PERMIT
Under the Environmental Conservation Law (ECL)

IDENTIFICATION INFORMATION

Permit Type: Air Title V Facility
Permit ID: 3-3926-00729/00054
Effective Date: 06/27/2022 Expiration Date: 06/26/2027

Permit Issued To: STRIDES PHARMA INC
2 TOWER CTR BLVD STE 1102
EAST BRUNSWICK, NJ 08816

Contact: MICHAEL UHRIN
1 RAM RIDGE RD
CHESTNUT RIDGE, NY 10977

Facility: STRIDES PHARMA INC
1 RAM RIDGE RD
CHESTNUT RIDGE, NY 10977

Contact: MICHAEL UHRIN
1 RAM RIDGE RD
CHESTNUT RIDGE, NY 10977

Description:
Strides Pharma Inc., formerly known as PAR Pharmaceutical, is a Title V facility that manufactures pharmaceutical products in the form of capsules and tablets using processing equipment (drying ovens, coaters, etc). There are multiple air pollution controls onsite including fabric filters, dust collectors, activated carbon adsorption, and wet scrubbers. Potential emissions of Volatile Organic Compounds (VOCs) exceed major source thresholds subjecting the facility to Title V permitting. The facility's actual emissions of individual and total Hazardous Air Pollutants (HAPs) are limited below major source thresholds. 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:

Methyl Alcohol = 19,000 pounds per year
Total HAP = 49,000 pounds per year

The Title V renewal would allow for the continued operation of existing infrastructure and does not include any new, expanded, or modified operations.
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.
<table>
<thead>
<tr>
<th>PAGE</th>
<th>DEC GENERAL CONDITIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>General Provisions</td>
</tr>
<tr>
<td>5 1</td>
<td>Facility Inspection by the Department</td>
</tr>
<tr>
<td>5 2</td>
<td>Relationship of this Permit to Other Department Orders and Determinations</td>
</tr>
<tr>
<td>5 3</td>
<td>Applications for permit renewals, modifications and transfers</td>
</tr>
<tr>
<td>6 4</td>
<td>Permit modifications, suspensions or revocations by the Department</td>
</tr>
<tr>
<td>6 5</td>
<td>Submission of application for permit modification or renewal</td>
</tr>
</tbody>
</table>

-REGION 3 HEADQUARTERS
Facility DEC ID: 3392600729

DEC GENERAL CONDITIONS

**** General Provisions ****
For the purpose of your Title V permit, the following section contains state-only enforceable terms and conditions.
GENERAL CONDITIONS - Apply to ALL Authorized Permits.

Condition 1: Facility Inspection by the Department
Applicable State Requirement: ECL 19-0305

Item 1.1:
The permitted site or facility, including relevant records, is subject to inspection at reasonable hours and intervals by an authorized representative of the Department of Environmental Conservation (the Department) to determine whether the permittee is complying with this permit and the ECL. Such representative may order the work suspended pursuant to ECL 71-0301 and SAPA 401(3).

Item 1.2:
The permittee shall provide a person to accompany the Department's representative during an inspection to the permit area when requested by the Department.

Item 1.3:
A copy of this permit, including all referenced maps, drawings and special conditions, must be available for inspection by the Department at all times at the project site or facility. Failure to produce a copy of the permit upon request by a Department representative is a violation of this permit.

Condition 2: Relationship of this Permit to Other Department Orders and Determinations
Applicable State Requirement: ECL 3-0301 (2) (m)

Item 2.1:
Unless expressly provided for by the Department, issuance of this permit does not modify, supersede or rescind any order or determination previously issued by the Department or any of the terms, conditions or requirements contained in such order or determination.

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

Item 3.1:
The permittee must submit a separate written application to the Department for renewal, modification or transfer of this permit. Such application must include any forms or supplemental information the Department requires. Any renewal, modification or transfer granted by the Department must be in writing.

Item 3.2:
The permittee must submit a renewal application at least 180 days before the expiration of permits for 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
Facility DEC ID: 3392600729

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
Permit Under the Environmental Conservation Law (ECL)

ARTICLE 19: AIR POLLUTION CONTROL - TITLE V PERMIT

IDENTIFICATION INFORMATION

Permit Issued To: STRIDES PHARMA INC
2 TOWER CTR BLVD STE 1102
EAST BRUNSWICK, NJ 08816

Facility: STRIDES PHARMA INC
1 RAM RIDGE RD
CHESTNUT RIDGE, NY 10977

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

Permit Effective Date: 06/27/2022       Permit Expiration Date: 06/26/2027
PAGE LOCATION 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 (c): 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
17  6 NYCRR 201-6.4 (a) (8): Right to Inspect
19  40 CFR Subpart F: Recycling and Emissions Reduction
20  6 NYCRR Subpart 201-6: Emission Unit Definition
21  6 NYCRR Subpart 201-6: Compliance Certification
22  6 NYCRR Subpart 201-6: Compliance Certification
23  6 NYCRR Subpart 201-6: Compliance Certification
24  6 NYCRR Subpart 201-6: Progress Reports Due Semiannually
25  6 NYCRR 201-6.4 (f): Operational Flexibility
26  6 NYCRR Subpart 201-7: Facility Permissible Emissions
27  6 NYCRR Subpart 201-7: Capping Monitoring Condition
28  6 NYCRR Subpart 201-7: Capping Monitoring Condition
29  6 NYCRR 202-1.1: Required Emissions Tests - Facility Level
30  6 NYCRR 211.2: Visible Emissions Limited
31  6 NYCRR 212-1.6 (a): Compliance Certification
32  6 NYCRR 212-1.7 (b) (3): Compliance Certification
33  6 NYCRR 212-2.4 (b): Compliance Certification
34  6 NYCRR 212-2.4 (c): Compliance Certification
35  6 NYCRR 212-3.1 (c) (4) (i): Compliance Certification
36  6 NYCRR 212-3.1 (c) (4) (ii): Compliance Certification
37  6 NYCRR 225-1.2 (d): Compliance Certification

Emission Unit Level

38  6 NYCRR Subpart 201-6: Emission Point Definition By Emission Unit
39  6 NYCRR Subpart 201-6: Process Definition By Emission Unit
40  6 NYCRR Subpart 201-7: Emission Unit Permissible Emissions

STATE ONLY ENFORCEABLE CONDITIONS
Facility Level

54  41  ECL 19-0301: Contaminant List
54  42  6 NYCRR 201-1.4: Malfunctions and Start-up/Shutdown Activities
55  43  6 NYCRR 201-6.5 (a): CLCPA Applicability
56  44  6 NYCRR 211.1: Air pollution prohibited
56  45  6 NYCRR 212-2.3 (b): Compliance Demonstration
57  46  6 NYCRR 212-2.3 (b): Compliance Demonstration
58  47  6 NYCRR 212-2.3 (b): Compliance Demonstration
59  48  6 NYCRR 212-2.3 (b): Compliance Demonstration

NOTE: * preceding the condition number indicates capping.
FEDERALLY ENFORCEABLE CONDITIONS
Renewal 3/FINAL

**** 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 06/27/2022 and 06/26/2027

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
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 06/27/2022 and 06/26/2027

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 06/27/2022 and 06/26/2027

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 06/27/2022 and 06/26/2027

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...
Condition 5: Compliance Certification
Effective between the dates of 06/27/2022 and 06/26/2027

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,
the report shall be contained in the 6 month monitoring report required above.

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

If above paragraphs (1) or (2) are met, the source must notify the permitting authority by telephone during normal business hours at the Regional Office of jurisdiction for this permit, attention Regional Air Pollution Control Engineer (RAPCE) according to the timetable listed in paragraphs (1) and (2) of this section. For deviations and incidences that must be reported outside of normal business hours, on weekends, or holidays, the DEC Spill Hotline phone number at 1-800-457-7362 shall be used. A written notice, certified by a responsible official consistent with 6 NYCRR Part 201-6.2(d)(12), must be submitted within 10 working days of an occurrence for deviations reported under (1) and (2). All deviations reported under paragraphs (1) and (2) of this section must also be identified in the 6 month monitoring report required above.

The provisions of 6 NYCRR 201-1.4 shall apply if the permittee seeks to have a violation excused unless otherwise limited by regulation. In order to have a violation of a federal regulation (such as a new source performance standard or national emissions standard for hazardous air pollutants) excused, the specific federal regulation must provide for an affirmative defense during start-up, shutdowns, malfunctions or upsets. Notwithstanding any recordkeeping and reporting requirements in 6 NYCRR 201-1.4, reports of any deviations shall not be on a less frequent basis than the reporting periods described in paragraphs (1) and (4) above.

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

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

All semiannual reports 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 7/30/2022.
Subsequent reports are due every 6 calendar month(s).

**Condition 6: Compliance Certification**
Effective between the dates of 06/27/2022 and 06/26/2027

**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 – Air Compliance Branch
USEPA Region 2 DECA/ACB
290 Broadway, 21st Floor
New York, NY 10007

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
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 1/30/2023.
Subsequent reports are due on the same day each year

**Condition 7:** Compliance Certification
**Effective between the dates of 06/27/2022 and 06/26/2027**

**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 are to be electronically submitted and are required by any new or renewed Title V permits issued after January 1, 2021. The first reporting year under this provision will be the reporting year in which the permit was issued or reporting year 2025 (emission statements due in 2026), whichever is earlier.

Monitoring Frequency: ANNUALLY
Reporting Requirements: ANNUALLY (CALENDAR)
Reports due 0 days after the reporting period.
The initial report is due 4/15/2023.
Subsequent reports are due every 12 calendar month(s).

**Condition 8:** Recordkeeping requirements
**Effective between the dates of 06/27/2022 and 06/26/2027**

**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 06/27/2022 and 06/26/2027

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 06/27/2022 and 06/26/2027

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 06/27/2022 and 06/26/2027

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 06/27/2022 and 06/26/2027

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 06/27/2022 and 06/26/2027

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.

**Condition 14: Compliance Certification**  
**Effective between the dates of 06/27/2022 and 06/26/2027**

**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 06/27/2022 and 06/26/2027**

**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 06/27/2022 and 06/26/2027**

**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 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 17:** Right to Inspect
Effective between the dates of 06/27/2022 and 06/26/2027

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

**Item 17.1:**
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:** Accidental release provisions.
Effective between the dates of 06/27/2022 and 06/26/2027

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

**Item 18.1:**
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
Condition 19: Recycling and Emissions Reduction
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable Federal Requirement: 40 CFR 82, Subpart F

Item 19.1: The permittee shall comply with all applicable provisions of 40 CFR Part 82.

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

Condition 20: Emission Unit Definition
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable Federal Requirement: 6 NYCRR Subpart 201-6

Item 20.1: 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 20.2: The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000B
Emission Unit Description: Drying aqueous based pharmaceutical products using an aeromatic fluidized bed dryer. Emissions are exhausted through emission point 00003.

Building(s): 01

Item 20.3: The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000C
Emission Unit Description: Chemical storage room.
Item 20.4:
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 20.5:
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000F
Emission Unit Description:
Aqueous coating of pharmaceutical tablets. Particulate emissions are controlled by a dust collector exhausted to emission point 00021.

Building(s): 01

Item 20.6:
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 20.7:
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 20.8:
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 (0DC04) exhausted to emission point 00024.
Item 20.9:
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 (0DC05) exhausted to emission point 00025.
- Building(s): 01

Item 20.10:
The facility is authorized to perform regulated processes under this permit for:
- Emission Unit: 0-0000K
- Emission Unit Description:
  Chemical storage building.
- Building(s): 03

Item 20.11:
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 20.12:
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 (0DC16) and exhausted through Emission Point 00034.
- Building(s): 01

Item 20.13:
The facility is authorized to perform regulated processes under this permit for:
- Emission Unit: 0-0000N
- Emission Unit Description:
  Packaging lines A, D, E and F. Particulate emissions are controlled by dust collector DC-07 vented to EP00035.
Item 20.14:
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 20.15:
The facility is authorized to perform regulated processes under this permit for:
Emission Unit: 0-0000R
Emission Unit Description:
Activities associated with granulation rooms No. 2, No. 4 and No. 6A. Emission sources are a portable Fitzmill, a granulator, a blender and a sifter. Air is collected from each room, routed to separate in line HEPA filters, combined, and vented to a common dust collector to control particulate emissions prior to exiting through emission point 00043.

Building(s): 01

Item 20.16:
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 20.17:
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 (ACG) (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, ACG, 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 batchers.

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/POOD2 and COAT6/POOD3. This equipment can also operate in aqueous mode. When doing so, SCR01 and CA1RR are bypassed and emissions from COAT5/POOD2 exhaust via bypass vent EP00026; and COAT6/POOD3 exhaust via bypass vent EP00042.

AGC (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

**Item 20.18:**
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 (0PL-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 0PL-J.

Building(s): 01

**Condition 21:** Compliance Certification

*Effective between the dates of 06/27/2022 and 06/26/2027*

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

**Item 21.1:**
The Compliance Certification activity will be performed for the Facility.

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

**Item 21.2:**
Compliance Certification shall include the following monitoring:

- **Monitoring Type:** MONITORING OF PROCESS OR CONTROL DEVICE PARAMETERS AS SURROGATE
- **Monitoring Description:**
  The facility 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. All records used to determine compliance with the applicable limit(s) must be kept at the facility (or other Department approved location) for a minimum of five years.

Parameter Monitored: BATCHES  
Upper Permit Limit: 100 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 7/30/2022.  
Subsequent reports are due every 6 calendar month(s).

**Condition 22: Compliance Certification**  
Effective between the dates of 06/27/2022 and 06/26/2027

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

**Item 22.1:** The Compliance Certification activity will be performed for the Facility.

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

**Item 22.2:** Compliance Certification shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL DEVICE PARAMETERS AS SURROGATE  
Monitoring Description:  
The facility shall limit the acetone based production associated with Process P16, process equipment COAT4 and COAT7, fume hoods HOOD1 and HOOD4, and control equipment COND1 and COND2 to 65 commercial batches per year. All records used to determine compliance with the applicable limit(s) must be kept at the facility (or other Department approved location) for a minimum of five years.

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 7/30/2022.  
Subsequent reports are due every 6 calendar month(s).
Condition 23: Compliance Certification
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable Federal Requirement: 6 NYCRR Subpart 201-6

Item 23.1:
The Compliance Certification activity will be performed for the Facility.

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

Item 23.2:
Compliance Certification shall include the following monitoring:

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. All records used to determine compliance with the applicable limit(s) must be kept at the facility (or other Department approved location) for a minimum of five years.

Work Practice Type: PROCESS MATERIAL THRUPUT
Process Material: SOLVENT
Upper Permit Limit: 20 batches per year
Monitoring Frequency: MONTHLY
Averaging Method: ANNUAL MAXIMUMROLLED MONTHLY
Reporting Requirements: SEMI-ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 7/30/2022.
Subsequent reports are due every 6 calendar month(s).

Condition 24: Progress Reports Due Semiannually
Effective between the dates of 06/27/2022 and 06/26/2027

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

Item 24.1:
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 25: Operational Flexibility
Effective between the dates of 06/27/2022 and 06/26/2027

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

Item 25.1:
A permit modification is not required for changes that are provided for in the permit. Such changes include approved alternate operating scenarios and changes that have been submitted and approved pursuant to an established operational flexibility protocol and the requirements of this section. Each such change cannot be a modification under any provision of Title I of the Clean Air Act or exceed, or cause the facility to exceed, an emissions cap or limitation in the permit. The facility owner or operator must incorporate all changes into any compliance certifications, record keeping, and/or reporting required by the permit.

Condition 26: Facility Permissible Emissions
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable Federal Requirement: 6 NYCRR Subpart 201-7

Item 26.1:
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:

<table>
<thead>
<tr>
<th>CAS No: 000067-56-1</th>
<th>PTE: 19,000 pounds per year</th>
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<tbody>
<tr>
<td>Name: METHYL ALCOHOL</td>
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<table>
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<th>CAS No: 0NY100-00-0</th>
<th>PTE: 49,000 pounds per year</th>
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<tbody>
<tr>
<td>Name: TOTAL HAP</td>
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</tbody>
</table>

Condition 27: Capping Monitoring Condition
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable Federal Requirement: 6 NYCRR Subpart 201-7

Item 27.1:
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 27.2:
Operation of this facility shall take place in accordance with the approved criteria, emission limits, terms, conditions and standards in this permit.

Item 27.3:
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 27.4:
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 27.5:
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 27.6:
The Compliance Certification activity will be performed for the Facility.

Regulated Contaminant(s):
   CAS No: 000067-56-1 METHYL ALCOHOL

Item 27.7:
Compliance Certification shall include the following monitoring:

Capping: Yes
Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS
Monitoring Description:
The facility shall demonstrate that its emissions are equal to or below the 9.5 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. All records used to determine compliance with the applicable limit(s) must be kept at the facility (or other Department approved...
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 7/30/2022.  
Subsequent reports are due every 6 calendar month(s).

**Condition 28: Capping Monitoring Condition**  
**Effective between the dates of 06/27/2022 and 06/26/2027**

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

**Item 28.1:**  
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 28.2:**  
Operation of this facility shall take place in accordance with the approved criteria, emission limits, terms, conditions and standards in this permit.

**Item 28.3:**  
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 28.4:**  
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 28.5:**  
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 28.6:**  
The Compliance Certification activity will be performed for the Facility.
Regulated Contaminant(s):
   CAS No: 0NY100-00-0    TOTAL HAP

Item 28.7:
Compliance Certification shall include the following monitoring:

   Capping: Yes
Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS
Monitoring Description:
The facility shall demonstrate that its emissions are equal to or below the 24.5 tons per year of total HAPs based on a 12-month rolling average by maintaining records of all required measurements and emission calculations of individual HAP and total HAPs from coating, drying, 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. All records used to determine compliance with the applicable limit(s) must be kept at the facility (or other Department approved location) for a minimum of five years.

   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 7/30/2022.
Subsequent reports are due every 6 calendar month(s).

Condition 29: Required Emissions Tests - Facility Level
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable Federal Requirement:6 NYCRR 202-1.1

Condition 30: Visible Emissions Limited
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable Federal Requirement:6 NYCRR 211.2

Item 30.1:
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 31: Compliance Certification
Effective between the dates of 06/27/2022 and 06/26/2027

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

Item 31.1: The Compliance Certification activity will be performed for the Facility.

Item 31.2: 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 and 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.
All records used to determine compliance with the
applicable limit(s) must be kept at the facility (or other
Department approved location) for a minimum of five
years.

Parameter Monitored: OPACITY
Upper Permit Limit: 20 percent
Reference Test Method: EPA Method 9 as necessary
Monitoring Frequency: MONTHLY
Averaging Method: 6 MINUTE AVERAGE
Reporting Requirements: SEMI-ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 7/30/2022.
Subsequent reports are due every 6 calendar month(s).

Condition 32: Compliance Certification
Effective between the dates of 06/27/2022 and 06/26/2027

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

Item 32.1:
The Compliance Certification activity will be performed for the facility:
The Compliance Certification applies to:

Emission Unit: 0-0000T  Emission Point: 00040

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

**Item 32.2:**
Compliance Certification shall include the following monitoring:

Monitoring Type: CONTINUOUS EMISSION MONITORING (CEM)
Monitoring Description:
The facility 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. All records used to determine compliance with the applicable limit(s) must be kept at the facility (or other Department approved location) for a minimum of five years.

Manufacturer Name/Model Number: Riken Keiki GD-70D CEMS
Parameter Monitored: CONCENTRATION
Upper Permit Limit: 150  parts per million (by volume)
Reference Test Method: EPA Approved Method
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 7/30/2022.
Subsequent reports are due every 6 calendar month(s).

**Condition 33:  Compliance Certification**
**Effective between the dates of 06/27/2022 and 06/26/2027**

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

**Item 33.1:**
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: 0-0000I
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 33.2:**
Compliance Certification shall include the following monitoring:

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

**Monitoring Description:**
The dust collectors must not exceed a pressure drop of 6 inches of water. The facility operator is required to monitor and record the pressure drop across the dust collectors manually on a weekly basis, when in operation, to ensure compliance with the emission rate limit of 0.050 grains of particulates per cubic foot of exhaust gas, expressed at standard conditions on a dry gas basis.

The facility owner or operator must notify the Department if the pressure drop exceeds the permitted limit. Formal notification shall include:
- date and time
- pressure drop value
- any issues found resulting in exceedance
- correction action taken

All records used to determine compliance must be kept at the facility (or other Department approved location) for a minimum of five years.
Parameter Monitored: PRESSURE DROP  
Upper Permit Limit: 6 inches of water  
Monitoring Frequency: WEEKLY  
Averaging Method: MAXIMUM - NOT TO EXCEED STATED VALUE - SEE MONITORING DESCRIPTION  
Reporting Requirements: SEMI-ANNUALLY (CALENDAR)  
Reports due 30 days after the reporting period.  
The initial report is due 7/30/2022.  
Subsequent reports are due every 6 calendar month(s).

**Condition 34: Compliance Certification**  
Effective between the dates of 06/27/2022 and 06/26/2027  

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

**Item 34.1:**  
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: 0-0000I  
- 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 34.2:**
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 facility is required to monitor and record the pressure drop across the dust collectors manually on a weekly basis when in operation to ensure compliance with this emission rate limit. The Department has the right to require further testing, if deemed necessary.

If required to test, the facility 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 within 60 days after the completion of compliance testing.

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. All records used to determine compliance with the applicable limit(s) must be kept at the facility (or other Department approved location) for a minimum of five years.

**Upper Permit Limit:** 0.050 grains per dscf
**Reference Test Method:** EPA Reference Method 5
**Monitoring Frequency:** UPON REQUEST OF REGULATORY AGENCY
**Averaging Method:** 1-HOUR AVERAGE
**Reporting Requirements:** AS REQUIRED - SEE MONITORING DESCRIPTION

**Condition 35:** Compliance Certification

Effective between the dates of 06/27/2022 and 06/26/2027

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

**Item 35.1:**
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
Regulated Contaminant(s):
CAS No: 0NY998-00-0   VOC

Item 35.2:
Compliance Certification shall include the following monitoring:

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

Monitoring Description:
The scrubbers must be operated within a water flow rate range of 14 to 20 gallons per minute. The facility operator is required to monitor and record the flow rate manually on a weekly basis, when in operation, to ensure compliance with the VOC capture and control efficiency of at least 81 percent.

The facility owner or operator must notify the Department if the flow rate is not within the permitted range. Formal notification shall include:
- date and time
- flow rate value
- any issues found
- correction action taken

All records used to determine compliance must be kept at the facility (or other Department approved location) for a minimum of five years.

Parameter Monitored: FLOW RATE
Lower Permit Limit: 14   gallons per minute
Upper Permit Limit: 20   gallons per minute
Monitoring Frequency: WEEKLY
Averaging Method: RANGE - NOT TO FALL OUTSIDE OF STATED RANGE AT ANY TIME
Reporting Requirements: SEMI-ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 7/30/2022.
Subsequent reports are due every 6 calendar month(s).

Condition 36:   Compliance Certification
Effective between the dates of  06/27/2022 and 06/26/2027

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

Item 36.1:
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 36.2:**
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. The facility shall maintain a capture system and a control device with an overall removal efficiency of at least 81 percent.

The facility shall monitor and record the scrubber water flow rate manually on a weekly basis when in operation. The Department has the right to require further testing, if deemed necessary.

If required to test, the facility 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 within 60 days after the completion of compliance testing.

All records used to determine compliance with the applicable limit(s) must be kept at the facility (or other Department approved location) for a minimum of five years.

Lower Permit Limit: 81 percent
Reference Test Method: EPA Reference Method 25
Monitoring Frequency: UPON REQUEST OF REGULATORY AGENCY
Averaging Method: 1-HOUR BLOCK AVERAGE
Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

**Condition 37:** Compliance Certification
Effective between the dates of 06/27/2022 and 06/26/2027

**Applicable Federal Requirement:** 6 NYCRR 225-1.2 (d)
Item 37.1:
The Compliance Certification activity will be performed for the Facility.

Item 37.2:
Compliance Certification shall include the following monitoring:

Monitoring Type: WORK PRACTICE INVOLVING SPECIFIC OPERATIONS
Monitoring Description:
Owners or operators of emission sources that fire distillate oil are limited to a 0.0015 percent sulfur content by weight of the fuel. Compliance with the sulfur-in-fuel limitation is based on fuel vendor receipts. All fuel vendor receipts must be maintained on site or at a Department approved alternative location for a minimum of five years.

Note - Process sources and incinerators must comply with the above requirements on or after July 1, 2023.

Work Practice Type: PARAMETER OF PROCESS MATERIAL
Process Material: DISTILLATES - NUMBER 1 AND NUMBER 2 OIL
Parameter Monitored: SULFUR CONTENT
Upper Permit Limit: 0.0015 percent by weight
Monitoring Frequency: PER DELIVERY
Averaging Method: MAXIMUM - NOT TO BE EXCEEDED AT ANY TIME (INSTANTANEOUS/DISCRETE OR GRAB)
Reporting Requirements: SEMI-ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 7/30/2022.
Subsequent reports are due every 6 calendar month(s).

**** Emission Unit Level ****

Condition 38: Emission Point Definition By Emission Unit
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable Federal Requirement: 6 NYCRR Subpart 201-6

Item 38.1:
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
Item 38.2:
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000B
Emission Point: 00003
Height (ft.): 14
Length (in.): 24
Width (in.): 30
NYTMN (km.): 4548.171
NYTME (km.): 579.551
Building: 01

Item 38.3:
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 38.4:
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 38.5:
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 38.6:
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 38.7:
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 38.8:
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 38.9:
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 38.10:
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 38.11:
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 38.12:
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 38.13:
The following emission points are included in this permit for the cited Emission Unit:
Item 38.14:
The following emission points are included in this permit for the cited Emission Unit:

Emission Unit: 0-0000N

Emission Point: 00035
Height (ft.): 30 Diameter (in.): 9
NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01

Item 38.15:
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 38.16:
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 38.17:
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

Emission Point: 00045
Height (ft.): 31 Diameter (in.): 20
NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01

Emission Point: 00046
Height (ft.): 31 Diameter (in.): 20
NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01

Emission Point: 00047
Height (ft.): 31 Diameter (in.): 20
NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01

Emission Point: 00048
Height (ft.): 31 Diameter (in.): 20
NYTMN (km.): 4548.171 NYTME (km.): 579.551 Building: 01

Emission Point: 00008
Item 38.18:
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
Building: 01
Condition 39: Process Definition By Emission Unit
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable Federal Requirement: 6 NYCRR Subpart 201-6

Item 39.1:
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000A
Process: D01Source 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 39.2:
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000B
Process: D02Source Classification Code: 3-01-060-09
Process Description: Drying aqueous based pharmaceutical products.

Emission Source/Control: FBD01 - Process

Item 39.3:
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000C
Process: S01Source Classification Code: 3-01-060-10
Process Description: Chemical Storage.

Emission Source/Control: CHEM1 - Process

Item 39.4:
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000E
Process: P01Source 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 39.5:
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000F
Process: P02Source 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 39.6:**
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 39.7:**
This permit authorizes the following regulated processes for the cited Emission Unit:

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

Emission Source/Control: FUG01 - Process

**Item 39.8:**
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 39.9:**
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 39.10:**
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 39.11:**
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 39.12:**
This permit authorizes the following regulated processes for the cited Emission Unit:

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

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

**Item 39.13:**
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 39.14:**
This permit authorizes the following regulated processes for the cited Emission Unit:

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

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

Emission Source/Control: 0PL-B - Process

Emission Source/Control: 0PL-C - Process

Emission Source/Control: PL-BL - Process

**Item 39.15:**
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 39.16:**
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 39.17:**
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 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 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 39.18:**
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000T  
Process: D04  
Source Classification Code: 3-01-060-09
Process Description:
Drying ovens #283 (DRY06), #284 (DRY07), and #285 (DRY08) when operating in aqueous mode. Emissions will exhaust through the following emission points: DRY06 to EP00008, DRY07 to EP00009, DRY08 to EP00010.

Emission Source/Control: DRY06 - Process
Emission Source/Control: DRY07 - Process
Emission Source/Control: DRY08 - Process

Item 39.19:
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:
Operation of the following equipment in solvent mode utilizing isopropyl alcohol and/or ethanol or methanol:

The 48" Accela-Cota Tablet Coater (COAT4), two Glatt GPCG-60 coater/granulation/dryer units (COAT5 & COAT6), and one ACG Fluid Bed Dryer (FBD) (COAT8), each with a dedicated fume hood used to dispense raw materials (HOOD1/COAT4, HOOD2/COAT5, HOOD3/COAT6, and HOOD5/COAT8).

Methanol is also used in the two Glatts and associated fume hoods (COAT5/HOOD2 and COAT6/HOOD3).

All equipment is used in pharmaceutical production and/or research & development purposes. All equipment can be used in solvent mode (VOCs). COAT5/HOOD2 and COAT6/HOOD3 can use methanol (HAP) in addition to VOC.

Particulate emissions from COAT4, COAT5, COAT6, and COAT8 are controlled by dust collectors (DC-11, DC-12 [internal], DC-13 [internal], and DC-19 [internal], respectively) before being manifolded to its dedicated fume hood and directed to VOC control.

VOC emissions are controlled by a wet scrubber or the carbon absorption system as follows: COAT4/HOOD1 to CAIRR (EP00040); COAT5/HOOD2 to SCR01 (EP00005) or CAIRR (EP00040) as a backup; COAT6/HOOD3 to SCR01 (EP00005) or CAIRR (EP00040) as a backup, and COAT8/HOOD5 to SCR03 (EP00007).

Methanol emissions are controlled as follows: COAT5/HOOD2 to CAIRR (EP00040) and COAT6/HOOD3 to CAIRR (EP00040).
Emission Source/Control:   CA1RR - Control
Control Type: ACTIVATED CARBON ADSORPTION

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

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

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

Emission Source/Control:   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:   COAT8 - Process

Emission Source/Control:   HOOD1 - Process

Emission Source/Control:   HOOD2 - Process

Emission Source/Control:   HOOD3 - Process

Emission Source/Control:   HOOD5 - Process

**Item 39.20:**
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit:    0-0000T  Source Classification Code: 3-01-060-11
Process: P08  Process Description:
A Glatt GPCG-60 coater/granulation/dryer units (COAT5) with a dedicated fume hood (HOOD2) used to dispense raw materials operates in aqueous mode.

Particulate emissions from COAT5 are controlled by an internal dust collector (DC-12) before being manifolded to HOOD2 and vented to atmosphere (EP00026).
Emission Source/Control:   DC-12 - Control  
Control Type: DUST COLLECTOR

Emission Source/Control:   COAT5 - Process

Emission Source/Control:   HOOD2 - Process

**Item 39.21:**
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:
A 48" Accela-Cota Tablet Coater (COAT4) with a dedicated fume hood (HOOD1) used to dispense raw materials operates in aqueous mode.

Particulate emissions from COAT4 are controlled by an external dust collector (DC-11) before being manifolded to HOOD1 and vented to atmosphere (EP00041).

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

Emission Source/Control:   COAT4 - Process

Emission Source/Control:   HOOD1 - Process

**Item 39.22:**
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:
A Glatt GPCG-60 coater/granulation/dryer units (COAT6) with a dedicated fume hood (HOOD3) used to dispense raw materials operates in aqueous mode.

Particulate emissions from COAT6 are controlled by an internal dust collector (DC-13) before being manifolded to HOOD3 and vented to atmosphere (EP00042).

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

Emission Source/Control:   COAT6 - Process

Emission Source/Control:   HOOD3 - Process

**Item 39.23:**
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:
A 60" Accela-Cota Tablet Coater (COAT7) with a dedicated fume hood (HOOD4) used to dispense raw materials operates in aqueous mode.

Particulate emissions from COAT7 are controlled by an external dust collector (DC-18) before being manifolded to HOOD4 and vented to atmosphere (EP00047).

Emission Source/Control: DC-18 - Control  
Control Type: DUST COLLECTOR

Emission Source/Control: COAT7 - Process

Emission Source/Control: HOOD4 - Process

**Item 39.24:**
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:
An ACG Fluid Bed Dryer (FBD) (COAT8) with a dedicated fume hood (HOOD5) used to dispense raw materials operates in aqueous mode.

Particulate emissions from COAT8 are controlled by an internal dust collector (DC-19) before being manifolded to HOOD5 and vented to atmosphere (EP00048).

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

Emission Source/Control: COAT8 - Process

Emission Source/Control: HOOD5 - Process

**Item 39.25:**
This permit authorizes the following regulated processes for the cited Emission Unit:

Emission Unit: 0-0000T  
Process: P16  
Source Classification Code: 3-01-060-99

Process Description:
Operation of the following equipment when utilizing acetone:

The 48" (COAT4) and 60" (COAT7) Accela-Cota Tablet Coaters, each with a dedicated fume hood used to dispense raw materials (HOOD1/COAT4, and HOOD4/COAT7).
COAT4/HOOD1 & COAT7/HOOD4 will not operate at the same time when processing acetone batches.

Particulate emissions from COAT4 & COAT7 are controlled by dust collectors (DC-11, & DC-18, respectively) before being manifolded to its dedicated fume hood & directed to acetone control.

Acetone emissions are controlled by condensers as follows: COAT4/HOOD1 to COND1(EP00045) & COAT7/HOOD4 to COND2 (EP00046).

Item 39.26:
This permit authorizes the following regulated processes for the cited Emission Unit:

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-18 - Control
Control Type: DUST COLLECTOR

Emission Source/Control:   COAT4 - Process

Emission Source/Control:   COAT7 - Process

Emission Source/Control:   HOOD1 - Process

Emission Source/Control:   HOOD4 - Process

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 (0PL-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 0PL-J.

Emission Source/Control:   DC-20 - Control
Control Type: DUST COLLECTOR
Emission Source/Control: 0PL-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 40:** Emission Unit Permissible Emissions
Effective between the dates of 06/27/2022 and 06/26/2027

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

**Item 40.1:**
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: 0NY100-00-0
Name: TOTAL HAP
PTE(s): 2.8 pounds per hour

110.3 pounds per year
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 in 6 NYCRR 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 demonstrate, 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 facility was being properly operated and maintained;
   (3) during the period of the emergency the facility owner or operator took all reasonable steps to minimize the 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 any 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 malfunction 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 41: Contaminant List
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable State Requirement:ECL 19-0301

Item 41.1:
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 42: Malfunctions and Start-up/Shutdown Activities
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable State Requirement:6 NYCRR 201-1.4
Item 42.1:
(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 maintenance and start-up/shutdown activities when they are expected to result in an exceedance of any applicable emission standard, and shall submit a report of such activities to the department when required by a permit condition or upon request by the department. Such reports shall state whether an exceedance occurred and if it was unavoidable, include the time, frequency and duration of the exceedance, 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 monitoring and quarterly reporting requirements need not submit additional reports of exceedances to the department.

(c) In the event that air contaminant emissions exceed any applicable emission standard due to a malfunction, the facility owner or operator shall 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. In addition, the facility owner or operator shall compile and maintain a record of all malfunctions. Such records shall be maintained at the facility for a period of at least five years and must be made available to the department upon request. 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, the air contaminants emitted, and the resulting emission rates and/or opacity.

(d) The department may also require the facility 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 43: CLCPA Applicability
Effective between the dates of 06/27/2022 and 06/26/2027

Applicable State Requirement: 6 NYCRR 201-6.5 (a)

Item 43.1:
Pursuant to The New York State Climate Leadership and Community Protection Act (CLCPA) and Article 75 of the Environmental Conservation Law, emission sources shall comply with regulations to be promulgated by the Department to ensure that by 2030 statewide greenhouse
gas emissions are reduced by 40% of 1990 levels, and by 2050 statewide greenhouse gas emissions are reduced by 85% of 1990 levels.

**Condition 44:** Air pollution prohibited

Effective between the dates of 06/27/2022 and 06/26/2027

Applicable State Requirement: 6 NYCRR 211.1

**Item 44.1:**
No person shall cause or allow emissions of air contaminants to the outdoor atmosphere of such quantity, characteristic or duration which are injurious to human, plant or animal life or to property, or which unreasonably interfere with the comfortable enjoyment of life or property. Notwithstanding the existence of specific air quality standards or emission limits, this prohibition applies, but is not limited to, any particulate, fume, gas, mist, odor, smoke, vapor, pollen, toxic or deleterious emission, either alone or in combination with others.

**Condition 45:** Compliance Demonstration

Effective between the dates of 06/27/2022 and 06/26/2027

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

**Item 45.1:**
The Compliance Demonstration activity will be performed for the facility:
The Compliance Demonstration applies to:

<table>
<thead>
<tr>
<th>Emission Unit: 0-0000T</th>
<th>Emission Point: 00045</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process: P16</td>
<td></td>
</tr>
</tbody>
</table>

Regulated Contaminant(s):

| CAS No: 000067-64-1 | DIMETHYL KETONE |

**Item 45.2:**
Compliance Demonstration shall include the following monitoring:

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

Monitoring Description:

Condenser 1 (COND1) must not exceed a coolant exit temperature of -18 degrees Fahrenheit. The facility operator is required to monitor and record the coolant exit temperature manually on a weekly basis, when in operation, to ensure compliance with a capture system and a control device with an overall removal efficiency of at least 77 percent.

The facility owner or operator must notify the Department if the coolant exit temperature exceeds the permitted limit. Formal notification shall include:
- date and time
Parameter Monitored: TEMPERATURE
Upper Permit Limit: -18 degrees Fahrenheit
Monitoring Frequency: WEEKLY
Averaging Method: MAXIMUM - NOT TO EXCEED STATED VALUE - SEE MONITORING DESCRIPTION
Reporting Requirements: SEMI-ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 7/30/2022.
Subsequent reports are due every 6 calendar month(s).

Condition 46: Compliance Demonstration
Effective between the dates of 06/27/2022 and 06/26/2027

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

Item 46.1:
The Compliance Demonstration activity will be performed for the facility:
The Compliance Demonstration applies to:

Emission Unit: 0-0000T
Emission Point: 00046
Process: P16

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

Item 46.2:
Compliance Demonstration shall include the following monitoring:

Monitoring Type: MONITORING OF PROCESS OR CONTROL DEVICE PARAMETERS AS SURROGATE
Monitoring Description:
Condenser 2 (COND2) must not exceed a coolant exit temperature of -15 degrees Fahrenheit. The facility operator is required to monitor and record the coolant exit temperature manually on a weekly basis, when in operation, to ensure compliance with a capture system and a control device with an overall removal efficiency of at least 75 percent.

The facility owner or operator must notify the Department if the coolant exit temperature exceeds the permitted limit. Formal notification shall include:
- date and time
- coolant exit temperature
- any issues found resulting in exceedance
- correction action taken

All records used to determine compliance must be kept at the facility (or other Department approved location) for a minimum of five years.

Parameter Monitored: TEMPERATURE
Upper Permit Limit: -15 degrees Fahrenheit
Monitoring Frequency: WEEKLY
Averaging Method: MAXIMUM - NOT TO EXCEED STATED VALUE - SEE MONITORING DESCRIPTION
Reporting Requirements: SEMI-ANNUALLY (CALENDAR)
Reports due 30 days after the reporting period.
The initial report is due 7/30/2022.
Subsequent reports are due every 6 calendar month(s).

**Condition 47: Compliance Demonstration**
**Effective between the dates of 06/27/2022 and 06/26/2027**

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

**Item 47.1:**
The Compliance Demonstration activity will be performed for the facility:
The Compliance Demonstration applies to:

- Emission Unit: 0-0000T
- Emission Point: 00046
- Process: P16

Regulated Contaminant(s):

- CAS No: 000067-64-1 DIMETHYL KETONE

**Item 47.2:**
Compliance Demonstration shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING
Monitoring Description:
For the removal of acetone associated with Process P16 (process equipment COAT7/HOOD4) and control equipment (COND2/DC-18), the facility shall maintain a capture and control system with an overall removal efficiency of at least 75 percent.

The facility shall monitor and record coolant exit temperature manually on a weekly basis when in operation. The Department has the right to require further testing, if deemed necessary.

If required to test, the facility 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 within 60 days after the completion of compliance testing.

All records used to determine compliance with the applicable limit(s) must be kept at the facility (or other Department approved location) for a minimum of five years.

Lower Permit Limit: 75 percent
Reference Test Method: EPA Method 25
Monitoring Frequency: UPON REQUEST OF REGULATORY AGENCY
Averaging Method: 1-HOUR AVERAGE
Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION

Condition 48: Compliance Demonstration
Effective between the dates of 06/27/2022 and 06/26/2027

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

Item 48.1:
The Compliance Demonstration activity will be performed for the facility:
The Compliance Demonstration applies to:

Emission Unit: 0-0000T Emission Point: 00045
Process: P16

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

Item 48.2:
Compliance Demonstration shall include the following monitoring:

Monitoring Type: INTERMITTENT EMISSION TESTING
Monitoring Description:
For the removal of acetone associated with Process P16 (process equipment COAT4/HOOD1) and control equipment (COND1/DC-11), the facility shall maintain a capture and control system with an overall removal efficiency of at least 77 percent.

The facility shall monitor and record coolant exit temperature manually on a weekly basis when in operation. The Department has the right to require further testing, if deemed necessary.

If required to test, the facility 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 within 60 days after the completion of compliance testing.
All records used to determine compliance with the applicable limit(s) must be kept at the facility (or other Department approved location) for a minimum of five years.

Lower Permit Limit: 77 percent
Reference Test Method: EPA Method 25
Monitoring Frequency: UPON REQUEST OF REGULATORY AGENCY
Averaging Method: 1-HOUR AVERAGE
Reporting Requirements: AS REQUIRED - SEE MONITORING DESCRIPTION