



PERMIT
Under the Environmental Conservation Law (ECL)

IDENTIFICATION INFORMATION

Permit Type: Air State Facility
Permit ID: 7-0842-00071/00001
Effective Date: 10/22/2002 Expiration Date: No expiration date

Permit Issued To:ALVOGEN GROUP INC
1500 BROADWAY 14TH FL
NEW YORK, NY 10036

Facility: NORWICH PHARMACEUTICALS INC
ST RTE 320 - E OF ST RTE 12|
WOODS CORNERS, NY 13815

Contact: DAVID BERNARDINI
NORWICH PHARMACUETICALS INC
6826 ST RTE 12
NORWICH, NY 13815
(607) 335-3360

Description:

TYPE OF EQUIPMENT AND OPERATION AT THE FACILITY

The OSG Norwich facility (SIC 2834- Pharmaceutical Preparations) primarily consists of two (2) pharmaceutical manufacturing processes consisting of reactors, vessels, centrifuges, dryers, blender, storage tanks and a scrubber for air pollution control, and miscellaneous material handling operations.

AIR PERMIT APPLICABILITY

Facility is subject to the following air pollution control requirements: 6 NYCRR Parts 200, 201, 202, 211, 215, 233

CAPPING

The facility emissions of volatile organic compounds (VOCs), and hazardous air pollutants (HAPs) are limited (capped) below the applicability thresholds of 6 NYCRR Part 201-6, Title V Facility Permits and 40 CFR 63, subpart GGG, National Emission Standards for Pharmaceuticals Production.



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: MICHAEL K BARYLSKI
 DIVISION OF ENVIRONMENTAL PERMITS
 1285 FISHER AVE
 CORTLAND, NY 13045-1090

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 and Modifications
Permit Modifications, Suspensions and Revocations by the Department

Facility Level

Submission of Applications for Permit Modification or Renewal -REGION
7 SUBOFFICE



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: Applications for Permit Renewals and Modifications
Applicable State Requirement: 6NYCRR 621.13

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.

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.

Item 3.3:

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

Item 4.1:

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 5: Submission of Applications for Permit Modification or Renewal -REGION 7
SUBOFFICE
Applicable State Requirement: 6NYCRR 621.5(a)

Item 5.1:

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

NYSDEC Regional Permit Administrator
Region 7 Sub-office
Division of Environmental Permits
1285 Fisher Avenue
Cortland, NY 13045-1090
(607) 753-3095



Permit Under the Environmental Conservation Law (ECL)

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

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1500 BROADWAY 14TH FL
NEW YORK, NY 10036

Facility: NORWICH PHARMACEUTICALS INC
ST RTE 320 - E OF ST RTE 12|
WOODS CORNERS, NY 13815

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

Permit Effective Date: 10/22/2002
date.

Permit Expiration Date: No expiration
date.



LIST OF CONDITIONS

DEC GENERAL CONDITIONS

General Provisions

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Facility Level

Submission of Applications for Permit Modification or Renewal -REGION
7 SUBOFFICE

FEDERALLY ENFORCEABLE CONDITIONS

Facility Level

- 1 6NYCRR 201-6.1(a): Facility Permissible Emissions
- *2 6NYCRR 201-6.1(a): Compliance Demonstration
- *3 6NYCRR 201-6.1(a): Compliance Demonstration
- *4 6NYCRR 201-6.1(a): Compliance Demonstration
- 5 6NYCRR 201-7.2: Synthetic minor facility capping provisions.

Emission Unit Level

EU=1-MANUF

- 6 6NYCRR 233.3(d): Storage tank requirements
- 7 6NYCRR 233.3(e): Centrifuge and filter requirements
- 8 6NYCRR 233.3(f): In-process tank requirements
- 9 6NYCRR 233.3(g): Leak requirements
- 10 6NYCRR 233.5: Recordkeeping - Part 233.5(a)
- 11 6NYCRR 233.5: Recordkeeping for leaks - Part 233.5(b)

EU=1-MANUF,EP=73001,Proc=102

- 12 6NYCRR 233.3(b)(2): Compliance Demonstration

STATE ONLY ENFORCEABLE CONDITIONS

Facility Level

- 13 ECL 19-0301: Contaminant List
- 14 6NYCRR 201-1.4: Unavoidable noncompliance and violations
- 15 6NYCRR 201-5: Emission Unit Definition
- 16 6NYCRR 201-5.4(b): Compliance Demonstration
- 17 6NYCRR 211.2: Air pollution prohibited

Emission Unit Level

- 18 6NYCRR 201-5: Emission Point Definition By Emission Unit
- 19 6NYCRR 201-5: Process Definition By Emission Unit

NOTE: * preceding the condition number indicates capping.



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 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 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 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 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: Facility Permissible Emissions
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 201-6.1(a)

Item 1.1:

The sum of emissions from the emission units specified in this permit shall not equal or exceed the following

Potential To Emit (PTE) rate for each regulated contaminant:

CAS No: 000067-56-1 Name: METHYL ALCOHOL	PTE: 19,800 pounds per year
CAS No: 000302-01-2 Name: HYDRAZINE	PTE: 19,800 pounds per year
CAS No: 007647-01-0 Name: HYDROGEN CHLORIDE	PTE: 19,800 pounds per year
CAS No: 0NY100-00-0 Name: HAP	PTE: 49,500 pounds per year
CAS No: 0NY998-00-0 Name: VOC	PTE: 99,000 pounds per year

Condition 2: Compliance Demonstration
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 201-6.1(a)

Item 2.1:

The Compliance Demonstration activity will be performed for the Facility.

Regulated Contaminant(s):

CAS No: 000302-01-2	HYDRAZINE
CAS No: 007647-01-0	HYDROGEN CHLORIDE
CAS No: 000067-56-1	METHYL ALCOHOL

Item 2.2:

Compliance Demonstration shall include the following monitoring:

Capping: Yes

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

Facility emissions of any individual Hazardous Air Pollutant (HAP) shall not equal or exceed 10 tons in any consecutive 12 month period (annual maximum rolled



monthly). Any HAP, not listed above, added and emitted from the facility as a result of operational flexibility pursuant to 6 NYCRR Part 201-5.4(b) shall also comply with the individual HAP limitation of less than 10 tons in any consecutive month period. Compliance with this emission limit (cap) is required for the facility to remain non-applicable to Title V permitting and the requirements of 40CFR63, subpart GGG, National Emissions Standards for Pharmaceutical Production. Verification of HAP emissions shall be determined using procedures acceptable to the Department. A summary of emissions shall be submitted annually in accordance with the permit condition for 6 NYCRR 201-7.2, contained elsewhere in this permit.

Work Practice Type: PARAMETER OF PROCESS MATERIAL

Process Material: MATERIAL

Parameter Monitored: HAP

Upper Permit Limit: 9.9 tons per year

Monitoring Frequency: MONTHLY

Averaging Method: ANNUAL MAXIMUM ROLLED MONTHLY

Reporting Requirements: ANNUALLY (ANNIVERSARY)

Initial Report Due: 11/20/2003 for the period 10/22/2002 through 10/21/2003

Condition 3: Compliance Demonstration
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement: 6 NYCRR 201-6.1(a)

Item 3.1:

The Compliance Demonstration activity will be performed for the Facility.

Regulated Contaminant(s):

CAS No: 0NY100-00-0 HAP

Item 3.2:

Compliance Demonstration shall include the following monitoring:

Capping: Yes

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

Total facility emissions of Hazardous Air Pollutants (HAPs) shall not equal or exceed 25 tons in any consecutive 12 month period (annual maximum rolled monthly). Compliance with this emission limit (cap) is required for the facility to remain non-applicable to Title V permitting and the requirements of 40CFR63, subpart GGG, National Emissions Standards for Pharmaceutical Production. Verification of HAP emissions shall be determined using procedures acceptable to the Department. A summary of emissions shall be submitted annually in accordance with the permit condition for 6 NYCRR 201-7.2, contained elsewhere in this permit.



Work Practice Type: PARAMETER OF PROCESS MATERIAL

Process Material: MATERIAL

Parameter Monitored: HAP

Upper Permit Limit: 24.75 tons per year

Monitoring Frequency: MONTHLY

Averaging Method: ANNUAL MAXIMUM ROLLED MONTHLY

Reporting Requirements: ANNUALLY (ANNIVERSARY)

Initial Report Due: 11/20/2003 for the period 10/22/2002 through 10/21/2003

Condition 4: Compliance Demonstration
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 201-6.1(a)

Item 4.1:

The Compliance Demonstration activity will be performed for the Facility.

Regulated Contaminant(s):

CAS No: 0NY998-00-0 VOC

Item 4.2:

Compliance Demonstration shall include the following monitoring:

Capping: Yes

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

Total facility emissions of Volatile Organic Compounds (VOCs) shall not equal or exceed 50 tons in any consecutive 12 month period (annual maximum rolled monthly). Compliance with this emission limit (cap) is required for the facility to remain non-applicable to Title V permitting. Verification of VOC emissions shall be determined using procedures acceptable to the Department. A summary of emissions shall be submitted annually in accordance with the permit condition for 6 NYCRR 201-7.2, contained elsewhere in this permit.

Work Practice Type: PARAMETER OF PROCESS MATERIAL

Process Material: MATERIAL

Parameter Monitored: VOC

Upper Permit Limit: 49.5 tons per year

Monitoring Frequency: MONTHLY

Averaging Method: ANNUAL MAXIMUM ROLLED MONTHLY

Reporting Requirements: ANNUALLY (ANNIVERSARY)

Initial Report Due: 11/20/2003 for the period 10/22/2002 through 10/21/2003

Condition 5: Synthetic minor facility capping provisions.
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 201-7.2



Item 5.1:

Operation of this facility shall take place in accordance with the approved criteria, emission limits, terms, conditions and standards in this permit.

Item 5.2:

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.

Item 5.3:

On an annual basis, beginning one year after the granting of an emissions cap, the responsible official shall provide a certification to the Department that the facility has operated all emission units within the limits imposed by the emission cap. This certification shall include a brief summary of the emissions subject to the cap for that time period and a comparison to those threshold levels that would require the submission of an application for a Title V facility permit, or compliance with an applicable requirement.

Item 5.4:

The emission of pollutants in exceedance of the applicability thresholds for obtaining a Title V facility permit or other applicable requirements constitutes a violation of Part 201 and of the Act.

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

Condition 6: Storage tank requirements
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 233.3(d)

Item 6.1:

This Condition applies to Emission Unit: 1-MANUF

Item 6.2:

For all storage tanks that store volatile organic compounds with vapor pressure greater than 1.5 psi at 20 degrees C, pressure/vacuum conservation vents set at 0.03 psi must be installed, unless more effective control equipment is used.

Condition 7: Centrifuge and filter requirements
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 233.3(e)

Item 7.1:

This Condition applies to Emission Unit: 1-MANUF



Item 7.2:

All centrifuges containing volatile organic compounds, rotary vacuum filters processing volatile organic compounds, and any other filters having an exposed liquid surface where the liquid contains volatile organic compounds and exerts a total vapor pressure of 0.5 psi or more at 20 degrees C must be enclosed unless production, sampling, maintenance, or inspection procedures require operator access.

Condition 8: In-process tank requirements
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 233.3(f)

Item 8.1:

This Condition applies to Emission Unit: 1-MANUF

Item 8.2:

For in-process tanks containing a volatile organic compound, covers must be installed on openings to these tanks. Tank openings must remain covered unless production, sampling, maintenance, or inspection procedures require operator access.

Condition 9: Leak requirements
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 233.3(g)

Item 9.1:

This Condition applies to Emission Unit: 1-MANUF

Item 9.2:

All leaks from which a liquid containing volatile organic compounds can be observed running or dripping must be repaired the first time the equipment is off-line for a period of time long enough to complete the repair, but not later than 15 days after the leak is discovered. If the leaking component cannot be repaired until the process is shut down, and a shut down cannot be done within the 15 days after the leak is detected, the leaking component must then be repaired before the process is restarted.

Condition 10: Recordkeeping - Part 233.5(a)
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 233.5

Item 10.1:

This Condition applies to Emission Unit: 1-MANUF

Item 10.2:

The owner or operator of processes subject to this Part must maintain the following records at the facility for a period of five years:

- (1) parameters listed in Part 233.4(c) and Part 233.4(d) must be recorded and;



(2) the vapor pressure of the volatile organic compound at 20 degrees C being controlled must be recorded for every process.

Condition 11: Recordkeeping for leaks - Part 233.5(b)
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 233.5

Item 11.1:

This Condition applies to Emission Unit: 1-MANUF

Item 11.2:

For any leak subject to Part 233.3(g), which cannot be readily repaired within one day after detection, the following records must be kept:

- (1) the name of the leaking equipment;
- (2) the date and time the leak is detected;
- (3) the action taken to repair the leak; and
- (4) the date and time the leak is repaired.

Condition 12: Compliance Demonstration
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 233.3(b)(2)

Item 12.1:

The Compliance Demonstration activity will be performed for:

Emission Unit: 1-MANUF Emission Point: 73001
Process: 102

Regulated Contaminant(s):
CAS No: 0NY998-00-0 VOC

Item 12.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING

Monitoring Description:

Each air dryer or production equipment exhaust system with an emission rate potential less than 330 pounds per day (before control) must reduce emission to 33 pounds per day or less. The source owner shall verify the emission limit upon written request of the Department.

Manufacturer Name/Model Number: METH 18,25,OR 25A

Parameter Monitored: VOC

Upper Permit Limit: 33 pounds per day

Reference Test Method: Method 18, 25 or 25A

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING



DESCRIPTION

Averaging Method: AVERAGING METHOD - SEE MONITORING

DESCRIPTION

Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE



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 law.

STATE ONLY APPLICABLE REQUIREMENTS

The following conditions are state only enforceable.



Condition 13: Contaminant List
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable State Requirement:ECL 19-0301

Item 13.1:

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

CAS No: 000067-56-1
Name: METHYL ALCOHOL

CAS No: 000302-01-2
Name: HYDRAZINE

CAS No: 007647-01-0
Name: HYDROGEN CHLORIDE

CAS No: 0NY100-00-0
Name: HAP

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

Condition 14: Unavoidable noncompliance and violations
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable State Requirement:6NYCRR 201-1.4

Item 14.1:

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 15: Emission Unit Definition
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable State Requirement:6NYCRR 201-5

Item 15.1:

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

Emission Unit: 1-MANUF

Emission Unit Description:

THE FACILITY HAS TWO (2) MANUFACTURING PROCESSES WHICH PRODUCE PHARMACEUTICAL PRODUCTS FOR SALE. THE PROCESSES ARE LOCATED IN BUILDING 7 AND BUILDING 1. THE EMISSION POINTS ASSOCIATED WITH THE PROCESSES ARE EPS 73001 (BUILDING 7) AND 80001 (BUILDING 1). A SCRUBBER WAS INSTALLED TO CONTROL THE EMISSIONS OF METHANOL THROUGH EP 73001.

Building(s): 01
07

Condition 16: Compliance Demonstration
Effective between the dates of 10/22/2002 and Permit Expiration Date



Applicable State Requirement:6NYCRR 201-5.4(b)

Item 16.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 16.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Operational Flexibility - Prior to any proposed changes or modifications the owner or operator shall identify all potential pollutants, including A-rated contaminants, hazardous air pollutants (HAPs), volatile organic compounds (VOCs), and non-VOC pollutants, and the corresponding emission rates that will occur as a result of the proposed changes or modifications. A-rated contaminants are those contaminants listed with a "high" toxicity in the Department's most recent DAR -1 (formerly Air Guide 1) guidance document, and any other contaminants that may be A-rated by the Department.

Physical and operational changes are subject to the following:

(1) Certain changes which meet the criteria under (i) - (iii) below may be conducted without prior approval of the Department and shall not require modification of the permit. The facility owner and/or operator must however maintain records of the date and description of such changes and make such records available for review by Department representatives upon request.

(i) Changes that do not cause emissions to exceed any emission limitation contained in regulations or applicable requirements under 6 NYCRR.

(ii) Changes which do not cause the subject emission unit, emission source, process, or emission point to become subject to any additional regulations or requirements under 6 NYCRR.

(iii) Changes that do not seek to establish or modify a federally-enforceable emission cap or limit.

(2) In addition to the record keeping required under (1) above, the permittee must notify the Department in writing at least 30 calendar days in advance of making changes involving:



(i) the installation or relocation of any emission unit, emission source, process, or emission point within a facility;

(ii) the emission of any air pollutant not previously authorized or emitted in accordance with a permit issued by the Department;

(iii) the installation or alteration of any air cleaning installation, device or control equipment.

(3) The Department may require a permit modification, in order to impose applicable requirements or special permit conditions if it determines that changes proposed pursuant to notification under (2) above do not meet the criteria under (1) above or the change may have a significant air quality impact. In such cases the Department may require that the permittee not undertake the proposed change until it completes a more detailed review of the change for air quality impacts and/or applicable requirements. The Department shall respond to the permittee in writing with such a determination within 15 days of receipt of the 30 day advance notification from the permittee. The Department's determination shall include a listing of information necessary to further review the proposed change.

(4) A summary of all activities conducted under this operational flexibility shall be reported in the facility's annual emissions cap certification submitted pursuant to 6 NYCRR Part 201-7.2.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: ANNUALLY (ANNIVERSARY)

Initial Report Due: 11/20/2003 for the period 10/22/2002 through 10/21/2003

**Condition 17: Air pollution prohibited
Effective between the dates of 10/22/2002 and Permit Expiration Date**

Applicable State Requirement:6NYCRR 211.2

Item 17.1:

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 18: Emission Point Definition By Emission Unit
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable State Requirement:6NYCRR 201-5

Item 18.1:

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

Emission Unit: 1-MANUF

Emission Point: 01002

Height (ft.): 25 Diameter (in.): 12
NYTMN (km.): 4711.622 NYTME (km.): 457.032 Building: 01

Emission Point: 73001

Height (ft.): 26 Diameter (in.): 12
NYTMN (km.): 4711.622 NYTME (km.): 457.032 Building: 07

Emission Point: 80001

Height (ft.): 10 Diameter (in.): 6
NYTMN (km.): 4711.622 NYTME (km.): 457.032 Building: 01

Condition 19: Process Definition By Emission Unit
Effective between the dates of 10/22/2002 and Permit Expiration Date

Applicable State Requirement:6NYCRR 201-5

Item 19.1:

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

Emission Unit: 1-MANUF

Process: 102 Source Classification Code: 3-01-060-09

Process Description:

ETIDRONATE DISODIUM IS MANUFACTURED IN BUILDING 7. THE PROCESS CONSISTS OF TWO REACTORS (EMISSION SOURCE IDS 07101, 07103). A VESSEL (EMISSION SOURCE ID 07102), A CENTRIFUGE (EMISSION SOURCE ID 07104), AND A DRYER (EMISSION SOURCE ID 07105). THE EXHAUST FOR THE PROCESS LOCATED IN BUILDING 7 PASSES THROUGH A SCRUBBER BEFORE BEING EMITTED TO THE ATMOSPHERE (EP07001).

Emission Source/Control: 07001 - Control

Control Type: WET SCRUBBER

Emission Source/Control: 07101 - Process



Emission Source/Control: 07102 - Process

Emission Source/Control: 07103 - Process

Emission Source/Control: 07104 - Process

Emission Source/Control: 07105 - Process

Item 19.2:

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

Emission Unit: 1-MANUF

Process: 103

Source Classification Code: 3-01-060-09

Process Description:

SEMICARBAZIDOACETIC ACID IS MANUFACTURED IN BUILDING 1. THE PROCESS CONSISTS OF FIVE REACTORS (EMISSION SOURCE IDS 01101, 01103, 01104, 01109, 01111), FIVE VESSELS (EMISSION SOURCE IDS 0110E, 01105, 01107, 01108, 01110), A DISTILLATION COLUMN (EMISSIONS SOURCE ID 01106), A CETRIFUGE (EMISSION SOURCE ID 01112), A BLENDER (EMISSION SOURCE ID 01113), AND A DRYER (EMISSIONS SOURCE ID 01001).

Emission Source/Control: 01001 - Process

Emission Source/Control: 01101 - Process

Emission Source/Control: 01102 - Process

Emission Source/Control: 01103 - Process

Emission Source/Control: 01104 - Process

Emission Source/Control: 01105 - Process

Emission Source/Control: 01106 - Process

Emission Source/Control: 01107 - Process

Emission Source/Control: 01108 - Process

Emission Source/Control: 01109 - Process

Emission Source/Control: 01110 - Process

Emission Source/Control: 01111 - Process

Emission Source/Control: 01112 - Process

Emission Source/Control: 01113 - Process

New York State Department of Environmental Conservation

Permit ID: 7-0842-00071/00001

Facility DEC ID: 7084200071



