

19 December 2014

Ms. Pamela Patrick  
Vice President Operations  
Denison Pharmaceuticals LLC  
1 Powder Hill Road  
Lincoln, RI 02865

Dear Ms. Patrick:

The Department of Environmental Management, Office of Air Resources has reviewed and approved your request for a minor source permit for process equipment at your 1 Powder Hill Road, Lincoln, Rhode Island location.

Enclosed is a minor source permit issued pursuant to our review (Approval No. 2273).

Any source with the potential to emit greater than major source thresholds as defined under Air Pollution Control Regulation No. 29, "Operating Permits" is subject to the Operating Permit Program. Your facility is currently subject to the Operating Permit Program as an Emissions Cap Source, with allowable emissions restricted to below the major source threshold. An emissions cap means any emission limitation or physical or operational limitation, imposed in a federally enforceable document that establishes the maximum quantity of emissions which may be released from a stationary source. The Office of Air Resources considers this minor source permit an emissions cap. Air Pollution Control Regulation No. 28, "Operating Permit Fees" requires stationary sources with an emissions cap to pay an annual compliance/assurance fee of \$350.00. Notification concerning the payment of this fee will typically be mailed to you during the fall of each year.

If there are any questions concerning this permit, please contact me at 401-222-2808, extension 7177 or at [kasandra.mckenzie@dem.ri.gov](mailto:kasandra.mckenzie@dem.ri.gov).

Sincerely,

Kasandra McKenzie, EIT  
Air Quality Specialist  
Office of Air Resources

cc: Lincoln Building Official

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS  
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
OFFICE OF AIR RESOURCES

MINOR SOURCE PERMIT

*DENISON PHARMACEUTICALS LLC*

APPROVAL NO. 2273

Pursuant to the provisions of Air Pollution Control Regulation No. 9, this minor source permit is issued to:

*Denison Pharmaceuticals LLC*

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For the following:

*Installation of process and ancillary equipment for the production of pharmaceuticals.*

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Located at: *1 Powder Hill Road, Lincoln, RI*

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**This permit shall be effective from the date of its issuance and shall remain in effect until revoked by or surrendered to the Department. This permit does not relieve *Denison Pharmaceuticals LLC* from compliance with applicable state and federal air pollution control rules and regulations. The design, construction and operation of this equipment shall be subject to the attached permit conditions and emission limitations.**

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Douglas L. McVay, Chief  
Office of Air Resources

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Date of issuance

**STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS  
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
OFFICE OF AIR RESOURCES**

Permit Conditions and Emission Limitations

**DENISON PHARMACEUTICALS LLC**

**APPROVAL NO. 2273**

A. Emission Standards

1. Isopropyl Alcohol (IPA)

The total quantity of Isopropyl Alcohol (IPA) emissions discharged to the atmosphere from the entire facility shall not exceed 25.86 pounds per hour.

2. Phenol

The total quantity of Phenol emissions discharged to the atmosphere from the entire facility shall not exceed:

- a. 0.69 pounds per hour.
- b. 6,044 pounds in any consecutive 12-month period.

3. Formaldehyde

The total quantity of Formaldehyde emissions discharged to the atmosphere from the entire facility shall not exceed:

- a. 0.43 pounds per hour.
- b. 10.32 pounds per day.
- c. 86.21 pounds in any consecutive 12-month period.

4. Volatile Organic Compounds (VOCs)

The total quantity of VOC emissions discharged to the atmosphere from the entire facility shall not exceed 8,167 pounds of VOC per calendar month based upon a 12-month rolling average.

5. Hazardous Air Pollutants (HAPs)

The total quantity of HAP emissions discharged to the atmosphere from the entire facility shall not exceed 1,500 pounds of any one (1) HAP or 4,000 pounds of any combination of HAPs per calendar month based upon a 12-month rolling average.

Hazardous Air Pollutant shall mean an air pollutant which has been listed pursuant to Section 112(b) of the Clean Air Act Amendments of 1990.

6. Listed Toxic Air Contaminants

The total quantity of emissions discharged to the atmosphere from the entire facility, of any Listed Toxic Air Contaminant, with the exception of isopropyl alcohol, phenol and formaldehyde, shall not exceed the minimum quantity for that contaminant as specified in Appendix A of Air Pollution Control Regulation No. 9, during a calendar year. Emissions from activities exempted from the provisions of APC Regulation No. 22 in subsection 22.2.2 are not included in this limitation.

7. Opacity

Visible emissions from the facility shall not exceed 10% opacity (six-minute average). Where the presence of uncombined water is the only reason for failure to meet this requirement, such failure shall not be a violation of this requirement.

8. Odors

Any air contaminant or combination of air contaminants discharged to the atmosphere from the facility shall not create an objectionable odor beyond the property line of this facility. Odor evaluations shall be conducted according to the provisions of Air Pollution Control Regulation No. 17.

B. Operating Requirements

1. An initial compliance certification plan, that meets the requirements of Subsection 26.7.1 of Air Pollution Control Regulation No. 26, shall be submitted to the Office of Air Resources within 90 days of issuance of this permit approval.
2. A final compliance certification, that meets the requirements of Subsection 26.7.2 of Air Pollution Control Regulation No. 26, shall be submitted to the Office of Air Resources within 180 days of issuance of this permit approval.
3. A leak detection and repair (LDAR) program, that meets the requirements of Subsection 26.3.6 of RI Air Pollution Control Regulation No. 26, for any equipment listed under Subsection 26.2.1 (a) through (k) which is a source of volatile organic compounds, shall be submitted to the Office of Air Resources within 90 days of issuance of this permit approval. The LDAR program shall be implemented no later than 180 days after issuance of this permit approval.
4. The facility shall utilize good management practices to minimize the use of isopropyl alcohol for vessel cleaning purposes, in accordance with pharmaceutical industry standards and requirements.
5. The owner or operator shall install covers on all in-process tanks that contain VOC at any time. These covers shall be constructed of a nonporous or nonabsorbent material and form a tight seal with the sides of the tank and have no gaps or holes.

These covers shall remain closed at all times except when production, sampling, maintenance, or inspection procedures require operator access.

C. Record Keeping and Reporting

1. The owner/operator shall maintain the following records:
  - a. The types and amounts of VOCs, HAPs, and Listed Toxic Air Contaminants used in each batch product.
  - b. The number of batches per month for each product, the emissions per batch, and the batch duration in hours.
  - c. Calculations used to determine the VOC, HAP and Listed Toxic Air Contaminant emissions from each product.
  - d. The amount of isopropyl alcohol used each day for Large Vessel Cleaning, COOP Room cleaning, and Lee 50 dispensing.
2. For each new product produced, the owner/operator shall prepare and maintain the following information for review by the Office of Air Resources upon request:
  - a. The raw material content, including VOCs, HAPs and Listed Toxic Air Contaminants of the product.
  - b. The batch size, mixing temperature and batch duration in hours.
  - c. The emissions associated with the product on a pounds per batch basis.
  - d. The emissions associated with the product on an annual potential-to-emit basis.
  - e. If the annual potential-to-emit as determined in Condition C.2.d for any Listed Air Toxic Contaminant exceeds the minimum quantity for that contaminant as specified in Appendix A of Air Pollution Control Regulation No. 9, with the exception of IPA, phenol and formaldehyde, the owner/operator shall notify the Office of Air Resources, in writing, within 15 days.
3. The owner/operator shall, on a monthly basis, no later than 15 days after the first of the month, determine the total quantity of IPA, phenol and formaldehyde discharged to the atmosphere from the entire facility during the previous month. Hourly emission averages shall be calculated for IPA, phenol and formaldehyde. These hourly averages shall be used for comparison to hourly emission limitations. Daily emission totals shall be calculated for Phenol. Monthly and 12-month rolling averages shall be calculated for Phenol and Formaldehyde. The owner/operator shall keep records of this determination and provide such records to the Office of Air Resources upon request.

4. The owner/operator shall notify the Office of Air Resources in writing, within 15 days of determining that the total quantity of IPA emissions discharged to the atmosphere from the entire facility exceeds 25.86 pound per hour.
5. The owner/operator shall notify the Office of Air Resources in writing, within 15 days of determining that the total quantity of phenol missions discharged to the atmosphere from the entire facility exceeds 0.69 pound per hour and/or 6,044 pounds in any consecutive 12-month period.
6. The owner/operator shall notify the Office of Air Resources in writing, within 15 days of determining that the total quantity of formaldehyde emissions discharged to the atmosphere from the entire facility exceeds 0.43 pound per hour, 10.32 pounds per day, and/or 86.21 pounds in any consecutive 12-month period.
7. The owner/operator shall, on a monthly basis, no later than 15 days after the first of the month, determine the total quantity of VOC emissions discharged to the atmosphere from all operations at the entire facility. Monthly and 12-month rolling averages shall be calculated. The 12-month rolling average shall be used for comparison with emission limitations. The owner/operator shall keep records of this determination and provide such records to the Office of Air Resources upon request.
8. The owner/operator shall notify the Office of Air Resources in writing, within 15 days of determining that the total quantity of VOCs discharged to the atmosphere from all operations at this facility exceeds 8,167 pounds per calendar month (12-month rolling average).
9. The owner/operator shall, on a monthly basis, no later than 15 days after the first of the month, determine the total quantity of HAP emissions discharged to the atmosphere from all operations at the entire facility. Monthly and 12-month rolling averages shall be calculated. The 12-month rolling average shall be used for comparison with emission limitations. The owner/operator shall keep records of this determination and provide such records to the Office of Air Resources upon request.
10. The owner/operator shall notify the Office of Air Resources in writing, within 15 days of determining that the total quantity of HAPs discharged to the atmosphere from all operations at this facility exceeds 1,500 pounds of any single HAP or 4,000 pounds of any combination of HAPs per calendar month (12-month rolling average).
11. The owner/operator shall, for each calendar year, determine the total quantity of each Listed Toxic Air Contaminant in Appendix A of Air Pollution Control Regulation No. 9 discharged to the atmosphere from all operations for the entire facility with the exception of IPA, phenol and formaldehyde. The owner/operator shall keep records of this determination and provide such records to the Office of Air Resources upon request.

12. The owner/operator shall notify the Office of Air Resources in writing, within 15 days of determining that the total quantity of emissions discharged to the atmosphere from the entire facility, of any Listed Toxic Air Contaminant, with the exception of IPA, phenol and formaldehyde, exceeds the minimum quantity for that contaminant as specified in Appendix A of Air Pollution Control Regulation No. 9.
13. For any leak detected pursuant to the LDAR program, the owner/operator shall record the following information:
  - a. The name of the leaking equipment;
  - b. The date and time the leak is detected;
  - c. The action taken to repair the leak;
  - d. The date and time the leak is repaired.
14. For any leak inspection conducted pursuant to the LDAR program during which no leaks are detected, the owner/operator shall record the following information:
  - a. A record that the inspection was performed;
  - b. The date and time of the inspection;
  - c. A statement that no leaks were detected
15. The owner/operator shall notify the Office of Air Resources in writing of any planned physical or operational change to any equipment that would:
  - a. Change the representation of the facility in the application.
  - b. Alter the applicability of any state or federal air pollution rules or regulations.
  - c. Result in the violation of any terms or conditions of this permit.
  - d. Qualify as a modification under APC Regulation No. 9.

Such notification shall include:

- Information describing the nature of the change.
- Information describing the effect of the change on the emission of any air contaminant.
- The scheduled completion date of the planned change.

Any such change shall be consistent with the appropriate regulation and have the prior approval of the Director.

16. The owner/operator shall notify the Office of Air Resources of any anticipated noncompliance with the terms of this permit or any other applicable air pollution control rules and regulations.
17. The owner/operator shall notify the Office of Air Resources, in writing, of any noncompliance with the terms of this permit within 30 calendar days of becoming aware of such occurrence and supply the Director with the following information:
  - a. The name and location of the facility;
  - b. The subject source(s) that caused the noncompliance with the permit term;
  - c. The time and date of first observation of the incident of noncompliance;
  - d. The cause and expected duration of the incident of noncompliance;
  - e. The estimated rate of emissions (expressed in lbs/hr or lbs/day) during the incident and the operating data and calculations used in estimating the emission rate.
  - f. The proposed corrective actions and schedule to correct the conditions causing the incidence of noncompliance.
18. All records required in this permit shall be maintained for a minimum of five years after the date of each record and shall be made available to representatives of the Office of Air Resources upon request.

D. Other Permit Conditions

1. To the extent consistent with the requirements of this permit and applicable federal and state laws, the facility shall be designed, constructed and operated in accordance with the representation of the facility in the permit application.
2. The emission and dispersion characteristics of all sources of isopropyl alcohol, phenol and formaldehyde at the facility shall be consistent with the parameters used in the air quality modeling to demonstrate that the emissions of isopropyl alcohol, phenol and formaldehyde do not cause an impact, at or beyond the property line of the facility, which exceeds the Acceptable Ambient Level for that substance. The Office of Air Resources, in its sole discretion, may reopen this minor source permit if it determines that the emission and dispersion characteristics have changed significantly and that emission limitations must be revised and/or added to this permit to ensure compliance with Air Pollution Control Regulation No. 22.
3. Employees of the Office of Air Resources and its authorized representatives shall be allowed to enter the facility at all times for the purpose of inspecting any air



pollution source, investigation any condition it believes may be causing air pollution or examining any records required to be maintained by the Office of Air Resources.

4. At all times, including periods of startup, shutdown and malfunction, the owner/operator shall, to the extent practicable, maintain and operate the facility in a manner consistent with good air pollution control practice for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by this permit have been achieved. Determination of whether acceptable operating and maintenance procedures are being used will be based on information available to the Office of Air Resources, which may include, but is not limited to, monitoring results, opacity observations, review of operating and maintenance procedures and inspection of the source.

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