



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

**IDENTIFICATION INFORMATION**

Permit Type: Air Title V Facility  
Permit ID: 3-3926-00729/00054  
Mod 0 Effective Date: 04/25/2016 Expiration Date: 04/24/2021  
Mod 1 Effective Date: 10/17/2017 Expiration Date: 04/24/2021  
Mod 2 Effective Date: 06/11/2018 Expiration Date: 04/24/2021  
Mod 3 Effective Date: 01/18/2019 Expiration Date: 04/24/2021

Permit Issued To: PAR PHARMACEUTICAL INC  
1 RAM RIDGE RD  
CHESTNUT RIDGE, NY 10977

Contact: TODD ARNOLD  
1 RAM RIDGE RD  
CHESTNUT RIDGE, NY 10977  
(845) 364-4868

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

Contact: TODD ARNOLD  
1 RAM RIDGE RD  
CHESTNUT RIDGE, NY 10977  
(845) 364-4868

Description:

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: REBECCA S CRIST  
21 S PUTT CORNERS RD  
NEW PALTZ, NY 12561

Authorized Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_



**Notification of Other State Permittee Obligations**

**Item A: Permittee Accepts Legal Responsibility and Agrees to Indemnification**

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

**Item B: Permittee's Contractors to Comply with Permit**

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

**Item C: Permittee Responsible for Obtaining Other Required Permits**

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

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

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



**LIST OF CONDITIONS**

**DEC GENERAL CONDITIONS**

**General Provisions**

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

**Facility Level**

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



**DEC GENERAL CONDITIONS**

**\*\*\*\* General Provisions \*\*\*\***

**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 1-1: Applications for permit renewals, modifications and transfers**

**Applicable State Requirement: 6 NYCRR 621.11**

**Expired by Mod No: 3**

**Item 1-1.1:**

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

**Item 1-1.2:**

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

**Item 1-1.3**



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

**Condition 3: Applications for permit renewals, modifications and transfers**  
**Applicable State Requirement: 6 NYCRR 621.11**

**Expired by Mod No: 3**

**Item 3.1:**

The permittee must submit a renewal application at least 180 days before expiration of permits for both Title V and 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 2-1: Applications for permit renewals, modifications and transfers**  
**Applicable State Requirement: 6 NYCRR 621.11**

**Item 2-1.1:**

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

**Item 2-1.2:**

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

**Item 2-1.3**

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

**Condition 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 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.

**\*\*\*\* 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

**New York State Department of Environmental Conservation**

Permit ID: 3-3926-00729/00054

Facility DEC ID: 3392600729



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

**ARTICLE 19: AIR POLLUTION CONTROL - TITLE V PERMIT**

**IDENTIFICATION INFORMATION**

Permit Issued To: PAR PHARMACEUTICAL INC  
1 RAM RIDGE RD  
CHESTNUT RIDGE, NY 10977

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

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

Mod 0 Permit Effective Date: 04/25/2016

Permit Expiration Date: 04/24/2021

Mod 1 Permit Effective Date: 10/17/2017

Permit Expiration Date: 04/24/2021

Mod 2 Permit Effective Date: 06/11/2018

Permit Expiration Date: 04/24/2021

Mod 3 Permit Effective Date: 01/18/2019

Permit Expiration Date: 04/24/2021



**LIST OF CONDITIONS**

**FEDERALLY ENFORCEABLE CONDITIONS**

**Facility Level**

- 1 6 NYCRR 200.6: Acceptable Ambient Air Quality
- 2 6 NYCRR 201-6.4 (a) (7): Fees
- 3 6 NYCRR 201-6.4 (c): Recordkeeping and Reporting of Compliance Monitoring
- 4 6 NYCRR 201-6.4 (c) (2): Records of Monitoring, Sampling, and Measurement
- 5 6 NYCRR 201-6.4 (c) (3) (ii): Compliance Certification
- 6 6 NYCRR 201-6.4 (e): Compliance Certification
- 7 6 NYCRR 202-2.1: Compliance Certification
- 8 6 NYCRR 202-2.5: Recordkeeping requirements
- 9 6 NYCRR 215.2: Open Fires - Prohibitions
- 10 6 NYCRR 200.7: Maintenance of Equipment
- 11 6 NYCRR 201-1.7: Recycling and Salvage
- 12 6 NYCRR 201-1.8: Prohibition of Reintroduction of Collected Contaminants to the air
- 13 6 NYCRR 201-3.2 (a): Exempt Sources - Proof of Eligibility
- 14 6 NYCRR 201-3.2 (a): Compliance Certification
- 15 6 NYCRR 201-3.3 (a): Trivial Sources - Proof of Eligibility
- 16 6 NYCRR 201-6.4 (a) (4): Requirement to Provide Information
- 1-1 6 NYCRR 201-6.4 (a) (8): Right to Inspect
- 18 6 NYCRR 201-6.4 (f) (6): Off Permit Changes
- 19 6 NYCRR 202-1.1: Required Emissions Tests
- 20 40 CFR Part 68: Accidental release provisions.
- 21 40CFR 82, Subpart F: Recycling and Emissions Reduction
- 22 6 NYCRR Subpart 201-6: Emission Unit Definition
- 23 6 NYCRR 201-6.4 (d) (4): Progress Reports Due Semiannually
- 24 6 NYCRR 201-6.4 (g): Non Applicable requirements
- 25 6 NYCRR Subpart 201-7: Facility Permissible Emissions
- \*3-1 6 NYCRR Subpart 201-7: Capping Monitoring Condition
- \*2-2 6 NYCRR Subpart 201-7: Capping Monitoring Condition
- \*3-2 6 NYCRR Subpart 201-7: Capping Monitoring Condition
- \*3-3 6 NYCRR Subpart 201-7: Capping Monitoring Condition
- 37 6 NYCRR 211.2: Visible Emissions Limited
- 2-3 6 NYCRR 212-1.6 (a): Compliance Certification
- 2-4 6 NYCRR 212-1.7 (b) (3): Compliance Certification
- 3-4 6 NYCRR 212-2.4 (b): Compliance Certification
- 3-5 6 NYCRR 212-3.1 (c) (4) (i): Compliance Certification

**Emission Unit Level**

- 33 6 NYCRR Subpart 201-6: Emission Point Definition By Emission Unit
- 34 6 NYCRR Subpart 201-6: Process Definition By Emission Unit
- 3-6 6 NYCRR Subpart 201-7: Emission Unit Permissible Emissions

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- \*3-7 6 NYCRR Subpart 201-7: Capping Monitoring Condition

**STATE ONLY ENFORCEABLE CONDITIONS**



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- 35 ECL 19-0301: Contaminant List
- 36 6 NYCRR 201-1.4: Malfunctions and start-up/shutdown activities
- 28 6 NYCRR 211.1: Air pollution prohibited
- 2-7 6 NYCRR 212-2.3 (b): Compliance Demonstration
- 2-8 6 NYCRR 212-2.3 (b): Compliance Demonstration

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: 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 B: 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 C: 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 D: 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 E: 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 F: 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 G: 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 H: 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 I: 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 J: 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. When additional applicable requirements under the act become applicable to a title V facility with a remaining permit term of 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 the 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 section 201- 6.6 of this Subpart.

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 K: 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 L: 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 1: Acceptable Ambient Air Quality  
Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement: 6 NYCRR 200.6**

**Item 1.1:**

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

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contravention occurs or may occur, the Commissioner shall specify the degree and/or method of emission control required.

**Condition 2: Fees**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

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

**Item 2.1:**

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 3: Recordkeeping and Reporting of Compliance Monitoring**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

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

**Item 3.1:**

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 4: Records of Monitoring, Sampling, and Measurement**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

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

**Item 4.1:**

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 5: Compliance Certification**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

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

**Item 5.1:**

The Compliance Certification activity will be performed for the Facility.

**Item 5.2:**

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,

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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



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report a summary of the testing results and shall indicate whether or not the Department or EPA has approved the results.

All semiannual reports may be submitted electronically or physically. Electronic reports shall be submitted using the Department's Air Compliance and Emissions Electronic-Reporting system (ACE). If the facility owner or operator elects to send physical copies instead, two copies shall be sent 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) and one copy shall be sent to the Administrator (or his or her representative). 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 7/30/2016.

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

**Condition 6: Compliance Certification**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

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

**Item 6.1:**

The Compliance Certification activity will be performed for the Facility.

**Item 6.2:**

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 annual compliance certifications may be submitted electronically or physically. Electronic reports shall be submitted using the Department's Air Compliance and Emissions Electronic-Reporting system (ACE). If the facility owner or operator elects to send physical copies instead, two copies shall be sent 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) and one copy shall be sent to the Administrator (or his or her representative). The mailing addresses for the above referenced persons are:

Chief – Stationary Source Compliance Section  
USEPA Region 2  
Air Compliance Branch  
290 Broadway  
New York, NY 10007-1866

The address for the RAPCE is as follows:

Regional Air Pollution Control Engineer  
NYSDEC  
21 South Putt Corners Road  
New Paltz, NY 12561-1696

The address for the BQA is as follows:

NYSDEC

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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 1/30/2017.  
Subsequent reports are due on the same day each year

**Condition 7: Compliance Certification**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR 202-2.1**

**Item 7.1:**

The Compliance Certification activity will be performed for the Facility.

**Item 7.2:**

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 8: Recordkeeping requirements**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR 202-2.5**

**Item 8.1:**

(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 9: Open Fires - Prohibitions**  
**Effective between the dates of 04/25/2016 and 04/24/2021**



**Applicable Federal Requirement:6 NYCRR 215.2**

**Item 9.1:**

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 9.2**

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 04/25/2016 and 04/24/2021**

**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 11: Recycling and Salvage**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR 201-1.7**

**Item 11.1:**

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 04/25/2016 and 04/24/2021**

**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 13: Exempt Sources - Proof of Eligibility**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

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

**Item 13.1:**

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.

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**Condition 14: Compliance Certification**  
Effective between the dates of 04/25/2016 and 04/24/2021

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

**Item 14.1:**

The Compliance Certification activity will be performed for the Facility.

**Item 14.2:**

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 15: Trivial Sources - Proof of Eligibility**  
Effective between the dates of 04/25/2016 and 04/24/2021

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

**Item 15.1:**

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 16: Requirement to Provide Information**  
Effective between the dates of 04/25/2016 and 04/24/2021

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

**Item 16.1:**

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

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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 1-1: Right to Inspect**

**Effective between the dates of 10/17/2017 and 04/24/2021**

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

**Replaces Condition(s) 17**

**Item 1-1.1:**

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 18: Off Permit Changes**

**Effective between the dates of 04/25/2016 and 04/24/2021**

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

**Item 18.1:**

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.

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(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 04/25/2016 and 04/24/2021**

**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 20: Accidental release provisions.**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement:40 CFR Part 68**

**Item 20.1:**

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 21: Recycling and Emissions Reduction**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement:40CFR 82, Subpart F**

**Item 21.1:**

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



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

**Condition 22: Emission Unit Definition**  
Effective between the dates of 04/25/2016 and 04/24/2021

**Applicable Federal Requirement:6 NYCRR Subpart 201-6**

**Item 22.1(From Mod 3):**

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. Products are aqueous based only.

Building(s): 01

**Item 22.2(From Mod 3):**

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 22.3(From Mod 3):**

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 22.4(From Mod 3):**

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 22.5(From Mod 3):**

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

Emission Unit: 0-0000F

Emission Unit Description:

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Aqueous coating of pharmaceutical tablets. Particulate emissions are controlled by a dust collector exhausted to emission point 00021.

Building(s): 01

**Item 22.6(From Mod 3):**

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 22.7(From Mod 3):**

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 22.8(From Mod 3):**

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 (ODC04) exhausted to emission point 00024.

Building(s): 01

**Item 22.9(From Mod 3):**

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 (ODC05) exhausted to emission point 00025.

Building(s): 01

**Item 22.10(From Mod 3):**

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

Emission Unit: 0-0000K

Emission Unit Description:

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Chemical storage building.

Building(s): 03

**Item 22.11(From Mod 3):**

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 22.12(From Mod 3):**

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 the Pharmacy Dispensing Area room and three Compression Area tablet presses.

Particulate emissions are controlled by a DFT 2-4 PulseJet Cartridge Dust Collector (ODC16) and exhausted through Emission Point 00034.

Building(s): 01

**Item 22.13(From Mod 3):**

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 22.14(From Mod 3):**

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-08 vented to EP00036.

Building(s): 01

**Item 22.15(From Mod 3):**

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

Emission Unit: 0-0000R

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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 22.16(From Mod 3):**

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

Emission Unit: 0-0000S

Emission Unit Description:

Creams and Gels Area consisting of one - Fette 1200i tablet press, one - Woowon mixer and dust pickups in six pharmaceutical manufacturing rooms. Particulate emissions are controlled by a DFT 2-4 PulseJet Cartridge Dust Collector (DC-17).

Building(s): 01

**Item 22.17(From Mod 3):**

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

Emission Unit: 0-0000T

Emission Unit Description:

Drying ovens No. 6 (DRY06), No. 7 (DRY07), and No. 8 (DRY08) are used to remove isopropyl alcohol (IPA) and/or ethanol (EtOH) from solvent-based pharmaceutical products or water from aqueous based pharmaceutical products. Solvent and aqueous modes are identified as process D03. In solvent mode, the dryers are vented to a dedicated scrubber for the first six hours of the drying cycle as follows: DRY06 vents to Scrubber No. 2 (SCR02) then exhausts via EP00006; DRY07 vents to Scrubber No. 1 (SCR01) then exhausts via EP00005; DRY08 vents to Scrubber No. 3 (SCR03) then exhausts via EP00007. Then the scrubbers will be turned off and emissions from the remaining portion of the drying cycle exhausts through a bypass vent (DRY06 to EP00008, DRY07 to EP00009, DRY08 to EP00010). When operating in aqueous mode, the dryers will exhaust via dedicated bypass vents (DRY06 to EP00008, DRY07 to EP00009, DRY08 to EP00010).

This emission unit also consists of a 48" (COAT4) and 60" (COAT7) Accela-Cota Tablet Coaters, two Glatt GPCG-60 coater/granulation/dryer units (COAT5 and COAT6), and one ACG Fluid Bed Dryer (FBD) (COAT8). Each has a dedicated fume hood (HOOD1, HOOD2, HOOD3, HOOD4, and HOOD5), which is used to dispense raw materials used in the process.



Solvent mode operation is identified as one process ID (P07). IPA and/or EtOH are used in the 48" Tablet Coater, two Glatts, FBD #3, and associated fume hoods. Acetone is used in the 48" and 60" Tablet Coaters and associated fume hoods. Methanol (MeOH) is also used in the two Glatts and associated fume hoods. This equipment can be used in aqueous mode (process IDs: P08, P09, P10, P13 & P14).

The 48" Tablet Coater (COAT4) is associated with HOOD1. Particulate emissions from COAT4 are controlled by dust collector (DC-11). COAT4/HOOD1 is controlled by the carbon absorption system (CA1RR) and exhausted via EP00040 when using IPA and EtOH. When acetone is used, emissions are controlled by Condenser (COND1) and exhausted via EP00045. When operating in aqueous mode, COND1 and CA1RR are bypassed and emissions exhaust via bypass vent EP00041.

The 60" Tablet Coater (COAT7) is associated with HOOD4. Particulate emissions from COAT7 are controlled by dust collector (DC-18). When acetone is used, COAT7/HOOD4 vents to Condenser (COND2) and exhaust via EP00046. When operating in aqueous mode, COND2 is bypassed, and emissions exhaust via bypass vent EP00047.

COAT4/HOOD1 and COAT7/HOOD4 will not operate at the same time when processing acetone batches.

Glatt #1 (COAT5) is associated with HOOD2 and Glatt #2 (COAT6) is associated with HOOD3. Particulate emissions from COAT5 and COAT6 are controlled by internal dust collectors DC-12 and DC-13, respectively. When using solvent in the Glatts and their associated fume hoods, the emissions are either directed to SCR01 and exhausted via EP00005 if IPA and/or EtOH is used or CA1RR and exhausted via EP00040 if MeOH is used. CA1RR can also be used as a backup to SCR01 when using IPA and/or EtOH in COAT5/HOOD2 and COAT6/HOOD3. This equipment can also operate in aqueous mode. When doing so, SCR01 and CA1RR are bypassed and emissions from COAT5/HOOD2 exhaust via bypass vent EP00026; and COAT6/HOOD3 exhaust via bypass vent EP00042.

FBD (COAT8) is associated with HOOD5. Particulates from COAT8 will be controlled by an internal dust collector DC-19. SCR03 will be used to reduce the solvent emissions from COAT8 and HOOD5 (EP00007). When in aqueous mode, SCR03 is bypassed and emissions from COAT8 and HOOD5 exhaust via bypass vent EP00048.

Building(s): 01

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**Item 22.18(From Mod 3):**

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

Emission Unit: 0-0000U

Emission Unit Description:

A dust collector system will pick up particulate matter (PM) from spot areas and/or room ventilation pick up points in five new manufacturing clean rooms (MCR) (rooms 37, 38, 39, 40, & 41) (MCR37, MCR38, MCR39, MCR40, MCR41) plus one new packaging line (OPL-J) . The PM collected from this system will be manifolded and directed to a Torit dust collector (DC-20) and exhausted via Emission Point EP00049. Only aqueous products will be produced in the manufacturing clean rooms and pre made pharmaceutical products will be packaged on the packaging line OPL-J.

Building(s): 01

**Condition 23: Progress Reports Due Semiannually**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

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

**Item 23.1:**

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 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR 201-6.4 (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: The facility does not engage in chemical synthesis and is therefore not subject to Part 233. Packaging and formulation is not considered to be synthesized pharmaceutical manufacturing as defined in 233.2(13) of the regulation.

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40 CFR Part 63, Subpart GGG

Reason: The facility does not emit greater than 10 tons per year of an individual Hazardous Air Pollutant or greater than 25 tons per year of total Hazardous Air Pollutants. Therefore, the facility is not subject to the National Emission Standards for Pharmaceutical Production as defined in 40 CFR 63.GGG.1250(a).

**Condition 25: Facility Permissible Emissions**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR Subpart 201-7**

**Item 25.1:**

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:

per year	CAS No: 000067-56-1 (From Mod 3)	PTE: 19,000 pounds
	Name: METHYL ALCOHOL	
per year	CAS No: 000067-64-1 (From Mod 3)	PTE: 27,966 pounds
	Name: DIMETHYL KETONE	
per year	CAS No: 0NY100-00-0 (From Mod 3)	PTE: 49,000 pounds
	Name: TOTAL HAP	
per year	CAS No: 0NY998-00-0 (From Mod 3)	PTE: 73,043 pounds
	Name: VOC	

**Condition 3-1: Capping Monitoring Condition**  
**Effective between the dates of 01/18/2019 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR Subpart 201-7**

**Replaces Condition(s) 1-2**

**Item 3-1.1:**

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 3-1.2:**

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

**Item 3-1.3:**

The owner or operator of the permitted facility must maintain all required records on-site for a period of five years and make them available to representatives of the Department upon request. Department representatives must be granted access to any facility regulated by this Subpart, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations or law.

**Item 3-1.4:**

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

**Item 3-1.5:**

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

**Item 3-1.6:**

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

Emission Unit: 0-0000T Process: P07	Emission Point: 00005 Emission Source: COAT5
Emission Unit: 0-0000T Process: P07	Emission Point: 00040 Emission Source: COAT5
Emission Unit: 0-0000T Process: P07	Emission Point: 00005 Emission Source: COAT6
Emission Unit: 0-0000T Process: P07	Emission Point: 00040 Emission Source: COAT6
Emission Unit: 0-0000T Process: P07	Emission Point: 00005 Emission Source: HOOD2
Emission Unit: 0-0000T Process: P07	Emission Point: 00040 Emission Source: HOOD2
Emission Unit: 0-0000T Process: P07	Emission Point: 00005 Emission Source: HOOD3
Emission Unit: 0-0000T Process: P07	Emission Point: 00040 Emission Source: HOOD3

Regulated Contaminant(s):



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CAS No: 0NY998-00-0 VOC

**Item 3-1.7:**

Compliance Certification shall include the following monitoring:

Capping: Yes

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

PAR Pharmaceutical shall limit the combined solvent based production batches associated with Glatt GPCG-60 #1 and Glatt GPCG-60 #2 (Emission Sources COAT5 and COAT6) to 100 commercial batches 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: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 7/30/2019.

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

**Condition 2-2: Capping Monitoring Condition**

**Effective between the dates of 06/11/2018 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR Subpart 201-7**

**Item 2-2.1:**

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

6 NYCRR 212-2.3 (b)

**Item 2-2.2:**

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

**Item 2-2.3:**

The owner or operator of the permitted facility must maintain all required records on-site for a period of five years and make them available to representatives of the Department upon request. Department representatives must be granted access to any facility regulated by this Subpart, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations or law.

**Item 2-2.4:**



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

**Item 2-2.5:**

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

**Item 2-2.6:**

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

Emission Unit: 0-0000T	Emission Point: 00045
Process: P07	Emission Source: COND1
Emission Unit: 0-0000T	Emission Point: 00046
Process: P07	Emission Source: COND2
Regulated Contaminant(s):	
CAS No: 000067-64-1	DIMETHYL KETONE

**Item 2-2.7:**

Compliance Certification shall include the following monitoring:

Capping: Yes

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

Monitoring Description:

PAR Pharmaceutical shall limit the acetone based production associated with Process P07, process equipment COAT4 and COAT7, fume hoods HOOD1 and HOOD4, and control equipment COND1 and COND2 to 65 commercial batches per year.

Process Material: COATING

Parameter Monitored: BATCHES

Upper Permit Limit: 65 batches per year

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING  
DESCRIPTION

Averaging Method: 12-MONTH TOTAL, ROLLED MONTHLY

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 7/30/2018.

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

**Condition 3-2: Capping Monitoring Condition**  
**Effective between the dates of 01/18/2019 and 04/24/2021**



**Applicable Federal Requirement:6 NYCRR Subpart 201-7**

**Replaces Condition(s) 2-1**

**Item 3-2.1:**

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

40 CFR 63.1250 (c)

**Item 3-2.2:**

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

**Item 3-2.3:**

The owner or operator of the permitted facility must maintain all required records on-site for a period of five years and make them available to representatives of the Department upon request. Department representatives must be granted access to any facility regulated by this Subpart, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations or law.

**Item 3-2.4:**

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

**Item 3-2.5:**

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

**Item 3-2.6:**

The Compliance Certification activity will be performed for the Facility.

Regulated Contaminant(s):

CAS No: 0NY100-00-0 TOTAL HAP

**Item 3-2.7:**

Compliance Certification shall include the following monitoring:

Capping: Yes

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

PAR Pharmaceutical shall demonstrate that its emissions are 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

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individual HAP and total HAPs from coating, drying, clearing, 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.

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: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 7/30/2019.

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

**Condition 3-3: Capping Monitoring Condition**  
**Effective between the dates of 01/18/2019 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR Subpart 201-7**

**Item 3-3.1:**

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

40 CFR 63.1250 (c)

**Item 3-3.2:**

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

**Item 3-3.3:**

The owner or operator of the permitted facility must maintain all required records on-site for a period of five years and make them available to representatives of the Department upon request. Department representatives must be granted access to any facility regulated by this Subpart, during normal operating hours, for the purpose of determining compliance with this and any other state and federal air pollution control requirements, regulations or law.

**Item 3-3.4:**

On an annual basis, unless otherwise specified below, beginning one year after the granting of an emissions cap, the responsible official shall provide a certification to the Department that the facility has operated all emission units within the limits imposed by the emission cap. This certification shall include a brief summary of the emissions subject to the cap for that time period and a comparison to the threshold levels that would require compliance with an

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applicable requirement.

**Item 3-3.5:**

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

**Item 3-3.6:**

The Compliance Certification activity will be performed for the Facility.

Regulated Contaminant(s):

CAS No: 000067-56-1 METHYL ALCOHOL

**Item 3-3.7:**

Compliance Certification shall include the following monitoring:

Capping: Yes

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

PAR Pharmaceutical shall demonstrate that its emissions are below the 10 tons per year of any individual HAP, including Methyl Alcohol, 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.

Work Practice Type: PROCESS MATERIAL THRUPUT

Process Material: COATING

Upper Permit Limit: 19000 pounds per year

Monitoring Frequency: MONTHLY

Averaging Method: ANNUAL TOTAL ROLLED MONTHLY

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 7/30/2019.

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

**Condition 37: Visible Emissions Limited**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR 211.2**

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**Item 37.1:**

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.

**Condition 2-3: Compliance Certification**  
**Effective between the dates of 06/11/2018 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR 212-1.6 (a)**

**Replaces Condition(s) 1-4**

**Item 2-3.1:**

The Compliance Certification activity will be performed for the Facility.

**Item 2-3.2:**

Compliance Certification shall include the following monitoring:

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

Monitoring Description:

The facility shall not cause or allow emissions having an average opacity during any six consecutive minutes of 20 percent or greater from any process emission source, except only the emission of uncombined water. The facility shall conduct a visible survey of emission points once monthly during process operations. If the survey identifies visible emissions, the facility shall implement corrective action as needed.

The Department reserves the right to conduct or require the facility to conduct a Method 9 opacity observation.

Parameter Monitored: OPACITY

Upper Permit Limit: 20 percent

Reference Test Method: EPA Method 9 as necessary

Monitoring Frequency: AS REQUIRED - SEE PERMIT MONITORING  
DESCRIPTION

Averaging Method: 6 MINUTE AVERAGE

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 7/30/2018.

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

**Condition 2-4: Compliance Certification**  
**Effective between the dates of 06/11/2018 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR 212-1.7 (b) (3)**

**Replaces Condition(s) 1-5**

**Item 2-4.1:**

The Compliance Certification activity will be performed for the facility:



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The Compliance Certification applies to:

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

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

**Item 2-4.2:**

Compliance Certification shall include the following monitoring:

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

Monitoring Description:

PAR Pharmaceutical 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: SEMI-ANNUALLY (CALENDAR)  
Reports due 30 days after the reporting period.  
The initial report is due 7/30/2018.  
Subsequent reports are due every 6 calendar month(s).

**Condition 3-4: Compliance Certification**  
**Effective between the dates of 01/18/2019 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR 212-2.4 (b)**

**Replaces Condition(s) 2-5**

**Item 3-4.1:**

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

- Emission Unit: 0-0000A
- Emission Unit: 0-0000B
- Emission Unit: 0-0000E
- Emission Unit: 0-0000F
- Emission Unit: 0-0000G
- Emission Unit: 0-0000H

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Emission Unit: 0-0000I

Emission Unit: 0-0000J

Emission Unit: 0-0000M

Emission Unit: 0-0000N

Emission Unit: 0-0000O

Emission Unit: 0-0000R

Emission Unit: 0-0000S

Emission Unit: 0-0000T

Emission Unit: 0-0000U

Regulated Contaminant(s):

CAS No: 0NY075-00-0 PARTICULATES

**Item 3-4.2:**

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 conduct or require the facility to conduct performance testing (Method 5) to verify compliance with the standard.

Any required performance testing 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 excursions and execute the necessary corrective action. Records of these verifications, investigations and



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corrective actions shall be available for Department review.

Upper Permit Limit: 0.050 grains per dscf  
Reference Test Method: EPA Reference Method 5  
Monitoring Frequency: UPON REQUEST OF REGULATORY AGENCY  
Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST METHOD INDICATED  
Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE

**Condition 3-5: Compliance Certification**  
**Effective between the dates of 01/18/2019 and 04/24/2021**

**Applicable Federal Requirement: 6 NYCRR 212-3.1 (c) (4) (i)**

**Replaces Condition(s) 2-6**

**Item 3-5.1:**

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

Emission Unit: 0-0000T	Emission Point: 00005
Emission Unit: 0-0000T	Emission Point: 00006
Emission Unit: 0-0000T	Emission Point: 00007
Emission Unit: 0-0000T	Emission Point: 00040

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

**Item 3-5.2:**

Compliance Certification shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING

Monitoring Description:

For the removal of isopropyl alcohol and/or ethanol associated with Process D03 (drying ovens - DRY06, DRY07 and DRY08) and when utilizing solvent based materials associated with Process P07 (coaters/granulators/fume hoods - COAT4, COAT5, COAT6, COAT8, HOOD1, HOOD2, HOOD3, and HOOD5), when using CA1RR, SCR01, SCR02 or SCR03 as control. PAR Pharmaceutical shall maintain a capture system and a control device with an overall removal efficiency of at least 81 percent.

PAR Pharmaceutical shall conduct a performance test for process operations at the emission points identified above at the request of the Department. PAR Pharmaceutical shall submit a test protocol detailing methods and procedures to be used during the performance stack testing at least 60 days prior to the scheduled test. Performance test results

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must be reported within 60 days after completion of compliance testing.

Lower Permit Limit: 81 percent  
Reference Test Method: EPA Reference Method 25  
Monitoring Frequency: UPON REQUEST OF REGULATORY AGENCY  
Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST METHOD INDICATED  
Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE

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

**Condition 33: Emission Point Definition By Emission Unit**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR Subpart 201-6**

**Item 33.1(From Mod 3):**

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

- Emission Unit: 0-0000T
- Emission Point: 00005
  - Height (ft.): 31 Diameter (in.): 20
  - NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01
- Emission Point: 00006
  - Height (ft.): 31 Diameter (in.): 20
  - NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01
- Emission Point: 00007
  - Height (ft.): 31 Diameter (in.): 20
  - NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01
- Emission Point: 00008
  - Height (ft.): 30 Length (in.): 19 Width (in.): 14
  - NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01
- Emission Point: 00009
  - Height (ft.): 31 Length (in.): 19 Width (in.): 14
  - NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01
- Emission Point: 00010
  - Height (ft.): 31 Length (in.): 19 Width (in.): 14
  - NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01
- Emission Point: 00026
  - Height (ft.): 28 Diameter (in.): 18
  - NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01

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Emission Point: 00040  
Height (ft.): 13                      Diameter (in.): 18  
NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

Emission Point: 00041  
Height (ft.): 28                      Diameter (in.): 20  
NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

Emission Point: 00042  
Height (ft.): 28                      Diameter (in.): 18  
NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

Emission Point: 00045  
Height (ft.): 34                      Diameter (in.): 12  
NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

Emission Point: 00046  
Height (ft.): 35                      Diameter (in.): 14  
NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

Emission Point: 00047  
Height (ft.): 28                      Diameter (in.): 12  
NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

Emission Point: 00048  
Height (ft.): 28                      Diameter (in.): 12  
NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

**Item 33.2(From Mod 3):**

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

Emission Unit: 0-0000U

Emission Point: 00049  
Height (ft.): 35                      Diameter (in.): 8  
NYTMN (km.): 4548.171    NYTME (km.): 579.551

**Item 33.3(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.): 4548.171    NYTME (km.): 579.551    Building: 01

Emission Point: 00002  
Height (ft.): 17                      Length (in.): 30                      Width (in.): 30  
NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

**Item 33.4(From Mod 2):**

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

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Emission Unit: 0-0000B

Emission Point: 00003

Height (ft.): 14                      Length (in.): 24                      Width (in.): 30  
NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

**Item 33.5(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.): 4548.171    NYTME (km.): 579.551    Building: 01

**Item 33.6(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.): 4548.171    NYTME (km.): 579.551    Building: 01

**Item 33.7(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.): 4548.171    NYTME (km.): 579.551    Building: 01

**Item 33.8(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.): 4548.171    NYTME (km.): 579.551    Building: 01

**Item 33.9(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.): 4548.171    NYTME (km.): 579.551    Building: 01



**Item 33.10(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.): 4548.171 NYTME (km.): 579.551 Building: 01

**Item 33.11(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.): 4548.171 NYTME (km.): 579.551 Building: 01

**Item 33.12(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.): 4548.171 NYTME (km.): 579.551 Building: 03

**Item 33.13(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.): 4548.171 NYTME (km.): 579.551 Building: 04

**Item 33.14(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.): 4548.171 NYTME (km.): 579.551 Building: 01

**Item 33.15(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

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NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

**Item 33.16(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.): 4548.171    NYTME (km.): 579.551    Building: 01

**Item 33.17(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.): 4548.171    NYTME (km.): 579.551    Building: 01

**Item 33.18(From Mod 2):**

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

Emission Unit: 0-0000S

Emission Point: 00044

Height (ft.): 30

Diameter (in.): 10

NYTMN (km.): 4548.171    NYTME (km.): 579.551    Building: 01

**Condition 34:    Process Definition By Emission Unit**

**Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR Subpart 201-6**

**Item 34.1(From Mod 3):**

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 34.2(From Mod 3):**

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 34.3(From Mod 3):**

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 34.4(From Mod 3):**

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 34.5(From Mod 3):**

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 34.6(From Mod 3):**

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 34.7(From Mod 3):**

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

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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 34.8(From Mod 3):**

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 34.9(From Mod 3):**

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 34.10(From Mod 3):**

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 34.11(From Mod 3):**

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 34.12(From Mod 3):**

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



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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 34.13(From Mod 3):**

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 pharmaceutical production and or R & D.  
Dust collector DC-07 is utilized to control particulate emissions exhausted through emission point 35.

Emission Source/Control: DC-07 - 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 34.14(From Mod 3):**

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

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Emission Source/Control: 0PL-C - Process

Emission Source/Control: PL-BL - Process

**Item 34.15(From Mod 3):**

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

Emission Unit: 0-0000R

Process: P11

Source Classification Code: 3-01-060-12

Process Description: Process associated with granulation.

Emission Source/Control: DC-15 - Control

Control Type: DUST COLLECTOR

Emission Source/Control: BLND1 - Process

Emission Source/Control: GRAN2 - Process

Emission Source/Control: MILL1 - Process

Emission Source/Control: SIFT1 - Process

**Item 34.16(From Mod 3):**

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

Emission Unit: 0-0000S

Process: P12

Source Classification Code: 3-01-060-99

Process Description:

Pharmaceutical production associated with Creams and Gel areas.

Emission Source/Control: DC-17 - Control

Control Type: DUST COLLECTOR

Emission Source/Control: CG-01 - Process

Emission Source/Control: MIX01 - Process

Emission Source/Control: TAB04 - Process

**Item 34.17(From Mod 3):**

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

Emission Unit: 0-0000T

Process: D03

Source Classification Code: 3-01-060-09

Process Description:

Drying ovens #283 (DRY06), #284 (DRY07), and #285 (DRY08) are used to remove isopropyl alcohol and/or ethanol from pharmaceutical products. Emissions will exhaust through

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wet scrubbers as follows: DRY07 to SCR01 (EP00005), DRY06 to SCR02 (EP00006), and DRY08 to SCR03 (EP00007) for the first six hours of the drying cycle. Then scrubbers will be turned off and emissions will exhaust through bypass emission points for the remainder of the drying cycle or when operating in aqueous mode as follows: DRY06 to EP00008, DRY07 to EP00009, DRY08 to EP00010.

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 34.18(From Mod 3):**

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

Emission Unit: 0-0000T

Process: P07

Source Classification Code: 3-01-060-99

Process Description:

Solvent emissions from Glatt GPGC-60 #1 (COAT5), Glatt GPGC-60 #2 (COAT6), and Fume Hoods #2 and #3 (HOOD2 and HOOD3) are controlled by a wet scrubber SCR01 (EP00005) and CA1RR (EP00040) will be used as a back-up control device when isopropyl alcohol or ethanol is used. In addition, CA1RR (EP00040) will continue to be used as the primary control device for COAT5, COAT6, HOOD2, and HOOD3 when methanol is used. Glatt GPGC-60 #1 (COAT5) and Glatt GPGC-60 #2 (COAT6) vent to internal dust collectors (DC-12 & DC-13, respectively) before venting to SCR01 (EP00005) or CA1RR (EP00040).

VOC emissions from the 48" Accela-Coata tablet coater (COAT4)/fume hood #1 (HOOD1) vent to CA1RR (EP00040) when isopropyl alcohol or ethanol is used. The 48" Tablet Coater (COAT4) and Fume Hood #1 (HOOD1) vent to Condenser (COND1) and (EP00045) when acetone is used. COAT4 also vents to an external dust collector (DC-11) before venting to CA1RR (EP00040) or COND1 (EP00045).

VOC emissions from the 60" Accela-Coata tablet coater (COAT7) and Fume Hood #4 (HOOD4) vent to a Condenser (COND2) and (EP00046) when acetone is used. COAT7 will

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also vent to an external dust collector (DC-18) before venting to COND2 (EP00046). COAT7/HOOD4 and COAT4/HOOD1 will not be used at the same time when processing acetone batches.

VOC emissions from the ACG Fluid Bed Dryer (COAT8) and Fume Hood #5 (HOOD5) vent to wet scrubber SCR03 (EP00007) when isopropyl alcohol or ethanol is used. COAT8 will also vent to an internal dust collector DC-19 before venting to SCR03 (EP00007).

All equipment is used in pharmaceutical production and/or research & development purposes. All equipment can be used in solvent mode (VOCs or HAPs).

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

Emission Source/Control: COND1 - Control  
Control Type: REFRIGERATED CONDENSER

Emission Source/Control: COND2 - Control  
Control Type: REFRIGERATED CONDENSER

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: DC-18 - Control  
Control Type: DUST COLLECTOR

Emission Source/Control: DC-19 - Control  
Control Type: DUST COLLECTOR

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

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

Emission Source/Control: COAT4 - Process

Emission Source/Control: COAT5 - Process

Emission Source/Control: COAT6 - Process

Emission Source/Control: COAT7 - Process

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Emission Source/Control: COAT8 - Process

Emission Source/Control: HOOD1 - Process

Emission Source/Control: HOOD2 - Process

Emission Source/Control: HOOD3 - Process

Emission Source/Control: HOOD4 - Process

Emission Source/Control: HOOD5 - Process

**Item 34.19(From Mod 3):**

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

Emission Unit: 0-0000T

Process: P08

Source Classification Code: 3-01-060-11

Process Description:

Glatt GPCG-60 #1 (COAT5) coater/granulator/dryer is used to coat/granulate and/or dry pharmaceutical materials for production and/or for research & development. Glatt GPCG-60 #1 (COAT5) vents to an internal dust collector (DC-12). Pharmaceutical fume hood #2 (HOOD2) is used to dispense raw materials used in the process. Both pieces of equipment vent through EP00026 when in aqueous mode.

Emission Source/Control: DC-12 - Control

Control Type: DUST COLLECTOR

Emission Source/Control: COAT5 - Process

Emission Source/Control: HOOD2 - Process

**Item 34.20(From Mod 3):**

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

Emission Unit: 0-0000T

Process: P09

Source Classification Code: 3-01-060-11

Process Description:

48" Accela-Coata tablet coater (COAT4) is used to coat pharmaceutical materials for production and/or for research & development. Pharmaceutical fume hood #1 (HOOD1) is used to dispense raw materials in the process. The 48" tablet coater vents to an external stand alone dust collector (DC-11). Both pieces of equipment vent through EP00041 when in aqueous mode.

Emission Source/Control: DC-11 - Control

Control Type: DUST COLLECTOR

Emission Source/Control: COAT4 - Process



Emission Source/Control: HOOD1 - Process

**Item 34.21(From Mod 3):**

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

Emission Unit: 0-0000T

Process: P10

Source Classification Code: 3-01-060-11

Process Description:

Glatt GPCG-60 #2 (COAT6) coater/granulator/dryer is used to coat/granulate and/or dry pharmaceutical materials for production and/or for research & development. Glatt GPCG-60 #2 (COAT6) vents to an internal duct collector (DC-13). Pharmaceutical fume hood #3 (HOOD3) is used to dispense raw materials used in the process. Both pieces of equipment vent through EP00042 when in aqueous mode.

Emission Source/Control: DC-13 - Control

Control Type: DUST COLLECTOR

Emission Source/Control: COAT6 - Process

Emission Source/Control: HOOD3 - Process

**Item 34.22(From Mod 3):**

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

Emission Unit: 0-0000T

Process: P13

Source Classification Code: 3-01-060-12

Process Description:

60" tablet coater (COAT7) is used to coat pharmaceutical materials for production and/or for research & development. Pharmaceutical fume hood #4 (HOOD4) is used to dispense raw materials used in the process. COAT7 vents to an external stand alone dust collector (DC-18). Both pieces of equipment vent through EP00047 when in aqueous mode.

Emission Source/Control: DC-18 - Control

Control Type: DUST COLLECTOR

Emission Source/Control: COAT7 - Process

Emission Source/Control: HOOD4 - Process

**Item 34.23(From Mod 3):**

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

Emission Unit: 0-0000T

Process: P14

Source Classification Code: 3-01-060-11

Process Description:

ACG Fluid Bed Dryer #3 (COAT8) Coater/Granulator/Dryer is

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used to coat/granulate and/or dry pharmaceutical materials for production and/or R&D. ACG Fluid Bed Dryer #3 (COAT8) vents to an internal dust collector (DC-19). Pharmaceutical fume hood #5 (HOOD5) is used to prepare materials for the process. Both pieces of equipment vent through EP00048 when in aqueous mode.

Emission Source/Control: DC-19 - Control  
Control Type: DUST COLLECTOR

Emission Source/Control: COAT8 - Process

Emission Source/Control: HOOD5 - Process

**Item 34.24(From Mod 3):**

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

Emission Unit: 0-0000U

Process: P15

Source Classification Code: 3-01-060-99

Process Description:

A dust collection system will pick up particulate matter (PM) from spot areas and/or room ventilation pick up points in five new manufacturing clean rooms (MCR) (rooms 37, 38, 39, 40 & 41) (MCR37, MCR38, MCR39, MCR40, MCR41) plus one new packaging line (OPL-J). The PM collected from this system will be manifolded and directed to a Torit dust collector (DC-20) and exhausted via Emission Point EP00049. Only aqueous products will be produced in the manufacturing clean rooms and pre made pharmaceutical products will be packaged on the packaging line OPL-J.

Emission Source/Control: DC-20 - Control  
Control Type: DUST COLLECTOR

Emission Source/Control: OPL-J - Process

Emission Source/Control: MCR37 - Process

Emission Source/Control: MCR38 - Process

Emission Source/Control: MCR39 - Process

Emission Source/Control: MCR40 - Process

Emission Source/Control: MCR41 - Process

**Condition 3-6: Emission Unit Permissible Emissions**

**Effective between the dates of 01/18/2019 and 04/24/2021**

**Applicable Federal Requirement:6 NYCRR Subpart 201-7**

**Item 3-6.1:**

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The sum of emissions from all regulated processes specified in this permit for the emission unit cited

shall not exceed the following Potential to Emit (PTE) rates for each regulated contaminant:

Emission Unit: 0-0000T

CAS No: 000067641 (From Mod 3)

Name: DIMETHYL KETONE

PTE(s): 27,964 pounds per year

28.3 pounds per hour

CAS No: 0NY998000 (From Mod 3)

Name: VOC

PTE(s): 46.7 pounds per hour

11,345 pounds per year

CAS No: 0NY100000 (From Mod 3)

Name: TOTAL HAP

PTE(s): 110.3 pounds per year

2.8 pounds per hour

**Condition 3-7: Capping Monitoring Condition**

**Effective between the dates of 01/18/2019 and 04/24/2021**

**Applicable Federal Requirement: 6 NYCRR Subpart 201-7**

**Item 3-7.1:**

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:

6 NYCRR Subpart 231-6

**Item 3-7.2:**

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

**Item 3-7.3:**

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 3-7.4:**

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.



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**Item 3-7.5:**

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 3-7.6:**

The Compliance Certification activity will be performed for:

Emission Unit: 0-0000T

Regulated Contaminant(s):

CAS No: 0NY998-00-0 VOC

**Item 3-7.7:**

Compliance Certification shall include the following monitoring:

Capping: Yes

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS

Monitoring Description:

Emissions of isopropyl alcohol and ethyl alcohol from the ACG Fluid Bed Dryer #3 (COAT8)/Fume Hood #5 (HOOD5) will be reduced by 95% in wet scrubber (SCR03/EP00007). Maximum number of total batches for COAT8/HOOD5 will be 20 commercial batches per 12-month period.

The facility owner or operator shall maintain a record of each commercial batch, and shall tabulate the monthly and rolling 12-month total number of batches on a monthly basis. Such records shall include the date of the batch, the amount of isopropyl alcohol used, and the amount of ethyl alcohol used. Records kept pursuant to this condition must be maintained at the facility for a period of at least five years, and must be made available to the Department upon request.

Work Practice Type: PROCESS MATERIAL THRUPUT

Process Material: SOLVENT

Upper Permit Limit: 20 batches per year

Monitoring Frequency: MONTHLY

Averaging Method: ANNUAL MAXIMUM ROLLED MONTHLY

Reporting Requirements: SEMI-ANNUALLY (CALENDAR)

Reports due 30 days after the reporting period.

The initial report is due 7/30/2019.

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



**STATE ONLY ENFORCEABLE CONDITIONS**

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

**NOTIFICATION OF GENERAL PERMITTEE OBLIGATIONS**

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

**Item A: 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: 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 04/25/2016 and 04/24/2021**

**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: 000067-64-1  
Name: DIMETHYL KETONE

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

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

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

**Condition 36: Malfunctions and start-up/shutdown activities**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

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



**Item 36.1:**

(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 28: Air pollution prohibited**  
**Effective between the dates of 04/25/2016 and 04/24/2021**

**Applicable State Requirement:6 NYCRR 211.1**

**Item 28.1:**

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.

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**Condition 2-7: Compliance Demonstration**  
Effective between the dates of 06/11/2018 and 04/24/2021

**Applicable State Requirement:6 NYCRR 212-2.3 (b)**

**Item 2-7.1:**

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

Emission Unit: 0-0000T                      Emission Point: 00045  
Process: P07

Regulated Contaminant(s):  
CAS No: 000067-64-1                      DIMETHYL KETONE

**Item 2-7.2:**

Compliance Demonstration shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING

Monitoring Description:

For the removal of acetone associated with Process P07, process equipment COAT4, HOOD1, Control equipment COND1 and Dust Collector DC-11, PAR Pharmaceutical shall maintain a capture system and a control device with an overall removal efficiency of at least 77 percent. PAR Pharmaceutical shall conduct a performance test at the request of the Department for process operations at the emission points identified above. If requested, PAR Pharmaceutical shall submit, at least 60 days prior to the scheduled test, a test protocol detailing methods and procedures to be used during the performance stack testing. Performance test results must be reported within 60 days after completion of compliance testing.

Lower Permit Limit: 77 percent

Reference Test Method: EPA Method 25

Monitoring Frequency: UPON REQUEST OF REGULATORY AGENCY

Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST  
METHOD INDICATED

Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE

**Condition 2-8: Compliance Demonstration**  
Effective between the dates of 06/11/2018 and 04/24/2021

**Applicable State Requirement:6 NYCRR 212-2.3 (b)**

**Replaces Condition(s) 1-8**

**Item 2-8.1:**

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

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Emission Unit: 0-0000T  
Process: P07

Emission Point: 00046

Regulated Contaminant(s):  
CAS No: 000067-64-1      DIMETHYL KETONE

**Item 2-8.2:**

Compliance Demonstration shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING

Monitoring Description:

For the removal of acetone associated with Process P07, process equipment COAT7, HOOD4, control equipment COND2, and dust collector DC-18, PAR Pharmaceutical shall maintain a capture system and a control device with an overall removal efficiency of at least 75 percent. The facility shall conduct a performance test at the request of the Department for process operations at the emission points identified above. If requested, PAR Pharmaceutical shall submit a test protocol detailing methods and procedures to be used during the performance stack testing at least 60 days prior to the scheduled test. Performance test results must be reported to the department within 60 days after completion of compliance testing.

Lower Permit Limit: 75 percent

Reference Test Method: EPA Method 25

Monitoring Frequency: UPON REQUEST OF REGULATORY AGENCY

Averaging Method: AVERAGING METHOD AS PER REFERENCE TEST

METHOD INDICATED

Reporting Requirements: ONCE / BATCH OR MONITORING OCCURRENCE