PERMIT
Under the Environmental Conservation Law (ECL)

IDENTIFICATION INFORMATION

Permit Type: Air Title V Facility
Permit ID: 3-3926-00134/00054
Mod 0 Effective Date: 09/14/2010 Expiration Date: 09/13/2015

Mod 1 Effective Date: 04/17/2012 Expiration Date: 09/13/2015

Mod 2 Effective Date: 08/05/2013 Expiration Date: 09/13/2015

Permit Issued To:PAR PHARMACEUTICAL INC
1 RAM RIDGE RD
SPRING VALLEY, NY 10977-6714

Contact: THOMAS J DEPOTO
PAR PHARMACEUTICAL INC
1 RAM RIDGE RD
SPRING VALLEY, NY 10977
(845) 573-5633

Facility: PAR PHARMACEUTICAL INC
1 RAM RIDGE RD
SPRING VALLEY, NY 10977

Contact: THOMAS J DEPOTO
PAR PHARMACEUTICAL INC
1 RAM RIDGE RD
SPRING VALLEY, NY 10977
(845) 573-5633

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

Minor Modification 2

Revise packaging line D identifier to line F.
Revise semi-annual reporting from 60 days to 30 days after applicable period.
Redefine emission units M, N and R.

Modification 1

Installation of a new Glatt GPCG-60 Coater/Granulator/Dryer with associated fume hood and

dust collector. The new equipment is subject to the existing 6NYCRR Part 212 particulate and Volatile Organic Compound control requirements. Operations are limited to 100 solvent based production batches per year to avoid New Source Review applicability.

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: GEORGE A SWEIKERT
NYSDEC
21 S PUTT CORNERS RD
NEW PALTZ, NY 12561-1696

Authorized Signature: _____ Date: ___ / ___ / _____

Notification of Other State Permittee Obligations

Item A: Permittee Accepts Legal Responsibility and Agrees to Indemnification

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

Item B: Permittee's Contractors to Comply with Permit

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

Item C: Permittee Responsible for Obtaining Other Required Permits

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

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

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

LIST OF CONDITIONS

DEC GENERAL CONDITIONS
General Provisions
Facility Inspection by the Department
Relationship of this Permit to Other Department Orders and Determinations
Applications for permit renewals, modifications and transfers
Permit modifications, suspensions or revocations by the Department
Permit modifications, suspensions or revocations by the Department
Facility Level
Submission of application for permit modification or renewal-REGION 3 HEADQUARTERS

DEC GENERAL CONDITIONS
****** General Provisions ******
For the purpose of your Title V permit, the following section contains state-only enforceable terms and conditions.
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: 6 NYCRR 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 1-1: Permit modifications, suspensions or revocations by the Department
Applicable State Requirement: 6 NYCRR 621.13

Item 1-1.1:
The Department reserves the right to exercise all available authority to modify, suspend, or revoke this permit in accordance with 6NYCRR Part 621. The grounds for modification, suspension or revocation include:

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

Condition 4: Permit modifications, suspensions or revocations by the Department
Applicable State Requirement: 6 NYCRR 621.13

Item 4.1:
The Department reserves the right to modify, suspend, or revoke this permit in accordance with 6NYCRR Part 621. The grounds for modification, suspension or revocation include:

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

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

Condition 5: Submission of application for permit modification or renewal-REGION 3 HEADQUARTERS
Applicable State Requirement: 6 NYCRR 621.6 (a)

Item 5.1:
Submission of applications for permit modification or renewal are to be submitted to:
NYSDEC Regional Permit Administrator
Region 3 Headquarters
Division of Environmental Permits
21 South Putt Corners Road
New Paltz, NY 12561-1696

(845) 256-3054

Permit Under the Environmental Conservation Law (ECL)

ARTICLE 19: AIR POLLUTION CONTROL - TITLE V PERMIT

IDENTIFICATION INFORMATION

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1 RAM RIDGE RD
SPRING VALLEY, NY 10977-6714

Facility: PAR PHARMACEUTICAL INC
1 RAM RIDGE RD
SPRING VALLEY, NY 10977

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

Mod 0 Permit Effective Date: 09/14/2010 Permit Expiration Date: 09/13/2015

Mod 1 Permit Effective Date: 04/17/2012 Permit Expiration Date: 09/13/2015

Mod 2 Permit Effective Date: 08/05/2013 Permit Expiration Date: 09/13/2015

LIST OF CONDITIONS

FEDERALLY ENFORCEABLE CONDITIONS
Facility Level

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2-1 6 NYCRR 201-6.4 (a) (7): Fees
2-2 6 NYCRR 201-6.4 (c): Recordkeeping and Reporting of Compliance Monitoring
2-3 6 NYCRR 201-6.4 (c) (2): Records of Monitoring, Sampling, and Measurement
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2-5 6 NYCRR 201-6.4 (e): Compliance Certification
1-4 6 NYCRR 202-2.1: Compliance Certification
9 6 NYCRR 202-2.5: Recordkeeping requirements
1 6 NYCRR 215.2: Open Fires - Prohibitions
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2-10 6 NYCRR 201-6.4 (a) (4): Requirement to Provide Information
2-11 6 NYCRR 201-6.4 (a) (8): Right to Inspect
2-12 6 NYCRR 201-6.4 (f) (6): Off Permit Changes
19 6 NYCRR 202-1.1: Required Emissions Tests
21 40 CFR Part 68: Accidental release provisions.
22 40CFR 82, Subpart F: Recycling and Emissions Reduction
23 6 NYCRR Subpart 201-6: Emission Unit Definition
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24 6 NYCRR 201-6.5 (g): Non Applicable requirements
1-5 6 NYCRR Subpart 201-7: Facility Permissible Emissions
*1-6 6 NYCRR Subpart 201-7: Capping Monitoring Condition
*1-7 6 NYCRR Subpart 201-7: Capping Monitoring Condition
1-8 6 NYCRR 211.1: Air pollution prohibited
2-14 6 NYCRR 212.4 (c): Compliance Certification
2-15 6 NYCRR 212.6 (a): Compliance Certification
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29 6 NYCRR Subpart 201-6: Process Definition By Emission Unit

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NOTE: * preceding the condition number indicates capping.

FEDERALLY ENFORCEABLE CONDITIONS
****** Facility Level ******

NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS
The items listed below are not subject to the annual compliance certification requirements under Title V. Permittees may also have other obligations under regulations of general applicability.

Item A: Emergency Defense - 6 NYCRR 201-1.5

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

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

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

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

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

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

Item C: **Timely Application for the Renewal of Title V Permits - 6 NYCRR 201-6.2 (a) (4)**
Owners and/or operators of facilities having an issued Title V permit shall submit a complete application at least 180 days, but not more than eighteen months, prior to the date of permit expiration for permit renewal purposes.

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

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

Item F: **Permit Revocation, Modification, Reopening, Reissuance or Termination, and Associated Information Submission Requirements - 6 NYCRR 201-6.4 (a) (3)**
This permit may be modified, revoked, reopened and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit condition.

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

Item H: **Property Rights - 6 NYCRR 201-6.4 (a) (6)**

This permit does not convey any property rights of any sort or any exclusive privilege.

Item I: **Severability - 6 NYCRR 201-6.4 (a) (9)**

If any provisions, parts or conditions of this permit are found to be invalid or are the subject of a challenge, the remainder of this permit shall continue to be valid.

Item J: **Permit Shield - 6 NYCRR 201-6.4 (g)**

All permittees granted a Title V facility permit shall be covered under the protection of a permit shield, except as provided under 6 NYCRR Subpart 201-6. Compliance with the conditions of the permit shall be deemed compliance with any applicable requirements as of the date of permit issuance, provided that such applicable requirements are included and are specifically identified in the permit, or the Department, in acting on the permit application or revision, determines in writing that other requirements specifically identified are not applicable to the major stationary source, and the permit includes the determination or a concise summary thereof. Nothing herein shall preclude the Department from revising or revoking the permit pursuant to 6 NYCRR Part 621 or from exercising its summary abatement authority. Nothing in this permit shall alter or affect the following:

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

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

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

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

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

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

i. If additional applicable requirements under the Act become applicable where this permit's remaining term is

three or more years, a reopening shall be completed not later than 18 months after promulgation of the applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which this permit is due to expire, unless the original permit or any of its terms and conditions has been extended by the Department pursuant to the provisions of Part 201-6.7 and Part 621.

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

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

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

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

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

Item L: **Permit Exclusion - ECL 19-0305**

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

(NYCRR). The issuance of this permit also shall not in any way affect pending or future enforcement actions under the Clean Air Act brought by the United States or any person.

Item M: **Federally Enforceable Requirements - 40 CFR 70.6 (b)**
All terms and conditions in this permit required by the Act or any applicable requirement, including any provisions designed to limit a facility's potential to emit, are enforceable by the Administrator and citizens under the Act. The Department has, in this permit, specifically designated any terms and conditions that are not required under the Act or under any of its applicable requirements as being enforceable under only state regulations.

MANDATORY FEDERALLY ENFORCEABLE PERMIT CONDITIONS SUBJECT TO ANNUAL CERTIFICATIONS AT ALL TIMES

The following federally enforceable permit conditions are mandatory for all Title V permits and are subject to annual compliance certification requirements at all times.

Condition 2: **Acceptable Ambient Air Quality**
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 200.6

Item 2.1:
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.

Condition 2-1: **Fees**
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-6.4 (a) (7)

Item 2-1.1:
The owner and/or operator of a stationary source shall pay fees to the Department consistent with the fee schedule authorized by ECL 72-0303.

Condition 2-2: **Recordkeeping and Reporting of Compliance Monitoring**
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-6.4 (c)

Item 2-2.1:
The following information must be included in any required compliance monitoring records and reports:

(i) The date, place, and time of sampling or measurements;

(ii) The date(s) analyses were performed;

(iii)The company or entity that performed the analyses;

(iv) The analytical techniques or methods used including quality assurance and quality control procedures if required;

(v) The results of such analyses including quality assurance data where required; and

(vi) The operating conditions as existing at the time of sampling or measurement.

Any deviation from permit requirements must be clearly identified in all records and reports. Reports must be certified by a responsible official, consistent with Section 201-6.2 of Part 201.

Condition 2-3: Records of Monitoring, Sampling, and Measurement
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-6.4 (c) (2)

Item 2-3.1:
Compliance monitoring and recordkeeping shall be conducted according to the terms and conditions contained in this permit and shall follow all quality assurance requirements found in applicable regulations. Records of all monitoring data and support information must be retained for a period of at least 5 years from the date of the monitoring, sampling, measurement, report, or application. Support information includes all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by the permit.

Condition 2-4: Compliance Certification
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-6.4 (c) (3) (ii)

Item 2-4.1:
The Compliance Certification activity will be performed for the Facility.

Item 2-4.2:
Compliance Certification shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES
Monitoring Description:
To meet the requirements of this facility permit with respect to reporting, the permittee must:

Submit reports of any required monitoring at a minimum frequency of every 6 months, based on a calendar year reporting schedule. These reports shall be submitted to the Department within 30 days after the end of a reporting period. All instances of deviations from permit requirements must be clearly identified in such reports. All required reports must be certified by the responsible official for this facility.

Notify the Department and report permit deviations and incidences of noncompliance stating the probable cause of such deviations, and any corrective actions or preventive measures taken. Where the underlying applicable requirement contains a definition of prompt or otherwise specifies a time frame for reporting deviations, that definition or time frame shall govern. Where the underlying applicable requirement fails to address the time frame for reporting deviations, reports of deviations shall be submitted to the permitting authority based on the following schedule:

(1) For emissions of a hazardous air pollutant (as identified in an applicable regulation) that continue for more than an hour in excess of permit requirements, the report must be made within 24 hours of the occurrence.

(2) For emissions of any regulated air pollutant, excluding those listed in paragraph (1) of this section, that continue for more than two hours in excess of permit requirements, the report must be made within 48 hours.

(3) For all other deviations from permit requirements, the report shall be contained in the 6 month monitoring report required above.

(4) This permit may contain a more stringent reporting requirement than required by paragraphs (1), (2) or (3) above. If more stringent reporting requirements have been placed in this permit or exist in applicable requirements that apply to this facility, the more stringent reporting requirement shall apply.

If above paragraphs (1) or (2) are met, the source must notify the permitting authority by telephone during normal business hours at the Regional Office of jurisdiction for this permit, attention Regional Air Pollution Control Engineer (RAPCE) according to the timetable listed in paragraphs (1) and (2) of this section. For deviations and incidences that must be reported outside of normal business hours, on weekends, or holidays, the DEC Spill

Hotline phone number at 1-800-457-7362 shall be used. A written notice, certified by a responsible official consistent with 6 NYCRR Part 201-6.2(d)(12), must be submitted within 10 working days of an occurrence for deviations reported under (1) and (2). All deviations reported under paragraphs (1) and (2) of this section must also be identified in the 6 month monitoring report required above.

The provisions of 6 NYCRR 201-1.4 shall apply if the permittee seeks to have a violation excused unless otherwise limited by regulation. 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. Notwithstanding any recordkeeping and reporting requirements in 6 NYCRR 201-1.4, reports of any deviations shall not be on a less frequent basis than the reporting periods described in paragraphs (1) and (4) above.

In the case of any condition contained in this permit with a reporting requirement of "Upon request by regulatory agency" the permittee shall include in the semiannual report, a statement for each such condition that the monitoring or recordkeeping was performed as required or requested and a listing of all instances of deviations from these requirements.

In the case of any emission testing performed during the previous six month reporting period, either due to a request by the Department, EPA, or a regulatory requirement, the permittee shall include in the semiannual report a summary of the testing results and shall indicate whether or not the Department or EPA has approved the results.

All semiannual reports shall be submitted to the Administrator (or his or her representative) as well as two copies to the Department (one copy to the regional air pollution control engineer (RAPCE) in the regional office and one copy to the Bureau of Quality Assurance (BQA) in the DEC central office). Mailing addresses for the above referenced persons are contained in the monitoring condition for 6 NYCRR Part 201-6.4(e), contained elsewhere in this permit.

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 1/30/2014.
Subsequent reports are due every 6 calendar month(s).

Condition 2-5: Compliance Certification
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-6.4 (e)

Item 2-5.1:
The Compliance Certification activity will be performed for the Facility.

Item 2-5.2:
Compliance Certification shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES
Monitoring Description:

Requirements for compliance certifications with terms and conditions contained in this facility permit include the following:

i. Compliance certifications shall contain:
- the identification of each term or condition of the permit that is the basis of the certification;
- the compliance status;
- whether compliance was continuous or intermittent;
- the method(s) used for determining the compliance status of the facility, currently and over the reporting period consistent with the monitoring and related record keeping and reporting requirements of this permit;
- such other facts as the Department may require to determine the compliance status of the facility as specified in any special permit terms or conditions; and
- such additional requirements as may be specified elsewhere in this permit related to compliance certification.

ii. The responsible official must include in the annual certification report all terms and conditions contained in this permit which are identified as being subject to certification, including emission limitations, standards, or work practices. That is, the provisions labeled herein as "Compliance Certification" are not the only provisions of this permit for which an annual certification is required.

iii. Compliance certifications shall be submitted annually. Certification reports are due 30 days after the anniversary date of four consecutive calendar quarters. The first report is due 30 days after the calendar quarter that occurs just prior to the permit anniversary date, unless another quarter has been acceptable by the Department.

iv. All compliance certifications shall be submitted to the Administrator (or his or her representative) as well as two copies to the Department (one copy to the regional air pollution control engineer (RAPCE) in the regional office and one copy to the Bureau of Quality Assurance (BQA) in the DEC central office). Please send annual compliance certifications to Chief of the Stationary Source Compliance Section, the Region 2 EPA representative for the Administrator, at the following address:

USEPA Region 2
Air Compliance Branch
290 Broadway
New York, NY 10007-1866

The address for the RAPCE is as follows:

NYSDEC
21 South Putt Corners Road
New Paltz, NY 12561-1696

The address for the BQA is as follows:

NYSDEC
Bureau of Quality Assurance
625 Broadway
Albany, NY 12233-3258

Monitoring Frequency: ANNUALLY
Reporting Requirements: ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 1/30/2011.
Subsequent reports are due on the same day each year

Condition 1-4: Compliance Certification
Effective between the dates of 04/17/2012 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 202-2.1

Replaces Condition(s) 8

Item 1-4.1:
The Compliance Certification activity will be performed for the Facility.

Item 1-4.2:
Compliance Certification shall include the following monitoring:

Monitoring Type: RECORD KEEPING/MAINTENANCE PROCEDURES
Monitoring Description:
Emission statements shall be submitted on or before April 15th each year for emissions of the previous calendar year. Statements are to be mailed to: New York State Department of Environmental Conservation, Division of Air

Resources, Bureau of Air Quality Planning, 625 Broadway,
Albany NY 12233-3251

Monitoring Frequency: ANNUALLY
Reporting Requirements: ANNUALLY (CALENDAR)
Reports due by April 15th for previous calendar year

Condition 9: Recordkeeping requirements
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 202-2.5

Item 9.1:
(a) The following records shall be maintained for at least five years:

(1) a copy of each emission statement submitted to the department; and

(2) records indicating how the information submitted in the emission statement was determined, including any calculations, data, measurements, and estimates used.

(b) These records shall be made available at the facility to the representatives of the department upon request during normal business hours.

Condition 1: Open Fires - Prohibitions
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 215.2

Item 1.1:
Except as allowed by Title 6 NYCRR Section 215.3, no person shall burn, cause, suffer, allow or permit the burning of any materials in an open fire.

Item 1.2
Per Section 215.3, burning in an open fire, provided it is not contrary to other law or regulation, will be allowed as follows:
(a) On-site burning in any town with a total population less than 20,000 of downed limbs and branches (including branches with attached leaves or needles) less than six inches in diameter and eight feet in length between May 15th and the following March 15th. For the purposes of this subdivision, the total population of a town shall include the population of any village or portion thereof located within the town. However, this subdivision shall not be construed to allow burning within any village.
(b) Barbecue grills, maple sugar arches and similar outdoor cooking devices when actually used for cooking or processing food.
(c) Small fires used for cooking and camp fires provided that only charcoal or untreated wood is used as fuel and the fire is not left unattended until extinguished.
(d) On-site burning of agricultural wastes as part of a valid agricultural operation on contiguous agricultural lands larger than five acres actively devoted to agricultural or horticultural use, provided such waste is actually grown or generated on those lands and such waste is capable of being fully burned within a 24-hour period.
(e) The use of liquid petroleum fueled smudge pots to prevent frost damage to crops.
(f) Ceremonial or celebratory bonfires where not otherwise prohibited by law, provided that only untreated wood or other agricultural products are used as fuel and the fire is not left unattended

until extinguished.
(g) Small fires that are used to dispose of a flag or religious item, and small fires or other smoke producing process where not otherwise prohibited by law that are used in connection with a religious ceremony.
(h) Burning on an emergency basis of explosive or other dangerous or contraband materials by police or other public safety organization.
(i) Prescribed burns performed according to Part 194 of this Title.
(j) Fire training, including firefighting, fire rescue, and fire/arson investigation training, performed under applicable rules and guidelines of the New York State Department of State's Office of Fire Prevention and Control. For fire training performed on acquired structures, the structures must be emptied and stripped of any material that is toxic, hazardous or likely to emit toxic smoke (such as asbestos, asphalt shingles and vinyl siding or other vinyl products) prior to burning and must be at least 300 feet from other occupied structures. No more than one structure per lot or within a 300 foot radius (whichever is bigger) may be burned in a training exercise.
(k) Individual open fires as approved by the Director of the Division of Air Resources as may be required in response to an outbreak of a plant or animal disease upon request by the commissioner of the Department of Agriculture and Markets, or for the destruction of invasive plant and insect species.
(l) Individual open fires that are otherwise authorized under the environmental conservation law, or by rule or regulation of the Department.

MANDATORY FEDERALLY ENFORCEABLE PERMIT CONDITIONS SUBJECT TO ANNUAL CERTIFICATIONS ONLY IF APPLICABLE

The following federally enforceable permit conditions are mandatory for all Title V permits and are subject to annual compliance certification requirements only if effectuated during the reporting period. [NOTE: The corresponding annual compliance certification for those conditions not effectuated during the reporting period shall be specified as "not applicable".]

Condition 10: Maintenance of Equipment
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 200.7

Item 10.1:
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.

Condition 2-6: Recycling and Salvage
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-1.7

Item 2-6.1:
Where practical, the owner or operator of an air contamination source shall recycle or salvage air

contaminants collected in an air cleaning device according to the requirements of the ECL.

Condition 12: Prohibition of Reintroduction of Collected Contaminants to the air
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-1.8

Item 12.1:
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.

Condition 2-7: Exempt Sources - Proof of Eligibility
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-3.2 (a)

Item 2-7.1:
The owner or operator of an emission source or activity that is listed as being exempt may be required to certify that it is operated within the specific criteria described in this Subpart. The owner or operator of any such emission source or activity must maintain all records necessary for demonstrating compliance with this Subpart on-site for a period of five years, and make them available to representatives of the department upon request.

Condition 2-8: Compliance Certification
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-3.2 (a)

Item 2-8.1:
The Compliance Certification activity will be performed for the Facility.

Item 2-8.2:
Compliance Certification shall include the following monitoring:

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS
Monitoring Description:
AS PROOF OF EXEMPT ELIGIBILITY FOR THE EMERGENCY GENERATORS, THE FACILITY MUST MAINTAIN MONTHLY RECORDS WHICH DEMONSTRATE THAT EACH ENGINE IS OPERATED LESS THAN 500 HOURS PER YEAR, ON A 12-MONTH ROLLING TOTAL BASIS.

Work Practice Type: HOURS PER YEAR OPERATION
Upper Permit Limit: 500.0 hours
Monitoring Frequency: MONTHLY
Averaging Method: ANNUAL MAXIMUM ROLLED MONTHLY
Reporting Requirements: UPON REQUEST BY REGULATORY AGENCY

Condition 2-9: Trivial Sources - Proof of Eligibility
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-3.3 (a)

Item 2-9.1:
The owner or operator of an emission source or activity that is listed as being trivial in this Section may be required to certify that it is operated within the specific criteria described in this Subpart. The owner or operator of any such emission source or activity must maintain all required records on-site for a period of five years and make them available to representatives of the department upon request.

Condition 2-10: Requirement to Provide Information
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-6.4 (a) (4)

Item 2-10.1:
The owner and/or operator shall furnish to the department, within a reasonable time, any information that the department may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee shall also furnish to the department copies of records required to be kept by the permit or, for information claimed to be confidential, the permittee may furnish such records directly to the administrator along with a claim of confidentiality, if the administrator initiated the request for information or otherwise has need of it.

Condition 2-11: Right to Inspect
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-6.4 (a) (8)

Item 2-11.1:
The department or an authorized representative shall be allowed upon presentation of credentials and other documents as may be required by law to:

(i) enter upon the permittee's premises where a facility subject to the permitting requirements of this Subpart is located or emissions-related activity is conducted, or where records must be kept under the conditions of the permit;

(ii) have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit;

(iii) inspect at reasonable times any emission sources, equipment (including monitoring and air pollution control equipment), practices, and operations regulated or required under the permit; and

(iv) sample or monitor at reasonable times substances or parameters for the purpose of assuring compliance with the permit or applicable requirements.

Condition 2-12: Off Permit Changes

Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-6.4 (f) (6)

Item 2-12.1:
No permit revision will be required for operating changes that contravene an express permit term, provided that such changes would not violate applicable requirements as defined under this Part or contravene federally enforceable monitoring (including test methods), recordkeeping, reporting, or compliance certification permit terms and conditions. Such changes may be made without requiring a permit revision, if the changes are not modifications under any provision of title I of the act and the changes do not exceed the emissions allowable under the permit (whether expressed therein as a rate of emissions or in terms of total emissions) provided that the facility provides the administrator and the department with written notification as required below in advance of the proposed changes within a minimum of seven days. The facility owner or operator, and the department shall attach each such notice to their copy of the relevant permit.

(i) For each such change, the written notification required above shall include a brief description of the change within the permitted facility, the date on which the change will occur, any change in emissions, and any permit term or condition that is no longer applicable as a result of the change.

(ii) The permit shield described in section 6 NYCRR 201-6.4 shall not apply to any change made pursuant to this paragraph.

Condition 19: Required Emissions Tests
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 202-1.1

Item 19.1:
For the purpose of ascertaining compliance or non-compliance with any air pollution control code, rule or regulation, the commissioner may require the person who owns such air contamination source to submit an acceptable report of measured emissions within a stated time.

Condition 21: Accidental release provisions.
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:40 CFR Part 68

Item 21.1:
If a chemical is listed in Tables 1,2,3 or 4 of 40 CFR §68.130 is present in a process in quantities greater than the threshold quantity listed in Tables 1,2,3 or 4, the following requirements will apply:

a) The owner or operator shall comply with the provisions of 40 CFR Part 68 and;

b) The owner or operator shall submit at the time of permit issuance (if not previously submitted) one of the following, if such quantities are present:

1) A compliance schedule for meeting the requirements of 40 CFR Part 68 by the date provided

in 40 CFR §68.10(a) or,

2) A certification statement that the source is in compliance with all requirements of 40 CFR Part 68, including the registration and submission of the Risk Management Plan. Information should be submitted to:

Risk Management Plan Reporting Center
C/O CSC
8400 Corporate Dr
Carrollton, Md. 20785

Condition 22: Recycling and Emissions Reduction
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:40CFR 82, Subpart F

Item 22.1:
The permittee shall comply with all applicable provisions of 40 CFR Part 82.

The following conditions are subject to annual compliance certification requirements for Title V permits only.

Condition 23: Emission Unit Definition
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:6 NYCRR Subpart 201-6

Item 23.1(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000A
Emission Unit Description:
Drying pharmaceutical products using oven No.4 and oven No.5 (each lydon brothers model 3469-5-t2wm). Products are aqueous based only.

Building(s): 01

Item 23.2(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000B
Emission Unit Description:
Drying aqueous based pharmaceutical products using an aeromatic fluidized bed dryer. Emissions are exhausted through emission point 00003.

Building(s): 01

Item 23.3(From Mod 2):

The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000C
Emission Unit Description:
Chemical storage room.

Building(s): 01

Item 23.4(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000D
Emission Unit Description:
Removal of isopropyl alcohol from pharmaceutical products utilizing drying ovens No. 6, No. 7 and No. 8. Three scrubbers are used to control VOC emissions identified as Scrubber No. 1, No. 2 and No. 3.
Process flow as follows:

Drying oven No. 6 vents to scrubber No. 2 which exhausts to emission point 00006 for the first 6 hours of the drying cycle. Then scrubber will be turned off and emissions from the remaining portion of the drying cycle exhausted through emission point 00008.

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

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

Building(s): 01

Item 23.5(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000E
Emission Unit Description:
Aqueous coating of pharmaceutical tablets. Particulate emissions are controlled by a dust collector exhausted to emission point 00020.

Building(s): 01

Item 23.6(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000F
Emission Unit Description:
Aqueous coating of pharmaceutical tablets. Particulate

emissions are controlled by a dust collector exhausted to emission point 00021.

Building(s): 01

Item 23.7(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000G
Emission Unit Description:
Aqueous based compu-lab tablet coater. Particulate emissions are controlled by a dust collector exhausted to emission point 00022.

Building(s): 01

Item 23.8(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000H
Emission Unit Description:
This emission unit defines overall facility fugitive volatile organic compound (VOC) emissions associated with sanitizing solvents used and batch production of pharmaceutical products. Fugitive VOC emissions are assumed exhausting through emission point 00023.

Building(s): 01

Item 23.9(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000I
Emission Unit Description:
Operations associated with the compression area. Particulate emissions are controlled by a dust collector (DC04) exhausted to emission point 00024.

Building(s): 01

Item 23.10(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000J
Emission Unit Description:
Operations associated with the granulation area. Particulate emissions are controlled by a dust collector (DC05) exhausted to emission point 00025.

Building(s): 01

Item 23.11(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000K
Emission Unit Description:
Chemical storage building.

Building(s): 03

Item 23.12(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000L
Emission Unit Description:
Operations associated with the storage of hazardous waste.

Building(s): 04

Item 23.13(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000M
Emission Unit Description:
This emission unit is comprised of the Compression Area (Rooms 23, 27 and 28) and relocated Pharmacy Dispensing Area (Rooms 1, 2 and 3). Negative pressure is maintained on emission sources consisting of each Pharmacy Dispensing Area room and three Compression Area tablet presses; (2) Fette 3090 tablet presses and one (1) Fette 2090 tablet press.
Particulate emissions are controlled by a DFT 2-4 PulseJet Cartridge Dust Collector (control ID DC16) and exhausted through Emission Point 00034.

Building(s): 01

Item 23.14(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000N
Emission Unit Description:
Packaging lines lines A, D, E and F. Particulate emissions are controlled by dust collector DC-07 vented to EP00035.

Building(s): 01

Item 23.15(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000O
Emission Unit Description:
Two Packaging lines B and C and one blister packaging line. Particulate emissions are controlled by dust collector DC-8 vented to EP00036.

Building(s): 01

Item 23.16(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000Q
Emission Unit Description:
This emission unit consists of a 48" Tablet Coater(Accela-Coater) and two Glatt GPCG-60 coater/granulation/dryer units. There are three fume hoods HOOD01, HOOD02 and HOOD03 which collect emissions from the devices. Particulate emissions from the 48 inch tablet coater is controlled by dust collector DC-11. Particulate emissions from the Glatt units are controlled by internal dust collectors DC-12 and DC-13. A carbon absorption system CA-1RR serves to control volatile organic compound emissions while production is utilizing solvent materials which is exhausted to EP00040.

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

Building(s): 01

Item 23.17(From Mod 2):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000R
Emission Unit Description:
Activities associated with granulation rooms No. 2, No. 4 and No. 6A. Emission sources are a portable Fitzmill, a granulator, a blender and a sifter. Air is collected from each room, routed to separate in line HEPA filters, combined, and vented to a common dust collector to control particulate emissions prior to exiting through emission point 00043.

Building(s): 01

Item 23.18(From Mod 0):
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000P End Date: 09/01/2013
Emission Unit Description:
Pharmacy dispensing areas operated under negative pressure conditions controlled by dust collectors and HEPA filters.

Building(s): 01

Condition 2-13: Progress Reports Due Semiannually
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-6.4 (d) (4)

Item 2-13.1:
Progress reports consistent with an applicable schedule of compliance are to be submitted at least semiannually, or at a more frequent period if specified in the applicable requirement or by the department. Such progress reports shall contain the following:

(i) dates for achieving the activities, milestones, or compliance required in the schedule of compliance, and dates when such activities, milestones or compliance were achieved; and

(ii) an explanation of why any dates in the schedule of compliance were not or will not be met, and any preventive or corrective measures adopted.

Condition 24: Non Applicable requirements
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 201-6.5 (g)

Item 24.1:
This section contains a summary of those requirements that have been specifically identified as being not applicable to this facility and/or emission units, emission points, processes and/or emission sources within this facility. The summary also includes a justification for classifying any such requirements as non-applicable.

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

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

Condition 1-5: Facility Permissible Emissions
Effective between the dates of 04/17/2012 and 09/13/2015

Applicable Federal Requirement:6 NYCRR Subpart 201-7

Item 2-5.1:
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 (From Mod 2) PTE: 49,000 pounds per year

Name: TOTAL HAP

Condition 1-6: Capping Monitoring Condition
Effective between the dates of 04/17/2012 and 09/13/2015

Applicable Federal Requirement:6 NYCRR Subpart 201-7

Item 1-6.1:
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:

6 NYCRR 231-2.2 (a)

Item 1-6.2:
Operation of this facility shall take place in accordance with the approved criteria, emission limits, terms, conditions and standards in this permit.

Item 1-6.3:
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 1-6.4:
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 1-6.5:
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 1-6.6:
The Compliance Certification activity will be performed for the facility:
The Compliance Certification applies to:

Emission Unit: 0-0000Q
Process: P07 Emission Source: COAT6

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

Item 1-6.7:
Compliance Certification shall include the following monitoring:

Capping: Yes
Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS
Monitoring Description:
Par shall limit solvent based production batches associated with Glatt #2 to 100 per year.

Work Practice Type: PROCESS MATERIAL THRUPUT
Process Material: SOLVENT
Upper Permit Limit: 100 batches 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 1/30/2013.
Subsequent reports are due every 12 calendar month(s).

Condition 1-7: Capping Monitoring Condition
Effective between the dates of 04/17/2012 and 09/13/2015

Applicable Federal Requirement:6 NYCRR Subpart 201-7

Item 1-7.1:
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:

40 CFR 63.1250 (c)

Item 1-7.2:
Operation of this facility shall take place in accordance with the approved criteria, emission limits, terms, conditions and standards in this permit.

Item 1-7.3:
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 1-7.4:
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 1-7.5:
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 1-7.6:
The Compliance Certification activity will be performed for the Facility.

Regulated Contaminant(s):
CAS No: 000067-56-1 METHYL ALCOHOL
CAS No: 0NY100-00-0 TOTAL HAP

Item 1-7.7:
Compliance Certification shall include the following monitoring:

Capping: Yes
Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS
Monitoring Description:
Par 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, 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: 49000 pounds per year
Monitoring Frequency: MONTHLY
Averaging Method: ANNUAL TOTAL ROLLED MONTHLY
Reporting Requirements: ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 1/30/2013.
Subsequent reports are due every 12 calendar month(s).

Condition 1-8: Air pollution prohibited

Effective between the dates of 04/17/2012 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 211.1

Item 1-8.1:
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 2-14: Compliance Certification
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 212.4 (c)

Replaces Condition(s) 1-9, 1-10

Item 2-14.1:
The Compliance Certification activity will be performed for the facility:
The Compliance Certification applies to:

Emission Unit: 0-0000A	Emission Point: 00001
Emission Unit: 0-0000A	Emission Point: 00002
Emission Unit: 0-0000B	Emission Point: 00003
Emission Unit: 0-0000D	Emission Point: 00005
Emission Unit: 0-0000D	Emission Point: 00006
Emission Unit: 0-0000D	Emission Point: 00007
Emission Unit: 0-0000D	Emission Point: 00008
Emission Unit: 0-0000D	Emission Point: 00009
Emission Unit: 0-0000D	Emission Point: 00010
Emission Unit: 0-0000E	Emission Point: 00020
Emission Unit: 0-0000F	Emission Point: 00021
Emission Unit: 0-0000G	Emission Point: 00022
Emission Unit: 0-0000H	Emission Point: 00023
Emission Unit: 0-0000I	Emission Point: 00024
Emission Unit: 0-0000J	Emission Point: 00025

Emission Unit: 0-0000M Emission Point: 00034

Emission Unit: 0-0000N Emission Point: 00035

Emission Unit: 0-0000O Emission Point: 00036

Emission Unit: 0-0000Q Emission Point: 00026

Emission Unit: 0-0000Q Emission Point: 00040

Emission Unit: 0-0000Q Emission Point: 00041

Emission Unit: 0-0000Q Emission Point: 00042

Emission Unit: 0-0000R Emission Point: 00043

Regulated Contaminant(s):
CAS No: 0NY075-00-0 PARTICULATES

Item 2-14.2:
Compliance Certification shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING
Monitoring Description:

Emissions of solid particulates are limited to less than 0.050 grains of particulates per cubic foot of exhaust gas, expressed at standard conditions on a dry gas basis. The Department reserves the right to perform or require the facility perform a Method 5 emissions evaluation at any time.

Emissions evaluation shall include a review of pertinent information relating to particulate emissions of the source, including but not limited to production rate, process material, air flow rate, control equipment parameters, visible emissions, etc. The facility shall confirm that during source operation all relative parameters (whether used to directly calculate particulate emission rate, or as surrogates) are within ranges that ensure compliance with the particulate emission rate.

Additionally, the permittee shall investigate, in a timely manner, any instance where there is cause to believe that particulate emissions above 0.050 gr/dscf are occurring or have occurred. These instances include but are not limited to process upsets, control device malfunctions or problems, abnormal visible emissions, complaints, etc. The facility shall determine the cause of any exceedance, make the necessary correction, and verify that the excess

emissions problem has been corrected.

Records of these verifications, investigations and corrective actions shall be available for Department review.

Upper Permit Limit: 0.05 grains per dscf
Reference Test Method: USEPA method 5
Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION
Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST METHOD INDICATED
Reporting Requirements: ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 1/30/2014.
Subsequent reports are due every 12 calendar month(s).

Condition 2-15: Compliance Certification
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 212.6 (a)

Item 2-15.1:
The Compliance Certification activity will be performed for the facility:
The Compliance Certification applies to:

Emission Unit: 0-0000A	Emission Point: 00001
Emission Unit: 0-0000A	Emission Point: 00002
Emission Unit: 0-0000B	Emission Point: 00003
Emission Unit: 0-0000C	Emission Point: 00004
Emission Unit: 0-0000D	Emission Point: 00005
Emission Unit: 0-0000D	Emission Point: 00006
Emission Unit: 0-0000D	Emission Point: 00007
Emission Unit: 0-0000D	Emission Point: 00008
Emission Unit: 0-0000D	Emission Point: 00009
Emission Unit: 0-0000D	Emission Point: 00010
Emission Unit: 0-0000E	Emission Point: 00020
Emission Unit: 0-0000F	Emission Point: 00021
Emission Unit: 0-0000G	Emission Point: 00022

Emission Unit: 0-0000H	Emission Point: 00023
Emission Unit: 0-0000I	Emission Point: 00024
Emission Unit: 0-0000J	Emission Point: 00025
Emission Unit: 0-0000K	Emission Point: 00031
Emission Unit: 0-0000L	Emission Point: 00032
Emission Unit: 0-0000M	Emission Point: 00034
Emission Unit: 0-0000N	Emission Point: 00035
Emission Unit: 0-0000O	Emission Point: 00036
Emission Unit: 0-0000Q	Emission Point: 00026
Emission Unit: 0-0000Q	Emission Point: 00040
Emission Unit: 0-0000Q	Emission Point: 00041
Emission Unit: 0-0000Q	Emission Point: 00042
Emission Unit: 0-0000R	Emission Point: 00043

Item 2-15.2:
Compliance Certification shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL DEVICE PARAMETERS AS SURROGATE
Monitoring Description:
No person shall cause or allow emissions having an average opacity during any six consecutive minutes of 20 percent or greater from any process emission source, except only the emission of uncombined water. Compliance with this requirement shall be determined by the facility owner/operator conducting a daily survey of visible emissions whenever a process is in operation. If any visible emissions are identified, corrective action is required. The Department reserves the right to perform or require the performance of a Method 9 opacity evaluation

Parameter Monitored: OPACITY
Upper Permit Limit: 20 percent
Reference Test Method: EPA Method 9
Averaging Method: 6-MINUTE AVERAGE (METHOD 9)
Reporting Requirements: ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 1/30/2014.
Subsequent reports are due every 12 calendar month(s).

Condition 2-16: Compliance Certification
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 212.10 (c) (4) (i)

Replaces Condition(s) 1-11

Item 2-16.1:
The Compliance Certification activity will be performed for the facility:
The Compliance Certification applies to:

Emission Unit: 0-0000Q Emission Point: 00040
Process: P07

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

Item 2-16.2:
Compliance Certification shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING
Monitoring Description:
While utilizing solvent based materials, Par shall maintain a capture system and a control device with an overall removal efficiency of at least 81 percent. Verification testing shall be as requested by the Department.

At least 60 days prior to actual testing, the facility shall submit to the NYSDEC a Test Protocol detailing methods and procedures to be used during the performance stack testing.

Performance test results must be reported to NYSDEC within 60 days after completion of compliance testing.

Lower Permit Limit: 81 percent
Reference Test Method: EPA Reference Method 25
Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION
Averaging Method: MINIMUM - NOT TO FALL BELOW STATED VALUE - SEE MONITORING DESCRIPTION
Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE

Condition 2-17: Compliance Certification
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 212.10 (c) (4) (i)

Replaces Condition(s) 1-12

Item 2-17.1:

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

Emission Unit: 0-0000D Emission Point: 00005
Process: D03

Emission Unit: 0-0000D Emission Point: 00006
Process: D03

Emission Unit: 0-0000D Emission Point: 00007
Process: D03

Emission Unit: 0-0000D Emission Point: 00008
Process: D03

Emission Unit: 0-0000D Emission Point: 00009
Process: D03

Emission Unit: 0-0000D Emission Point: 00010
Process: D03

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

Item 2-17.2:
Compliance Certification shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING
Monitoring Description:

For the removal of Isopropyl Alcohol associated with drying ovens #6, #7 and #8, Par shall maintain a capture system and a control device with an overall removal efficiency of at least 81 percent. Verification testing shall be as requested by the Department.

At least 60 days prior to actual testing, the facility shall submit to the NYSDEC a Test Protocol detailing methods and procedures to be used during the performance stack testing.

Performance test results must be reported to NYSDEC within 60 days after completion of compliance testing.

Lower Permit Limit: 81 percent
Reference Test Method: EPA Reference Method 25
Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING DESCRIPTION
Averaging Method: MINIMUM - NOT TO FALL BELOW STATED VALUE - SEE MONITORING DESCRIPTION
Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE

Condition 1-13: Compliance Certification

Effective between the dates of 04/17/2012 and 09/13/2015

Applicable Federal Requirement:6 NYCRR 212.11 (b) (3)

Item 1-13.1:
The Compliance Certification activity will be performed for the facility:
The Compliance Certification applies to:

Emission Unit: 0-0000Q
Process: P07 Emission Source: CA1RR

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

Item 1-13.2:
Compliance Certification shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL DEVICE PARAMETERS AS SURROGATE
Monitoring Description:
Par shall maintain a continuous monitor and data recorder for measuring the volatile organic compound outlet concentration from the fixed-bed carbon adsorption unit. Each device shall be operated according to quality assurance procedures provided by the manufacturer.

Parameter Monitored: CONCENTRATION
Upper Permit Limit: 150 parts per million (by volume)
Monitoring Frequency: CONTINUOUS
Averaging Method: 1-HOUR AVERAGE
Reporting Requirements: ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 1/30/2013.
Subsequent reports are due every 12 calendar month(s).

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

Condition 28: Emission Point Definition By Emission Unit
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:6 NYCRR Subpart 201-6

Item 28.1(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000A

Emission Point: 00001
Height (ft.): 17 Length (in.): 30 Width (in.): 30
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Emission Point: 00002
Height (ft.): 17 Length (in.): 30 Width (in.): 30
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.2(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000B

Emission Point: 00003
Height (ft.): 14 Length (in.): 24 Width (in.): 30
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.3(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000C

Emission Point: 00004
Height (ft.): 12 Diameter (in.): 16
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.4(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000D

Emission Point: 00005
Height (ft.): 31 Diameter (in.): 20
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Emission Point: 00006
Height (ft.): 31 Diameter (in.): 20
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Emission Point: 00007
Height (ft.): 31 Diameter (in.): 20
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Emission Point: 00008
Height (ft.): 31 Length (in.): 19 Width (in.): 14
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Emission Point: 00009
Height (ft.): 31 Length (in.): 19 Width (in.): 14
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Emission Point: 00010
Height (ft.): 31 Length (in.): 19 Width (in.): 14
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.5(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000E

Emission Point: 00020
Height (ft.): 38 Diameter (in.): 18
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.6(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000F

Emission Point: 00021
Height (ft.): 38 Diameter (in.): 14
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.7(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000G

Emission Point: 00022
Height (ft.): 38 Diameter (in.): 16
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.8(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000H

Emission Point: 00023
Height (ft.): 31 Diameter (in.): 20
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.9(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000I

Emission Point: 00024
Height (ft.): 31 Diameter (in.): 20
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.10(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000J

Emission Point: 00025
Height (ft.): 31 Diameter (in.): 20
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.11(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000K

Emission Point: 00031
Height (ft.): 11 Diameter (in.): 12
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 03

Item 28.12(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000L

Emission Point: 00032
Height (ft.): 11 Diameter (in.): 12
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 04

Item 28.13(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000M

Emission Point: 00034
Height (ft.): 21 Diameter (in.): 8
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Item 28.14(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000N

Emission Point: 00035
Height (ft.): 30 Diameter (in.): 9
NYTMN (km.): 4551.3 NYTME (km.): 581. Building: 01

Item 28.15(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000O

Emission Point: 00036
Height (ft.): 30 Diameter (in.): 9
NYTMN (km.): 4551.3 NYTME (km.): 581. Building: 01

Item 28.16(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000Q

Emission Point: 00026
Height (ft.): 30 Diameter (in.): 18
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Emission Point: 00040
Height (ft.): 30 Diameter (in.): 18
NYTMN (km.): 4551.3 NYTME (km.): 581. Building: 01

Emission Point: 00041
Height (ft.): 30 Diameter (in.): 20
NYTMN (km.): 4551.323 NYTME (km.): 581.033 Building: 01

Emission Point: 00042
Height (ft.): 29 Diameter (in.): 18
NYTMN (km.): 4551.3 NYTME (km.): 581. Building: 01

Item 28.17(From Mod 2):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000R

Emission Point: 00043
Height (ft.): 32 Diameter (in.): 10
NYTMN (km.): 4551.3 NYTME (km.): 581. Building: 01

Item 28.18(From Mod 0):
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000P

Emission Point: 00038
Height (ft.): 14 Length (in.): 12 Width (in.): 12
NYTMN (km.): 4551.3 NYTME (km.): 581. Building: 01

Emission Point: 00039
Height (ft.): 16 Length (in.): 12 Width (in.): 12
NYTMN (km.): 4551.3 NYTME (km.): 581. Building: 01

Condition 29: Process Definition By Emission Unit
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable Federal Requirement:6 NYCRR Subpart 201-6

Item 29.1(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000A

Process: D01 Source Classification Code: 3-01-060-09
Process Description: Drying of aqueous based pharmaceutical products.

Emission Source/Control: DRY04 - Process

Emission Source/Control: DRY05 - Process

Item 29.2(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000B
Process: D02 Source Classification Code: 3-01-060-09
Process Description: Drying aqueous based pharmaceutical products.

Emission Source/Control: FBD01 - Process

Item 29.3(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000C
Process: S01 Source Classification Code: 3-01-060-10
Process Description: Chemical Storage.

Emission Source/Control: CHEM1 - Process

Item 29.4(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000D
Process: D03 Source Classification Code: 3-01-060-10
Process Description:
Removal of isopropyl alcohol from pharmaceutical products.

Emission Source/Control: SCR01 - Control
Control Type: WET SCRUBBER

Emission Source/Control: SCR02 - Control
Control Type: WET SCRUBBER

Emission Source/Control: SCR03 - Control
Control Type: WET SCRUBBER

Emission Source/Control: DRY06 - Process

Emission Source/Control: DRY07 - Process

Emission Source/Control: DRY08 - Process

Item 29.5(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000E
Process: P01 Source Classification Code: 3-01-060-11
Process Description: Aqueous coating of pharmaceutical tablets.

Emission Source/Control: 0DC01 - Control
Control Type: FABRIC FILTER

Emission Source/Control: COAT1 - Process

Item 29.6(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000F
Process: P02 Source Classification Code: 3-01-060-11
Process Description: Aqueous coating of pharmaceutical tablets.

Emission Source/Control: 0DC02 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: COAT2 - Process

Item 29.7(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000G
Process: P03 Source Classification Code: 3-01-060-11
Process Description: Aqueous based compu-lab tablet coater.

Emission Source/Control: 0DC03 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: COAT3 - Process

Item 29.8(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000H
Process: F01 Source Classification Code: 3-01-060-22
Process Description:
Fugitive volatile organic compound (VOC) emissions associated with sanitizing solvents used and batch production of pharmaceutical products.

Emission Source/Control: FUG01 - Process

Item 29.9(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000I
Process: P04 Source Classification Code: 3-01-060-99
Process Description: Operations associated with the compression area.

Emission Source/Control: 0DC04 - Control
Control Type: FABRIC FILTER

Emission Source/Control: COMP1 - Process

Item 29.10(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000J
Process: P05 Source Classification Code: 3-01-060-12
Process Description: Operations associated with the granulation area.

Emission Source/Control: 0DC05 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: GRAN1 - Process

Item 29.11(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000K
Process: S02 Source Classification Code: 3-01-060-10
Process Description: Chemical storage.

Emission Source/Control: CHEM2 - Process

Item 29.12(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000L
Process: S03 Source Classification Code: 3-01-060-10
Process Description: Storage of hazardous wastes.

Emission Source/Control: HAZW1 - Process

Item 29.13(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000M
Process: P06 Source Classification Code: 3-01-060-99
Process Description:
Combined process consisting of the pharmacy dispensing area and compression area activities.

Emission Source/Control: 0DC16 - Control
Control Type: HIGH EFFICIENCY PARTICULATE AIR FILTER

Emission Source/Control: 00PDA - Process

Emission Source/Control: TAB01 - Process

Emission Source/Control: TAB02 - Process

Emission Source/Control: TAB03 - Process

Item 29.14(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000N
Process: PLA Source Classification Code: 3-01-060-99
Process Description:
Packaging of pharmaceutical products Lines A, D, E and F in support of equipment used in pharmaceutical production and or R & D. Dust collector DC07 is utilized to control particulate emissions exhausted through emission point 35.

Emission Source/Control: DC-O7 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: PL-AO - Process

Emission Source/Control: PL-DO - Process

Emission Source/Control: PL-EO - Process

Emission Source/Control: PL-FO - Process

Item 29.15(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000O
Process: PLB Source Classification Code: 3-01-060-99
Process Description:
Packaging of pharmaceutical products Lines B, C and Blister.

Emission Source/Control: DC-08 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: 0PL-B - Process

Emission Source/Control: 0PL-C - Process

Emission Source/Control: PL-BL - Process

Item 29.16(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000Q
Process: P07 Source Classification Code: 3-01-060-99
Process Description:
All pharmaceutical components associated with this emission unit operated utilizing solvent materials vented

to EP00040.

Emission Source/Control: CA1RR - Control
Control Type: ACTIVATED CARBON ADSORPTION

Emission Source/Control: DC-11 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: DC-12 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: DC-13 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: COAT4 - Process

Emission Source/Control: COAT6 - Process

Emission Source/Control: COT05 - Process

Emission Source/Control: HOOD1 - Process

Emission Source/Control: HOOD2 - Process

Emission Source/Control: HOOD3 - Process

Item 29.17(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000Q
Process: P08 Source Classification Code: 3-01-060-99
Process Description:
Aqueous materials used in the unit components Glatt GPCG-60 No. 1, Dust collector No. 12 and Hood No. 2 exhausted through EP00026.

Emission Source/Control: DC-12 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: COT05 - Process

Emission Source/Control: HOOD2 - Process

Item 29.18(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000Q
Process: P09 Source Classification Code: 3-01-060-99
Process Description:
Aqueous materials used in the unit components 48 inch tablet coater, Dust collector No. 11 and Hood No. 1 exhausted through EP00041.

Emission Source/Control: DC-11 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: COAT4 - Process

Emission Source/Control: HOOD1 - Process

Item 29.19(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000Q
Process: P10 Source Classification Code: 3-01-060-99
Process Description:
Aqueous materials used in the unit components Glatt GPCG-60 No. 2, Dust collector No. 13 and Hood No. 3 exhausted through EP00042.

Emission Source/Control: DC-13 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: COAT6 - Process

Emission Source/Control: HOOD3 - Process

Item 29.20(From Mod 2):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000R
Process: P11 Source Classification Code: 3-01-060-99
Process Description: Process associated with granulation.

Emission Source/Control: DC-15 - Control
Control Type: DUST COLLECTOR

Emission Source/Control: GRAN2 - Process

Emission Source/Control: MILL1 - Process

Emission Source/Control: SIFT1 - Process

Item 29.21(From Mod 0):
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000P
Process: PDA Source Classification Code: 3-01-060-11
Process End Date: 9/1/2013
Process Description:
Operations and control associated with the pharmacy dispensing area.

Emission Source/Control: 00PDA - Process

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: **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 applicable requirements and are not subject to compliance certification requirements unless otherwise noted or required under 6 NYCRR Part 201.

Condition 35: Contaminant List
Effective between the dates of 09/14/2010 and 09/13/2015

Applicable State Requirement:ECL 19-0301

Item 35.1:
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: 0NY075-00-0
Name: PARTICULATES

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

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

Condition 2-18: Malfunctions and start-up/shutdown activities
Effective between the dates of 08/05/2013 and 09/13/2015

Applicable State Requirement:6 NYCRR 201-1.4

Item 2-18.1:
(a) The facility owner or operator shall take all necessary and appropriate actions to prevent the emission of air pollutants that result in contravention of any applicable emission standard during periods of start-up, shutdown, or malfunction.

(b) The facility owner or operator shall compile and maintain records of all equipment malfunctions, 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 department when requested to do so, or when so required by a condition of a permit issued for the corresponding air contamination source. Such reports shall state whether any violations occurred and, if so, whether they were unavoidable, include the time, frequency and duration of the maintenance and/or start-up/shutdown activities, and an estimate of the emission rates of any air contaminants released. Such records shall be maintained for a period of at least five years and made available for review to department representatives upon request. Facility owners or operators subject to continuous stack monitoring and quarterly reporting requirements need not submit additional reports for equipment maintenance or start-up/shutdown activities for the facility to the department.

(c) In the event that emissions of air contaminants in excess of any emission standard in this Subchapter occur due to a malfunction, the facility owner or operator shall compile and maintain records of the malfunction and notify the department as soon as possible during normal working hours, but not later than two working days after becoming aware that the malfunction occurred. When requested by the department, the facility owner or operator shall submit a written report to the department describing the malfunction, the corrective action taken, identification of air contaminants, and an estimate of the emission rates.

(d) The department may also require the owner or operator to include, in reports described under Subdivisions (b) and (c) of this Section, an estimate of the maximum ground level concentration of each air contaminant emitted and the effect of such emissions.

(e) A violation of any applicable emission standard resulting from start-up, shutdown, or malfunction conditions at a permitted or registered facility may not be subject to an enforcement action by the department and/or penalty if the department determines, in its sole discretion, that such a violation was unavoidable. The actions and recordkeeping and reporting requirements listed above must be adhered to in such circumstances.

Condition 36: Unavoidable noncompliance and violations

Effective between the dates of 09/14/2010 and 09/13/2015

Applicable State Requirement:6 NYCRR 201-1.4

Item 36.1:
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 1-14: Visible Emissions Limited
Effective between the dates of 04/17/2012 and 09/13/2015

Applicable State Requirement:6 NYCRR 211.2

Item 1-14.1:
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.