

**AIR EMISSION PERMIT NO. 07700010-003
Major Amendment**

IS ISSUED TO

ANI Pharmaceuticals Incorporated

ANI PHARMACEUTICALS INC.
210 Main Street West
Baudette, Lake of the Woods County, Minnesota 56623

The emission units, control equipment and emission stacks at the stationary source authorized in this permit amendment are as described in the Permit Applications Table.

This permit amendment supersedes Air Emission Permit No. 07700010-002, and authorizes the Permittee to operate and modify the stationary source at the address listed above unless otherwise noted in Table A. The Permittee must comply with all the conditions of the permit. Any changes or modifications to the stationary source must be performed in compliance with Minn. R. 7007.1150 to 7007.1500. Terms used in the permit are as defined in the state air pollution control rules unless the term is explicitly defined in the permit.

Unless otherwise indicated, all the Minnesota rules cited as the origin of the permit terms are incorporated into the SIP under 40 CFR § 52.1220, and as such as are enforceable by U.S. Environmental Protection Agency (EPA) Administrator or citizens under the Clean Air Act.

Permit Type: State; Limits to Avoid Part 70/True Minor for NSR

Operating Permit Issue Date: September 3, 2002

Major Amendment Issue Date: October 12, 2011

Expiration Date: Permit does not expire – Title I Conditions do not expire.

Don Smith, P.E., Manager
Air Quality Permits Section
Industrial Division

for Paul Aasan
Commissioner
Minnesota Pollution Control Agency

Permit Applications Table

Permit Type	Application Date	Permit Action
Total Facility Operating Permit	4/17/95; 1/15/01; 10/23/01	001
Administrative Amendment	05/18/2007	002
Major Amendment	03/23/2011	003

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NOTICE TO THE PERMITTEE:

Your stationary source may be subject to the requirements of the Minnesota Pollution Control Agency's (MPCA) solid waste, hazardous waste, and water quality programs. If you wish to obtain information on these programs, including information on obtaining any required permits, please contact the MPCA general information number at:

Metro Area	(651) 296-6300
Outside Metro Area	1-800-657-3864
TTY	(651) 282-5332

The rules governing these programs are contained in Minn. R. chs. 7000-7105. Written questions may be sent to: Minnesota Pollution Control Agency, 520 Lafayette Road North, St. Paul, Minnesota 55155-4194.

Questions about this air emission permit or about air quality requirements can also be directed to the telephone numbers and address listed above.

PERMIT SHIELD:

Subject to the limitations in Minn. R. 7007.1800, compliance with the conditions of this permit shall be deemed compliance with the specific provision of the applicable requirement identified in the permit as the basis of each condition. Subject to the limitations of Minn. R. 7007.1800 and 7017.0100, subp. 2, notwithstanding the conditions of this permit specifying compliance practices for applicable requirements, any person (including the Permittee) may also use other credible evidence to establish compliance or noncompliance with applicable requirements.

FACILITY DESCRIPTION:

ANI Pharmaceuticals, Inc. (Permittee) produces pharmaceutical products. Methylene chloride and methanol are hazardous air pollutants (HAPs) emitted from the tablet finishing process. Potential uncontrolled HAP emissions exceed the part 70 and part 63 major source thresholds.

ACTION 002:

This amendment changed the owner of the facility to ANI Pharmaceuticals, Inc.

ACTION 003:

This is a major amendment to the existing federally enforceable state operating permit. Permit action 003 authorizes retirement of the RTO system (that previously controlled the Accela-Cota tablet coating process) and imposes emission limits to restrict total facility HAP emissions to less than the major source thresholds of parts 63 and 70. The use of HAPs has declined since the RTO system installation (circa 2002) which enables the facility to remain a non-major source for HAPs without the use of add-on control equipment. This action also adds requirements for EU 009 (emergency diesel engine) from Title 40 CFR part 63, subpart ZZZZ.

TABLE A: LIMITS AND OTHER REQUIREMENTS

Facility Name: ANI Pharmaceuticals Inc
 Permit Number: 07700010 - 003

Table A contains limits and other requirements with which your facility must comply. The limits are located in the first column of the table (What To do). The limits can be emission limits or operational limits. This column also contains the actions that you must take and the records you must keep to show that you are complying with the limits. The second column of Table A (Why to do it) lists the regulatory basis for these limits. Appendices included as conditions of your permit are listed in Table A under total facility requirements.

Subject Item:	Total Facility
What to do	Why to do it
This permit establishes limits on the facility to keep it a minor source under Part 63 and part 70. The Permittee cannot make any change at the source that would make the source a major source under Part 63 or Part 70 until a permit amendment has been issued. This includes changes that might otherwise qualify as insignificant modifications and minor or moderate amendments. The Permittee is allowed to use HAP-containing materials in GP 001 equipment only.	Title I Condition: To avoid major source classification under 40 CFR Section 63.2; To avoid major source classification under 40 CFR Section 70.2 and Minn. R. 7007.0200
OPERATIONAL REQUIREMENTS	hdr
Permit Appendix: This permit contains an appendix as listed in the permit Table of Contents. The Permittee shall comply with all requirements contained in the appendix.	Minn. R. 7007.0800, subp. 2
The Permittee shall comply with National Primary and Secondary Ambient Air Quality Standards, 40 CFR pt. 50, and the Minnesota Ambient Air Quality Standards, Minn. R. 7009.0010 to 7009.0080. Compliance shall be demonstrated upon written request by the MPCA.	40 CFR pt. 50; Minn. Stat. Section 116.07, subds. 4a & 9; Minn. R. 7007.0100, subp. 7(A), 7(L), & 7(M); Minn. R. 7007.0800, subps. 1, 2 & 4; Minn. R. 7009.0010-7009.0080
Circumvention: Do not install or use a device or means that conceals or dilutes emissions, which would otherwise violate a federal or state air pollution control rule, without reducing the total amount of pollutant emitted.	Minn. R. 7011.0020
Air Pollution Control Equipment: Operate all pollution control equipment whenever the corresponding process equipment and emission units are operated.	Minn. R. 7007.0800, subp. 2; Minn. R. 7007.0800, subp. 16(J)
Operation and Maintenance Plan: Retain at the stationary source an operation and maintenance plan for all air pollution control equipment. At a minimum, the O & M plan shall identify all air pollution control equipment and control practices and shall include a preventative maintenance program for the equipment and practices, a description of (the minimum but not necessarily the only) corrective actions to be taken to restore the equipment and practices to proper operation to meet applicable permit conditions, a description of the employee training program for proper operation and maintenance of the control equipment and practices, and the records kept to demonstrate plan implementation.	Minn. R. 7007.0800, subp. 14 and Minn. R. 7007.0800, subp. 16(J)
Operation Changes: In any shutdown, breakdown, or deviation the Permittee shall immediately take all practical steps to modify operations to reduce the emission of any regulated air pollutant. The Commissioner may require feasible and practical modifications in the operation to reduce emissions of air pollutants. No emissions units that have an unreasonable shutdown or breakdown frequency of process or control equipment shall be permitted to operate.	Minn. R. 7019.1000, subp. 4
Fugitive Emissions: Do not cause or permit the handling, use, transporting, or storage of any material in a manner which may allow avoidable amounts of particulate matter to become airborne. Comply with all other requirements listed in Minn. R. 7011.0150.	Minn. R. 7011.0150
Noise: The Permittee shall comply with the noise standards set forth in Minn. R. 7030.0010 to 7030.0080 at all times during the operation of any emission units. This is a state only requirement and is not enforceable by the EPA Administrator or citizens under the Clean Air Act.	Minn. R. 7030.0010 - 7030.0080
Inspections: The Permittee shall comply with the inspection procedures and requirements as found in Minn. R. 7007.0800, subp. 9(A).	Minn. R. 7007.0800, subp. 9(A)
The Permittee shall comply with the General Conditions listed in Minn. R. 7007.0800, subp. 16.	Minn. R. 7007.0800, subp. 16
MONITORING REQUIREMENTS	hdr
Monitoring Equipment Calibration: The Permittee shall calibrate all required monitoring equipment at least once every 12 months (any requirements applying to continuous emission monitors are listed separately in this permit).	Minn. R. 7007.0800, subp. 4(D)
Operation of Monitoring Equipment: Unless otherwise noted in Tables A, B, and/or C, monitoring a process or control equipment connected to that process is not necessary during periods when the process is shutdown, or during checks of the monitoring systems, such as calibration checks and zero and span adjustments. If monitoring records are required, they should reflect any such periods of process shutdown or checks of the monitoring system.	Minn. R. 7007.0800, subp. 4(D)
RECORDKEEPING REQUIREMENTS	hdr

TABLE A: LIMITS AND OTHER REQUIREMENTS

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

<p>Recordkeeping: Retain all records at the stationary source, unless otherwise specified within this permit, for a period of five (5) years from the date of monitoring, sample, measurement, or report. Records which must be retained at this location include all calibration and maintenance records, all original recordings for continuous monitoring instrumentation, and copies of all reports required by the permit. Records must conform to the requirements listed in Minn. R. 7007.0800, subp. 5(A).</p>	<p>Minn. R. 7007.0800, subp. 5(C)</p>
<p>Recordkeeping: Maintain records describing any insignificant modifications (as required by Minn. R. 7007.1250, subp. 3) or changes contravening permit terms (as required by Minn. R. 7007.1350, subp. 2), including records of the emissions resulting from those changes.</p>	<p>Minn. R. 7007.0800, subp. 5(B)</p>
<p>If the Permittee determines that no permit amendment or notification is required prior to making a change, the Permittee must retain records of all calculations required under Minn. R. 7007.1200. These records shall be kept for a period of five years from the date that the change was made. The records shall be kept at the stationary source for the current calendar year of operation and may be kept at the stationary source or office of the stationary source for all other years. The records may be maintained in either electronic or paper format.</p>	<p>Minn. R. 7007.1200, subp. 4</p>
<p>REPORTING/SUBMITTALS</p>	<p>hdr</p>
<p>Shutdown Notifications: Notify the Commissioner at least 24 hours in advance of a planned shutdown of any control equipment or process equipment if the shutdown would cause any increase in the emissions of any regulated air pollutant. If the owner or operator does not have advance knowledge of the shutdown, notification shall be made to the Commissioner as soon as possible after the shutdown. However, notification is not required in the circumstances outlined in Items A, B, and C of Minn. R. 7019.1000, subp. 3.</p> <p>At the time of notification, the owner or operator shall inform the Commissioner of the cause of the shutdown and the estimated duration. The owner or operator shall notify the Commissioner when the shutdown is over.</p>	<p>Minn. R. 7019.1000, subp. 3</p>
<p>Breakdown Notifications: Notify the Commissioner within 24 hours of a breakdown of more than one hour duration of any control equipment or process equipment if the breakdown causes any increase in the emissions of any regulated air pollutant. The 24-hour time period starts when the breakdown was discovered or reasonably should have been discovered by the owner or operator. However, notification is not required in the circumstances outlined in Items A, B, and C of Minn. R. 7019.1000, subp. 2.</p> <p>At the time of notification or as soon as possible thereafter, the owner or operator shall inform the Commissioner of the cause of the breakdown and the estimated duration. The owner or operator shall notify the Commissioner when the breakdown is over.</p>	<p>Minn. R. 7019.1000, subp. 2</p>
<p>Notification of Deviations Endangering Human Health or the Environment: As soon as possible after discovery, notify the Commissioner or the state duty officer, either orally or by facsimile, of any deviation from permit conditions which could endanger human health or the environment.</p>	<p>Minn. R. 7019.1000, subp. 1</p>
<p>Notification of Deviations Endangering Human Health or the Environment Report: Within two working days of discovery, notify the Commissioner in writing of any deviation from permit conditions which could endanger human health or the environment. Include the following information in this written notification:</p> <ol style="list-style-type: none"> 1. the cause of the deviation; 2. the exact dates of the period of the deviation, if the deviation has been corrected; 3. whether or not the deviation has been corrected; 4. the anticipated time by which the deviation is expected to be corrected, if not yet corrected; and 5. steps taken or planned to reduce, eliminate, and prevent reoccurrence of the deviation. 	<p>Minn. R. 7019.1000, subp. 1</p>
<p>Application for Permit Amendment: If a permit amendment is needed, submit an application in accordance with the requirements of Minn. R. 7007.1150 through Minn. R. 7007.1500. Submittal dates vary, depending on the type of amendment needed.</p>	<p>Minn. R. 7007.1150 through Minn. R. 7007.1500</p>
<p>Extension Requests: The Permittee may apply for an Administrative Amendment to extend a deadline in a permit by no more than 120 days, provided the proposed deadline extension meets the requirements of Minn. R. 7007.1400, subp. 1(H). Performance testing deadlines from the General Provisions of 40 CFR pt. 60 and pt. 63 are examples of deadlines for which the MPCA does not have authority to grant extensions and therefore do not meet the requirements of Minn. R. 7007.1400, subp. 1(H).</p>	<p>Minn. R. 7007.1400, subp. 1(H)</p>

TABLE A: LIMITS AND OTHER REQUIREMENTS

A-3

10/12/11

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Emission Inventory Report: due on or before April 1 of each calendar year following permit issuance. The report shall be submitted on a form approved by the Commissioner.	Minn. R. 7019.3000 through Minn. R. 7019.3010
Emission Fees: due 60 days after receipt of an MPCA bill.	Minn. R. 7002.0005 through Minn. R. 7002.0095

TABLE A: LIMITS AND OTHER REQUIREMENTS

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: GP 001 Accela-Cota and Coating Prep Room

Associated Items: EU 011 Accela-Cota Room 1858

EU 012 Coating Prep Room 1854

SV 003 Accela-Cota

What to do	Why to do it
LIMITS	hdr
<p>HAP-Single: less than or equal to 3.0 tons/year using 12-month Rolling Sum calculated by the 15th day of each month for the previous 12-month period.</p> <p>HAP contents for each HAP-containing material shall be determined as described under the Material Content requirement.</p>	<p>Title I Condition: To avoid major source classification under 40 CFR Section 63.2; To avoid major source classification under 40 CFR Section 70.2 and Minn. R. 7007.0200</p>
<p>HAPs - Total: less than or equal to 6.0 tons/year using 12-month Rolling Sum calculated by the 15th day of each month for the previous 12-month period.</p> <p>HAP contents for each HAP-containing material shall be determined as described under the Material Content requirement.</p>	<p>Title I Condition: To avoid major source classification under 40 CFR Section 63.2; To avoid major source classification under 40 CFR Section 70.2 and Minn. R. 7007.0200</p>
<p>Total Particulate Matter: less than or equal to 0.30 grains/dry standard cubic foot of exhaust gas unless required to further reduce emissions to comply with the less stringent limit of either Minn. R. 7011.0730 or Minn. R. 7011.0735.</p>	<p>Minn. R. 7011.0715, subp. 1(A)</p>
<p>Opacity: less than or equal to 20 percent opacity</p>	<p>Minn. R. 7011.0715, subp. 1(B)</p>
RECORDKEEPING	hdr
<p>Daily Recordkeeping. On each day of operation, the Permittee shall calculate, record, and maintain a record of the total quantity of each HAP-containing material used by GP 001 equipment.</p>	<p>Title I Condition: To avoid major source classification under 40 CFR Section 63.2; To avoid major source classification under 40 CFR Section 70.2 and Minn. R. 7007.0200; Minn. R. 7007.0800, subps. 4 and 5</p>
<p>Monthly Recordkeeping - HAP Emissions. By the 15th day of each month, the Permittee shall calculate and record the following using the formulas specified in this permit:</p> <ol style="list-style-type: none"> 1. The total amount of each HAP-containing material used in the previous calendar month using the daily usage records. This record shall include the individual and total HAP contents of each HAP-containing material used during the previous month, as determined by the Material Content requirement of this permit; 2. The single HAP and total HAP emissions for the previous month using the formulas specified in this permit; and 3. The 12-month rolling sum single HAP and total HAP emissions for the previous 12-month period by summing the monthly emissions data for the previous 12 months. 	<p>Minn. R. 7007.0800, subps. 4 and 5</p>
<p>Monthly Calculation - HAP Emissions. The Permittee shall calculate each single HAP and total HAP emissions using the following equations:</p> <p>HAP Emissions (tons/month) = H - W $H = (A1 \times B1) + (A2 \times B2) + (A3 \times B3) + \dots$ $W = (C1 \times D1) + (C2 \times D2) + (C3 \times D3) + \dots$</p>	<p>Minn. R. 7007.0800, subps. 4 and 5</p>
<p>Monthly HAP Emissions Calculation Continued:</p> <p>Where: H = the amount of each pollutant (either total HAP or each single HAP), used, in tons/month. A# = Amount of each HAP-containing material used in the previous month, in tons/month. B# = weight percent of single individual or total HAP in A#, as a fraction (e.g., 50% is 0.50). W = the amount of each pollutant (either total HAP or each insingle HAP) shipped in waste, in tons/month. C# = amount, in tons/month, of each HAP-containing waste material shipped. If the Permittee chooses to not take credit for waste shipments, this parameter would be zero. D# = weight percent of each single or total HAP in C#, as a fraction.</p>	<p>Minn. R. 7007.0800, subps. 4 and 5</p>

TABLE A: LIMITS AND OTHER REQUIREMENTS

A-5

10/12/11

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

<p>Material Content. HAPs contents in coating materials shall be determined by the Material Safety Data Sheet (MSDS) provided by the supplier for each material used. If a material content range is given on the MSDS, the highest number in the range shall be used in all compliance calculations. Other alternative methods approved by the MPCA may be used to determine the HAPs content. The Commissioner reserves the right to require the Permittee to determine the HAP content of any material, according to EPA or ASTM reference methods. If an EPA or ASTM reference method is used for material content determination, the data obtained shall supersede the MSDS.</p>	Minn. R. 7007.0800, subps. 4 and 5
<p>Waste Credit: If the Permittee elects to obtain credit for HAPs shipped in waste materials, the Permittee shall either follow item 1 or 2 below to determine the total and individual HAP content for each credited shipment.</p> <p>1) The Permittee shall analyze a composite sample of each waste shipment to determine the weight content of total HAP and each single HAP, excluding water.</p> <p>2) The Permittee may use supplier data for raw materials to determine the total and single HAP contents of each waste shipment, using the same content data used to determine the content of raw materials. If the waste contains several materials, the content of mixed waste shall be assumed to be the lowest total and single HAP content of any of the materials.</p>	Minn. R. 7007.0800, subps. 4 and 5

TABLE A: LIMITS AND OTHER REQUIREMENTS

A-6

10/12/11

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: EU 007 Boiler 7 Kewanee

What to do	Why to do it
Total Particulate Matter: less than or equal to 0.4 lbs/million Btu heat input (PTE is 0.007 lb/million Btu per design, using AP-42 emission factors)	Minn. R. 7011.0515, subp. 1
Opacity: less than or equal to 20 percent opacity except for one six-minute period per hour of not more than 60 percent opacity.	Minn. R. 7011.0515, subp. 2
Fuel Type: Natural gas only, by design	Minn. R. 7007.0800, subp. 2

TABLE A: LIMITS AND OTHER REQUIREMENTS

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: EU 009 Emergency Diesel Generator

Associated Items: SV 006 Emergency Generator

What to do	Why to do it
Opacity: less than or equal to 20 percent opacity once operating temperatures have been attained.	Minn. R. 7011.2300, subp. 1
Sulfur Dioxide: less than or equal to 0.5 lbs/million Btu heat input (PTE is 0.29 lbs/million Btu per equipment design, using AP-42 emission factors).	Minn. R. 7011.2300, subp. 2
Fuel Type: No. 2 distillate fuel only, by design.	Minn. R. 7007.0800, subp. 2
Hours of Operation: The Permittee shall maintain documentation on site that the unit is an emergency generator by design that qualifies under the U.S. EPA memorandum entitled "Calculating Potential to Emit (PTE) for Emergency Generators" dated September 6, 1995, limiting operation to 500 hours per year.	Minn. R. 7007.0800, subps. 4 and 5
Fuel Supplier Certification: The Permittee shall obtain and maintain a fuel supplier certification for each shipment of No. 2 fuel oil, certifying that the sulfur content does not exceed 0.49% by weight.	Minn. R. 7007.0800, subps. 4 and 5
PART 63 SUBPART ZZZZ REQUIREMENTS	hdr
EU 009 is a 375 hp existing compression ignition emergency reciprocating internal combustion engine affected source subject to the requirements of 40 CFR part 63, subp. ZZZZ. The compliance date for EU 009 is May 2, 2013.	40 CFR part 63, subp. ZZZZ
<p>The Permittee shall comply with the following applicable requirements from part 63, subpart ZZZZ Table 2d, no later than the May 2, 2013 compliance date:</p> <ul style="list-style-type: none"> a. Change oil and filter every 500 hours of operation or annually, whichever comes first (the Permittee has the option to utilize an oil analysis program as described in Section 63.6625(i) in order to extend the specified oil change requirement in Table 2d of part 63 subpart ZZZZ); b. Inspect air cleaner every 1,000 hours of operation or annually, whichever comes first; and c. Inspect all hoses and belts every 500 hours of operation or annually, whichever comes first, and replace as necessary. <p>Table 2d Footnote 1: The facility has the option to utilize an oil analysis program as described in Section 63.6625(i) in order to extend the specified oil change requirement in part 63 subpart ZZZZ Table 2d.</p> <p>(continued)</p>	40 CFR Section 63.6603(a)
<p>(continued from above)</p> <p>Table 2d Footnote 2: If EU 009 is operating during an emergency and it is not possible to shut down the engine in order to perform the management practice requirements on the schedule required in part 63 subpart ZZZZ Table 2d, or if performing the management practice on the required schedule would otherwise pose an unacceptable risk under Federal, State, or local law, the management practice can be delayed until the emergency is over or the unacceptable risk under Federal, State, or local law has abated. The management practice should be performed as soon as practicable after the emergency has ended or the unacceptable risk under Federal, State, or local law has abated. The Permittee must report any failure to perform the management practice on the schedule required and the Federal, State or local law under which the risk was deemed unacceptable.</p>	40 CFR Section 63.6603(a)
<p>(a) The Permittee must be in compliance with applicable emission limitations and operating limitations in part 63 subpart ZZZZ all times.</p> <p>(b) The Permittee must at all times operate EU 009 in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the Permittee to make any further efforts to reduce emissions if levels required by this standard have been achieved. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.</p>	40 CFR Section 63.6605
The Permittee shall operate and maintain EU 009 according to the manufacturer's emission-related written instructions or develop a maintenance plan which must provide to the extent practicable for the maintenance and operation of EU 009 in a manner consistent with good air pollution control practice for minimizing emissions.	40 CFR Section 63.6625(e)(3)

TABLE A: LIMITS AND OTHER REQUIREMENTS

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

<p>Install a non-resettable hour meter if one is not already installed.</p>	<p>40 CFR Section 63.6625(f)</p>
<p>Minimize EU 009 idle time during startup and minimize EU 009 startup time to a period needed for appropriate and safe loading of the engine, not to exceed 30 minutes, after which time the emission standards applicable to all times other than startup in Table 2d to part 63 subpart ZZZZ apply.</p>	<p>40 CFR Section 63.6625(h)</p>
<p>For item 4 of Table 2d to part 63 subpart ZZZZ, the Permittee has the option of utilizing an oil analysis program in order to extend the specified oil change requirement in Table 2d to part 63 subpart ZZZZ. The oil analysis must be performed at the same frequency specified for changing the oil in Table 2d to part 63 subpart ZZZZ.</p> <p>The analysis program must at a minimum analyze the following three parameters: Total Base Number, viscosity, and percent water content. The condemning limits for these parameters are as follows: Total Base Number is less than 30 percent of the Total Base Number of the oil when new; viscosity of the oil has changed by more than 20 percent from the viscosity of the oil when new; or percent water content (by volume) is greater than 0.5.</p> <p>(continued)</p>	<p>40 CFR Section 63.6625(i)</p>
<p>(continued from above)</p> <p>If all of these condemning limits are not exceeded, the Permittee is not required to change the oil. If any of the limits are exceeded, the Permittee must change the oil within 2 days of receiving the results of the analysis; if the engine is not in operation when the results of the analysis are received, the Permittee must change the oil within 2 days or before commencing operation, whichever is later. The Permittee must keep records of the parameters that are analyzed as part of the program, the results of the analysis, and the oil changes for the engine. The analysis program must be part of the maintenance plan for the engine.</p>	<p>40 CFR Section 63.6625(i)</p>
<p>The Permittee must demonstrate continuous compliance with each applicable operating limitation in part 63 subpart ZZZZ Table 2d according to methods specified in part 63 subpart ZZZZ Table 6 (Table 6 item 9 work or management practices).</p>	<p>40 CFR Section 63.6640(a)</p>
<p>The Permittee must report each instance in which the operating limitations in part 63 subpart ZZZZ Table 2d were not met. These instances are deviations from the operating limitations in subpart ZZZZ. These deviations must be reported according to the requirements in Section 63.6650.</p>	<p>40 CFR Section 63.6640(b)</p>
<p>The Permittee shall comply with part 63 subpart A applicable requirements listed at part 63 subpart ZZZZ Table 8.</p>	<p>40 CFR Section 63.6640(e)</p>
<p>The Permittee shall operate EU 009 according to the requirements in paragraphs (f)(1)(i) through (iii) of section 63.6640. Any EU 009 operation other than emergency operation, maintenance and testing, and operation in non-emergency situations for 50 hours per year, as described in paragraphs (f)(1)(i) through (iii) of section 63.6640, is prohibited. If the Permittee does not operate EU 009 according to the requirements in paragraphs (f)(1)(i) through (iii) of section 63.6640, EU 009 will not be considered an emergency engine under part 63 subpart ZZZZ and will need to meet all requirements for non-emergency engines.</p>	<p>40 CFR Section 63.6640(f)(1)</p>
<p>(i) There is no time limit on the use of EU 009 in emergency situations.</p> <p>(ii) The Permittee may operate EU 009 for the purpose of maintenance checks and readiness testing, provided that the tests are recommended by Federal, State or local government, the manufacturer, the vendor, or the insurance company associated with the engine. Maintenance checks and readiness testing of such units is limited to 100 hours per year. The Permittee may petition the Administrator for approval of additional hours to be used for maintenance checks and readiness testing, but a petition is not required if the Permittee maintains records indicating that Federal, State, or local standards require maintenance and testing of emergency RICE beyond 100 hours per year.</p>	<p>40 CFR Section 63.6640(f)(1)</p>
<p>(iii) The Permittee may operate EU 009 up to 50 hours per year in non-emergency situations, but those 50 hours are counted towards the 100 hours per year provided for maintenance and testing. The 50 hours per year for non-emergency situations cannot be used for peak shaving or to generate income for a facility to supply power to an electric grid or otherwise supply power as part of a financial arrangement with another entity; except the Permittee may operate EU 009 for a maximum of 15 hours per year as part of a demand response program if the regional transmission organization or equivalent balancing authority and transmission operator has determined there are emergency conditions that could lead to a potential electrical blackout, such as unusually low frequency, equipment overload, capacity or energy deficiency, or unacceptable voltage level.</p> <p>(continued below)</p>	<p>40 CFR Section 63.6640(f)(1)(iii)</p>

TABLE A: LIMITS AND OTHER REQUIREMENTS

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

<p>(continued from above)</p> <p>EU 009 may not be operated for more than 30 minutes prior to the time when the emergency condition is expected to occur, and the engine operation must be terminated immediately after the facility is notified that the emergency condition is no longer imminent. The 15 hours per year of demand response operation are counted as part of the 50 hours of operation per year provided for non-emergency situations. The supply of emergency power to another entity or entities pursuant to financial arrangement is not limited by this paragraph (f)(1)(iii), as long as the power provided by the financial arrangement is limited to emergency power.</p>	<p>40 CFR Section 63.6640(f)(1)(iii)</p>
<p>Notifications in Sections 63.7(b) and (c), 63.8(e), (f)(4) and (f)(6), and 63.9(b)-(e), (g) and (h) do not apply to EU 009.</p>	<p>40 CFR Section 63.6645(a)(5)</p>
<p>Keep records described in Section 63.6655 paragraphs (a)(1) through (a)(5), (b)(1) through (b)(3) and (c).</p> <p>(1) A copy of each notification and report submitted to comply with subpart ZZZZ including all documentation supporting any Initial Notification or Notification of Compliance Status submitted, according to the requirement in Section 63.10(b)(2)(xiv).</p> <p>(2) Records of the occurrence and duration of each EU 009 malfunction or monitoring equipment malfunction.</p> <p>(3) Records of performance tests and performance evaluations as required in Section 63.10(b)(2)(viii).</p> <p>(4) Records of all required maintenance performed on the monitoring equipment.</p> <p>(5) Records of actions taken during periods of malfunction to minimize emissions in accordance with Section 63.6605(b), including corrective actions to restore malfunctioning process and monitoring equipment to its normal or usual manner of operation.</p>	<p>40 CFR Section 63.6655</p>
<p>(d) The Permittee must keep the records required in subpart ZZZZ Table 6 to show continuous compliance with each applicable EU 009 operating limitation.</p> <p>(e)(2) The Permittee must keep records of the maintenance conducted on EU 009 in order to demonstrate that the Permittee operated and maintained EU 009 according to the Permittee's maintenance plan.</p> <p>(f)(2) The Permittee must keep records of the EU 009 hours of operation that is recorded through the non-resettable hour meter. The Permittee must document how many hours are spent for emergency operation, including what classified the operation as emergency and how many hours are spent for non-emergency operation. If EU 009 is used for demand response operation, the Permittee must keep records of the notification of the emergency situation, and the time EU 009 was operated as part of demand response.</p>	<p>40 CFR Section 63.6655</p>

TABLE A: LIMITS AND OTHER REQUIREMENTS

A-10

10/12/11

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: EU 034 Burnham Boiler 2

What to do	Why to do it
Total Particulate Matter: less than or equal to 0.4 lbs/million Btu heat input (PTE is 0.007 lb/million Btu per design, using AP-42 emission factors).	Minn. R. 7011.0515, subp. 1
Opacity: less than or equal to 20 percent opacity except for one six-minute period per hour of not more than 60 percent opacity.	Minn. R. 7011.0515, subp. 2
Fuel Type: Natural gas only, by design.	Minn. R. 7007.0800, subp. 2

TABLE A: LIMITS AND OTHER REQUIREMENTS

A-11

10/12/11

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: EU 035 Burnham Boiler 3

What to do	Why to do it
Total Particulate Matter: less than or equal to 0.4 lbs/million Btu heat input (PTE is 0.007 lb/million Btu per design, using AP-42 emission factors).	Minn. R. 7011.0515, subp. 1
Opacity: less than or equal to 20 percent opacity except for one six-minute period per hour of not more than 60 percent opacity.	Minn. R. 7011.0515, subp. 2
Fuel Type: Natural gas only, by design.	Minn. R. 7007.0800, subp. 2

TABLE B: SUBMITTALS

B-1 10/12/11

Facility Name: ANI Pharmaceuticals Inc
Permit Number: 07700010 - 003

Also, where required by an applicable rule or permit condition, send to the Permit Document Coordinator notices of:

- accumulated insignificant activities,
- installation of control equipment,
- replacement of an emissions unit, and
- changes that contravene a permit term.

Send any application for a permit or permit amendment to:

AQ Permit Document Coordinator
Industrial Division
Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, Minnesota 55155-4194

Unless another person is identified in the applicable Table, send all other submittals to:

AQ Compliance Tracking Coordinator
Industrial Division
Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, Minnesota 55155-4194

Each submittal must be postmarked or received by the date specified in the applicable Table. Those submittals required by parts 7007.0100 to 7007.1850 must be certified by a responsible official, defined in Minn. R. 7007.0100, subp. 21. Other submittals shall be certified as appropriate if certification is required by an applicable rule or permit condition.

Send submittals that are required to be submitted to the U.S. EPA regional office to:

Mr. George Czerniak
Air and Radiation Branch
EPA Region V
77 West Jackson Boulevard
Chicago, Illinois 60604

Send submittals that are required by the Acid Rain Program to:

U.S. Environmental Protection Agency
Clean Air Markets Division
1200 Pennsylvania Avenue NW (6204N)
Washington, D.C. 20460

Table B lists most of the submittals required by this permit. Please note that some submittal requirements may appear in Table A or, if applicable, within a compliance schedule located in Table C. Table B is divided into two sections in order to separately list one-time only and recurrent submittal requirements.

TABLE B: RECURRENT SUBMITTALS

B-2 10/12/11

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

What to send	When to send	Portion of Facility Affected
Semiannual Deviations Report	due 30 days after end of each calendar half-year starting 09/15/2008. The first semiannual report submitted by the Permittee shall cover the calendar half-year in which the permit is issued. The first report of each calendar year covers January 1 - June 30. The second report of each calendar year covers July 1 - December 31. If no deviations have occurred, the Permittee shall submit the report stating no deviations.	Total Facility
Compliance Certification	due 31 days after end of each calendar year starting 09/03/2002 (for the previous calendar year). The Permittee shall submit the certification to the Commissioner on a form approved by the Commissioner. The certification covers all deviations experienced during the calendar year.	Total Facility

Facility Name: ANI Pharmaceuticals Inc.
 Permit Number: 07700010-003

Appendix A: Insignificant Activities and Applicable Requirements

Under Minn. R. 7007.1250, subp. 1(A), the Permittee may add insignificant activities to the stationary source throughout the term of the permit without getting permit amendments. Certain exclusions apply and are listed in Minn. R. 7007.1250, subp. 2.

The following sources at the Permittee's facility qualify as insignificant activities under Minn. R. 7007.1300, subps. 3 are not required to be listed in the permit.

Minn. R. 7007.1300, subpart	Rule Description of the Activity	Likely Applicable Requirement
3(G)	Emissions from a laboratory. <ul style="list-style-type: none"> • <i>Various laboratories, currently No. 1400 and No. 1500 areas, which provide quality control testing support to the facility production.</i> 	Minn. R. 7011.0715
3(H)(3)	Miscellaneous (brazing, soldering, or welding equipment) <ul style="list-style-type: none"> • <i>Facility maintenance welding operations</i> 	Minn. R. 7011.0715
3(H)(7)	Miscellaneous (cleaning operations) <ul style="list-style-type: none"> • <i>Various production process equipment cleaned with alkaline-based cleaning solutions</i> 	Minn. R. 7011.0715
3(I)	Individual emission units at a stationary source which each have a potential to emit of each of the following pollutants less than: 4,000 pounds per year of carbon monoxide; 2,000 pounds per year each of nitrogen oxide, sulfur dioxide, particulate matter, particulate matter less than ten microns, VOCs, and ozone; 1,000 tons per year of CO ₂ e. <i>ANI has several of these individual emissions units; many of these are controlled by a dust collector. These include:</i> <ul style="list-style-type: none"> • <i>Cooling tower</i> • <i>Vector coater</i> • <i>Inspection room</i> • <i>Tablet polishing</i> • <i>Imprinting rooms 1 and 2</i> • <i>Mixing rooms 1 and 2</i> • <i>Gemco</i> • <i>Tech services mixing room</i> • <i>Tech services prep area</i> • <i>QA sample room</i> • <i>Packaging Lines 1,2, 3, and 4</i> 	Minn. R. 7011.0715

Facility Name: ANI Pharmaceuticals Inc.
 Permit Number: 07700010-003

Minn. R. 7007.1300, subpart	Rule Description of the Activity	Likely Applicable Requirement
	<ul style="list-style-type: none"> • <i>Gruenberg ovens (nos. 8 and 11)</i> • <i>Dristeam Humidifiers 1 and 2</i> • <i>Imprinters (Ackley – room 1846, Markem 156A – room 1844, Markem 156MK2 – room 1844)</i> • <i>Equipment parts washer, located in Room No. 1802 – 30 gallon capacity (Davco petroleum naphtha solvent)</i> • <i>Various small tanks containing aqueous-based chemical treatment solutions for process water supply purification and cooling tower water supply conditioning</i> • <i>Cleaning of production process equipment and operation with an alcohol-based solvent</i> 	
3(K)	<p>Plant upkeep</p> <ul style="list-style-type: none"> • <i>Infrequent use of spray paint equipment</i> 	Minn. R. 7011.0715
Minn. R. 7008.4110	<ul style="list-style-type: none"> • <i>Torit-Donaldson Model 84 dust collector unit, located in Room No. 1608, which services activities in Technical Services Rooms No. 1416 and 1418;</i> • <i>Torit-Donaldson Model 66 portable dust collector unit, located in Room No. 1212, which services activities in the liquid processing area (Room Nos. 1212, 1214, 1216)</i> 	Minn. R. 7011.0715

TECHNICAL SUPPORT DOCUMENT
For
AIR EMISSION PERMIT NO. 07700010-003

This technical support document (TSD) is intended for all parties interested in the permit and to meet the requirements that have been set forth by the federal and state regulations (40 CFR § 70.7(a)(5) and Minn. R. 7007.0850, subp. 1). The purpose of this document is to provide the legal and factual justification for each applicable requirement or policy decision considered in the determination to issue the permit.

1. General Information

1.1 Applicant and Stationary Source Location:

Table 1. Applicant and Source Address

Applicant/Address	Stationary Source/Address (SIC Code: 2834)
ANI Pharmaceuticals 210 Main St W Baudette Lake of the Woods County	210 Main St W Baudette Lake of the Woods County, Minnesota 56623
Contact: James Marken Phone: 218-634-3584 james.marken@anipharmaceuticals.com	

1.2 Facility Description

ANI Pharmaceuticals, Inc. (Permittee) produces pharmaceutical products. Methylene chloride and methanol are hazardous air pollutants (HAPs) emitted from the tablet finishing process. Potential uncontrolled HAP emissions exceed the part 70 and part 63 major source thresholds. HAPs were formerly controlled by a regenerative thermal oxidizer (RTO) system composed of the RTO and a scrubber to control hydrogen chloride emissions generated by oxidation of methylene chloride. These controls are no longer active and the RTO system was condemned by the Permittee.

1.3 Description of the Activities Allowed by this Permit Action

This is a major amendment to the existing federally enforceable state operating permit. This amendment authorizes retirement of the RTO system, and imposes emission limits to restrict HAP emissions to less than the major source thresholds of parts 63 and 70. The Permittee indicates in the application for this major amendment that the RTO is no longer safe to operate, and the use of HAPs has declined since the RTO system installation (circa 2002) so that it is able to remain a non-major source for HAPs without the use of add-on control equipment.

1.4. Facility Emissions:

Table 2. Title I Emissions Increase Summary

Pollutant	Limited Potential Emissions from the Modification (tpy)	NSR/112(g) Threshold for New Major Source (tpy)	NSR/ 112(g) Review Required? (Yes/No)
PM	0	250	No
PM ₁₀	0	250	No
PM _{2.5}	0	250	No
NO _x	0	250	No
SO ₂	0	250	No
CO	0	250	No
Ozone (VOC)	3.0	250	No
Lead	0	250	No
CO ₂ e*	0	100,000	No
Individual and total HAPs	3.0/6.0	10/25	No

*Carbon dioxide equivalents as defined in Minn. R. 7007.0100.

Table 3. Total Facility Limited Potential To Emit Summary

Subject Item	Subject Item Description	PM tpy	PM ₁₀ tpy	*PM _{2.5} tpy	SO ₂ tpy	NO _x tpy	CO tpy	VOC tpy	CO ₂ e tpy	methylene chloride tpy	methanol tpy	total HAPs Tpy
EU 007	Boiler 7 Kewanee	0.15	0.15	0.15	0.013	2.0	1.6	0.11	2406			0.04
EU 009	Emergency Generator	0.21	0.21	0.21	0.19	2.9	0.63	0.24	106			0.002
EU 034	Burnham Boiler 2	0.15	0.15	0.15	0.013	2.0	1.6	0.11	2406			0.04
EU 035	Burnham Boiler 3	0.15	0.15	0.15	0.013	2.0	1.6	0.11	2406			0.04
GP 001 (EU 011 EU 012)	Coating and Coating Prep							3.0		3.0	3.0	6.0
Total		0.66	0.66	0.66	0.23	8.90	5.43	3.57	7325	3.0	3.0	6.12
Actual Emissions (2009)		0.08	0.08	NR***	0.01	0.99	0.83	0.20	NR	NR	NR	NR

*Assumes all PM₁₀ is PM_{2.5}

**neg = negligible

***Not reported in MN emissions inventory

Table 4. Facility Classification

Classification	Major/Affected Source	Synthetic Minor/Area	Minor/Area
PSD			X
Part 70 Permit Program		HAP	All Other Pollutants
Part 63 NESHAP		X	

2. Regulatory and/or Statutory Basis

New Source Review

The facility is an existing minor source under New Source Review regulations. No changes are authorized by this permit.

Part 70 Permit Program

The facility is a minor source under the Part 70 permit program. No changes are authorized by this permit.

New Source Performance Standards (NSPS)

There are no New Source Performance Standards applicable to the operations at this facility.

National Emission Standards for Hazardous Air Pollutants (NESHAP)

The facility has accepted HAP emission limits to remain an area source under 40 CFR pt. 63 and therefore no major source NESHAPs apply. EU 009 is an existing 375 hp emergency compression ignition reciprocating internal combustion engine (Caterpillar 3306B D1) constructed before 06/12/2006 located at an area source, with a compliance date of 5/2/2013. Requirements from the NESHAP are included in this permit action. In addition, the Permittee has stated that no other area source NESHAPs apply to the facility.

Compliance Assurance Monitoring (CAM)

CAM does not apply to the modification allowed in this permit amendment, because emissions from the units that are the subject of this permit amendment are uncontrolled, and the facility is not a major part 70 source.

Environmental Review & AERA

The emission changes allowed by this permit action do not trigger environmental review or an air emissions risk assessment.

Minnesota State Rules

Portions of the facility are subject to the following Minnesota Standards of Performance:

- Minn. R. 7011.0515 Standards of Performance for New Indirect Heating Equipment
- Minn. R. 7011.0715 Standards of Performance for Post-1969 Industrial Process Equipment
- Minn. R. 7011.2300 Standards of Performance for Stationary Internal Combustion Engines

Table 5. Regulatory Overview of Units Affected by the Modification/Permit Amendment

Subject Item*	Applicable Regulations	Comments:
GP 001	Title I Emission Limits to avoid major source status under part 63 Minn. R. 7011.0715	Single and total HAP limits apply to coating operations to avoid major source classification under 40 CFR pt. 63. Standards of Performance for Post 1969 Industrial Process Equipment
EU 009	Minn. R. 7011.2300	Emergency Internal Combustion Diesel Engine
EU 007 EU 034 EU 035	Minn. R. 7011.0515	Standards of Performance for Existing Indirect Heating Equipment.

*Location of the requirement in the permit (e.g., EU, SV, GP, etc.)

3. Technical Information

As part of its tablet coating process, the Permittee previously (circa 2002) installed and operated a RTO system for control of methylene chloride and methanol (organic HAPs) emissions from the tablet coating system (EU011 Accela-coater and EU012 Coating Prep Room). The system was composed of the RTO for control of the organic HAPs, and a scrubber for control of HCl produced from the combustion of methylene chloride. The facility operating permit (No. 07700010-002) required operation of these controls at a specified minimum efficiency and the Permittee relied on the controls to restrict total facility HAPs to less than the parts 63 and 70 major source thresholds.

On September 20, 2010, the MPCA permitting staff received from the Permittee an application for a minor permit amendment requesting removal of requirements to operate the RTO system from their permit, and replacement of the requirements with a limit on production to keep HAP emissions below the parts 63 and 70 major source thresholds. The Permittee stated that the RTO was no longer safe to operate. The Permittee proposed a production limit of six batches a year, each batch producing approximately 1,500,000 tablets, which it states is twice as many as needed. The six batches would emit 1.7 tons of methylene chloride and 0.8 tons of methanol.

On September 29, 2010, the MPCA permitting staff contacted the Permittee to inform it that removing the requirement to operate the RTO system from its air emission permit required a major amendment to the permit because the change could not be made as a minor permit amendment.

On October 7, 2010, the MPCA enforcement staff contacted the Permittee. The Permittee was notified that it had violated its permit by not operating the RTO system. A Notice of Violation was issued to the Permittee on November 22, 2011 for the violation, and the MPCA and Permittee entered into a Schedule of Compliance on January 14, 2011 to allow the Permittee to not operate the RTO system and to impose interim production and emission limits to restrict facility HAP emissions to less than major source thresholds.

This permit carries forth the requirement to restrict single and total HAP emission to less than 3.0 and 6.0 tons per year, respectively (on a 12-month rolling sum basis). The production limit is not included in this permit action (No. 07700010-003) because it is redundant with the HAP emission limits.

3.1 Emission Changes

The emission changes at this facility are documented in Attachment 1 to this Technical Support Document. Total facility emissions were determined using PER 001 TSD data and changes associated with permit action 003.

3.2 Periodic Monitoring

In accordance with the Clean Air Act, it is the responsibility of the owner or operator of a facility to have sufficient knowledge of the facility to certify that the facility is in compliance with all applicable requirements.

In evaluating the monitoring included in the permit, the MPCA considers the following:

- The likelihood of violating the applicable requirements;
- Whether add-on controls are necessary to meet the emission limits;
- The variability of emissions over time;
- The type of monitoring, process, maintenance, or control equipment data already available for the emission unit;
- The technical and economic feasibility of possible periodic monitoring methods; and
- The kind of monitoring found on similar units elsewhere.

The table below summarizes the periodic monitoring requirements for those emission units for which the monitoring required by the applicable requirement is nonexistent or inadequate.

Table 6. Periodic Monitoring

Subject Item*	Requirement (rule basis)	Additional Monitoring	Discussion
GP 001	Single and Total HAPs: ≤ 3.0 and 6.0 tons per year, respectively, on a 12 month rolling basis (limit to avoid major source classification under 40 CFR pts. 63 and 70)	Recordkeeping: Daily records of material usage; On-going MSDS records of material HAP contents; Monthly calculations of emissions.	Records can be generated on a daily basis. Credit can be taken for waste materials collected and shipped off-site (usage - waste = emissions). Since this is done at most monthly, calculating emissions more frequently than monthly would result in large spikes (while waste is accumulating) and dips (when waste is shipped) – resulting in possible paperwork violations and days with negative emissions. For these reasons, 12-month rolling sum limits are reasonable for this Facility.

Subject Item*	Requirement (rule basis)	Additional Monitoring	Discussion
EU 007 EU 034 EU 035	PM: ≤ 0.4 lb/mmBtu; Opacity: $\leq 20\%$ with exceptions (Minn. R. 7011.0515)	None	These units are designed to and use only natural gas; therefore, the likelihood of violating either of the emission limits is very small. The Permittee can demonstrate that these units will continue to operate such that emissions are well below the emission limits by only burning natural gas. Since this is a permit condition, the semi-annual deviations report will document any deviations from this condition. Design based PTE for each unit, using AP-42, is 0.0072 compared to the rule limit of 0.4 lb/mmBtu.
EU 009	SO ₂ ≤ 0.5 lb/mmBtu and opacity $\leq 20\%$ after attaining operating temperature (Minn. R. 7011.2300)	Documentation to verify the unit is operated only as an emergency generator	Fuel limited to diesel fuel. Records required as described by the September 6, 1995 EPA Emergency Generator PTE memo. Part 63 subp. ZZZZ imposes adequate MACT monitoring requirements for this engine.

*Location of the requirement in the permit (e.g., EU, SV, GP, etc.).

3.3 Insignificant Activities

Some activities at the Facility are classified as insignificant activities. These are listed in the permit appendix. No changes to insignificant activities are associated with this permit action.

The permit is required to include periodic monitoring for all emissions units, including insignificant activities, per EPA guidance. The insignificant activities at this Facility are only subject to general applicable requirements. Using the criteria outlined earlier in this TSD, the following table documents the justification why no additional periodic monitoring is necessary for the current insignificant activities.

Table 7. Insignificant Activities

Insignificant Activity	General Applicable Emission limit	Discussion
Emissions from a laboratory, as defined in Minn. R. 7007.1300, subp. 3(G)	PM, variable depending on airflow Opacity $\leq 20\%$ (Minn. R. 7011.0710/7011.0715)	These are very small operations that typically do not even have any emissions. It is highly unlikely that they could violate the applicable requirement.

Insignificant Activity	General Applicable Emission limit	Discussion
Brazeing, soldering or welding equipment	PM, variable depending on airflow Opacity \leq 20% (Minn. R. 7011.0710/7011.0715)	For these units, based on EPA published emissions factors, it is highly unlikely that they could violate the applicable requirement. In addition, these units are typically operated and vented inside a building, so testing for PM or opacity is not feasible.
Cleaning operations: alkaline/phosphate cleaners and associated burners	PM, variable depending on airflow Opacity \leq 20% (Minn. R. 7011.0610 & Minn. R. 7011.0710/7011.0715)	For these units, there are some factors available for the burners, but very little information regarding the cleaning operation itself. However, based on general knowledge of how they operate, it is highly unlikely that they could violate the applicable requirement or that testing would be feasible.
Individual units with potential emissions less than specific thresholds for certain pollutants	PM, variable depending on airflow Opacity \leq 20% (with exceptions) (Minn. R. 7011.0715 & Minn. R. 7011.610)	Numerous small processes such as cooling towers, mixing, inspection, packaging, humidifiers, and tablet polishing with emissions based on EPA published emissions factors that are highly unlikely to violate the applicable requirement.
Infrequent use of spray paint equipment for routine housekeeping or plant upkeep activities not associated with primary production processes at the stationary source	PM, variable depending on airflow or process weight rate Opacity \leq 20% (Minn. R. 7011.0715)	While spray equipment will have the potential to emit particulate matter, these particular activities are those not associated with production, so they would be infrequent and usually occur outdoors. Testing or monitoring is not feasible.
Equipment venting PM/PM ₁₀ inside a building, provided that emissions from the equipment are: a) filtered through an air cleaning system; and b) vented inside of the building 100% of the time	PM, variable depending on airflow Opacity \leq 20% (Minn. R. 7011.0715)	For these units, it is highly unlikely that they could violate the applicable requirement. In addition, these units are vented inside a building, so testing for PM or opacity is not feasible.

3.4 Permit Organization

The permit meets the MPCA Delta Guidance for ordering and grouping of requirements.

3.5 Comments Received

Public Notice and EPA Review Period: August 31, 2011 – September 29, 2011

No comments were received.

4. Permit Fee Assessment

TSD Attachment 3 is the MPCA assessment of Application and Additional Points used to determine the permit application fee for this permit action as required by Minn. R. 7002.0019. The permit action is based on an application for a major amendment received after the effective date of the rule (July 1, 2009). The permit includes a new set of HAP limits to avoid part 63 and part 70 major source status. The addition of part 63 subpart ZZZZ requirements under EU 009 is not a chargeable permit change.

5. Conclusion

Based on the information provided by ANI Pharmaceuticals, Inc., the MPCA has reasonable assurance that the proposed operation of the emission facility, as described in the Air Emission Permit No. 07700010-003 and this TSD, will not cause or contribute to a violation of applicable federal regulations and Minnesota Rules.

Staff Members on Permit Team: Marshall Cole (permit writer/engineer)
 Rachel Studanski (enforcement)
 Jeff Hedman (peer reviewer)

AQ File No. 2435A; DQ 3433

Attachments: 1. Emissions Changes Spreadsheet
 2. Facility Description and CD-01 Forms
 3. Points Calculator

Total Facility Limited Potential Emissions Permit 001													
			PM	PM ₁₀		SO ₂	NO _x	CO	VOC	methylene chloride	methanol	Total HAPs	
	EU/SV	Emission Unit Description	tpy	tpy		tpy	tpy	tpy	tpy	tpy	tpy	tpy	
	EU 007	Boiler 7 Kewanee	0.15	0.15		0.01	2.00	1.60	0.11				
	EU 009	Emergency Generator	0.21	0.21		0.19	2.90	0.63	0.24				
	EU 034	Burnham Boiler 2	0.15	0.15		0.01	2.00	1.60	0.11				
	EU 035	Burnham Boiler 3	0.15	0.15		0.01	2.00	1.60	0.11				
	SV 009	RTO System	0.05	0.05		0.00	1.00	0.49	1.10	2.20	1.10	3.30	
		Totals	0.71	0.71		0.23	9.90	5.90	1.70	2.20	1.10	3.30	
Total Facility Limited Potential Emissions Permit 003													
			PM	PM ₁₀	PM _{2.5}	SO ₂	NO _x	CO	VOC	GHG	methylene chloride	methanol	Total HAPs
	EU/SV	Emission Unit Description	tpy	tpy	tpy	tpy	tpy	tpy	tpy	tpy	tpy	tpy	tpy
	EU 007	Boiler 7 Kewanee	0.15	0.15	0.15	0.01	2.00	1.60	0.11	2406			0.038
	EU 009	Emergency Generator	0.21	0.21	0.21	0.19	2.90	0.63	0.24	106			0.002
	EU 034	Burnham Boiler 2	0.15	0.15	0.15	0.01	2.00	1.60	0.11	2406			0.038
	EU 035	Burnham Boiler 3	0.15	0.15	0.15	0.01	2.00	1.60	0.11	2406			0.038
	GP 001	Accela-Cota	0.00	0.00	0.00	0.00	0.00	0.00	3.00		3.00	3.00	6.00
		Totals	0.66	0.66	0.66	0.23	8.90	5.43	3.57	7325	3.00	3.00	6.08
Permit 003 emissions are based on PER 001 TSD emissions data minus SV 009 plus GP 001													



EC-17

Greenhouse Gas Emissions

Air Quality Permit Program

Doc Type: Permit Application

Instructions on Page 2.

Greenhouse Gas Emissions Summary. Use this table to document GHG emissions from the unit or operation listed above. You must provide mass emissions of each pollutant, as well as carbon dioxide equivalents (CO₂e). For hydrofluorocarbon (HFCs) and perfluorocarbons (PFCs), you will have to calculate emissions of individual compounds on the separate spreadsheet and report the total HFCs and PFCs in the table below. Instructions are provided starting on page 2. Please report all numbers using three (3) significant digits; use scientific notation if necessary (for example, report 379,355 tons as 3.79E5).

1a) AQ Facility ID No.:	7700010	1b) AQ File No.:	
2) Facility Name:	ANI Pharmaceutical		
3) Emission unit ID number:	EU 007	EU 034	EU 035 Boilers
4) Stack/Vent designation number(s):			
Maximum Rated Capacity:	4.7	4.7	4.7 MMBtu/hr 14.1 MMBtu/hr total 123,516 MMBtu/yr total
5) Control equipment number(s):	N/A		
6) Operating Limitations, if applicable:			

7) Greenhouse Gas Emissions Summary. Use this table to document GHG emissions from the unit or operation listed above. You must provide mass emissions of each pollutant, as well as carbon dioxide equivalents (CO₂e). For hydrofluorocarbons (HFCs) and perfluorocarbons (PFCs), you will have to calculate emissions of individual compounds on the separate spreadsheet and report the total HFCs and PFCs in the table below. Instructions are provided starting on page 2. Please report all numbers using three (3) significant digits; use scientific notation if necessary (for example, report 379,355 tons as "3.79E5").

Fuel Parameters:

Fuel Type	Heat Value	Max Capacity (MMBtu/hr)	Fuel Consumption Rate	Limited Fuel Consumption Rate ¹	
Natural Gas	1,028 btu/scf	14.10	13,716 cf/hr	NA	MMBtu/yr

Primary Fuel: Natural Gas

7a) GHG Pollutant	7b) GWP	7c) Emission Factor (lb/MMBtu) ¹	7d) Uncontrolled Emission Rate			7e) Pollution Control Efficiency (%)	7f) Controlled Emission Rate			7g) Limited and Controlled Emission Rate			7h) Actual Controlled Emission Rate	
			(lb/hr)	(tpy) ²	CO ₂ e (tpy)		(lb/hr)	(tpy) ²	CO ₂ e (tpy)	(lb/hr)	(tpy) ²	CO ₂ e (tpy)	(tpy)	CO ₂ e (tpy)
CO ₂	1	116.89	1,648	7,219	7,219	0.0%	1,648	7,219	7,219	1,648	7,219	7,219	0	0
CH ₄	21	2.20E-03	0.0	0.14	2.9	0.0%	0.03	0.14	2.9	0.03	0.14	2.9	0.00	0.00
N ₂ O	310	2.20E-04	0.0	0.01	4.2	0.0%	0.00	0.01	4.2	0.00	0.01	4.2	0.00	0.00
HFCs	XXXX	N/A	--	--	--	--	--	--	--	--	--	--	--	--
PFCs	XXXX	N/A	--	--	--	--	--	--	--	--	--	--	--	--
SF ₆	23,900	N/A	--	--	--	--	--	--	--	--	--	--	--	--
Total GHG (CO₂e)		XXXX	XXXX	XXXX	7,226	XXXX	XXXX	XXXX	7,226	XXXX	XXXX	7,226	XXXX	0

¹ - Emission Factors from:

40 CFR Part 98 Subpart C (EPA GHG Mandatory Reporting Rule), final rule published in Federal Register 10/30/09 and revisions to the final rule published in the Federal Register 12/17/10.

For Natural Gas:

Emission Factor	kg/MMBtu	lb/MMBtu
CO ₂	53.02	116.89
CH ₄	1.00E-03	2.20E-03
N ₂ O	1.00E-04	2.20E-04

² - Maximum emissions based on operating 8,760 hr/yr

Worst-Case Potential-to-Emit Summary

Note: Emissions are total for all 3 boilers.

GHG Pollutant	Maximum Uncontrolled Emissions CO ₂ e (tpy)	Controlled Emission Rate (lb/hr)	Maximum Controlled Emissions CO ₂ e (tpy)	Limited Controlled Emissions CO ₂ e (tpy)
CO ₂	7,219	N/A	7,219	7,219
CH ₄	3	N/A	3	3
N ₂ O	4	N/A	4	4
HFCs	--	N/A	--	--
PFCs	--	N/A	--	--
SF ₆	--	N/A	--	--
Total (CO₂e)	7,226		7,226	7,226

3) Emission unit ID number: EU 009 Emergency Generator
 4) Stack/Vent designation number(s): _____
 Fuel consumption capacity: 18.9 gal/hr Fuel heat content 137 mmBtu/mgal
 Rated mechanical output: 375 hp
 Maximum Rated Capacity: 2.59 MMBtu/hr

7a) GHG Pollutant	7b) GWP	7c) Emission Factor	7d) Uncontrolled Emission Rate			7e) Pollution Control Efficiency	7f) Controlled Emission Rate			7g) Limited and Controlled Emission Rate		
			(lb/MMBtu) ¹	(lb/hr)	(tpy) ²		CO ₂ e (tpy)	(lb/hr)	(tpy) ²	CO ₂ e (tpy)	(lb/hr)	(tpy) ³
CO ₂	1	163.05	422	1,849	1,849	0.0%	422	1,849	1,849	422	106	106
CH ₄	21	6.61E-03	0.017	0.08	1.58	0.0%	0.017	0.08	1.58	0.017	0.004	0.090
N ₂ O	310	1.32E-03	0.003	0.02	4.65	0.0%	0.003	0.02	4.65	0.003	0.001	0.265
HFCs	XXXX	N/A	--	--	--	--	--	--	--	--	--	--
PFCs	XXXX	N/A	--	--	--	--	--	--	--	--	--	--
SF ₆	23,900	N/A	--	--	--	--	--	--	--	--	--	--
Total GHG (CO₂e)					1,855				1,855			105.9

¹ - Emission Factors from: 40 CFR Part 98 Subpart C (EPA GHG Mandatory Reporting Rule), final rule published in Federal Register 10/30/09 and revisions to the final rule published in the Federal Register 12/17/10.

Diesel	Emission Factor	kg/MMBtu	lb/MMBtu
	CO ₂	73.96	163.05
	CH ₄	3.00E-03	6.61E-03
	N ₂ O	6.00E-04	1.32E-03

²Based on operating 8,760 hr/yr

³Based on operating 500 hr/yr



MINNESOTA POLLUTION CONTROL AGENCY
 AIR QUALITY DIVISION
 520 LAFAYETTE ROAD
 ST. PAUL, MN 55155-4194

PERMIT APPLICATION FORM

EC-13C . 07700010-003

**HAZARDOUS AIR POLLUTANTS
 CALCULATION FORM (FUEL COMBUSTION)**

5/27/1998

Permit No.. 09900002-010

1) AQD Facility ID No.:	7700010
2) Facility Name:	ANI Pharmaceuticals Inc
3) Emission Unit Identification No.:	boiler 7, 2, and 3
4) Stack/Vent Designation No.:	
5) Maximum Rated Boiler Capacity:	14.10 MMBTU/hr total (each is 4.7)
6) Control Equipment:	NA
7) Fuel Parameters	

7a) Fuel Type	7b) % Sulfur	7c) % Ash	7d) Heat Value	Units	7e) Maximum Fuel Consumption Rate	Units
Natural Gas	0.0001	negligible	1,020	Btu/scf	0.0138	MMscf/hr

When calculating Potential Emissions, use items 8a, 8b, 8d, 8e, 8g, 8h, and 8i (if a limit is proposed in item 12).

When calculating Actual Emissions, use items 8a, 8b, 8c, 8f, 8g, and 8j.

8) Calculations Summary - Primary Fuel : Natural Gas

8a) HAP Name (CAS)	8b) Emission Factor (lbs/MMcf) ^d	8c) Actual Annual Fuel Use (MMcf)	8d) Emission Rate (lbs/hr)	8e) Maximum Uncontrolled Emissions (tons/yr)	8f) Actual Uncontrolled Emissions (tons/yr)	8g) Pollution Control Efficiency (%)	8h) Maximum Controlled Emissions (tons/yr)	8i) Limited Controlled Emissions (tons/yr)	8j) Actual Controlled Emissions (tons/yr)
Benzene (71-43-2)	2.1E-03	NA	2.9E-05	1.27E-04	NA	0.0	1.3E-04	1.3E-04	NA
Dichlorobenzene (25321-22-6)	1.2E-03	NA	1.7E-05	7.27E-05	NA	0.0	7.3E-05	7.3E-05	NA
Formaldehyde (50-00-0)	7.5E-02	NA	1.0E-03	4.54E-03	NA	0.0	4.5E-03	4.5E-03	NA
Hexane (110-54-3)	1.8E+00	NA	2.5E-02	1.09E-01	NA	0.0	1.1E-01	1.1E-01	NA
Naphthalene (91-20-3) ^b	6.1E-04	NA	8.4E-06	3.69E-05	NA	0.0	3.7E-05	3.7E-05	NA
Toluene (108-88-3)	3.4E-03	NA	4.7E-05	2.06E-04	NA	0.0	2.1E-04	2.1E-04	NA
Polycyclic Organic Matter (POM) ^c	8.6E-05	NA	1.2E-06	5.23E-06	NA	0.0	5.2E-06	5.2E-06	NA
Arsenic (7440-38-2)	2.0E-04	NA	2.8E-06	1.21E-05	NA	0.0	1.2E-05	1.2E-05	NA
Beryllium (7440-41-7)	1.2E-05	NA	1.7E-07	7.27E-07	NA	0.0	7.3E-07	7.3E-07	NA
Cadmium (7440-43-9)	1.1E-03	NA	1.5E-05	6.66E-05	NA	0.0	6.7E-05	6.7E-05	NA
Chromium (7440-47-3)	1.4E-03	NA	1.9E-05	8.48E-05	NA	0.0	8.5E-05	8.5E-05	NA
Manganese (7439-96-5)	3.8E-04	NA	5.3E-06	2.30E-05	NA	0.0	2.3E-05	2.3E-05	NA
Mercury (7439-97-6)	2.6E-04	NA	3.6E-06	1.57E-05	NA	0.0	1.6E-05	1.6E-05	NA
Nickel (7440-02-0)	2.1E-03	NA	2.9E-05	1.27E-04	NA	0.0	1.3E-04	1.3E-04	NA
Selenium (7782-49-2)	2.4E-05	NA	3.3E-07	1.45E-06	NA	0.0	1.5E-06	1.5E-06	NA
Totals			0.03	0.11			0.11	0.11	

^aAll emissions are calculated based on emission factors from AP-42, Section 1.4 "Natural Gas Combustion"(7/98).

^bNaphthalene is included in the Polycyclic Organic Matter (POM) emissions and is not double-counted in the total HAPs.

^cTotal POM emission factor is equal to the sum of the individual POM compounds.

When calculating Potential Emissions, use items 9a,9b,9d, 9e, 9g, 9h, and 9i (if a limit is proposed in item 12).

When calculating Actual Emissions, use items 9a, 9b, 9c, 9f, 9g, and 9j.

9) Calculations Summary - Back-up Fuel : NA

9a) HAP Name (CAS)	9b) Emission Factor (lbs/Mgal)	9c) Actual Annual Fuel Use (gallons)	9d) Emission Rate (lbs/hr)	9e) Maximum Uncontrolled Emissions (tons/yr)	9f) Actual Uncontrolled Emissions (tons/yr)	9g) Pollution Control Efficiency (%)	9h) Maximum Controlled Emissions (tons/yr)	9i) Limited Controlled Emissions (tons/yr)	9j) Actual Controlled Emissions (tons/yr)
Totals									

10) Worse-Case Potential-to-Emit Summary: (Ignore this item if filling out this form for a Registration Permit Option D)

10a) HAP Name (CAS)	10b) <i>Before Operating Limits</i> (lb/hr)	10c) <i>Before Operating Limits</i> (ton/yr)	10d) <i>After Operating Limits</i> (ton/yr)
Benzene (71-43-2)	2.9E-05	1.3E-04	1.3E-04
Dichlorobenzene (25321-22-6)	1.7E-05	7.3E-05	7.3E-05
Formaldehyde (50-00-0)	1.0E-03	4.5E-03	4.5E-03
Hexane (110-54-3)	2.5E-02	1.1E-01	1.1E-01
Naphthalene (91-20-3) ^a	8.4E-06	3.7E-05	3.7E-05
Toluene (108-88-3)	4.7E-05	2.1E-04	2.1E-04
POM ^b	1.2E-06	5.2E-06	5.2E-06
Arsenic (7440-38-2)	2.8E-06	1.2E-05	1.2E-05
Beryllium (7440-41-7)	1.7E-07	7.3E-07	7.3E-07
Cadmium (7440-43-9)	1.5E-05	6.7E-05	6.7E-05
Chromium (7440-47-3)	1.9E-05	8.5E-05	8.5E-05
Manganese (7439-96-5)	5.3E-06	2.3E-05	2.3E-05
Mercury (7439-97-6)	3.6E-06	1.6E-05	1.6E-05
Nickel (7440-02-0)	2.9E-05	1.3E-04	1.3E-04
Selenium (7782-49-2)	3.3E-07	1.5E-06	1.5E-06
Totals (tpy)		0.11	0.11

^aNaphthalene is included in the Polycyclic Organic Matter (POM) emissions and is not double-counted in the total HAPs.

^bTotal POM emission factor is equal to the sum of the individual POM compounds.

12) Operating Limitations, if applicable: (Ignore this item if filling out this form for a Registration Permit Option D):

NA

3) Emission unit ID number: **EU 009 Emergency Generator**

4) Stack/Vent designation number(s):

Fuel consumption capacity: **18.9 gal/hr Fuel heat content 137 mmBtu/mgal**

Rated mechanical output: **375 hp**

Maximum Rated Capacity: **2.59 MMBtu/hr**

Pollutant	emission factor		limited tpy @500	
	lb/mmBtu	lb/hr	tpy	hr/yr
benzene	9.33E-04	2.42E-03	1.06E-02	6.04E-04
toluene	4.09E-04	1.06E-03	4.64E-03	2.65E-04
xylene	2.85E-04	7.38E-04	3.23E-03	1.84E-04
1,3-butadiene	3.91E-05	1.01E-04	4.43E-04	2.53E-05
formaldehyde	1.18E-03	3.06E-03	1.34E-02	7.64E-04
acetaldehyde	7.67E-04	1.99E-03	8.70E-03	4.96E-04
acrolein	9.25E-05	2.40E-04	1.05E-03	5.99E-05
naphthalene	8.48E-05	2.20E-04	9.62E-04	5.49E-05
total HAP		9.81E-03	4.30E-02	2.45E-03



FACILITY DESCRIPTION: GROUPS (GP)

Show: Active and Pending Records

Action: PER 003

AQD Facility ID: 07700010

Facility Name: ANI Pharmaceuticals Inc

	ID No.	Group Status	Added By (Action)	Retired By (Action)	Include in EI	Operator ID for Item	Group Description	Group Items
1	GP 001	Active	PER 003		<input type="checkbox"/>		Accela-Cota and Coating Prep Room	EU 011, EU 012, SV 003



FACILITY DESCRIPTION: EMISSION UNIT (EU)

Show: Pending Records Only

Action: PER 003

AQD Facility ID: 07700010

Facility Name: ANI Pharmaceuticals Inc

ID No.	Emission Unit Status	Added By (Action)	Retired By (Action)	Insignificant Activity	Operator ID for Item	Stack/Vent ID No(s).	Control Equip. ID No(s).	Operator Description	Manufacturer	Model Number	SIC	Max. Design Capacity	Maximum Design Capacity			Max Fuel Input (mil Btu)
													Materials	Units n	Units d	
1	EU 007	Active	PER 003	<input type="checkbox"/>				Boiler 7 Kewanee	Kewanee		2834	4.7	Heat	Mmbtu	Hr	4.7
2	EU 009	Active	PER 003	<input type="checkbox"/>		SV 006		Emergency Diesel Generator	Caterpillar	3306	2834	18.9	Diesel Fuel	Gal	Hr	2.59
3	EU 011	Active	PER 003	<input type="checkbox"/>		SV 003		Accela-Cota Room 1858			2834					
4	EU 012	Active	PER 003	<input type="checkbox"/>		SV 003		Coating Prep Room 1854			2834					
5	EU 034	Active	PER 003	<input type="checkbox"/>				Burnham Boiler 2	Burnham		2834	4.7	Heat	Mmbtu	Hr	4.7
6	EU 035	Active	PER 003	<input type="checkbox"/>				Burnham Boiler 3	Burnham		2834	4.7	Heat	Mmbtu	Hr	4.7

FACILITY DESCRIPTION: EMISSION UNIT (EU)

	ID No.	Emission Unit Status	Added By (Action)	Commence Const. Date	Initial Startup Date	Removal Date	Firing Method	Pct. Fuel/Space Heat	Bottleneck	Elevator Type
1	EU 007	Active	PER 003							
2	EU 009	Active	PER 003		01/01/1995					
3	EU 011	Active	PER 003							
4	EU 012	Active	PER 003							
5	EU 034	Active	PER 003		01/01/1975					
6	EU 035	Active	PER 003		09/01/2000					



FACILITY DESCRIPTION: CONTROL EQUIPMENT (CE)

Show: Pending Records Only

Action: PER 003

AQD Facility ID: 07700010

Facility Name: ANI Pharmaceuticals Inc

	ID No.	Control Equip. Status	Added By (Action)	Retired By (Action)	Operator ID for Item	Control Equip. Type	Control Equipment Description	Manufacturer	Model	Pollutants Controlled	Capture Efficiency (%)	Destruction/Collection Efficiency (%)	Afterburner Combustion Parameters
1	CE 016	Removed	PER 003			022	Direct Flame Afterburner w/Heat Exchanger	Turner EnviroLogic		Methanol dichlorome VOC	100 100 100	95 95 95	1500 F
2	CE 017	Removed	PER 003			070	Sodium-Alkali Scrubbing	Turner EnviroLogic		Hyd. Acid	100	95	

FACILITY DESCRIPTION: Potential-to-emit (by item)

Show: Active and Pending Records

AQD Facility ID: 07700010

Facility Name: ANI Pharmaceuticals Inc

Item	Pollutant	Added By (Action)	Retired By (Action)	Hourly Potential (lbs per hr)	Unrestricted Potential (tons per yr)	Limited Potential (tons per yr)	Actual Emissions (tons per yr)
EU 007							
	Carbon Dioxide Equivalent	PER 003		5.50E+02	2.41E+03	2.41E+03	
	Methane	PER 003		1.00E-02	4.50E-02	4.50E-02	
	Carbon Monoxide	PER 001		3.76E-01	1.65E+00	1.65E+00	2.70E-01
	Carbon Dioxide	PER 003		5.49E+02	2.41E+03	2.41E+03	
	HAPs - Total	PER 003		8.70E-03	3.81E-02	3.81E-02	
	Nitrous Oxide	PER 003		1.00E-03	4.50E-03	4.50E-03	
	Nitrogen Oxides	PER 001		4.48E-01	1.96E+00	1.96E+00	3.30E-01
	PM < 2.5 micron	PER 003		3.40E-02	1.49E-01	1.49E-01	
	PM < 10 micron	PER 001		3.40E-02	1.49E-01	1.49E-01	5.00E-04
	Total Particulate Matter	PER 001		3.40E-02	1.49E-01	1.49E-01	5.00E-04
	Sulfur Dioxide	PER 001		3.00E-03	1.30E-02	1.30E-02	4.00E-03
	Volatile Organic Compounds	PER 001		2.50E-02	1.10E-01	1.10E-01	2.00E-02
EU 009							
	Carbon Dioxide Equivalent	PER 003		4.24E+02	1.06E+02	1.06E+02	
	Methane	PER 003		1.70E-02	4.00E-03	4.00E-03	
	Carbon Monoxide	PER 001		2.52E+00	1.10E+01	6.30E-01	1.00E-02
	Carbon Dioxide	PER 003		4.22E+02	1.06E+02	1.06E+02	
	HAPs - Total	PER 003		9.81E-03	2.45E-03	2.45E-03	
	Nitrous Oxide	PER 003		3.00E-03	1.00E-03	1.00E-03	
	Nitrogen Oxides	PER 001		1.17E+01	5.12E+01	2.92E+00	6.00E-02
	PM < 2.5 micron	PER 003		8.29E-01	3.63E+00	2.07E-01	
	PM < 10 micron	PER 001		8.29E-01	3.63E+00	2.07E-01	5.00E-03
	Total Particulate Matter	PER 001		8.29E-01	3.63E+00	2.07E-01	5.00E-03
	Sulfur Dioxide	PER 001		7.73E-01	3.39E+00	1.93E-01	4.00E-03
	Volatile Organic Compounds	PER 001		9.48E-01	4.15E+00	2.37E-01	5.00E-03
EU 034							
	Carbon Dioxide Equivalent	PER 003		5.50E+02	2.41E+03	2.41E+03	
	Methane	PER 003		1.00E-02	4.50E-02	4.50E-02	
	Carbon Monoxide	PER 001		3.76E-01	1.65E+00	1.65E+00	2.70E-01
	Carbon Dioxide	PER 003		5.49E+02	2.41E+03	2.41E+03	
	HAPs - Total	PER 003		8.70E-03	3.81E-02	3.81E-02	
	Nitrous Oxide	PER 003		1.00E-03	4.50E-03	4.50E-03	
	Nitrogen Oxides	PER 001		4.48E-01	1.96E+00	1.96E+00	3.30E-01
	PM < 2.5 micron	PER 003		3.40E-02	1.49E-01	1.49E-01	
	PM < 10 micron	PER 001		3.40E-02	1.49E-01	1.49E-01	5.00E-03
	Total Particulate Matter	PER 001		3.40E-02	1.49E-01	1.49E-01	5.00E-03
	Sulfur Dioxide	PER 001		3.00E-03	1.30E-02	1.30E-02	4.00E-03
	Volatile Organic Compounds	PER 001		2.50E-02	1.10E-01	1.10E-01	2.00E-02
EU 035							
	Carbon Dioxide Equivalent	PER 003		5.50E+02	2.41E+03	2.41E+03	
	Methane	PER 003		1.00E-02	4.50E-02	4.50E-02	
	Carbon Monoxide	PER 001		3.76E-01	1.65E+00	1.65E+00	2.70E-01
	Carbon Dioxide	PER 003		5.49E+02	2.41E+03	2.41E+03	
	HAPs - Total	PER 003		8.70E-03	3.81E-02	3.81E-02	
	Nitrous Oxide	PER 003		1.00E-03	4.50E-03	4.50E-03	
	Nitrogen Oxides	PER 001		4.48E-01	1.96E+00	1.96E+00	3.30E-01

FACILITY DESCRIPTION: Potential-to-emit (by item)

Show: Active and Pending Records

AQD Facility ID: 07700010

Facility Name: ANI Pharmaceuticals Inc

Item	Pollutant	Added By (Action)	Retired By (Action)	Hourly Potential (lbs per hr)	Unrestricted Potential (tons per yr)	Limited Potential (tons per yr)	Actual Emissions (tons per yr)
EU 035							
	PM < 2.5 micron	PER 003		3.40E-02	1.49E-01	1.49E-01	
	PM < 10 micron	PER 001		3.40E-02	1.49E-01	1.49E-01	5.00E-04
	Total Particulate Matter	PER 001		3.40E-02	1.49E-01	1.49E-01	5.00E-04
	Sulfur Dioxide	PER 001		3.00E-03	1.30E-02	1.30E-02	4.00E-03
	Volatile Organic Compounds	PER 001		2.50E-02	1.10E-01	1.10E-01	2.00E-02
GP 001							
	Methanol	PER 003				3.00E+00	
	HAPs - Total	PER 003				6.00E+00	
	Methylene chloride (dichlorome	PER 003				3.00E+00	
	HAP-Single	PER 003				3.00E+00	
	Volatile Organic Compounds	PER 003				3.00E+00	
SV 009							
	Methanol	PER 001				1.10E+00	
	Methanol	PER 003					
	HAPs - Total	PER 001					
	Methylene chloride (dichlorome	PER 001				2.20E+00	
	Methylene chloride (dichlorome	PER 003					
	Nitrogen Oxides	PER 001				1.04E+00	
	Nitrogen Oxides	PER 003					
	PM < 10 micron	PER 001				4.80E-02	
	PM < 10 micron	PER 003					
	Total Particulate Matter	PER 001				4.80E-02	
	Total Particulate Matter	PER 003					
	Sulfur Dioxide	PER 001				2.50E-04	
	Sulfur Dioxide	PER 003					
	Volatile Organic Compounds	PER 001				1.10E+00	
	Volatile Organic Compounds	PER 003					



COMPLIANCE PLAN **CD-01**

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: Total Facility

	NC/CA	Type	Citation	Requirement
1.0		CD	Title I Condition: To avoid major source classification under 40 CFR Section 63.2; To avoid major source classification under 40 CFR Section 70.2 and Minn. R. 7007.0200	This permit establishes limits on the facility to keep it a minor source under Part 63 and part 70. The Permittee cannot make any change at the source that would make the source a major source under Part 63 or Part 70 until a permit amendment has been issued. This includes changes that might otherwise qualify as insignificant modifications and minor or moderate amendments. The Permittee is allowed to use HAP-containing materials in GP 001 equipment only.
2.0		CD	hdr	OPERATIONAL REQUIREMENTS
3.0		CD	Minn. R. 7007.0800, subp. 2	Permit Appendix: This permit contains an appendix as listed in the permit Table of Contents. The Permittee shall comply with all requirements contained in the appendix.
4.0		CD	40 CFR pt. 50; Minn. Stat. Section 116.07, subds. 4a & 9; Minn. R. 7007.0100, subp. 7(A), 7(L), & 7(M); Minn. R. 7007.0800, subps. 1, 2 & 4; Minn. R. 7009.0010-7009.0080	The Permittee shall comply with National Primary and Secondary Ambient Air Quality Standards, 40 CFR pt. 50, and the Minnesota Ambient Air Quality Standards, Minn. R. 7009.0010 to 7009.0080. Compliance shall be demonstrated upon written request by the MPCA.
5.0		CD	Minn. R. 7011.0020	Circumvention: Do not install or use a device or means that conceals or dilutes emissions, which would otherwise violate a federal or state air pollution control rule, without reducing the total amount of pollutant emitted.
6.0		CD	Minn. R. 7007.0800, subp. 2; Minn. R. 7007.0800, subp. 16(J)	Air Pollution Control Equipment: Operate all pollution control equipment whenever the corresponding process equipment and emission units are operated.
7.0		CD	Minn. R. 7007.0800, subp. 14 and Minn. R. 7007.0800, subp. 16(J)	Operation and Maintenance Plan: Retain at the stationary source an operation and maintenance plan for all air pollution control equipment. At a minimum, the O & M plan shall identify all air pollution control equipment and control practices and shall include a preventative maintenance program for the equipment and practices, a description of (the minimum but not necessarily the only) corrective actions to be taken to restore the equipment and practices to proper operation to meet applicable permit conditions, a description of the employee training program for proper operation and maintenance of the control equipment and practices, and the records kept to demonstrate plan implementation.
8.0		CD	Minn. R. 7019.1000, subp. 4	Operation Changes: In any shutdown, breakdown, or deviation the Permittee shall immediately take all practical steps to modify operations to reduce the emission of any regulated air pollutant. The Commissioner may require feasible and practical modifications in the operation to reduce emissions of air pollutants. No emissions units that have an unreasonable shutdown or breakdown frequency of process or control equipment shall be permitted to operate.
9.0		CD	Minn. R. 7011.0150	Fugitive Emissions: Do not cause or permit the handling, use, transporting, or storage of any material in a manner which may allow avoidable amounts of particulate matter to become airborne. Comply with all other requirements listed in Minn. R. 7011.0150.
10.0		CD	Minn. R. 7030.0010 - 7030.0080	Noise: The Permittee shall comply with the noise standards set forth in Minn. R. 7030.0010 to 7030.0080 at all times during the operation of any emission units. This is a state only requirement and is not enforceable by the EPA Administrator or citizens under the Clean Air Act.
11.0		CD	Minn. R. 7007.0800, subp. 9(A)	Inspections: The Permittee shall comply with the inspection procedures and requirements as found in Minn. R. 7007.0800, subp. 9(A).
12.0		CD	Minn. R. 7007.0800, subp. 16	The Permittee shall comply with the General Conditions listed in Minn. R. 7007.0800, subp. 16.
13.0		CD	hdr	MONITORING REQUIREMENTS
14.0		CD	Minn. R. 7007.0800, subp. 4(D)	Monitoring Equipment Calibration: The Permittee shall calibrate all required monitoring equipment at least once every 12 months (any requirements applying to continuous emission monitors are listed separately in this permit).
15.0		CD	Minn. R. 7007.0800, subp. 4(D)	Operation of Monitoring Equipment: Unless otherwise noted in Tables A, B, and/or C, monitoring a process or control equipment connected to that process is not necessary during periods when the process is shutdown, or during checks of the monitoring systems, such as calibration checks and zero and span adjustments. If monitoring records are required, they should reflect any such periods of process shutdown or checks of the monitoring system.
16.0		CD	hdr	RECORDKEEPING REQUIREMENTS



COMPLIANCE PLAN **CD-01**

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

17.0		CD	Minn. R. 7007.0800, subp. 5(C)	Recordkeeping: Retain all records at the stationary source, unless otherwise specified within this permit, for a period of five (5) years from the date of monitoring, sample, measurement, or report. Records which must be retained at this location include all calibration and maintenance records, all original recordings for continuous monitoring instrumentation, and copies of all reports required by the permit. Records must conform to the requirements listed in Minn. R. 7007.0800, subp. 5(A).
18.0		CD	Minn. R. 7007.0800, subp. 5(B)	Recordkeeping: Maintain records describing any insignificant modifications (as required by Minn. R. 7007.1250, subp. 3) or changes contravening permit terms (as required by Minn. R. 7007.1350, subp. 2), including records of the emissions resulting from those changes.
19.0		CD	Minn. R. 7007.1200, subp. 4	If the Permittee determines that no permit amendment or notification is required prior to making a change, the Permittee must retain records of all calculations required under Minn. R. 7007.1200. These records shall be kept for a period of five years from the date that the change was made. The records shall be kept at the stationary source for the current calendar year of operation and may be kept at the stationary source or office of the stationary source for all other years. The records may be maintained in either electronic or paper format.
20.0		CD	hdr	REPORTING/SUBMITTALS
21.0		CD	Minn. R. 7019.1000, subp. 3	Shutdown Notifications: Notify the Commissioner at least 24 hours in advance of a planned shutdown of any control equipment or process equipment if the shutdown would cause any increase in the emissions of any regulated air pollutant. If the owner or operator does not have advance knowledge of the shutdown, notification shall be made to the Commissioner as soon as possible after the shutdown. However, notification is not required in the circumstances outlined in Items A, B, and C of Minn. R. 7019.1000, subp. 3. At the time of notification, the owner or operator shall inform the Commissioner of the cause of the shutdown and the estimated duration. The owner or operator shall notify the Commissioner when the shutdown is over.
22.0		CD	Minn. R. 7019.1000, subp. 2	Breakdown Notifications: Notify the Commissioner within 24 hours of a breakdown of more than one hour duration of any control equipment or process equipment if the breakdown causes any increase in the emissions of any regulated air pollutant. The 24-hour time period starts when the breakdown was discovered or reasonably should have been discovered by the owner or operator. However, notification is not required in the circumstances outlined in Items A, B, and C of Minn. R. 7019.1000, subp. 2. At the time of notification or as soon as possible thereafter, the owner or operator shall inform the Commissioner of the cause of the breakdown and the estimated duration. The owner or operator shall notify the Commissioner when the breakdown is over.
23.0		CD	Minn. R. 7019.1000, subp. 1	Notification of Deviations Endangering Human Health or the Environment: As soon as possible after discovery, notify the Commissioner or the state duty officer, either orally or by facsimile, of any deviation from permit conditions which could endanger human health or the environment.
24.0		CD	Minn. R. 7019.1000, subp. 1	Notification of Deviations Endangering Human Health or the Environment Report: Within two working days of discovery, notify the Commissioner in writing of any deviation from permit conditions which could endanger human health or the environment. Include the following information in this written notification: 1. the cause of the deviation; 2. the exact dates of the period of the deviation, if the deviation has been corrected; 3. whether or not the deviation has been corrected; 4. the anticipated time by which the deviation is expected to be corrected, if not yet corrected; and 5. steps taken or planned to reduce, eliminate, and prevent reoccurrence of the deviation.
25.0		S/A	Minn. R. 7007.0800, subp. 6(A)(2)	Semiannual Deviations Report: due 30 days after end of each calendar half-year starting 09/15/2008. The first semiannual report submitted by the Permittee shall cover the calendar half-year in which the permit is issued. The first report of each calendar year covers January 1 - June 30. The second report of each calendar year covers July 1 - December 31. If no deviations have occurred, the Permittee shall submit the report stating no deviations.



COMPLIANCE PLAN **CD-01**

Facility Name: ANI Pharmaceuticals Inc

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26.0		CD	Minn. R. 7007.1150 through Minn. R. 7007.1500	Application for Permit Amendment: If a permit amendment is needed, submit an application in accordance with the requirements of Minn. R. 7007.1150 through Minn. R. 7007.1500. Submittal dates vary, depending on the type of amendment needed.
27.0		CD	Minn. R. 7007.1400, subp. 1(H)	Extension Requests: The Permittee may apply for an Administrative Amendment to extend a deadline in a permit by no more than 120 days, provided the proposed deadline extension meets the requirements of Minn. R. 7007.1400, subp. 1(H). Performance testing deadlines from the General Provisions of 40 CFR pt. 60 and pt. 63 are examples of deadlines for which the MPCA does not have authority to grant extensions and therefore do not meet the requirements of Minn. R. 7007.1400, subp. 1(H).
28.0		S/A	Minn. R. 7007.0800, subp. 6(C)	Compliance Certification: due 31 days after end of each calendar year starting 09/03/2002 (for the previous calendar year). The Permittee shall submit the certification to the Commissioner on a form approved by the Commissioner. The certification covers all deviations experienced during the calendar year.
29.0		CD	Minn. R. 7019.3000 through Minn. R. 7019.3010	Emission Inventory Report: due on or before April 1 of each calendar year following permit issuance. The report shall be submitted on a form approved by the Commissioner.
30.0		CD	Minn. R. 7002.0005 through Minn. R. 7002.0095	Emission Fees: due 60 days after receipt of an MPCA bill.



COMPLIANCE PLAN **CD-01**

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: GP 001 Accela-Cota and Coating Prep Room

Associated Items: EU 011 Accela-Cota Room 1858

EU 012 Coating Prep Room 1854

SV 003 Accela-Cota

	NC/CA	Type	Citation	Requirement
1.0		CD	hdr	LIMITS
2.0		LIMIT	Title I Condition: To avoid major source classification under 40 CFR Section 63.2; To avoid major source classification under 40 CFR Section 70.2 and Minn. R. 7007.0200	HAP-Single: less than or equal to 3.0 tons/year using 12-month Rolling Sum calculated by the 15th day of each month for the previous 12-month period. HAP contents for each HAP-containing material shall be determined as described under the Material Content requirement.
3.0		LIMIT	Title I Condition: To avoid major source classification under 40 CFR Section 63.2; To avoid major source classification under 40 CFR Section 70.2 and Minn. R. 7007.0200	HAPs - Total: less than or equal to 6.0 tons/year using 12-month Rolling Sum calculated by the 15th day of each month for the previous 12-month period. HAP contents for each HAP-containing material shall be determined as described under the Material Content requirement.
4.0		LIMIT	Minn. R. 7011.0715, subp. 1(A)	Total Particulate Matter: less than or equal to 0.30 grains/dry standard cubic foot of exhaust gas unless required to further reduce emissions to comply with the less stringent limit of either Minn. R. 7011.0730 or Minn. R. 7011.0735.
5.0		LIMIT	Minn. R. 7011.0715, subp. 1(B)	Opacity: less than or equal to 20 percent opacity
6.0		CD	hdr	RECORDKEEPING
7.0		CD	Title I Condition: To avoid major source classification under 40 CFR Section 63.2; To avoid major source classification under 40 CFR Section 70.2 and Minn. R. 7007.0200; Minn. R. 7007.0800, subps. 4 and 5	Daily Recordkeeping. On each day of operation, the Permittee shall calculate, record, and maintain a record of the total quantity of each HAP-containing material used by GP 001 equipment.
8.0		CD	Minn. R. 7007.0800, subps. 4 and 5	Monthly Recordkeeping - HAP Emissions. By the 15th day of each month, the Permittee shall calculate and record the following using the formulas specified in this permit: 1. The total amount of each HAP-containing material used in the previous calendar month using the daily usage records. This record shall include the individual and total HAP contents of each HAP-containing material used during the previous month, as determined by the Material Content requirement of this permit; 2. The single HAP and total HAP emissions for the previous month using the formulas specified in this permit; and 3. The 12-month rolling sum single HAP and total HAP emissions for the previous 12-month period by summing the monthly emissions data for the previous 12 months.
9.0		CD	Minn. R. 7007.0800, subps. 4 and 5	Monthly Calculation - HAP Emissions. The Permittee shall calculate each single HAP and total HAP emissions using the following equations: HAP Emissions (tons/month) = H - W $H = (A1 \times B1) + (A2 \times B2) + (A3 \times B3) + \dots$ $W = (C1 \times D1) + (C2 \times D2) + (C3 \times D3) + \dots$



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10.0		CD	Minn. R. 7007.0800, subps. 4 and 5	<p>Monthly HAP Emissions Calculation Continued:</p> <p>Where: H = the amount of each pollutant (either total HAP or each single HAP), used, in tons/month. A# = Amount of each HAP-containing material used in the previous month, in tons/month. B# = weight percent of single individual or total HAP in A#, as a fraction (e.g., 50% is 0.50). W = the amount of each pollutant (either total HAP or each insingle HAP) shipped in waste, in tons/month. C# = amount, in tons/month, of each HAP-containing waste material shipped. If the Permittee chooses to not take credit for waste shipments, this parameter would be zero. D# = weight percent of each single or total HAP in C#, as a fraction.</p>
11.0		CD	Minn. R. 7007.0800, subps. 4 and 5	<p>Material Content. HAPs contents in coating materials shall be determined by the Material Safety Data Sheet (MSDS) provided by the supplier for each material used. If a material content range is given on the MSDS, the highest number in the range shall be used in all compliance calculations. Other alternative methods approved by the MPCA may be used to determine the HAPs content. The Commissioner reserves the right to require the Permittee to determine the HAP content of any material, according to EPA or ASTM reference methods. If an EPA or ASTM reference method is used for material content determination, the data obtained shall supersede the MSDS.</p>
12.0		CD	Minn. R. 7007.0800, subps. 4 and 5	<p>Waste Credit: If the Permittee elects to obtain credit for HAPs shipped in waste materials, the Permittee shall either follow item 1 or 2 below to determine the total and individual HAP content for each credited shipment.</p> <p>1) The Permittee shall analyze a composite sample of each waste shipment to determine the weight content of total HAP and each single HAP, excluding water.</p> <p>2) The Permittee may use supplier data for raw materials to determine the total and single HAP contents of each waste shipment, using the same content data used to determine the content of raw materials. If the waste contains several materials, the content of mixed waste shall be assumed to be the lowest total and single HAP content of any of the materials.</p>



COMPLIANCE PLAN **CD-01**

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: EU 007 Boiler 7 Kewanee

	NC/ CA	Type	Citation	Requirement
1.0		LIMIT	Minn. R. 7011.0515, subp. 1	Total Particulate Matter: less than or equal to 0.4 lbs/million Btu heat input (PTE is 0.007 lb/million Btu per design, using AP-42 emission factors)
2.0		LIMIT	Minn. R. 7011.0515, subp. 2	Opacity: less than or equal to 20 percent opacity except for one six-minute period per hour of not more than 60 percent opacity.
3.0		CD	Minn. R. 7007.0800, subp. 2	Fuel Type: Natural gas only, by design



COMPLIANCE PLAN CD-01

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: EU 009 Emergency Diesel Generator

Associated Items: SV 006 Emergency Generator

	NC/CA	Type	Citation	Requirement
1.0		LIMIT	Minn. R. 7011.2300, subp. 1	Opacity: less than or equal to 20 percent opacity once operating temperatures have been attained.
2.0		LIMIT	Minn. R. 7011.2300, subp. 2	Sulfur Dioxide: less than or equal to 0.5 lbs/million Btu heat input (PTE is 0.29 lbs/million Btu per equipment design, using AP-42 emission factors).
3.0		CD	Minn. R. 7007.0800, subp. 2	Fuel Type: No. 2 distillate fuel only, by design.
4.0		CD	Minn. R. 7007.0800, subps. 4 and 5	Hours of Operation: The Permittee shall maintain documentation on site that the unit is an emergency generator by design that qualifies under the U.S. EPA memorandum entitled "Calculating Potential to Emit (PTE) for Emergency Generators" dated September 6, 1995, limiting operation to 500 hours per year.
5.0		CD	Minn. R. 7007.0800, subps. 4 and 5	Fuel Supplier Certification: The Permittee shall obtain and maintain a fuel supplier certification for each shipment of No. 2 fuel oil, certifying that the sulfur content does not exceed 0.49% by weight.
6.0		CD	hdr	PART 63 SUBPART ZZZZ REQUIREMENTS
7.0		CD	40 CFR part 63, subp. ZZZZ	EU 009 is a 375 hp existing compression ignition emergency reciprocating internal combustion engine affected source subject to the requirements of 40 CFR part 63, subp. ZZZZ. The compliance date for EU 009 is May 2, 2013.
8.0		CD	40 CFR Section 63.6603(a)	<p>The Permittee shall comply with the following applicable requirements from part 63, subpart ZZZZ Table 2d, no later than the May 2, 2013 compliance date:</p> <ul style="list-style-type: none"> a. Change oil and filter every 500 hours of operation or annually, whichever comes first (the Permittee has the option to utilize an oil analysis program as described in Section 63.6625(i) in order to extend the specified oil change requirement in Table 2d of part 63 subpart ZZZZ); b. Inspect air cleaner every 1,000 hours of operation or annually, whichever comes first; and c. Inspect all hoses and belts every 500 hours of operation or annually, whichever comes first, and replace as necessary. <p>Table 2d Footnote 1: The facility has the option to utilize an oil analysis program as described in Section 63.6625(i) in order to extend the specified oil change requirement in part 63 subpart ZZZZ Table 2d.</p> <p>(continued)</p>
9.0		CD	40 CFR Section 63.6603(a)	<p>(continued from above)</p> <p>Table 2d Footnote 2: If EU 009 is operating during an emergency and it is not possible to shut down the engine in order to perform the management practice requirements on the schedule required in part 63 subpart ZZZZ Table 2d, or if performing the management practice on the required schedule would otherwise pose an unacceptable risk under Federal, State, or local law, the management practice can be delayed until the emergency is over or the unacceptable risk under Federal, State, or local law has abated. The management practice should be performed as soon as practicable after the emergency has ended or the unacceptable risk under Federal, State, or local law has abated. The Permittee must report any failure to perform the management practice on the schedule required and the Federal, State or local law under which the risk was deemed unacceptable.</p>
10.0		CD	40 CFR Section 63.6605	<p>(a) The Permittee must be in compliance with applicable emission limitations and operating limitations in part 63 subpart ZZZZ all times.</p> <p>(b) The Permittee must at all times operate EU 009 in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the Permittee to make any further efforts to reduce emissions if levels required by this standard have been achieved. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.</p>



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Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

11.0		CD	40 CFR Section 63.6625(e)(3)	The Permittee shall operate and maintain EU 009 according to the manufacturer's emission-related written instructions or develop a maintenance plan which must provide to the extent practicable for the maintenance and operation of EU 009 in a manner consistent with good air pollution control practice for minimizing emissions.
12.0		CD	40 CFR Section 63.6625(f)	Install a non-resettable hour meter if one is not already installed.
13.0		CD	40 CFR Section 63.6625(h)	Minimize EU 009 idle time during startup and minimize EU 009 startup time to a period needed for appropriate and safe loading of the engine, not to exceed 30 minutes, after which time the emission standards applicable to all times other than startup in Table 2d to part 63 subpart ZZZZ apply.
14.0		CD	40 CFR Section 63.6625(i)	For item 4 of Table 2d to part 63 subpart ZZZZ, the Permittee has the option of utilizing an oil analysis program in order to extend the specified oil change requirement in Table 2d to part 63 subpart ZZZZ. The oil analysis must be performed at the same frequency specified for changing the oil in Table 2d to part 63 subpart ZZZZ. The analysis program must at a minimum analyze the following three parameters: Total Base Number, viscosity, and percent water content. The condemning limits for these parameters are as follows: Total Base Number is less than 30 percent of the Total Base Number of the oil when new; viscosity of the oil has changed by more than 20 percent from the viscosity of the oil when new; or percent water content (by volume) is greater than 0.5. (continued)
15.0		CD	40 CFR Section 63.6625(i)	(continued from above) If all of these condemning limits are not exceeded, the Permittee is not required to change the oil. If any of the limits are exceeded, the Permittee must change the oil within 2 days of receiving the results of the analysis; if the engine is not in operation when the results of the analysis are received, the Permittee must change the oil within 2 days or before commencing operation, whichever is later. The Permittee must keep records of the parameters that are analyzed as part of the program, the results of the analysis, and the oil changes for the engine. The analysis program must be part of the maintenance plan for the engine.
16.0		CD	40 CFR Section 63.6640(a)	The Permittee must demonstrate continuous compliance with each applicable operating limitation in part 63 subpart ZZZZ Table 2d according to methods specified in part 63 subpart ZZZZ Table 6 (Table 6 item 9 work or management practices).
17.0		CD	40 CFR Section 63.6640(b)	The Permittee must report each instance in which the operating limitations in part 63 subpart ZZZZ Table 2d were not met. These instances are deviations from the operating limitations in subpart ZZZZ. These deviations must be reported according to the requirements in Section 63.6650.
18.0		CD	40 CFR Section 63.6640(e)	The Permittee shall comply with part 63 subpart A applicable requirements listed at part 63 subpart ZZZZ Table 8.
19.0		CD	40 CFR Section 63.6640(f)(1)	The Permittee shall operate EU 009 according to the requirements in paragraphs (f)(1)(i) through (iii) of section 63.6640. Any EU 009 operation other than emergency operation, maintenance and testing, and operation in non-emergency situations for 50 hours per year, as described in paragraphs (f)(1)(i) through (iii) of section 63.6640, is prohibited. If the Permittee does not operate EU 009 according to the requirements in paragraphs (f)(1)(i) through (iii) of section 63.6640, EU 009 will not be considered an emergency engine under part 63 subpart ZZZZ and will need to meet all requirements for non-emergency engines.
20.0	(i)	CD	40 CFR Section 63.6640(f)(1)	(i) There is no time limit on the use of EU 009 in emergency situations. (ii) The Permittee may operate EU 009 for the purpose of maintenance checks and readiness testing, provided that the tests are recommended by Federal, State or local government, the manufacturer, the vendor, or the insurance company associated with the engine. Maintenance checks and readiness testing of such units is limited to 100 hours per year. The Permittee may petition the Administrator for approval of additional hours to be used for maintenance checks and readiness testing, but a petition is not required if the Permittee maintains records indicating that Federal, State, or local standards require maintenance and testing of emergency RICE beyond 100 hours per year.



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Facility Name: ANI Pharmaceuticals Inc

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21.0		CD	40 CFR Section 63.6640(f)(1)(iii)	<p>(iii) The Permittee may operate EU 009 up to 50 hours per year in non-emergency situations, but those 50 hours are counted towards the 100 hours per year provided for maintenance and testing. The 50 hours per year for non-emergency situations cannot be used for peak shaving or to generate income for a facility to supply power to an electric grid or otherwise supply power as part of a financial arrangement with another entity; except the Permittee may operate EU 009 for a maximum of 15 hours per year as part of a demand response program if the regional transmission organization or equivalent balancing authority and transmission operator has determined there are emergency conditions that could lead to a potential electrical blackout, such as unusually low frequency, equipment overload, capacity or energy deficiency, or unacceptable voltage level.</p> <p>(continued below)</p>
22.0		CD	40 CFR Section 63.6640(f)(1)(iii)	<p>(continued from above)</p> <p>EU 009 may not be operated for more than 30 minutes prior to the time when the emergency condition is expected to occur, and the engine operation must be terminated immediately after the facility is notified that the emergency condition is no longer imminent. The 15 hours per year of demand response operation are counted as part of the 50 hours of operation per year provided for non-emergency situations. The supply of emergency power to another entity or entities pursuant to financial arrangement is not limited by this paragraph (f)(1)(iii), as long as the power provided by the financial arrangement is limited to emergency power.</p>
23.0		CD	40 CFR Section 63.6645(a)(5)	<p>Notifications in Sections 63.7(b) and (c), 63.8(e), (f)(4) and (f)(6), and 63.9(b)-(e), (g) and (h) do not apply to EU 009.</p>
24.0		CD	40 CFR Section 63.6655	<p>Keep records described in Section 63.6655 paragraphs (a)(1) through (a)(5), (b)(1) through (b)(3) and (c).</p> <p>(1) A copy of each notification and report submitted to comply with subpart ZZZZ including all documentation supporting any Initial Notification or Notification of Compliance Status submitted, according to the requirement in Section 63.10(b)(2)(xiv).</p> <p>(2) Records of the occurrence and duration of each EU 009 malfunction or monitoring equipment malfunction.</p> <p>(3) Records of performance tests and performance evaluations as required in Section 63.10(b)(2)(viii).</p> <p>(4) Records of all required maintenance performed on the monitoring equipment.</p> <p>(5) Records of actions taken during periods of malfunction to minimize emissions in accordance with Section 63.6605(b), including corrective actions to restore malfunctioning process and monitoring equipment to its normal or usual manner of operation.</p>
25.0		CD	40 CFR Section 63.6655	<p>(d) The Permittee must keep the records required in subpart ZZZZ Table 6 to show continuous compliance with each applicable EU 009 operating limitation.</p> <p>(e)(2) The Permittee must keep records of the maintenance conducted on EU 009 in order to demonstrate that the Permittee operated and maintained EU 009 according to the Permittee's maintenance plan.</p> <p>(f)(2) The Permittee must keep records of the EU 009 hours of operation that is recorded through the non-resettable hour meter. The Permittee must document how many hours are spent for emergency operation, including what classified the operation as emergency and how many hours are spent for non-emergency operation. If EU 009 is used for demand response operation, the Permittee must keep records of the notification of the emergency situation, and the time EU 009 was operated as part of demand response.</p>



COMPLIANCE PLAN **CD-01**

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: EU 034 Burnham Boiler 2

	NC/ CA	Type	Citation	Requirement
1.0		LIMIT	Minn. R. 7011.0515, subp. 1	Total Particulate Matter: less than or equal to 0.4 lbs/million Btu heat input (PTE is 0.007 lb/million Btu per design, using AP-42 emission factors).
2.0		LIMIT	Minn. R. 7011.0515, subp. 2	Opacity: less than or equal to 20 percent opacity except for one six-minute period per hour of not more than 60 percent opacity.
3.0		CD	Minn. R. 7007.0800, subp. 2	Fuel Type: Natural gas only, by design.



COMPLIANCE PLAN **CD-01**

Facility Name: ANI Pharmaceuticals Inc

Permit Number: 07700010 - 003

Subject Item: EU 035 Burnham Boiler 3

	NC/ CA	Type	Citation	Requirement
1.0		LIMIT	Minn. R. 7011.0515, subp. 1	Total Particulate Matter: less than or equal to 0.4 lbs/million Btu heat input (PTE is 0.007 lb/million Btu per design, using AP-42 emission factors).
2.0		LIMIT	Minn. R. 7011.0515, subp. 2	Opacity: less than or equal to 20 percent opacity except for one six-minute period per hour of not more than 60 percent opacity.
3.0		CD	Minn. R. 7007.0800, subp. 2	Fuel Type: Natural gas only, by design.

Points Calculator

1) AQ Facility ID No.: 07700010
 2) Facility Name: ANI Pharmaceuticals Inc
 3) Small business? y/n? N
 4) DQ Numbers (including all rolled) : 3433
 5) Date of each Application Received: 3/23/2011
 6) Final Permit No. 07700010-003
 7) Permit Staff M Cole
 8) "Work completed" in which .xls file (i.e. unit 2b, unit 1a, biofuels)? NA

Total Points	10
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<u>Application Type</u>	<u>DQ No.</u>	<u>Qty.</u>	<u>Points</u>	<u>Total Points</u>	<u>Details</u>
Administrative Amendment			1	0	
Minor Amendment			4	0	
Applicability Request			10	0	
Moderate Amendment			15	0	
Major Amendment	3433		25	0	paid w/application
Individual State Permit (not reissuance)			50	0	
Individual Part 70 Permit (not reissuance)			75	0	
<u>Additional Points</u>					
Modeling Review			15	0	
BACT Review			15	0	
LAER Review			15	0	
CAIR/Part 75 CEM analysis			10	0	
NSPS Review			10	0	
NESHAP Review			10	0	
Case-by-case MACT Review			20	0	
Netting			10	0	
Limits to remain below threshold	3433	1	10	10	HAP limits to avoid pt. 63
Plantwide Applicability Limit (PAL)			20	0	
AERA review			15	0	
Variance request under 7000.7000			35	0	
Confidentiality request under 7000.1300			2	0	
<u>EAW review</u>					
Part 4410.4300, subparts 18, item A; and 29			15	0	
Part 4410.4300, subparts 8, items A & B; 10, items A to C; 16, items A & D; 17, items A to C & E to G; and 18, items B & C			35	0	
Part 4410.4300, subparts 4; 5 items A & B; 13; 15; 16, items B & C; and 17 item D			70	0	
				Add'l Points	10

NOTES: Application points paid with application