibited

**Emission Unit Level**

- 23 6NYCRR 201-5: Emission Point Definition By Emission Unit
- 24 6NYCRR 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 - 6NYCRR Part 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 - 6NYCRR Part 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 - 6NYCRR Part 200.7**

Any person who owns or operates an air contamination

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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 - 6NYCRR Part 201-1.2**

If an existing emission source was subject to the permitting requirements of 6NYCRR 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 - 6NYCRR Part 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



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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 - 6NYCRR Part 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 - 6NYCRR Part 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 Part 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 Part 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



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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 Part 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 6NYCRR Part 202-1.

**Item K: Visible Emissions Limited - 6 NYCRR Part 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



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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 2-1: Compliance Demonstration**

**Effective between the dates of 05/14/2004 and Permit Expiration Date**

**Applicable Federal Requirement: 6NYCRR 212.4(c)**

**Replaces Condition(s) 1-13**

**Item 2-1.1:**

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: M-00001 Emission Point: CEF33

Emission Unit: M-00001 Emission Point: CEF34

Emission Unit: M-00001 Emission Point: DC009

Emission Unit: M-00001 Emission Point: GLATT

Emission Unit: M-00001 Emission Point: MG002

Emission Unit: M-00001 Emission Point: MR018

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Emission Unit: M-00001 Emission Point: PACKV

Emission Unit: M-00001 Emission Point: PHARV

Emission Unit: M-00001 Emission Point: PR003

Regulated Contaminant(s):

CAS No: 0NY075-00-0 PARTICULATES

**Item 2-1.2:**

Compliance Demonstration shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING

Monitoring Description:

Particulate emissions shall not exceed 0.05 grains per cubic foot of exhaust gas, expressed at standard conditions on a dry gas basis.

To ensure compliance with this limit, emissions must be directed to a filtering device.

At the discretion of the Department, emission testing may be required to ascertain compliance with this limit.

Parameter Monitored: PARTICULATES

Upper Permit Limit: 0.05 grains per dscf

Reference Test Method: EPA Method 5

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Averaging Method: 1-HOUR AVERAGE

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

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

**Condition 3-1: Compliance Demonstration**

**Effective between the dates of 03/20/2007 and Permit Expiration Date**

**Applicable Federal Requirement: 6NYCRR 212.9(b)**

**Item 3-1.1:**

The Compliance Demonstration activity will be performed for:

Emission Unit: A-00001



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Regulated Contaminant(s):

CAS No: 000064-17-5 ETHYL ALCOHOL (ETHANOL)

**Item 3-1.2:**

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Based on an environmental rating of "C" and an emission rate potential of 49.52 pounds per hour, a 75 percent reduction in ethanol emissions must be achieved. This reduction will be achieved with carbon adsorption vessels or a thermal oxidizer. Manufacturer's specifications, which shows that the control devices were tested and the ethanol (or VOC) emission reduction is at least 75 percent, must be submitted to the Department and be kept on site at the facility.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

**Condition 3-2: Compliance Demonstration**

**Effective between the dates of 03/20/2007 and Permit Expiration Date**

**Applicable Federal Requirement: 6NYCRR 212.9(b)**

**Item 3-2.1:**

The Compliance Demonstration activity will be performed for:

Emission Unit: A-00001

**Item 3-2.2:**

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

If a thermal oxidizer is used as the emission control device, combustion temperature shall be monitored and a minimum temperature established, to assure at least a 75 percent reduction in ethanol emissions is achieved.

If the temperature falls below the minimum value, the coating process must be discontinued and the problem corrected before restarting the process. A record must be kept of oxidizer malfunctions.



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Monitoring Frequency: CONTINUOUS

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

**Condition 3-3: Compliance Demonstration**

**Effective between the dates of 03/20/2007 and Permit Expiration Date**

**Applicable Federal Requirement: 6NYCRR 212.11(b)**

**Item 3-3.1:**

The Compliance Demonstration activity will be performed for:

Emission Unit: A-00001

**Item 3-3.2:**

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

If carbon vessels are used as emission control devices, the on-line vessels shall be by monitored for breakthrough of ethanol with an LEL meter. Any of the four carbon vessels can be used at any time. If the LEL meter indicates 1.0 percent or greater, the facility must switch to another carbon vessel. In addition, after each pharmaceutical batch, the spent carbon must be removed from the vessels and new carbon installed. Records will kept of which carbon vessels are used and when the carbon is replaced.

Parameter Monitored: ETHYL ALCOHOL (ETHANOL)

Upper Permit Limit: 1.0 percent

Monitoring Frequency: CONTINUOUS

Averaging Method: MAXIMUM - NOT TO EXCEED STATED VALUE -  
SEE MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

**Condition 3-4: Compliance Demonstration**

**Effective between the dates of 03/20/2007 and Permit Expiration Date**

**Applicable Federal Requirement: 6NYCRR 212.11(b)(1)**

**Item 3-4.1:**

The Compliance Demonstration activity will be performed for:

Emission Unit: A-00001

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**Item 3-4.2:**

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Whenever a thermal oxidizer is used, the exhaust gas temperature must be monitored during coating operation except during any quality assurance and routine maintenance activities. This temperature must also be recorded and the temperature data maintained on site.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

**Condition 1-1: Compliance Demonstration**

**Effective between the dates of 03/25/2003 and Permit Expiration Date**

**Applicable Federal Requirement: 6NYCRR 227-1.3(a)**

**Item 1-1.1:**

The Compliance Demonstration activity will be performed for:

Emission Unit: B-00001

**Item 1-1.2:**

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

No owner or operator of a combustion installation shall emit greater than 20 percent opacity except for one six minute period per hour, not to exceed 27 percent, based upon the six minute average in reference test method 9 in Appendix A of 40 CFR 60.

Parameter Monitored: OPACITY

Upper Permit Limit: 20 percent

Reference Test Method: 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 1-14: Compliance Demonstration**

**Effective between the dates of 03/25/2003 and Permit Expiration Date**



**Applicable Federal Requirement: 6NYCRR 212.6(a)**

**Item 1-14.1:**

The Compliance Demonstration activity will be performed for:

Emission Unit: M-00001

**Item 1-14.2:**

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

No person will 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. The Department reserves the right to perform or require the performance of a Method 9 opacity evaluation at any time during facility operation.

Parameter Monitored: OPACITY

Upper Permit Limit: 20 percent

Reference Test Method: Method 9

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING  
DESCRIPTION

Averaging Method: 6-MINUTE AVERAGE (METHOD 9)

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 - 6NYCRR Part 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

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law.

**STATE ONLY APPLICABLE REQUIREMENTS**

**The following conditions are state only enforceable.**

**Condition 1-15: Contaminant List**

**Effective between the dates of 03/25/2003 and Permit Expiration Date**

**Applicable State Requirement: ECL 19-0301**

**Item 1-15.1:**

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

CAS No: 000064-17-5

Name: ETHYL ALCOHOL (ETHANOL)

CAS No: 0NY075-00-0

Name: PARTICULATES

**Condition 1-16: Unavoidable noncompliance and violations**

**Effective between the dates of 03/25/2003 and Permit Expiration Date**

**Applicable State Requirement: 6NYCRR 201-1.4**

**Item 1-16.1:**

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



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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 19: Emission Unit Definition**

**Effective between the dates of 08/30/2001 and Permit Expiration Date**

**Applicable State Requirement: 6NYCRR 201-5**

**Item 19.1(From Mod 3):**

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

Emission Unit: A-00001

Emission Unit Description:

THIS EMISSION UNIT CONSISTS OF THE PROCESS AND RELATED CONTROL DEVICES FOR THE MANUFACTURE OF DELAYED RELEASE SOLID DOSAGE PHARMACEUTICAL COMPOUNDS. THE CONTROL DEVICES ARE FOUR TIGG ACTIVATED CARBON VESSELS, MODEL # N-400PBD. EACH VESSEL HAS ITS OWN INDIVIDUAL STACK. EACH VESSEL HOLDS 5500 POUNDS OF ACTIVATED CARBON. THE VESSELS ARE CONFIGURED TO BE OPERATED IN PARALLEL AND ANY NUMBER OF THE VESSELS CAN BE RUN AT ANY TIME. A THERMAL OXIDIZER MAY BE USED FOR EMISSION CONTROL, AS AN ALTERNATIVE TO OR REPLACEMENT OF THE CARBON VESSELS.

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Building(s): 1033

**Item 19.2(From Mod 2):**

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

Emission Unit: B-00001

Emission Unit Description:

COMBUSTION SOURCES

Building(s): 1033

**Item 19.3(From Mod 2):**

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

Emission Unit: M-00001

Emission Unit Description:

MANUFACTURING OPERATIONS INCLUDE PHARMACY,  
COMPOUNDING, COMPRESSION, ENCAPSULATION,  
COATING AND PACKAGING.

Building(s): 1033

**Condition 2-2: Compliance Demonstration**

**Effective between the dates of 05/14/2004 and Permit Expiration Date**

**Applicable State Requirement: 6NYCRR 201-5.3(b)**

**Item 2-2.1:**

The Compliance Demonstration activity will be performed for the Facility.

**Item 2-2.2:**

Compliance Demonstration shall include the following monitoring:

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC  
OPERATIONS

Monitoring Description:

The sulfur concentration in any no.2 oil burned at the  
facility will be limited to 0.5 percent by weight.  
Compliance with this limit will be demonstrated by a  
certification from the fuel oil supplier. Compliance with  
the above requirements shall also demonstrate compliance  
with 6NYCRR Part 225-1.

Work Practice Type: PARAMETER OF PROCESS MATERIAL

Process Material: NUMBER 2 OIL

Parameter Monitored: SULFUR CONTENT

Upper Permit Limit: 0.5 percent by weight

Monitoring Frequency: PER DELIVERY



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Averaging Method: MAXIMUM - NOT TO BE EXCEEDED AT ANY  
TIME (INSTANTANEOUS/DISCRETE OR GRAB)

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

**Condition 22: Air pollution prohibited**  
**Effective between the dates of 08/30/2001 and Permit Expiration Date**

**Applicable State Requirement: 6NYCRR 211.2**

**Item 22.1:**

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 23: Emission Point Definition By Emission Unit**  
**Effective between the dates of 08/30/2001 and Permit Expiration Date**

**Applicable State Requirement: 6NYCRR 201-5**

**Item 23.1(From Mod 3):**

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

Emission Unit: A-00001

Emission Point: A00A1

Height (ft.): 15                      Diameter (in.): 14  
NYTMN (km.): 4585.1      NYTME (km.): 611.4      Building: 1033

Emission Point: A00A2

Height (ft.): 15                      Diameter (in.): 14  
NYTMN (km.): 4585.1      NYTME (km.): 611.4      Building: 1033

Emission Point: A00E1

Height (ft.): 15                      Diameter (in.): 14  
NYTMN (km.): 4585.1      NYTME (km.): 611.4      Building: 1033

Emission Point: A00E2

Height (ft.): 15                      Diameter (in.): 14  
NYTMN (km.): 4585.1      NYTME (km.): 611.4      Building: 1033



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**Item 23.2(From Mod 1):**

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

Emission Unit: B-00001

Emission Point: BS001

Height (ft.): 45                      Diameter (in.): 24  
NYTMN (km.): 4585.1              NYTME (km.): 611.4

**Item 23.3(From Mod 2):**

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

Emission Unit: M-00001

Emission Point: CEF33

Height (ft.): 35                      Diameter (in.): 12  
NYTMN (km.): 4585.1              NYTME (km.): 611.4              Building: 1033

Emission Point: CEF34

Height (ft.): 35                      Diameter (in.): 12  
NYTMN (km.): 4584.749              NYTME (km.): 611.391              Building: 1033

Emission Point: DC009

Height (ft.): 7                      Diameter (in.): 4  
NYTMN (km.): 4584.749              NYTME (km.): 611.391              Building: 1033

Emission Point: GLATT

Height (ft.): 16                      Diameter (in.): 16  
NYTMN (km.): 4584.749              NYTME (km.): 611.391              Building: 1033

Emission Point: MG002

Height (ft.): 20                      Diameter (in.): 20  
NYTMN (km.): 4585.1              NYTME (km.): 611.4              Building: 1033

Emission Point: MG005

Height (ft.): 22                      Length (in.): 26                      Width (in.): 18  
NYTMN (km.): 4585.1              NYTME (km.): 611.4              Building: 1033

Emission Point: MG01A

Height (ft.): 22                      Length (in.): 26                      Width (in.): 18  
NYTMN (km.): 4585.1              NYTME (km.): 611.4              Building: 1033

Emission Point: MG01B

Height (ft.): 22                      Length (in.): 26                      Width (in.): 18  
NYTMN (km.): 4585.1              NYTME (km.): 611.4              Building: 1033

Emission Point: MR017



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Height (ft.): 22                      Diameter (in.): 12  
NYTMN (km.): 4585.1              NYTME (km.): 611.4              Building: 1033

Emission Point: MR018  
Height (ft.): 25                      Length (in.): 18                      Width (in.): 18  
NYTMN (km.): 4585.1              NYTME (km.): 611.4              Building: 1033

Emission Point: PACKV  
Height (ft.): 6                      Diameter (in.): 4  
NYTMN (km.): 4585.1              NYTME (km.): 611.4              Building: 1033

Emission Point: PHARV  
Height (ft.): 28                      Diameter (in.): 4  
NYTMN (km.): 4585.1              NYTME (km.): 611.4              Building: 1033

Emission Point: PR003  
Height (ft.): 12                      Diameter (in.): 8  
NYTMN (km.): 4585.1              NYTME (km.): 611.4              Building: 1033

**Condition 24: Process Definition By Emission Unit**  
**Effective between the dates of 08/30/2001 and Permit Expiration Date**

**Applicable State Requirement: 6NYCRR 201-5**

**Item 24.1(From Mod 3):**

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

Emission Unit: A-00001

Process: A0A

Process Description:

THE MANUFACTURE OF DELAYED RELEASE SOLID  
DOSAGE PHARMACEUTICAL COMPOUNDS. A SOLVENT  
BASED COATING IS USED IN THE PROCESS. THE  
MAXIMUM NUMBER OF BATCHES OF PHARMACEUTICAL  
COMPOUNDS WHICH CAN BE PROCESSED IS 6 (SIX)  
PER MONTH.

Emission Source/Control: A00A1 - Control  
Control Type: ACTIVATED CARBON ADSORPTION

Emission Source/Control: A00A2 - Control  
Control Type: ACTIVATED CARBON ADSORPTION

Emission Source/Control: A00E1 - Control  
Control Type: ACTIVATED CARBON ADSORPTION

Emission Source/Control: A00E2 - Control



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Control Type: ACTIVATED CARBON ADSORPTION

Emission Source/Control: AT0X1 - Control  
Control Type: THERMAL OXIDATION

Emission Source/Control: A000A - Process

**Item 24.2(From Mod 2):**

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

Emission Unit: B-00001  
Process: BOA  
Process Description: BOILERS BURNING NATURAL GAS

Emission Source/Control: BS001 - Combustion

**Item 24.3(From Mod 2):**

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

Emission Unit: B-00001  
Process: BOB  
Process Description: BOILERS BURNING #2 FUEL OIL

Emission Source/Control: BS001 - Combustion

**Item 24.4(From Mod 2):**

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

Emission Unit: M-00001  
Process: MOA  
Process Description:  
MANUFACTURING OPERATIONS INCLUDING  
PHARMACY, COMPOUNDING, COMPRESSION,  
ENCAPSULATION, COATING AND PACKAGING.

Emission Source/Control: DC09A - Control  
Control Type: FABRIC FILTER

Emission Source/Control: EF33A - Control  
Control Type: FABRIC FILTER

Emission Source/Control: EF34A - Control  
Control Type: FABRIC FILTER

Emission Source/Control: GFILT - Control  
Control Type: FABRIC FILTER

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

Emission Source/Control: MR18A - Control  
Control Type: FABRIC FILTER

Emission Source/Control: PACKA - Control  
Control Type: FABRIC FILTER

Emission Source/Control: PHARA - Control  
Control Type: FABRIC FILTER

Emission Source/Control: PR03A - Control  
Control Type: FABRIC FILTER

Emission Source/Control: CEF33 - Process

Emission Source/Control: CEF34 - Process

Emission Source/Control: DC009 - Process

Emission Source/Control: GLATT - Process

Emission Source/Control: MG002 - Process

Emission Source/Control: MG005 - Process

Emission Source/Control: MG01A - Process

Emission Source/Control: MG01B - Process

Emission Source/Control: MR017 - Process

Emission Source/Control: MR018 - Process

Emission Source/Control: PACKV - Process

Emission Source/Control: PHARV - Process

Emission Source/Control: PR003 - Process