



PERMIT
Under the Environmental Conservation Law (ECL)

IDENTIFICATION INFORMATION

Permit Type: Air State Facility
Permit ID: 3-3926-00013/00291
Effective Date: 09/16/2009 Expiration Date: No expiration date

Permit Issued To: NOVARTIS PHARMACEUTICALS CORPORATION
1 HEALTH PLAZA
EAST HANOVER, NJ 07936

Facility: NOVARTIS -SUFFERN PLANT
25 OLD MILL RD
SUFFERN, NY 10901

Contact: JOEL M VALVANO
NOVARTIS
25 OLD MILL RD
SUFFERN, NY 10901
(845) 368-6902

Description:

The Novartis - Suffern Plant facility is a pharmaceutical manufacturer which produces tablets, capsules and transdermal systems. Process operations include blending, mixing, drying, milling, compression, coating, labeling and packaging. Three onsite boilers provide utility heating and cooling applications and process steam.

Process sources at the facility are subject to control of Volatile Organic Compounds (VOC) under 6 NYCRR Part 228 - Surface Coatings, 6NYCRR Part 233 - Pharmaceutical and Cosmetic Manufacturing Processes, and 6NYCRR Part 234 - Graphic Arts. Facility wide emissions of oxides of nitrogen (NOx) and Volatile Organic Compounds (VOC) are limited below major stationary source thresholds. Other applicable requirements include limited sulfur in fuel, limited opacity and limited particulate emissions.

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



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

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

Authorized Signature: _____ Date: ___ / ___ / _____



Notification of Other State Permittee Obligations

Item A: Permittee Accepts Legal Responsibility and Agrees to Indemnification

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

Item B: Permittee's Contractors to Comply with Permit

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

Item C: Permittee Responsible for Obtaining Other Required Permits

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

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

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



LIST OF CONDITIONS

DEC GENERAL CONDITIONS

General Provisions

- Facility Inspection by the Department
- Relationship of this Permit to Other Department Orders and Determinations
 - Applications for permit renewals, modifications and transfers
 - Applications for Permit Renewals and Modifications
 - Permit modifications, suspensions or revocations by the Department
 - Permit modifications, suspensions or 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 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: Applications for permit renewals, modifications and transfers
Applicable State Requirement: 6NYCRR 621.11

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: Applications for Permit Renewals and Modifications



Item 4.1:

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 4.2:

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 4.3:

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 5: Permit modifications, suspensions or revocations by the Department
Applicable State Requirement: 6NYCRR 621.13

Item 5.1:

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

Item 6.1:

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



Item 7.1:

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 8: Submission of Applications for Permit Modification or Renewal-REGION 3 HEADQUARTERS

Applicable State Requirement: 6NYCRR 621.5(a)

Item 8.1:

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

Applicable State Requirement: 6NYCRR 621.6(a)

Item 9.1:

Submission of applications for permit modification or renewal are to be submitted to:
NYSDEC Regional Permit Administrator
Region 3 Headquarters
Division of Environmental Permits
21 South Putt Corners Road
New Paltz, NY 12561-1696
(845) 256-3054



Permit Under the Environmental Conservation Law (ECL)

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

IDENTIFICATION INFORMATION

Permit Issued To: NOVARTIS PHARMACEUTICALS CORPORATION
1 HEALTH PLAZA
EAST HANOVER, NJ 07936

Facility: NOVARTIS -SUFFERN PLANT
25 OLD MILL RD
SUFFERN, NY 10901

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

Permit Effective Date: 09/16/2009
date.

Permit Expiration Date: No expiration
date.



LIST OF CONDITIONS

FEDERALLY ENFORCEABLE CONDITIONS

Facility Level

- 1 6NYCRR 201-7: Facility Permissible Emissions
- *2 6NYCRR 201-7: Capping Monitoring Condition
- *3 6NYCRR 201-7: Capping Monitoring Condition
- *4 6NYCRR 201-7: Capping Monitoring Condition
- 5 6NYCRR 212.6(a): Compliance Demonstration
- 6 6NYCRR 227-1.3(a): Compliance Demonstration
- 7 6NYCRR 228.3(a): Compliance Demonstration
- 8 6NYCRR 228.4: Compliance Demonstration
- 9 6NYCRR 228.10: Compliance Demonstration
- 10 6NYCRR 233.3(b)(1): Compliance Demonstration
- 11 6NYCRR 233.3(b)(1): Compliance Demonstration
- 12 6NYCRR 233.3(d): Compliance Demonstration
- 13 6NYCRR 233.3(f): Compliance Demonstration
- 14 6NYCRR 233.3(g): Compliance Demonstration
- 15 6NYCRR 233.5: Compliance Demonstration
- 16 6NYCRR 234.3(a)(3): Compliance Demonstration
- 17 6NYCRR 234.3(e): Compliance Demonstration
- 18 6NYCRR 234.6: Compliance Demonstration
- 19 40CFR 60.43c(c), NSPS Subpart Dc: Compliance Demonstration
- 20 40CFR 60.48c(c), NSPS Subpart Dc: Compliance Demonstration
- 21 40CFR 60.48c(e)(11), NSPS Subpart Dc: Compliance Demonstration
- 22 40CFR 60.48c(g)(2), NSPS Subpart Dc: Compliance Demonstration

STATE ONLY ENFORCEABLE CONDITIONS

Facility Level

- 23 ECL 19-0301: Contaminant List
- 24 6NYCRR 201-1.4: Unavoidable noncompliance and violations
- 25 6NYCRR 201-5: Emission Unit Definition
- 26 6NYCRR 211.2: Air pollution prohibited
- 27 6NYCRR 212.4(c): Compliance Demonstration
- 28 6NYCRR 225-1.2(a)(2): Compliance Demonstration

Emission Unit Level

- 29 6NYCRR 201-5: Emission Point Definition By Emission Unit
- 30 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 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 201-7

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: 0NY100-00-0 PTE: 48,000 pounds per year
Name: HAP

CAS No: 0NY210-00-0 PTE: 42,000 pounds per year
Name: OXIDES OF NITROGEN

CAS No: 0NY998-00-0 PTE: 48,000 pounds per year
Name: VOC

Condition 2: Capping Monitoring Condition
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 201-7

Item 2.1:

Under the authority of 6 NYCRR Part 201-7, this condition contains an emission cap for the purpose of limiting emissions from the facility, emission unit or process to avoid being subject to the following applicable requirement(s) that the facility, emission unit or process would otherwise be subject to:

6NYCRR 201-6

Item 2.2:

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

Item 2.3:

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 2.4:

On an annual basis, unless otherwise specified below, 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 the threshold levels that would require compliance with an applicable requirement.

Item 2.5:

The emission of pollutants that exceed the applicability thresholds for an applicable requirement, for which the facility has obtained an emissions cap, constitutes a violation of Part 201 and of the Act.

Item 2.6:

The Compliance Demonstration activity will be performed for the Facility.

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

Item 2.7:

Compliance Demonstration shall include the following monitoring:

Capping: Yes
Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

Novartis shall demonstrate that VOC emissions are below the 25 tons per year based on a 12-month rolling average by maintaining records of all required measurements and emission calculations from coating, printing, drying, cleaning and miscellaneous activities.

These records shall be kept on a monthly basis, and shall include mass of all VOC containing materials used during the month, and the mass fraction of VOC present. Records, including the calculations used to determine the emissions, shall be retained on site for a period of at least five years and shall be available for inspection by NYSDEC and/or USEPA inspectors during normal business hours.

Work Practice Type: PROCESS MATERIAL THRUPUT
Process Material: COATING
Upper Permit Limit: 24.0 tons per year
Monitoring Frequency: MONTHLY
Averaging Method: ANNUAL MAXIMUM ROLLED MONTHLY
Reporting Requirements: ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 1/30/2010.
Subsequent reports are due every 12 calendar month(s).

Condition 3: Capping Monitoring Condition
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 201-7



Item 3.1:

Under the authority of 6 NYCRR Part 201-7, this condition contains an emission cap for the purpose of limiting emissions from the facility, emission unit or process to avoid being subject to the following applicable requirement(s) that the facility, emission unit or process would otherwise be subject to:

6NYCRR 201-6
40CFR 63-GGG

Item 3.2:

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

Item 3.3:

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 3.4:

On an annual basis, unless otherwise specified below, 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 the threshold levels that would require compliance with an applicable requirement.

Item 3.5:

The emission of pollutants that exceed the applicability thresholds for an applicable requirement, for which the facility has obtained an emissions cap, constitutes a violation of Part 201 and of the Act.

Item 3.6:

The Compliance Demonstration activity will be performed for the Facility.

Regulated Contaminant(s):

CAS No: 000067-56-1	METHYL ALCOHOL
CAS No: 000075-05-8	ACETONITRILE
CAS No: 0NY100-00-0	HAP

Item 3.7:

Compliance Demonstration shall include the following monitoring:

Capping: Yes

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

Novartis shall demonstrate that its emissions are below the 10 tons per year of any individual HAP and below the 25 tons per year of total HAPs based on a 12-month rolling



average by maintaining records of all required measurements and emission calculations of individual HAP and total HAPs from coating, printing, drying, cleaning and miscellaneous activities.

These records shall be kept on a monthly basis, and shall include mass of all HAP-containing materials used during the month, and the mass fraction of HAP present in each HAP-containing material used. Records, including the calculations used to determine the emissions, shall be retained on site for a period of at least five years and shall be available for inspection by NYSDEC and/or USEPA inspectors during normal business hours.

The major source thresholds :

individual HAP: 10.0 tons per rolling 12-month period

total HAPs: 25.0 tons per rolling 12-month period

Work Practice Type: PROCESS MATERIAL THRUPUT

Process Material: COATING

Upper Permit Limit: 24.0 tons per year

Monitoring Frequency: MONTHLY

Averaging Method: ANNUAL MAXIMUM ROLLED MONTHLY

Reporting Requirements: ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 1/30/2010.

Subsequent reports are due every 12 calendar month(s).

Condition 4: Capping Monitoring Condition
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 201-7

Item 4.1:

Under the authority of 6 NYCRR Part 201-7, this condition contains an emission cap for the purpose of limiting emissions from the facility, emission unit or process to avoid being subject to the following applicable requirement(s) that the facility, emission unit or process would otherwise be subject to:

6NYCRR 201-6

6NYCRR 227-2

Item 4.2:

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

Item 4.3:



Reporting Requirements: ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 1/30/2010.
Subsequent reports are due every 12 calendar month(s).

Condition 5: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 212.6(a)

Item 5.1:

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

Emission Unit: M-00003	Emission Point: 00103
Emission Unit: M-00003	Emission Point: 00111
Emission Unit: M-00003	Emission Point: 00151
Emission Unit: M-00003	Emission Point: 00154
Emission Unit: M-00003	Emission Point: 00155
Emission Unit: M-00003	Emission Point: 00156
Emission Unit: M-00003	Emission Point: 00157
Emission Unit: M-00003	Emission Point: 00158
Emission Unit: M-00003	Emission Point: 00159
Emission Unit: M-00003	Emission Point: 00160
Emission Unit: M-00003	Emission Point: 00161
Emission Unit: M-00003	Emission Point: 00162
Emission Unit: M-00003	Emission Point: 00163
Emission Unit: M-00003	Emission Point: 00164
Emission Unit: M-00003	Emission Point: 00165
Emission Unit: M-00003	Emission Point: 00175
Emission Unit: M-00003	Emission Point: 00176
Emission Unit: M-00003	Emission Point: 00178
Emission Unit: M-00003	Emission Point: 00179
Emission Unit: M-00003	Emission Point: 00180



Emission Unit: M-00003	Emission Point: 00184
Emission Unit: M-00003	Emission Point: 00187
Emission Unit: M-00003	Emission Point: 00188
Emission Unit: M-00003	Emission Point: 00189
Emission Unit: M-00003	Emission Point: 00190
Emission Unit: M-00003	Emission Point: 00192
Emission Unit: M-00003	Emission Point: 00193
Emission Unit: M-00003	Emission Point: 00194
Emission Unit: M-00003	Emission Point: 00195
Emission Unit: M-00003	Emission Point: 00196
Emission Unit: M-00003	Emission Point: 00197
Emission Unit: M-00003	Emission Point: 00198
Emission Unit: M-00003	Emission Point: 00205
Emission Unit: M-00003	Emission Point: 00222
Emission Unit: M-00003	Emission Point: 00225
Emission Unit: M-00003	Emission Point: 00229
Emission Unit: M-00003	Emission Point: 00231
Emission Unit: M-00003	Emission Point: 0199A
Emission Unit: M-00003	Emission Point: 0199B
Emission Unit: M-00003	Emission Point: 0199C
Emission Unit: P-00002	Emission Point: 00098
Emission Unit: P-00002	Emission Point: 00099
Emission Unit: P-00002	Emission Point: 00105
Emission Unit: P-00002	Emission Point: 00140
Emission Unit: P-00002	Emission Point: 00141
Emission Unit: P-00002	Emission Point: 00191



Emission Unit: P-00002	Emission Point: 00234
Emission Unit: P-00002	Emission Point: 00235
Emission Unit: P-00002	Emission Point: 00236
Emission Unit: P-00002	Emission Point: 00237
Emission Unit: P-00002	Emission Point: 00238
Emission Unit: P-00002	Emission Point: 00239

Item 5.2:

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

Opacity is limited to less than 20 percent for any six consecutive minute average, except only the emission of uncombined water.

The Department reserves the right to perform or request the facility perform a Method 9 opacity evaluation.

Parameter Monitored: OPACITY

Upper Permit Limit: 20 percent

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING
DESCRIPTION

Averaging Method: 6-MINUTE AVERAGE (METHOD 9)

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 6: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

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

Item 6.1:

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: U-CMBST	Emission Point: BLR01
Emission Unit: U-CMBST	Emission Point: GEN01

Item 6.2:

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:



Novartis shall not cause to be discharged into the atmosphere any gases that exhibit greater than 20 percent opacity (6-minute average), except for one 6-minute period per hour of not more than 27 percent opacity.

The Department reserves the right to perform or request the performance of Method 9 evaluations following the issuance of the permit.

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 7: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 228.3(a)

Item 7.1:

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: M-00003

Process: M62

Emission Unit: M-00003

Process: M63

Emission Unit: M-00003

Process: M67

Emission Unit: M-00003

Process: M75

Regulated Contaminant(s):

CAS No: 0NY998-00-0 VOC

Item 7.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

Coating for pills and capsules may contain a maximum of 5.5 pounds of volatile organic compounds per gallon of coating (minus water and excluded VOC) as applied.

The facility shall retain records onsite, available for



Department review, which demonstrates compliance with the limit specified.

Work Practice Type: PARAMETER OF PROCESS MATERIAL
Process Material: COATING
Parameter Monitored: VOC CONTENT
Upper Permit Limit: 5.5 pounds per gallon
Reference Test Method: 40CFR Method 24
Monitoring Frequency: PER BATCH OF PRODUCT/RAW MATERIAL CHANGE
Averaging Method: MAXIMUM - NOT TO BE EXCEEDED AT ANY TIME (INSTANTANEOUS/DISCRETE OR GRAB)
Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

Condition 8: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 228.4

Item 8.1:

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

Emission Unit: M-00003	Emission Point: 00175
Emission Unit: M-00003	Emission Point: 00176
Emission Unit: M-00003	Emission Point: 00178
Emission Unit: M-00003	Emission Point: 00179
Emission Unit: M-00003	Emission Point: 00180

Item 8.2:

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

Opacity is limited to 20 percent for any consecutive six-minute period.

The Department reserves the right to perform or require the facility perform a Method 9 opacity evaluation.

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: ONCE / BATCH OR MONITORING OCCURRENCE

Condition 9: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 228.10

Item 9.1:

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: M-00003
Process: M62

Emission Unit: M-00003
Process: M63

Emission Unit: M-00003
Process: M67

Emission Unit: M-00003
Process: M75

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

Item 9.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Within the work area(s) associated with a coating line, the owner or operator of a facility subject to this Part must:

(a) use closed, non-leaking containers to store or dispose of cloth or other absorbent applicators impregnated with VOC solvents that are used for surface preparation, cleanup or coating removal;

(b) store in closed, non-leaking containers spent or fresh VOC solvents to be used for surface preparation, cleanup or coating removal;

(c) not use VOC solvents to cleanup spray equipment unless equipment is used to collect the cleaning compounds and to minimize VOC evaporation;

(d) not use open containers to store or dispense surface



coatings and/or inks unless production, sampling, maintenance or inspection procedures require operational access. This provision does not apply to the actual device or equipment designed for the purpose of applying a coating material to a substrate. These devices may include, but are not limited to: spray guns, flow coaters, dip tanks, rollers, knife coaters, and extrusion coaters;

(e) not use open containers to store or dispose of spent surface coatings, or spent VOC solvents;

(f) minimize spills during the handling and transfer of coatings and VOC solvents; and

Open containers, if found, shall be covered and such deviations shall be noted in a log maintained in the operating area. The log shall include the following information:

- date and time of observation
- description of observed deviation from this permit condition
- corrective measures taken, if necessary

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 10: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 233.3(b)(1)

Item 10.1:

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

Emission Unit: M-00003

Emission Point: 00229

Regulated Contaminant(s):

CAS No: 0NY998-00-0 VOC

Item 10.2:

Compliance Demonstration shall include the following monitoring:



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

Monitoring Description:

VOC emissions require 90 percent control. The scrubber shall be operated within the parameters specified below. Operating parameter shall be recorded during all periods of operation. Records of operation, if any, shall be maintained onsite for a period of 5 years.

The Department reserves the right to request the facility conduct future performance testing to demonstrate control efficiency.

Parameter Monitored: PRESSURE CHANGE

Upper Permit Limit: 6 inches of water

Monitoring Frequency: CONTINUOUS

Averaging Method: MAXIMUM - NOT TO BE EXCEEDED PER
OCCURRENCE

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 11: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 233.3(b)(1)

Item 11.1:

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

Emission Unit: M-00003 Emission Point: 00103
Process: M60

Emission Unit: M-00003 Emission Point: 00103
Process: M64

Emission Unit: M-00003 Emission Point: 00103
Process: M65

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

Item 11.2:

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

The facility shall maintain a continuous monitor that records temperature rise across the catalytic incinerator bed.



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.

Monitoring Frequency: CONTINUOUS

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 15: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 233.5

Item 15.1:

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

Emission Unit: M-00003

Item 15.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

For any leak subject to section 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.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 16: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement:6NYCRR 234.3(a)(3)

Item 16.1:

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

Emission Unit: P-00002

Emission Point: 00183



Upper Permit Limit: 10 percent
Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING
DESCRIPTION
Averaging Method: 6-MINUTE AVERAGE (METHOD 9)
Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 18: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement: 6NYCRR 234.6

Item 18.1:

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

Emission Unit: P-00002

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

Item 18.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

No owner or operator of a facility subject to this Part shall:

- (a) Use open containers to store or dispose of cloth or paper impregnated with VOC and/or solvents that are used for surface preparation, cleanup or ink/coating removal;
- (b) Store in open containers spent or fresh VOC and/or solvents to be used for surface preparation, cleanup or ink/coating removal;
- (c) Use open containers to store or dispose of inks and/or surface coatings; or
- (d) Use open containers to store or dispense inks and/or surface coating unless production, sampling, maintenance or inspection procedures require operational access. This provision does not apply to the actual device or equipment designed for the purposes of applying an ink or coating to a substrate.

Open containers, if found, shall be covered and such deviations shall be noted in a log maintained in the operating area. The log shall include the following information:



- date and time of observation
- description of observed deviation from this permit condition
- corrective measures taken, if necessary

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 19: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement: 40CFR 60.43c(c), NSPS Subpart Dc

Item 19.1:

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

Emission Unit: U-CMBST Emission Point: BLR03

Emission Unit: U-CMBST Emission Point: BLR04

Item 19.2:

Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

Novartis shall not cause to be discharged into the atmosphere any gases that exhibit greater than 20 percent opacity (6-minute average), except for one 6-minute period per hour of not more than 27 percent opacity.

The Department reserves the right to perform or request the performance of Method 9 evaluations following the issuance of the permit.

The opacity standards under this section apply at all times, except during periods of startup, shutdown, or malfunction.

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 20: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date



Applicable Federal Requirement:40CFR 60.48c(c), NSPS Subpart Dc

Item 20.1:

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: U-CMBST

Emission Point: BLR03

Emission Unit: U-CMBST

Emission Point: BLR04

Item 20.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Novartis, being subject to the opacity limits under §60.43c(c), shall submit excess emission reports for any excess emissions from the affected facility that occur during the reporting period.

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

Condition 21: Compliance Demonstration

Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable Federal Requirement:40CFR 60.48c(e)(11), NSPS Subpart Dc

Item 21.1:

The Compliance Demonstration activity will be performed for the Facility.

Item 21.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Novartis shall keep onsite records of fuel supplier certifications used to demonstrate compliance with the sulfur in fuel limit for a period of 5 years.

Monitoring Frequency: PER BATCH OF PRODUCT/RAW MATERIAL CHANGE

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 1/30/2010.

Subsequent reports are due every 6 calendar month(s).

Condition 22: Compliance Demonstration

Effective between the dates of 09/16/2009 and Permit Expiration Date



Applicable Federal Requirement:40CFR 60.48c(g)(2), NSPS Subpart Dc

Item 22.1:

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: U-CMBST

Emission Point: BLR03

Emission Unit: U-CMBST

Emission Point: BLR04

Item 22.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES

Monitoring Description:

Novartis shall maintain monthly fuel records.

Monitoring Frequency: MONTHLY

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 1/30/2010.

Subsequent reports are due every 6 calendar month(s).



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 23: Contaminant List
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable State Requirement:ECL 19-0301

Item 23.1:

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: 000075-05-8
Name: ACETONITRILE

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

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

CAS No: 0NY210-00-0
Name: OXIDES OF NITROGEN

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

Condition 24: Unavoidable noncompliance and violations
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable State Requirement:6NYCRR 201-1.4

Item 24.1:

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 25: Emission Unit Definition
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable State Requirement:6NYCRR 201-5

Item 25.1:

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

Emission Unit: M-00003

Emission Unit Description:

This emission unit includes all processes for the manufacturing of pharmaceutical tablets and capsules including granulation, compression, coating, milling, drying, branding, and weighing/dispensing. A VOC catalytic oxidizer (EP #00103) and scrubber (EP #00110) are control devices in place for solvent operations. Dust collectors provide control of particulate emissions.

Building(s): AREA-B

Item 25.2:

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

Emission Unit: P-00002

Emission Unit Description:

This emission unit includes packaging of pharmaceutical



tablets and capsules as well as printing of transdermal and blister pack systems.

Building(s): AREA-A

Item 25.3:

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

Emission Unit: U-CMBST

Emission Unit Description:

This emission unit includes operation of a 26.5 mmBTU/hr Babcock and Wilcox boiler (BLR1), a 50.2 mmBTU/hr Kewanee boiler (BLR3), a 63.8 mmBTU/hr Babcock and Wilcox boiler (BLR4) and a 650 KW electric generator. The boilers fire natural gas as the primary fuel with capability to fire No. 2 fuel oil. The generator fires No. 2 fuel oil. The boilers are located in the Energy Center.

Building(s): ENERGYCNTR

Condition 26: Air pollution prohibited
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable State Requirement:6NYCRR 211.2

Item 26.1:

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.

Condition 27: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable State Requirement:6NYCRR 212.4(c)

Item 27.1:

The Compliance Demonstration activity will be performed for the facility:

The Compliance Demonstration applies to:

Emission Unit: M-00003	Emission Point: 00103
Emission Unit: M-00003	Emission Point: 00111
Emission Unit: M-00003	Emission Point: 00151
Emission Unit: M-00003	Emission Point: 00154
Emission Unit: M-00003	Emission Point: 00155
Emission Unit: M-00003	Emission Point: 00156



Emission Unit: M-00003	Emission Point: 00157
Emission Unit: M-00003	Emission Point: 00158
Emission Unit: M-00003	Emission Point: 00159
Emission Unit: M-00003	Emission Point: 00160
Emission Unit: M-00003	Emission Point: 00161
Emission Unit: M-00003	Emission Point: 00162
Emission Unit: M-00003	Emission Point: 00163
Emission Unit: M-00003	Emission Point: 00164
Emission Unit: M-00003	Emission Point: 00165
Emission Unit: M-00003	Emission Point: 00175
Emission Unit: M-00003	Emission Point: 00176
Emission Unit: M-00003	Emission Point: 00178
Emission Unit: M-00003	Emission Point: 00179
Emission Unit: M-00003	Emission Point: 00180
Emission Unit: M-00003	Emission Point: 00184
Emission Unit: M-00003	Emission Point: 00187
Emission Unit: M-00003	Emission Point: 00188
Emission Unit: M-00003	Emission Point: 00189
Emission Unit: M-00003	Emission Point: 00190
Emission Unit: M-00003	Emission Point: 00192
Emission Unit: M-00003	Emission Point: 00193
Emission Unit: M-00003	Emission Point: 00194
Emission Unit: M-00003	Emission Point: 00195
Emission Unit: M-00003	Emission Point: 00196
Emission Unit: M-00003	Emission Point: 00197
Emission Unit: M-00003	Emission Point: 00198
Emission Unit: M-00003	Emission Point: 00205



The Department reserves the right to request the facility conduct a performance test to verify emissions are below the standard stated.

Parameter Monitored: PARTICULATES

Upper Permit Limit: 0.050 grains per dscf

Reference Test Method: Method 5

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION

Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST METHOD INDICATED

Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 28: Compliance Demonstration
Effective between the dates of 09/16/2009 and Permit Expiration Date

Applicable State Requirement: 6NYCRR 225-1.2(a)(2)

Item 28.1:

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

Emission Unit: U-CMBST

Item 28.2:

Compliance Demonstration shall include the following monitoring:

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

Novartis shall not fire fuel with a sulfur content greater than the limit presented below.

Work Practice Type: PARAMETER OF PROCESS MATERIAL

Process Material: DISTILLATES - NUMBER 1 AND NUMBER 2 OIL

Parameter Monitored: SULFUR CONTENT

Upper Permit Limit: 0.37 percent by weight

Monitoring Frequency: PER BATCH OF PRODUCT/RAW MATERIAL CHANGE

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

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 1/30/2010.

Subsequent reports are due every 6 calendar month(s).

**** Emission Unit Level ****



**Condition 29: Emission Point Definition By Emission Unit
Effective between the dates of 09/16/2009 and Permit Expiration Date**

Applicable State Requirement:6NYCRR 201-5

Item 29.1:

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

Emission Unit: M-00003			
Emission Point: 00103	Height (ft.): 46	Diameter (in.): 42	
	NYTMN (km.): 4552.	NYTME (km.): 572.	Building: AREA-B
Emission Point: 00111	Height (ft.): 66	Diameter (in.): 20	
	NYTMN (km.): 4552.223	NYTME (km.): 572.032	Building: AREA-B
Emission Point: 00151	Height (ft.): 32	Diameter (in.): 12	
			Building: AREA-B
Emission Point: 00154	Height (ft.): 65	Diameter (in.): 9	
			Building: AREA-B
Emission Point: 00155	Height (ft.): 65	Diameter (in.): 9	
			Building: AREA-B
Emission Point: 00156	Height (ft.): 65	Diameter (in.): 9	
			Building: AREA-B
Emission Point: 00157	Height (ft.): 65	Diameter (in.): 9	
			Building: AREA-B
Emission Point: 00158	Height (ft.): 63	Diameter (in.): 15	
			Building: AREA-B
Emission Point: 00159	Height (ft.): 63	Diameter (in.): 15	
			Building: AREA-B
Emission Point: 00160	Height (ft.): 63	Diameter (in.): 15	
			Building: AREA-B
Emission Point: 00161	Height (ft.): 65	Diameter (in.): 15	
	NYTMN (km.): 4552.223	NYTME (km.): 572.032	Building: AREA-B



Emission Point: 00162			
Height (ft.): 59	Diameter (in.): 15		
NYTMN (km.): 4552.223	NYTME (km.): 572.032	Building: AREA-B	
Emission Point: 00163			
Height (ft.): 55	Diameter (in.): 14		Building: AREA-B
Emission Point: 00164			
Height (ft.): 55	Diameter (in.): 14		Building: AREA-B
Emission Point: 00165			
Height (ft.): 55	Diameter (in.): 18		Building: AREA-B
Emission Point: 00175			
Height (ft.): 60	Diameter (in.): 15		Building: AREA-B
Emission Point: 00176			
Height (ft.): 60	Diameter (in.): 15		Building: AREA-B
Emission Point: 00178			
Height (ft.): 59	Diameter (in.): 16		Building: AREA-B
Emission Point: 00179			
Height (ft.): 59	Diameter (in.): 16		Building: AREA-B
Emission Point: 00180			
Height (ft.): 58	Diameter (in.): 16		Building: AREA-B
Emission Point: 00184			
Height (ft.): 54	Diameter (in.): 4		Building: AREA-B
Emission Point: 00187			
Height (ft.): 62	Diameter (in.): 10		Building: AREA-B
Emission Point: 00188			
Height (ft.): 62	Diameter (in.): 10		Building: AREA-B
Emission Point: 00189			
Height (ft.): 51	Diameter (in.): 10		Building: AREA-B



Emission Point: 00190 Height (ft.): 64	Diameter (in.): 14	Building: AREA-B
Emission Point: 00192 Height (ft.): 60	Diameter (in.): 10	Building: AREA-B
Emission Point: 00193 Height (ft.): 54	Diameter (in.): 10	Building: AREA-B
Emission Point: 00194 Height (ft.): 63	Diameter (in.): 32	Building: AREA-B
Emission Point: 00195 Height (ft.): 63	Diameter (in.): 32	Building: AREA-B
Emission Point: 00196 Height (ft.): 59 NYTMN (km.): 4552.223	Length (in.): 12 NYTME (km.): 572.032	Width (in.): 12 Building: AREA-B
Emission Point: 00197 Height (ft.): 59 NYTMN (km.): 4552.223	Length (in.): 12 NYTME (km.): 572.032	Width (in.): 12 Building: AREA-B
Emission Point: 00198 Height (ft.): 59 NYTMN (km.): 4552.223	Length (in.): 12 NYTME (km.): 572.032	Width (in.): 12 Building: AREA-B
Emission Point: 00205 Height (ft.): 51 NYTMN (km.): 4552.223	Diameter (in.): 49 NYTME (km.): 572.032	Building: AREA-B
Emission Point: 00206 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00207 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00208 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00209 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00210		



Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00211 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00212 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00213 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00214 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00215 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00216 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00217 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00218 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00219 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00220 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00221 Height (ft.): 66	Length (in.): 7	Width (in.): 7 Building: AREA-B
Emission Point: 00222 Height (ft.): 59	Length (in.): 12	Width (in.): 12 Building: AREA-B
Emission Point: 00225 Height (ft.): 63	Diameter (in.): 9	



			Building: AREA-B
Emission Point: 00229	Height (ft.): 56	Diameter (in.): 16	
			Building: AREA-B
Emission Point: 00231	Height (ft.): 37	Diameter (in.): 8	
			Building: AREA-B
Emission Point: 0199A	Height (ft.): 54	Diameter (in.): 30	
			Building: AREA-B
Emission Point: 0199B	Height (ft.): 58	Diameter (in.): 30	
			Building: AREA-B
Emission Point: 0199C	Height (ft.): 60	Diameter (in.): 30	
			Building: AREA-B

Item 29.2:

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

Emission Unit: P-00002			
Emission Point: 00098	Height (ft.): 32	Diameter (in.): 12	
	NYTMN (km.): 4552.223	NYTME (km.): 572.032	Building: AREA-A
Emission Point: 00099	Height (ft.): 29	Length (in.): 6	Width (in.): 8
	NYTMN (km.): 4552.223	NYTME (km.): 572.032	Building: AREA-A
Emission Point: 00105	Height (ft.): 35	Diameter (in.): 25	
	NYTMN (km.): 4552.223	NYTME (km.): 572.032	Building: AREA-A
Emission Point: 00140	Height (ft.): 27	Diameter (in.): 8	
			Building: AREA-A
Emission Point: 00141	Height (ft.): 22	Diameter (in.): 2	
			Building: AREA-A
Emission Point: 00183	Height (ft.): 33	Diameter (in.): 8	
			Building: AREA-A
Emission Point: 00191	Height (ft.): 62	Diameter (in.): 14	



			Building: AREA-A
Emission Point: 00234	Height (ft.): 26	Diameter (in.): 16	
			Building: AREA-A
Emission Point: 00235	Height (ft.): 26	Diameter (in.): 16	
			Building: AREA-A
Emission Point: 00236	Height (ft.): 30	Diameter (in.): 8	
			Building: AREA-A
Emission Point: 00237	Height (ft.): 26	Diameter (in.): 16	
			Building: AREA-A
Emission Point: 00238	Height (ft.): 26	Diameter (in.): 16	
			Building: AREA-A
Emission Point: 00239	Height (ft.): 26	Diameter (in.): 16	
			Building: AREA-A

Item 29.3:

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

Emission Unit: U-CMBST			
Emission Point: BLR01	Height (ft.): 42	Diameter (in.): 36	
	NYTMN (km.): 4552.2	NYTME (km.): 572.	Building:
ENERGYCNTR			
Emission Point: BLR03	Height (ft.): 42	Diameter (in.): 36	
	NYTMN (km.): 4552.2	NYTME (km.): 572.	Building:
ENERGYCNTR			
Emission Point: BLR04	Height (ft.): 42	Diameter (in.): 36	
	NYTMN (km.): 4552.2	NYTME (km.): 572.	Building:
ENERGYCNTR			
Emission Point: GEN01	Height (ft.): 18	Diameter (in.): 10	
	NYTMN (km.): 4552.2	NYTME (km.): 572.	Building:
ENERGYCNTR			

Condition 30: Process Definition By Emission Unit
Effective between the dates of 09/16/2009 and Permit Expiration Date



Applicable State Requirement:6NYCRR 201-5

Item 30.1:

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

Emission Unit: M-00003

Process: B06

Source Classification Code: 3-01-060-99

Process Description:

CATALYTIC OXIDIZERS IN MANUFACTURING AREA
B (EPID #103) BURNING NATURAL GAS.

Emission Source/Control: IN001 - Control

Control Type: CATALYTIC AFTERBURNER

Emission Source/Control: M4210 - Process

Item 30.2:

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

Emission Unit: M-00003

Process: M41

Source Classification Code: 3-01-060-99

Process Description: COMPACTING POLYBAGS

Emission Source/Control: DC152 - Control

Control Type: FABRIC FILTER

Emission Source/Control: M4101 - Process

Item 30.3:

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

Emission Unit: M-00003

Process: M42

Source Classification Code: 3-01-060-99

Process Description:

AQUEOUS OPERATIONS AT SOLUTION PREPARATION
TANKS AND MIXERS FOR GRANULATION LINES #1 -
#6. (SOLVENT OPERATIONS PERFORMED UNDER
PROCESS ID M60)

Emission Source/Control: DC01A - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC01B - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC01C - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC01D - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC01E - Control



Control Type: FABRIC FILTER

Emission Source/Control: DC01F - Control
Control Type: FABRIC FILTER

Emission Source/Control: M4201 - Process

Emission Source/Control: M4202 - Process

Emission Source/Control: M4203 - Process

Emission Source/Control: M4204 - Process

Emission Source/Control: M4205 - Process

Emission Source/Control: M4206 - Process

Emission Source/Control: M4207 - Process

Emission Source/Control: M4208 - Process

Emission Source/Control: M4209 - Process

Emission Source/Control: M4210 - Process

Emission Source/Control: M4212 - Process

Emission Source/Control: M4213 - Process

Emission Source/Control: M4215 - Process

Emission Source/Control: M4216 - Process

Emission Source/Control: M4218 - Process

Emission Source/Control: M4219 - Process

Emission Source/Control: M4220 - Process

Emission Source/Control: M4221 - Process

Emission Source/Control: M4222 - Process

Emission Source/Control: M4223 - Process

Emission Source/Control: M4224 - Process

Emission Source/Control: M4225 - Process

Item 30.4:

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

Emission Unit: M-00003



Process: M43 Source Classification Code: 3-01-060-12

Process Description:

BLENDING, FLUID BED DRYING AND MILLING FOR
GRANULATION LINES #1 - #6 (ONLY AQUEOUS
OPERATIONS FROM THESE SOURCES)

Emission Source/Control: DC01E - Control
Control Type: FABRIC FILTER

Emission Source/Control: DC01F - Control
Control Type: FABRIC FILTER

Emission Source/Control: DC02A - Control
Control Type: FABRIC FILTER

Emission Source/Control: DC02B - Control
Control Type: FABRIC FILTER

Emission Source/Control: DC02C - Control
Control Type: FABRIC FILTER

Emission Source/Control: DC02D - Control
Control Type: FABRIC FILTER

Emission Source/Control: M4301 - Process

Emission Source/Control: M4302 - Process

Emission Source/Control: M4303 - Process

Emission Source/Control: M4306 - Process

Emission Source/Control: M4307 - Process

Emission Source/Control: M4308 - Process

Emission Source/Control: M4311 - Process

Emission Source/Control: M4312 - Process

Emission Source/Control: M4313 - Process

Emission Source/Control: M4316 - Process

Emission Source/Control: M4317 - Process

Emission Source/Control: M4318 - Process

Emission Source/Control: M4321 - Process

Emission Source/Control: M4322 - Process

Emission Source/Control: M4323 - Process



Emission Source/Control: M4324 - Process

Emission Source/Control: M4325 - Process

Emission Source/Control: M4329 - Process

Emission Source/Control: M4330 - Process

Emission Source/Control: M4331 - Process

Emission Source/Control: M4332 - Process

Emission Source/Control: M4334 - Process

Emission Source/Control: M4335 - Process

Item 30.5:

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

Emission Unit: M-00003

Process: M44

Source Classification Code: 3-01-060-11

Process Description:

AQUEOUS OPERATIONS AT FILM COATING
SOLUTION PREPARATION AND LASERS. (SOLVENT
OPERATIONS PERFORMED UNDER PROCESS ID M61.)

Emission Source/Control: DC03A - Control

Control Type: FABRIC FILTER

Emission Source/Control: M4401 - Process

Emission Source/Control: M4402 - Process

Emission Source/Control: M4403 - Process

Emission Source/Control: M4404 - Process

Emission Source/Control: M4405 - Process

Emission Source/Control: M4406 - Process

Emission Source/Control: M4407 - Process

Item 30.6:

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

Emission Unit: M-00003

Process: M45

Source Classification Code: 3-01-060-12

Process Description: PHARMACEUTICAL PRE-MILLING

Emission Source/Control: DC11A - Control

Control Type: FABRIC FILTER



Emission Source/Control: M4704 - Process

Emission Source/Control: M4705 - Process

Emission Source/Control: M4706 - Process

Emission Source/Control: M4707 - Process

Emission Source/Control: M4708 - Process

Item 30.9:

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

Emission Unit: M-00003

Process: M48

Source Classification Code: 3-01-060-11

Process Description:

AQUEOUS FILM COATING OPERATIONS. (SOLVENT
OPERATIONS PERFORMED AT EP #00178, #00179
AND #00180 LOCATED UNDER PROCESS ID M63.)

Emission Source/Control: DC09A - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC09B - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC09C - Control

Control Type: FABRIC FILTER

Emission Source/Control: M4801 - Process

Emission Source/Control: M4802 - Process

Emission Source/Control: M4803 - Process

Item 30.10:

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

Emission Unit: M-00003

Process: M49

Source Classification Code: 3-01-060-99

Process Description:

VACUUM FOR PRODUCT TRANSFER FOR V-BLENDER
ON GRANULATION LINE #1

Emission Source/Control: VU001 - Control

Control Type: FABRIC FILTER

Emission Source/Control: M4901 - Process

Item 30.11:

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



Emission Unit: M-00003

Process: M50

Source Classification Code: 3-01-060-99

Process Description:

HOUSE VACUUM FOR COMPRESSION, BRANDING,
AND ENCAPSULATION OF UNCONTROLLED
SUBSTANCES LINES 1-6 (CONTROLLED
SUBSTANCES ON LINES #5 & #6 ARE LOCATED
UNDER PROCESS M73.)

Emission Source/Control: CSVC5 - Control

Control Type: FABRIC FILTER

Emission Source/Control: CSVC6 - Control

Control Type: FABRIC FILTER

Emission Source/Control: CSVC7 - Control

Control Type: FABRIC FILTER

Emission Source/Control: M5001 - Process

Emission Source/Control: M5002 - Process

Emission Source/Control: M5003 - Process

Emission Source/Control: M5004 - Process

Emission Source/Control: M5005 - Process

Emission Source/Control: M5006 - Process

Emission Source/Control: M5007 - Process

Emission Source/Control: M5008 - Process

Emission Source/Control: M5009 - Process

Emission Source/Control: M5010 - Process

Emission Source/Control: M5011 - Process

Emission Source/Control: M5012 - Process

Emission Source/Control: M5013 - Process

Emission Source/Control: M5014 - Process

Emission Source/Control: M5016 - Process

Emission Source/Control: M5017 - Process

Emission Source/Control: M5018 - Process

Emission Source/Control: M5019 - Process



Emission Source/Control: M5020 - Process

Emission Source/Control: M5021 - Process

Emission Source/Control: M5023 - Process

Emission Source/Control: M5024 - Process

Emission Source/Control: M5025 - Process

Emission Source/Control: M5026 - Process

Emission Source/Control: M5027 - Process

Emission Source/Control: M5028 - Process

Emission Source/Control: M5029 - Process

Emission Source/Control: M5030 - Process

Emission Source/Control: M5031 - Process

Item 30.12:

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

Emission Unit: M-00003

Process: M51

Source Classification Code: 3-01-060-99

Process Description: HOUSE VACUUM SYSTEM FOR MANUFACTURING

Emission Source/Control: MC001 - Control

Control Type: FABRIC FILTER

Emission Source/Control: M5101 - Process

Item 30.13:

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

Emission Unit: M-00003

Process: M52

Source Classification Code: 3-01-060-99

Process Description: HOUSE VACUUM SYSTEM FOR ENCAPSULATION AND
BRANDING

Emission Source/Control: CS4V3 - Control

Control Type: FABRIC FILTER

Emission Source/Control: M5201 - Process

Emission Source/Control: M5203 - Process

Emission Source/Control: M5204 - Process

Emission Source/Control: M5205 - Process



Emission Source/Control: M5206 - Process

Emission Source/Control: M5207 - Process

Item 30.14:

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

Emission Unit: M-00003

Process: M53

Source Classification Code: 3-01-060-09

Process Description:

AQUEOUS OPERATIONS AT FLUID BED DRYERS
(SOLVENT OPERATIONS UNDER PROCESS ID M64.)

Emission Source/Control: EF15A - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: EF15B - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: EF15C - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: EF15D - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: EF15E - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: EF15G - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: EF15H - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: EF15I - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: M5301 - Process

Emission Source/Control: M5302 - Process

Emission Source/Control: M5303 - Process

Emission Source/Control: M5304 - Process

Emission Source/Control: M5305 - Process

Emission Source/Control: M5306 - Process

Emission Source/Control: M5308 - Process

Item 30.15:



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

Emission Unit: M-00003
Process: M54 Source Classification Code: 3-01-060-09
Process Description:
AQUEOUS OPERATIONS - OVEN CHAMBER EXHAUST
(SOLVENT OPERATIONS PERFORMED UNDER PROCESS
ID M65.)

Emission Source/Control: M5401 - Process

Emission Source/Control: M5402 - Process

Emission Source/Control: M5403 - Process

Emission Source/Control: M5404 - Process

Emission Source/Control: M5405 - Process

Item 30.16:

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

Emission Unit: M-00003
Process: M55 Source Classification Code: 3-01-060-99
Process Description:
WASHDOWN OF MISCELLANEOUS MANUFACTURING
AND MANUFACTURING SUPPORT ROOMS

Emission Source/Control: M5501 - Process

Emission Source/Control: M5502 - Process

Emission Source/Control: M5503 - Process

Emission Source/Control: M5504 - Process

Emission Source/Control: M5505 - Process

Emission Source/Control: M5506 - Process

Emission Source/Control: M5507 - Process

Emission Source/Control: M5508 - Process

Emission Source/Control: M5509 - Process

Emission Source/Control: M5510 - Process

Emission Source/Control: M5511 - Process

Emission Source/Control: M5512 - Process

Emission Source/Control: M5513 - Process



Emission Source/Control: M5514 - Process

Emission Source/Control: M5515 - Process

Emission Source/Control: M5516 - Process

Emission Source/Control: M5517 - Process

Emission Source/Control: M5518 - Process

Emission Source/Control: M5519 - Process

Emission Source/Control: M5520 - Process

Emission Source/Control: M5521 - Process

Item 30.17:

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

Emission Unit: M-00003

Process: M56

Source Classification Code: 3-01-060-99

Process Description: PHARMACY WEIGHING, MILLING AND SIFTING

Emission Source/Control: F11AB - Control

Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: M5601 - Process

Emission Source/Control: M5602 - Process

Emission Source/Control: M5603 - Process

Emission Source/Control: M5604 - Process

Emission Source/Control: M5605 - Process

Emission Source/Control: M5606 - Process

Emission Source/Control: M5607 - Process

Item 30.18:

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

Emission Unit: M-00003

Process: M57

Source Classification Code: 3-01-060-09

Process End Date: 8/18/2009

Process Description: DRYING OF COATING

Emission Source/Control: M5701 - Process

Emission Source/Control: M5702 - Process



Emission Source/Control: M5901 - Process

Emission Source/Control: M5902 - Process

Emission Source/Control: M5903 - Process

Emission Source/Control: M5904 - Process

Item 30.21:

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

Emission Unit: M-00003

Process: M60

Source Classification Code: 3-01-060-99

Process Description:

SOLVENT OPERATIONS AT SOLUTION PREPARATION
TANKS AND MIXERS FOR GRANULATION LINES #1 -
#6. VOC EMISSIONS ARE VENTED THROUGH A
CATALYTIC OXIDIZER AT EMISSION POINT
#00103.

Emission Source/Control: DCIN1 - Control

Control Type: FABRIC FILTER

Emission Source/Control: IN001 - Control

Control Type: CATALYTIC AFTERBURNER

Emission Source/Control: M4201 - Process

Emission Source/Control: M4202 - Process

Emission Source/Control: M4203 - Process

Emission Source/Control: M4204 - Process

Emission Source/Control: M4205 - Process

Emission Source/Control: M4206 - Process

Emission Source/Control: M4207 - Process

Emission Source/Control: M4208 - Process

Emission Source/Control: M4209 - Process

Emission Source/Control: M4210 - Process

Emission Source/Control: M4212 - Process

Emission Source/Control: M4213 - Process

Emission Source/Control: M4215 - Process

Emission Source/Control: M4216 - Process



Emission Source/Control: M4218 - Process

Emission Source/Control: M4219 - Process

Emission Source/Control: M4220 - Process

Emission Source/Control: M4221 - Process

Emission Source/Control: M4222 - Process

Emission Source/Control: M4223 - Process

Emission Source/Control: M4224 - Process

Item 30.22:

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

Emission Unit: M-00003

Process: M61

Source Classification Code: 3-01-060-99

Process Description:

SOLVENT OPERATIONS AT FILM COATING
SOLUTION PREPARATION AND LASERS (AQUEOUS
OPERATIONS PERFORMED UNDER PROCESS ID M44.)

Emission Source/Control: DC03A - Control

Control Type: FABRIC FILTER

Emission Source/Control: M4403 - Process

Emission Source/Control: M4404 - Process

Emission Source/Control: M4405 - Process

Emission Source/Control: M4406 - Process

Emission Source/Control: M4407 - Process

Item 30.23:

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

Emission Unit: M-00003

Process: M62

Source Classification Code: 3-01-060-11

Process Description:

SOLVENT SUGAR COATING OPERATIONS.
(AQUEOUS OPERATIONS PERFORMED UNDER PROCESS
ID M47.)

Emission Source/Control: DC07A - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC07B - Control

Control Type: FABRIC FILTER



Emission Source/Control: M4701 - Process

Emission Source/Control: M4702 - Process

Emission Source/Control: M4703 - Process

Emission Source/Control: M4704 - Process

Emission Source/Control: M4705 - Process

Emission Source/Control: M4706 - Process

Emission Source/Control: M4707 - Process

Emission Source/Control: M4708 - Process

Item 30.24:

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

Emission Unit: M-00003

Process: M63

Source Classification Code: 3-01-060-11

Process Description:

SOLVENT FILM COATING OPERATIONS (AQUEOUS
OPERATIONS PERFORMED UNDER PROCESS ID M48.)

Emission Source/Control: DC09A - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC09B - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC09C - Control

Control Type: FABRIC FILTER

Emission Source/Control: M4801 - Process

Emission Source/Control: M4802 - Process

Emission Source/Control: M4803 - Process

Item 30.25:

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

Emission Unit: M-00003

Process: M64

Source Classification Code: 3-01-060-09

Process Description:

SOLVENT OPERATIONS AT FLUID BED DRYERS.
VOC EMISSIONS ARE VENTED THROUGH A
CATALYTIC OXIDIZER AT EMISSION POINT
#00103. OTHER VOC EMISSIONS ARE VENTED
THROUGH A SCRUBBER (EMISSION POINT #S
00229). (AQUEOUS OPERATIONS UNDER PROCESS



ID M53.)

Emission Source/Control: DCIN1 - Control
Control Type: FABRIC FILTER

Emission Source/Control: EF15H - Control
Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: EF15I - Control
Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: IN001 - Control
Control Type: CATALYTIC AFTERBURNER

Emission Source/Control: SB002 - Control
Control Type: WET SCRUBBER

Emission Source/Control: SB003 - Control
Control Type: WET SCRUBBER

Emission Source/Control: M5301 - Process

Emission Source/Control: M5302 - Process

Emission Source/Control: M5303 - Process

Emission Source/Control: M5304 - Process

Emission Source/Control: M5305 - Process

Emission Source/Control: M5306 - Process

Emission Source/Control: M5307 - Process

Emission Source/Control: M5308 - Process

Item 30.26:

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

Emission Unit: M-00003

Process: M65

Source Classification Code: 3-01-060-09

Process Description:

SOLVENT OPERATIONS - OVEN CHAMBER EXHAUST.
VOC EMISSIONS VENTED THROUGH A CATALYTIC
OXIDIZER AT EMISSION POINT #00103.
(AQUEOUS OPERATIONS PERFORMED UNDER PROCESS
ID M54.)

Emission Source/Control: DCIN1 - Control
Control Type: FABRIC FILTER

Emission Source/Control: IN001 - Control
Control Type: CATALYTIC AFTERBURNER



Emission Source/Control: M5401 - Process

Emission Source/Control: M5402 - Process

Emission Source/Control: M5403 - Process

Emission Source/Control: M5404 - Process

Emission Source/Control: M5405 - Process

Item 30.27:

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

Emission Unit: M-00003

Process: M67

Source Classification Code: 3-01-060-09

Process Description: SOLVENT OPERATIONS AT SOLVENT SUGAR COATING.

Emission Source/Control: DC008 - Control

Control Type: FABRIC FILTER

Emission Source/Control: SB001 - Control

Control Type: IMPINGEMENT PLATE SCRUBBER

Emission Source/Control: M5901 - Process

Emission Source/Control: M5902 - Process

Emission Source/Control: M5903 - Process

Emission Source/Control: M5904 - Process

Item 30.28:

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

Emission Unit: M-00003

Process: M68

Source Classification Code: 3-01-060-09

Process Description:

OVEN FOR DRYING TABLETS/PHARMACEUTICAL
INGREDIENTS.

Emission Source/Control: M6801 - Process

Item 30.29:

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

Emission Unit: M-00003

Process: M71

Source Classification Code: 3-01-060-10

Process Description: ALCOHOL STORAGE TANKS

Emission Source/Control: M71T1 - Process

Emission Source/Control: M71T2 - Process



Item 30.30:

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

Emission Unit: M-00003

Process: M72

Source Classification Code: 3-01-060-99

Process Description:

SOLVENT SUGAR COATING SOLUTION PREP

(AQUEOUS SUGAR COATING PERFORMED UNDER M77)

Emission Source/Control: M7201 - Process

Emission Source/Control: M7202 - Process

Emission Source/Control: M7203 - Process

Emission Source/Control: M7204 - Process

Item 30.31:

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

Emission Unit: M-00003

Process: M73

Source Classification Code: 3-01-060-99

Process Description:

HOUSE VACUUM SYSTEM FOR CONTROLLED
SUBSTANCES FROM COMPRESSION OR

ENCAPSULATION ON LINES #5 AND #6.

(UNCONTROLLED SUBSTANCES LISTED UNDER M50.)

Emission Source/Control: DC231 - Control

Control Type: FABRIC FILTER, GAS SCRUBBER (GENERAL,
NOT CLASSIFIED)

Emission Source/Control: M5010 - Process

Emission Source/Control: M5011 - Process

Emission Source/Control: M5012 - Process

Emission Source/Control: M5013 - Process

Emission Source/Control: M5014 - Process

Emission Source/Control: M5026 - Process

Emission Source/Control: M5027 - Process

Emission Source/Control: M5028 - Process

Emission Source/Control: M5029 - Process

Emission Source/Control: M5030 - Process



Emission Source/Control: M5031 - Process

Item 30.32:

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

Emission Unit: M-00003

Process: M74

Source Classification Code: 3-01-060-11

Process Description:

NEW FILM COATING OPERATION - AQUEOUS
(SOLVENT OPERATIONS PERFORMED UNDER M75)

Emission Source/Control: M7401 - Process

Emission Source/Control: M7402 - Process

Item 30.33:

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

Emission Unit: M-00003

Process: M75

Source Classification Code: 3-01-060-11

Process Description:

NEW FILM COATING OPERATION - SOLVENT
(AQUEOUS OPERATIONS PERFORMED UNDER M74)

Emission Source/Control: M7401 - Process

Emission Source/Control: M7402 - Process

Item 30.34:

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

Emission Unit: M-00003

Process: M76

Source Classification Code: 3-01-060-99

Process Description:

ENCAPSULATION AND COMPRESSION ON LINE #5
AND LINE #6. (FUTURE)

Emission Source/Control: DC01E - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC01F - Control

Control Type: FABRIC FILTER

Emission Source/Control: M5010 - Process

Emission Source/Control: M5011 - Process

Emission Source/Control: M5012 - Process

Emission Source/Control: M5026 - Process

Emission Source/Control: M5027 - Process



Emission Source/Control: M5028 - Process

Emission Source/Control: M5029 - Process

Emission Source/Control: M5030 - Process

Item 30.35:

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

Emission Unit: M-00003

Process: M77

Source Classification Code: 3-01-060-99

Process Description:

AQUEOUS SUGAR COATING SOLUTION PREP
(SOLVENT SUGAR COATING PERFORMED UNDER M72)

Emission Source/Control: M7201 - Process

Emission Source/Control: M7202 - Process

Emission Source/Control: M7203 - Process

Emission Source/Control: M7204 - Process

Item 30.36:

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

Emission Unit: P-00002

Process: P16

Source Classification Code: 3-01-060-99

Process Description: FABRICATION OF TRANSDERMAL SYSTEMS.

Emission Source/Control: P1601 - Process

Emission Source/Control: PT001 - Process

Emission Source/Control: PT002 - Process

Emission Source/Control: PT003 - Process

Emission Source/Control: PT004 - Process

Emission Source/Control: PT005 - Process

Emission Source/Control: PT006 - Process

Emission Source/Control: PT03A - Process

Item 30.37:

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

Emission Unit: P-00002

Process: P17

Source Classification Code: 4-05-005-97

Process Description:

PRINTING OF TRANSDERMAL AND BLISTER PACK



SYSTEMS (NON-FLEXOGRAPHIC). (FLEXOGRAPHIC
PRINTING PERFORMED UNDER P22.)

Emission Source/Control: PT001 - Process

Emission Source/Control: PT002 - Process

Emission Source/Control: PT004 - Process

Emission Source/Control: PT005 - Process

Emission Source/Control: PT03A - Process

Item 30.38:

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

Emission Unit: P-00002

Process: P18

Source Classification Code: 3-01-060-99

Process Description:

TRANSFER AND MIXING OF MATERIALS IN THE
TTS DRPA AREA WITH GLOVE BOX

Emission Source/Control: DC098 - Control

Control Type: FABRIC FILTER

Emission Source/Control: DC099 - Control

Control Type: FABRIC FILTER

Emission Source/Control: PDC10 - Control

Control Type: FABRIC FILTER

Emission Source/Control: P1801 - Process

Emission Source/Control: P1802 - Process

Emission Source/Control: P1803 - Process

Emission Source/Control: P1805 - Process

Item 30.39:

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

Emission Unit: P-00002

Process: P19

Source Classification Code: 3-01-060-08

Process Description:

PACKAGING OF PHARMACEUTICAL TABLETS AND
CAPSULES - CONTROLLED SUBSTANCES.
(UNCONTROLLED SUBSTANCES LOCATED UNDER
P23.)

Emission Source/Control: DC234 - Control

Control Type: FABRIC FILTER



Emission Source/Control: DC237 - Control
Control Type: FABRIC FILTER

Emission Source/Control: PP001 - Process

Emission Source/Control: PP006 - Process

Emission Source/Control: PP008 - Process

Emission Source/Control: PP009 - Process

Emission Source/Control: PP010 - Process

Emission Source/Control: PP011 - Process

Emission Source/Control: PP012 - Process

Emission Source/Control: PP013 - Process

Emission Source/Control: PP014 - Process

Emission Source/Control: PP015 - Process

Emission Source/Control: PP016 - Process

Emission Source/Control: PP04A - Process

Emission Source/Control: PP04B - Process

Emission Source/Control: PP07F - Process

Emission Source/Control: PP07I - Process

Item 30.40:

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

Emission Unit: P-00002

Process: P20

Source Classification Code: 4-05-005-97

Process Description:

PRINTING OF EXPIRATION DATE ON TABLET
BOTTLES AND/OR CARTONS -SOLVENT OPERATION

Emission Source/Control: PP001 - Process

Emission Source/Control: PP008 - Process

Emission Source/Control: PP015 - Process

Emission Source/Control: PP04A - Process

Emission Source/Control: PP04B - Process

Emission Source/Control: PP07F - Process



Emission Source/Control: PP5B1 - Process

Item 30.41:

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

Emission Unit: P-00002

Process: P21

Source Classification Code: 3-01-060-08

Process Description:

HOUSE VACUUM CLEANING SYSTEM FOR PACKAGING
OF UNCONTROLLED SUBSTANCES. (CONTROLLED
SUBSTANCES LOCATED UNDER P24.)

Emission Source/Control: PVC01 - Control

Control Type: FABRIC FILTER

Emission Source/Control: P2101 - Process

Item 30.42:

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

Emission Unit: P-00002

Process: P22

Source Classification Code: 4-05-003-12

Process Description:

FLEXOGRAPHIC PRINTING OF TRANSDERMAL &
BLISTER PACK SYSTEMS.

Emission Source/Control: AF131 - Control

Control Type: ACTIVATED CARBON ADSORPTION

Emission Source/Control: PP001 - Process

Emission Source/Control: PP006 - Process

Emission Source/Control: PP015 - Process

Emission Source/Control: PT002 - Process

Emission Source/Control: PT003 - Process

Emission Source/Control: PT006 - Process

Item 30.43:

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

Emission Unit: P-00002

Process: P23

Source Classification Code: 3-01-060-08

Process Description:

PACKAGING OF TABLETS AND CAPSULES -
UNCONTROLLED SUBSTANCES. (CONTROLLED
SUBSTANCES LOCATED UNDER P19.)

Emission Source/Control: DC235 - Control



Control Type: FABRIC FILTER

Emission Source/Control: DC238 - Control
Control Type: FABRIC FILTER

Emission Source/Control: DC239 - Control
Control Type: FABRIC FILTER

Emission Source/Control: PP001 - Process

Emission Source/Control: PP006 - Process

Emission Source/Control: PP008 - Process

Emission Source/Control: PP009 - Process

Emission Source/Control: PP010 - Process

Emission Source/Control: PP011 - Process

Emission Source/Control: PP012 - Process

Emission Source/Control: PP013 - Process

Emission Source/Control: PP014 - Process

Emission Source/Control: PP015 - Process

Emission Source/Control: PP016 - Process

Emission Source/Control: PP04A - Process

Emission Source/Control: PP04B - Process

Emission Source/Control: PP07F - Process

Emission Source/Control: PP07I - Process

Item 30.44:

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

Emission Unit: P-00002

Process: P24

Source Classification Code: 3-01-060-08

Process Description:

HOUSE VACUUM FOR PACKAGING OF CONTROLLED
SUBSTANCES. (UNCONTROLLED SUBSTANCES
LOCATED UNDER P21.)

Emission Source/Control: DC236 - Control
Control Type: FABRIC FILTER

Emission Source/Control: P2401 - Process



Item 30.45:

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

Emission Unit: U-CMBST
Process: DIS Source Classification Code: 1-02-005-01
Process Description: Boilers and generator firing distillate fuel.

Emission Source/Control: BLR01 - Combustion
Design Capacity: 26.5 million Btu per hour

Emission Source/Control: BLR03 - Combustion
Design Capacity: 50.2 million Btu per hour

Emission Source/Control: BLR04 - Combustion
Design Capacity: 63.9 million Btu per hour

Emission Source/Control: GEN01 - Combustion
Design Capacity: 650 kilowatts

Item 30.46:

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

Emission Unit: U-CMBST
Process: GAS Source Classification Code: 1-02-006-02
Process Description: Boilers firing natural gas.

Emission Source/Control: BLR01 - Combustion
Design Capacity: 26.5 million Btu per hour

Emission Source/Control: BLR03 - Combustion
Design Capacity: 50.2 million Btu per hour

Emission Source/Control: BLR04 - Combustion
Design Capacity: 63.9 million Btu per hour

