

Synthetic Minor Determination and/or Netting Determination

Permit To Install: 14-06009

A. Source Description

Pantheon is a manufacturer of pharmaceutical products, including tablets and capsules. The proposed emissions unit is an existing, previously de minimis emissions source, intermediate scale processing suite (ISPS) for production of various products. The proposed use of organic solvents would exceed 10 pounds per day of emissions of a new air contaminant, warranting this air permit to install.

Process equipment for the ISPS includes a mixer/granulator, a solution kettle, a wet mill, a fluid bed dryer, and a final dry mill. The company conservatively estimates a 0.5% by weight loss of particulate matter at the mixer/granulator, and 0.1 % organic compound (OC) loss at the mixer/granulator and the solution kettle. Remaining solvent is driven off of the milled product in the fluid bed dryer. OC emissions would be controlled by a 98% efficient thermal oxidizer, which also serves other existing emissions units. Potential solvents to be used include ethanol, acetone, isopropyl alcohol, and methanol. Aqueous solutions are also used. Methanol is a listed Hazardous Air Pollutant(HAP).

B. Facility Emissions and Attainment Status

The facility is located in Hamilton County which is non-attainment for ozone and PM2.5 and attainment for all other criteria pollutants. The facility is currently a synthetic minor organic compound source with facility-wide controlled OC* emissions are 80.04 tons per year (TPY).

Potential uncontrolled OC emissions from the proposed emissions unit are 321.9 TPY. The proposed allowable emission rate of 8.0 tons per year from this proposed emissions unit, will allow for a facility wide total of 88.04 tons per year. Facility-wide controlled PM emissions are 12.9 tons per year (TPY) plus 3.11 tons per year from this proposed emission unit, for a total of 16.01 tons per year.

Patheon currently has a synthetic minor permit (PTI 14-05727 issued 10/06/2005) limiting facility-wide hazardous air pollutant (HAP)emissions to 9.9 TPY for a single HAP and 24.9 TPY. The proposed permit includes this emissions unit in the facility wide cap.

The permit terms and conditions will limit the OC and HAP emissions to below major source thresholds.

*for purposes of non-attainment review for ozone, all volatile organic compound (VOC) emissions are considered to be OC.

C. Source Emissions

Emissions from the proposed emissions unit are 8.0 tons per year of OC, 3.11 tons per year of PE/PM10. Methanol is the only HAP or OAC 3745-114 material to be used in this process.

D. Conclusion

The proposed permit includes Operational Restrictions, Record keeping and Monitoring Requirements, Reporting Requirements, and emission compliance demonstration requirements which will allow the facility to determine compliance with the HAPs and OC Synthetic Minor limitations. Synthetic minor status is required for this PTI in order to avoid major source status with respect to HAPs and OC which would otherwise require nonattainment new source review and a title V operating permit. As a result of the permit being issued in draft and incorporating federally enforceable terms, Patheon will remain Synthetic Minor facility.



State of Ohio Environmental Protection Agency

Street Address:

Lazarus Gov. Center
50 West Town Street, Suite 700
Columbus, OH 43215

TELE: (614) 644-3020 FAX: (614) 644-2329

Mailing Address:

Lazarus Gov. Center
P.O. Box 1049
Columbus, OH 43216-1049

CERTIFIED MAIL

**RE: DRAFT PERMIT TO INSTALL
HAMILTON COUNTY
Application No: 14-06009
Fac ID: 1431380503**

Y	TOXIC REVIEW
	PSD
Y	SYNTHETIC MINOR
	CEMS
	MACT
	NSPS
	NESHAPS
	NETTING
	MAJOR NON-ATTAINMENT
	MODELING SUBMITTED
	GASOLINE DISPENSING FACILITY

DATE: 4/10/2008

Patheon Pharmaceuticals, Inc.
Teresa Turnbow
2110 Galbraith Road
Cincinnati, OH 45215-6300

You are hereby notified that the Ohio Environmental Protection Agency has made a draft action recommending that the Director issue a Permit to Install for the air contaminant source(s) [emissions unit(s)] shown on the enclosed draft permit. This draft action is not an authorization to begin construction or modification of your emissions unit(s). The purpose of this draft is to solicit public comments on the proposed installation. A public notice concerning the draft permit will appear in the Ohio EPA Weekly Review and the newspaper in the county where the facility will be located. Public comments will be accepted by the field office within 30 days of the date of publication in the newspaper. Any comments you have on the draft permit should be directed to the appropriate field office within the comment period. A copy of your comments should also be mailed to Robert Hodanbosi, Division of Air Pollution Control, Ohio EPA, P.O. Box 1049, Columbus, OH, 43216-1049.

A Permit to Install may be issued in proposed or final form based on the draft action, any written public comments received within 30 days of the public notice, or record of a public meeting if one is held. You will be notified in writing of a scheduled public meeting. Upon issuance of a final Permit to Install a fee of **\$200** will be due. Please do not submit any payment now.

The Ohio EPA is urging companies to investigate pollution prevention and energy conservation. Not only will this reduce pollution and energy consumption, but it can also save you money. If you would like to learn ways you can save money while protecting the environment, please contact our Office of Pollution Prevention at (614) 644-3469. If you have any questions about this draft permit, please contact the field office where you submitted your application, or Mike Ahern, Field Operations & Permit Section at (614) 644-3631.

Sincerely,

Michael W. Ahern, Manager
Permit Issuance and Data Management Section
Division of Air Pollution Control

HAMILTON COUNTY

PUBLIC NOTICE

**ISSUANCE OF DRAFT PERMIT TO INSTALL 14-06009 FOR AN AIR CONTAMINANT SOURCE
FOR **Patheon Pharmaceuticals, Inc.****

On 4/10/2008 the Director of the Ohio Environmental Protection Agency issued a draft action of a Permit To Install an air contaminant source for **Patheon Pharmaceuticals, Inc.**, located at **2110 East Galbraith Road, Cincinnati, Ohio.**

Installation of the air contaminant source identified below may proceed upon final issuance of Permit To Install 14-06009:

Intermediate Scale Processing suite for pharmaceutical products.

Comments concerning this draft action, or a request for a public meeting, must be sent in writing to the address identified below no later than thirty (30) days from the date this notice is published. All inquiries concerning this draft action may be directed to the contact identified below.

Brad Miller, Hamilton County Department of Environmental Services, 250 William Howard Taft Pkwy, Cincinnati, OH 45219-2660 [(513)946-7777]



**Permit To Install
Terms and Conditions**

**Issue Date: To be entered upon final issuance
Effective Date: To be entered upon final issuance**

DRAFT PERMIT TO INSTALL 14-06009

Application Number: 14-06009
Facility ID: 1431380503
Permit Fee: **To be entered upon final issuance**
Name of Facility: Patheon Pharmaceuticals, Inc.
Person to Contact: Teresa Turnbow
Address: 2110 Galbraith Road
Cincinnati, OH 45215-6300

Location of proposed air contaminant source(s) [emissions unit(s)]:
**2110 East Galbraith Road
Cincinnati, Ohio**

Description of proposed emissions unit(s):
Intermediate Scale Processing suite for pharmaceutical products.

The above named entity is hereby granted a Permit to Install for the above described emissions unit(s) pursuant to Chapter 3745-31 of the Ohio Administrative Code. Issuance of this permit does not constitute expressed or implied approval or agreement that, if constructed or modified in accordance with the plans included in the application, the above described emissions unit(s) of environmental pollutants will operate in compliance with applicable State and Federal laws and regulations, and does not constitute expressed or implied assurance that if constructed or modified in accordance with those plans and specifications, the above described emissions unit(s) of pollutants will be granted the necessary permits to operate (air) or NPDES permits as applicable.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Chris Korleski
Director

Part I - GENERAL TERMS AND CONDITIONS

A. Permit to Install General Terms and Conditions

1. Compliance Requirements

The emissions unit(s) identified in this Permit to Install shall remain in full compliance with all applicable State laws and regulations and the terms and conditions of this permit.

2. Reporting Requirements

The permittee shall submit required reports in the following manner:

- a. Reports of any required monitoring and/or recordkeeping information shall be submitted to the appropriate Ohio EPA District Office or local air agency.
- b. Except as otherwise may be provided in the terms and conditions for a specific emissions unit, quarterly written reports of (a) any deviations (excursions) from emission limitations, operational restrictions, and control device operating parameter limitations that have been detected by the testing, monitoring, and recordkeeping requirements specified in this permit, (b) the probable cause of such deviations, and (c) any corrective actions or preventive measures which have been or will be taken, shall be submitted to the appropriate Ohio EPA District Office or local air agency. If no deviations occurred during a calendar quarter, the permittee shall submit a quarterly report, which states that no deviations occurred during that quarter. The reports shall be submitted (i.e., postmarked) quarterly by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters. (These quarterly reports shall exclude deviations resulting from malfunctions reported in accordance with OAC rule 3745-15-06.)

3. Records Retention Requirements

Each record of any monitoring data, testing data, and support information required pursuant to this permit shall be retained for a period of five years from the date the record was created. Support information shall include, but not be limited to, all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by this permit. Such records may be maintained in computerized form.

4. Inspections and Information Requests

The Director of the Ohio EPA, or an authorized representative of the Director, may, subject to the safety requirements of the permittee and without undue delay, enter upon the premises of this source at any reasonable time for purposes of making inspections,

conducting tests, examining records or reports pertaining to any emission of air contaminants, and determining compliance with any applicable State air pollution laws and regulations and the terms and conditions of this permit. The permittee shall furnish to the Director of the Ohio EPA, or an authorized representative of the Director, upon receipt of a written request and within a reasonable time, any information that may be requested to determine whether cause exists for modifying, reopening or revoking this permit or to determine compliance with this permit. Upon verbal or written request, the permittee shall also furnish to the Director of the Ohio EPA, or an authorized representative of the Director, copies of records required to be kept by this permit.

5. Scheduled Maintenance/Malfunction Reporting

Any scheduled maintenance of air pollution control equipment shall be performed in accordance with paragraph (A) of OAC rule 3745-15-06. The malfunction of any emissions units or any associated air pollution control system(s) shall be reported to the appropriate Ohio EPA District Office or local air agency in accordance with paragraph (B) of OAC rule 3745-15-06. Except as provided in that rule, any scheduled maintenance or malfunction necessitating the shutdown or bypassing of any air pollution control system(s) shall be accompanied by the shutdown of the emissions unit(s) that is (are) served by such control system(s).

6. Permit Transfers

Any transferee of this permit shall assume the responsibilities of the prior permit holder. The appropriate Ohio EPA District Office or local air agency must be notified in writing of any transfer of this permit.

7. Air Pollution Nuisance

The air contaminants emitted by the emissions units covered by this permit shall not cause a public nuisance, in violation of OAC rule 3745-15-07.

8. Termination of Permit to Install

This Permit to Install shall terminate within eighteen months of the effective date of the Permit to Install if the owner or operator has not undertaken a continuing program of installation or modification or has not entered into a binding contractual obligation to undertake and complete within a reasonable time a continuing program of installation or modification. This deadline may be extended by up to 12 months if application is made to the Director within a reasonable time before the termination date and the party shows good cause for any such extension.

9. Construction of New Sources(s)

The proposed emissions unit(s) shall be constructed in strict accordance with the plans and application submitted for this permit to the Director of the Ohio Environmental

Protection Agency. There may be no deviation from the approved plans without the express, written approval of the Agency. Any deviations from the approved plans or the above conditions may lead to such sanctions and penalties as provided under Ohio law. Approval of these plans does not constitute an assurance that the proposed facilities will operate in compliance with all Ohio laws and regulations. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed sources cannot meet the requirements of this permit or cannot meet applicable standards.

If the construction of the proposed emissions unit(s) has already begun or has been completed prior to the date the Director of the Environmental Protection Agency approves the permit application and plans, the approval does not constitute expressed or implied assurance that the proposed facility has been constructed in accordance with the approved plans. The action of beginning and/or completing construction prior to obtaining the Director's approval constitutes a violation of OAC rule 3745-31-02. Furthermore, issuance of the Permit to Install does not constitute an assurance that the proposed source will operate in compliance with all Ohio laws and regulations. Approval of the plans in any case is not to be construed as an approval of the facility as constructed and/or completed. Moreover, issuance of the Permit to Install is not to be construed as a waiver of any rights that the Ohio Environmental Protection Agency (or other persons) may have against the applicant for starting construction prior to the effective date of the permit. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed facilities cannot meet the requirements of this permit or cannot meet applicable standards.

10. Public Disclosure

The facility is hereby notified that this permit, and all agency records concerning the operation of this permitted source, are subject to public disclosure in accordance with OAC rule 3745-49-03.

11. Applicability

This Permit To Install is applicable only to the emissions unit(s) identified in the Permit To Install. Separate Permit To Install for the installation or modification of any other emissions unit(s) are required for any emissions unit for which a Permit To Install is required.

12. Best Available Technology

As specified in OAC Rule 3745-31-05, all new sources must employ Best Available Technology (BAT). Compliance with the terms and conditions of this permit will fulfill this requirement.

13. Source Operation and Operating Permit Requirements After Completion of Construction

This facility is permitted to operate each source described by this Permit to Install for a period of up to one year from the date the source commenced operation. This permission to operate is granted only if the facility complies with all requirements contained in this permit and all applicable air pollution laws, regulations, and policies. Pursuant to OAC Chapter 3745-35, the permittee shall submit a complete operating permit application within ninety (90) days after commencing operation of the emissions unit(s) covered by this permit.

14. Construction Compliance Certification

The applicant shall provide Ohio EPA with a written certification (see enclosed form) that the facility has been constructed in accordance with the Permit to Install application and the terms and conditions of the Permit to Install. The certification shall be provided to Ohio EPA upon completion of construction but prior to startup of the source.

15. Fees

The permittee shall pay fees to the Director of the Ohio EPA in accordance with ORC section 3745.11 and OAC Chapter 3745-78. The permittee shall pay all applicable Permit to Install fees within 30 days after the issuance of this Permit to Install.

B. Permit to Install Summary of Allowable Emissions

The following information summarizes the total allowable emissions, by pollutant, based on the individual allowable emissions of each air contaminant source identified in this permit.

SUMMARY (for informational purposes only)
TOTAL PERMIT TO INSTALL ALLOWABLE EMISSIONS

<u>Pollutant</u>	<u>Tons Per Year</u>
OC	8.0
PE/PM10	1.8
Single HAP	9.9
Combined HAPs	24.9

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)**A. Applicable Emissions Limitations and/or Control Requirements**

1. The specific operations(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be specified in narrative form following the table.

Operations, Property, and/or Equipment - (P051) - Intermediate Scale Processing suite for pharmaceutical products

Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
OAC rule 3745-31-05(A)(3)(b)	See term and condition A.2.c.
OAC rule 3745-31-05(A)(3)	Emissions of Organic Compounds (OC) shall not exceed 1.82 lb/hour (not including clean up). See term and condition A.2.b. The requirements for this rule also include compliance with the requirements of OAC rule 3745-31-05(C).
OAC rule 3745-17-11	Particulate Emissions (PE) shall not exceed 0.80 lb/hr.
OAC rule 3745-17-07(A)(1)	Visible particulate emissions from any stack associated with this emissions unit shall not exceed 20 percent opacity, as a six-minute average, except as specified by rule.
OAC rule 3745-31-05(C) (Synthetic minor to avoid title V permitting)	See terms and conditions A.2.d and A.2.e.
OAC rule 3745-31-05(C) (Synthetic minor to avoid Major NSR permitting)	See term and condition A.2.d.

2. Additional Terms and Conditions

- 2.a Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by emission limitations and the use of a thermal oxidizer with an overall OC control efficiency of at least 98 percent.
- 2.b The permittee shall control organic compound emissions from this emissions unit by use of a thermal oxidizer with a minimum overall OC control efficiency of 98%

by weight. This requirement shall apply whenever the permittee is using OC-containing solvents.

- 2.c** The Best Available Technology (BAT) requirements under OAC rule 3745-31-05(A)(3) do not apply to the particulate emissions and particulate matter emissions 10 microns and less in diameter (PM10) from this air contaminant source since the calculated annual emission rate for particulate emissions is less than ten tons per year taking into account the federally enforceable rule limitation of 2.0 lbs/hr as derived from OAC 3745-17-11, and the uncontrolled potential to emit for PM10 is less than ten tons per year.
- 2.d** The actual emissions of Organic Compounds (OC) from emission unit P051 shall not exceed 8.0 tons per year (including clean up). Compliance with this limitation shall be based on a rolling, 12-month summation.

The permittee has existing records to demonstrate compliance with the limitations in term A.2.d upon permit issuance.

- 2.e** The actual emissions of Hazardous Air Pollutants (HAPs), as identified in Section 112(b) of Title III of the Clean Air Act from emissions units B003 (72.6 MMBtu/hr Natural Gas / No. 2 Fuel Oil Fired Boiler), P002 (capsule production line), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) P007 (fluid bed dryer), P008 (dry products line), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P044-P047 (drying ovens), P048 (Tablet coating line), P051 (Intermediate Scale Processing Suite for pharmaceutical products), any de minimis emissions units as defined in OAC rule 3745-15-05, and any registration status and/or permit exempt emissions units shall not exceed 9.9 TPY for any single HAP and 24.9 TPY for any combination of HAPs. Compliance with the above limitations shall be based on a rolling, 12-month summation.

The permittee has existing records to demonstrate compliance with the limitations in term A.2.e upon permit issuance.

B. Operational Restrictions

1. Except when employing only non-OC containing solvents, all of the OC emissions from the fluid bed dryer of this emissions unit shall be vented to the thermal oxidizer when in operation.

C. Monitoring and/or Record Keeping Requirements

1. The permittee shall collect and record the following information each month for this emissions unit:

- a. the company identification of each coating/solvent and cleanup material employed in these emissions units;
 - b. the amount of OC materials employed, in pounds per month;
 - c. the organic compound emissions, in tons per month;
 - d. the updated, rolling 12-month summation of the OC usage rate for emission unit P051. This shall include the information for the current month and the preceding eleven months; and
 - e. the updated, rolling 12-month summation of the OC emissions for emission unit P051, in tons. This shall include the information for the current month and the preceding eleven months.
2. The permittee shall collect and record the following information each month for emissions units B003 (72.6 MMBtu/hr Natural Gas / No. 2 Fuel Oil Fired Boiler), P002 (capsule production line), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) P007 (fluid bed dryer), P008 (dry products line), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P044-P047 (drying ovens), P048 (Tablet coating line), P051 (Intermediate Scale Processing Suite for pharmaceutical products), and any de minimis defined in OAC rule 3745-15-05, any registration status and/or permit exempt emissions units:
- a. The name and identification number of each coating or solvent employed;
 - b. The individual Hazardous Air Pollutant (HAP)* content for each HAP of each coating or solvent in pounds of individual HAP per pound of coating or solvent, as applied;
 - c. The total combined HAP content of each coating or solvent in pounds of combined HAPs per pound of coating or solvent, as applied [sum all the individual HAP contents from (b)];
 - d. The number of pounds of each coating or solvent employed;
 - e. The name and identification of each cleanup material employed;
 - f. The individual HAP content for each HAP of each cleanup material, in pounds of individual HAP per gallon of cleanup material, as applied;
 - g. The total combined HAP content of each cleanup material, in pounds of combined HAPs per gallon of cleanup material, as applied [sum all the individual HAP contents from (f)];
 - h. The number of gallons of each cleanup material employed;

- i. The total individual HAP emissions for each HAP from all coatings (or solvents) and cleanup materials employed, in pounds or tons per month [for each HAP the sum of (b) times (d) times the emissions factor (if applicable) for each coating or solvent plus the sum of (f) times (h) for each cleanup material plus individual HAP emissions from any de minimis, registration status and/or permit exempt emissions unit at the facility];
- j. The total combined HAP emissions from all coatings (or solvents) and cleanup materials employed, in pounds or tons per month [the sum of (c) times (d) times the emissions factor (if applicable) for each coating or solvent plus the sum of (g) times (h) for each cleanup material plus combined HAP emissions from any de minimis, registration status and/or permit exempt emissions unit at the facility];
- k. The updated rolling, 12-month summation of the individual HAP emissions, in pounds or tons. This shall include the information for the current month and the preceding eleven calendar months; and
- l. The updated rolling, 12-month summation of the combined HAP emissions, in pounds or tons. This shall include the information for the current month and the preceding eleven calendar months.

* A listing of the HAPs can be found in Section 112(b) of the Clean Air Act or can be obtained by contacting Hamilton County Department of Environmental Services. This information does not have to be kept on a individual emissions unit basis.

3. The permittee shall properly install, operate, and maintain equipment to continuously monitor and record the average combustion temperature within the thermal oxidizer during operation of this emissions unit, including periods of startup and shutdown. The monitoring equipment shall be installed, calibrated, operated, and maintained in accordance with the manufacturer's recommendations, instructions, and operating manual(s). The permittee shall record the temperature on a continuous basis.

Whenever the monitored value for the average combustion temperature within the thermal oxidizer deviates from the range specified below, the permittee shall promptly investigate the cause of the deviation. The permittee shall maintain records of the following information for each investigation: the date and time the deviation began and the magnitude of the deviation at that time, the date(s) the investigation was conducted, the names of the personnel who conducted the investigation, and the findings and recommendations.

In response to each required investigation to determine the cause of a deviation, the permittee shall take prompt corrective action to bring the operation of the control equipment within the acceptable value specified below, unless the permittee determines that corrective action is not necessary and documents the reasons for that determination and the date and time the deviation ended. The permittee shall maintain records of the following information for each corrective action taken: a description of the

corrective action, the date it was completed, the date and time the deviation ended, the total period of time (in minutes) during which there was a deviation, the average combustion temperature within the thermal oxidizer immediately after the corrective action, and the names of the personnel who performed the work. Investigation and records required by this paragraph does not eliminate the need to comply with the requirements of OAC rule 3745-15-06 if it is determined that a malfunction has occurred.

The acceptable values for the average combustion temperature within the thermal oxidizer, for any 3-hour block of time when the emissions unit is in operation, shall be maintained above 1550 degrees Fahrenheit or shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

These values are effective for the duration of this permit, unless revisions are requested by the permittee and approved in writing by the appropriate Ohio EPA District Office or local air agency. The permittee may request revisions to the values based upon information obtained during future organic compound emission tests that demonstrate compliance with the allowable organic compound emission rate for this emissions unit. In addition, approved revisions to the values will not constitute a relaxation of the monitoring requirements of this permit and may be incorporated into this permit by means of a administrative modification.

4. The permit to install for this/these emissions unit(s) P051 was evaluated based on the actual materials and the design parameters of the emissions unit's(s') exhaust system, as specified by the permittee in the permit application. The "Toxic Air Contaminant Statute", ORC 3704.03(F), was applied to this/these emissions unit(s) for each toxic air contaminant listed in OAC rule 3745-114-01, using data from the permit application; and modeling was performed for each toxic air contaminant(s) emitted at over one ton per year using an air dispersion model such as SCREEN 3.0, AERMOD, or ISCST3, or other Ohio EPA approved model. The predicted 1-hour maximum ground-level concentration result(s) from the approved air dispersion model, was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC), calculated as described in the Ohio EPA guidance document entitled "Review of New Sources of Air Toxic Emissions, Option A", as follows:
 - a. the exposure limit, expressed as a time-weighted average concentration for a conventional 8-hour workday and a 40-hour workweek, for each toxic compound(s) emitted from the emissions unit(s), (as determined from the raw materials processed and/or coatings or other materials applied) has been documented from one of the following sources and in the following order of preference (TLV was and shall be used, if the chemical is listed):
 - i. threshold limit value (TLV) from the American Conference of Governmental Industrial Hygienists' (ACGIH) "Threshold Limit Values for

Chemical Substances and Physical Agents Biological Exposure Indices”;
or

- ii. STEL (short term exposure limit) or the ceiling value from the American Conference of Governmental Industrial Hygienists’ (ACGIH) “Threshold Limit Values for Chemical Substances and Physical Agents Biological Exposure Indices”; the STEL or ceiling value is multiplied by 0.737 to convert the 15-minute exposure limit to an equivalent 8-hour TLV.
- b. The TLV is divided by ten to adjust the standard from the working population to the general public (TLV/10).
- c. This standard is/was then adjusted to account for the duration of the exposure or the operating hours of the emissions unit(s), i.e., 24 hours per day and 7 days per week, from that of 8 hours per day and 5 days per week. The resulting calculation was (and shall be) used to determine the Maximum Acceptable Ground-Level Concentration (MAGLC):

$$TLV/10 \times 8/X \times 5/Y = 4 TLV/XY = MAGLC$$

- d. The following summarizes the results of dispersion modeling for the significant toxic contaminants (emitted at 1 or more tons/year) or “worst case” toxic contaminant(s):

Toxic Contaminant: methanol

TLV (mg/m3): 262,086

Maximum Hourly Emission Rate (lbs/hr): 1.82

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 138.6

MAGLC (ug/m3): 6240

The permittee, has demonstrated that emissions of methanol from emissions unit(s) P051, is calculated to be less than eighty per cent of the maximum acceptable ground level concentration (MAGLC); any new raw material or processing agent shall not be applied without evaluating each component toxic air contaminant in accordance with the “Toxic Air Contaminant Statute”, ORC 3704.03(F).

- 5. Prior to making any physical changes to or changes in the method of operation of the emissions unit(s), that could impact the parameters or values that were used in the predicted 1-hour maximum ground-level concentration”, the permittee shall re-model the change(s) to demonstrate that the MAGLC has not been exceeded. Changes that can affect the parameters/values used in determining the 1-hour maximum ground-level concentration include, but are not limited to, the following:

- a. changes in the composition of the materials used or the use of new materials, that would result in the emission of a new toxic air contaminant with a lower Threshold Limit Value (TLV) than the lowest TLV previously modeled;
- b. changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any toxic air contaminant listed in OAC rule 3745-114-01, that was modeled from the initial (or last) application; and
- c. physical changes to the emissions unit(s) or its/their exhaust parameters (e.g., increased/ decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Toxic Air Contaminant Statute" will be satisfied for the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01 solely due to a non-restrictive change to a parameter or process operation, where compliance with the "Toxic Air Contaminant Statute", ORC 3704.03(F), has been documented. If the change(s) meet(s) the definition of a "modification" or if a new toxic is emitted, or the modeled toxic(s) is/are expected to exceed the previous modeled level(s), then the permittee shall apply for and obtain a final permit-to-install prior to the change. The Director may consider any significant departure from the operations of the emissions unit, described in the permit-to-install application, as a modification that results in greater emissions than the emissions rate modeled to determine the ground level concentration; and may require the permittee to submit a permit-to-install application for the increased emissions.

6. The permittee shall collect, record, and retain the following information for each toxic evaluation conducted to determine compliance with the "Toxic Air Contaminant Statute", ORC 3704.03(F):
 - a. a description of the parameters/values used in each compliance demonstration and the parameters or values changed for any re-evaluation of the toxic(s) modeled (the composition of materials, new toxic contaminants emitted, change in stack/exhaust parameters, etc.);
 - b. the Maximum Acceptable Ground-Level Concentration (MAGLC) for each significant toxic contaminant or worst-case contaminant, calculated in accordance with the "Toxic Air Contaminant Statute", ORC 3704.03(F);
 - c. a copy of the computer model run(s), that established the predicted 1-hour maximum ground-level concentration that demonstrated the emissions unit(s) to be in compliance with the "Toxic Air Contaminant Statute", ORC 3704.03(F), initially and for each change that requires re-evaluation of the toxic air contaminant emissions; and
 - d. the documentation of the initial evaluation of compliance with the "Toxic Air Contaminant Statute", ORC 3704.03(F), and documentation of any determination

that was conducted to re-evaluate compliance due to a change made to the emissions unit(s) or the materials applied.

7. The permittee shall maintain a record of any change made to a parameter or value used in the dispersion model, used to demonstrate compliance with the "Toxic Air Contaminant Statute", ORC 3704.03(F), through the predicted 1-hour maximum ground-level concentration. The record shall include the date and reason(s) for the change and if the change would increase the ground-level concentration.

D. Reporting Requirements

1. The permittee shall notify the Hamilton County Department of Environmental Services in writing of any exceedance of the OC emissions limitation outlined in term and condition A.2.d. If no exceedances occurred, the permittee shall state so in the report. The reports shall be submitted by January 31, April 30, July 31 and October 31 of each year and shall cover the previous calendar quarters (October through December, January through March, April through June and July through September, respectively.)
2. The permittee shall notify the Hamilton County Department of Environmental Services in writing of any exceedance of the HAP emissions limitations outlined in term and condition A.2.e. If no exceedances occurred, the permittee shall state so in the report. The reports shall be submitted by January 31, April 30, July 31 and October 31 of each year and shall cover the previous calendar quarters (October through December, January through March, April through June and July through September, respectively.)
3. The permittee shall submit quarterly reports that identify the following information concerning the operation of the control equipment during the operation of this emissions unit:
 - a. each 3-hour block of time when average combustion temperature within the thermal oxidizer was outside of the acceptable range;
 - b. an identification of each incident of deviation described in (a) where a prompt investigation was not conducted;
 - c. an identification of each incident of deviation described in (a) where prompt corrective action, that would bring the average combustion temperature within the thermal oxidizer into compliance with the acceptable range, was determined to be necessary and was not taken; and
 - d. an identification of each incident of deviation described in (a) where proper records were not maintained for the investigation and/or the corrective action.

These quarterly reports shall be submitted (i.e., postmarked) by January 31, April 30, July 31, and October 31 of each year; and each report shall cover the previous calendar quarter.

5. The permittee shall submit annual reports to the appropriate Ohio EPA District Office or local air agency, documenting any changes made to a parameter or value used in the dispersion model, that was used to demonstrate compliance with the "Toxic Air Contaminant Statute", ORC 3704.03(F), through the predicted 1-hour maximum ground-level concentration. If no changes to the emissions unit(s) or the exhaust stack have been made, then the report shall include a statement to this effect. This report shall be postmarked or delivered no later than January 31 following the end of each calendar year.

E. Testing Requirements

1. Compliance with the emissions limitation(s) specified in Section A.I of the terms and conditions of this permit shall be determined in accordance with the following method(s):

Emission Limitation:

Particulate Emissions (PE) shall not exceed 0.80 lb/hr.

Applicable Compliance Method:

The hourly PE limitation is based on Table I in OAC rule 3745-17-11(B). This emission limitation exceeds the emission unit's controlled potential to emit. Compliance with the emission limitations outlined in this permit shall be demonstrated by the emission factors, control efficiencies (if applicable) and the operational parameters as submitted in the PTI application 14-06009 submitted December 13, 2007. The controlled potential to emit was calculated by: $[(\text{solids usage in lbs/hr}) \times (\text{granulation solids lost at mixer}(\%)) + (\text{solids usage in lbs/hr}) \times (\text{granulation solids lost at FBD}(\%)) \times (1 - \text{cartridge filter efficiency } (99.97)))] + [(\text{solids usage in lbs/hr}) \times (\text{granulation solids lost at dry mill}(\%)) \times (1 - \text{HEPA filter efficiency } (99.97))]$

If required, the permittee shall demonstrate compliance by testing in accordance with Methods 1-4 and 5 of 40 CFR, Part 60, Appendix A for particulate emissions (PE).

Emission Limitation:

Particulate emissions (PE) and particulate matter emissions 10 microns and less in diameter (PM10) shall not exceed 10.0 TPY.

Applicable Compliance Method:

The emission limitations exceed the emission unit's potential to emit. The uncontrolled potential to emit was calculated by: $(\text{solids usage in lbs/hr}) \times [(\text{granulation solids lost at mixer}(\%)) + (\text{granulation solids lost at FBD}(\%)) + (\text{granulation solids lost at dry mill}(\%))] \times 7786 \text{ operating hours/yr} / 2000 \text{ pounds per ton}$. All PE is assumed to be PM10.

Emission Limitation:

Visible particulate emissions shall not exceed 20% opacity, as a six-minute average, except as specified by rule.

Applicable Compliance Method:

If required, compliance shall be determined through visible emission observations performed in accordance with 40 CFR Part 60, Appendix A, Method 9 and the procedures specified in OAC rule 3745-17-03(B)(1).

Emission Limitations:

1.82 lbs of OC/hour and 8.0 TPY OC

Applicable Compliance Method:

The hourly OC emissions rate shall be determined by multiplying the maximum OC throughput (pounds of OC per batch divided by the hours per batch) multiplied by 1 minus the capture efficiency of the system (99.8) for the amount of fugitive emissions added to the quantity of the maximum OC throughput (pounds of OC per batch divided by the hours per batch) multiplied by the capture efficiency of the system (99.8) multiplied by the control efficiency of the thermal oxidizer (1- 0.98), as provided in PTI application 14-06009 submitted on December 12, 2007. The annual OC emissions shall be reported to the Hamilton County Department of Environmental Services and determined by multiplying the amount of OC material employed per month over the preceding 12 month period multiplied by 1 minus the capture efficiency of the system (99.8) for the amount of fugitive emissions added to the quantity of the maximum OC throughput (pounds of OC per batch divided by the hours per batch) multiplied by the capture efficiency of the system (99.8) multiplied by the control efficiency of the thermal oxidizer (1- 0.98) and adding in the cleanup solvent usage and dividing the sum by 2000 lbs/ton to obtain tons OC per year.

If required, the permittee shall demonstrate compliance by testing in accordance with Methods 1-4 and 25 of 40 CFR, Part 60, Appendix A for OC emissions.

Emission limitation:

The total allowable emissions of Hazardous Air Pollutants (HAPs) from the emissions units identified in term and condition A.2.d shall not exceed 9.9 TPY for any single HAP and 24.9 TPY for any combination of HAPs.

Applicable Compliance Method:

Compliance with the HAP emission limitations shall be based on the record keeping requirements established in term and condition C.2.

F. Miscellaneous Requirements

Patheon Pharmaceuticals, Inc.

PTI Application: 14-06009

Issued: To be entered upon final issuance

Facility ID: 1431380503

Emissions Unit ID: P051

None

Patheon Pharmaceuticals, Inc.

Facility ID: 1431380503

PTI Application: 14-06009

Issued: To be entered upon final issuance

SIC CODE 2834 SCC CODE 3-01-060-09 EMISSIONS UNIT ID P051

EMISSIONS UNIT DESCRIPTION Intermediate Scale Processing suite for pharmaceutical products

DATE INSTALLED 6/08

EMISSIONS: (Click on bubble help for Air Quality Descriptions)

Pollutants	Air Quality Description	Actual Emissions Rate		PTI Allowable	
		Short Term Rate	Tons Per Year	Short Term Rate	Tons Per Year
Particulate Matter	attainment	0.45 lb/hr	1.8	0.80	1.8
PM ₁₀	attainment	0.45 lb/hr	1.8	0.80	1.8
Sulfur Dioxide					
Organic Compounds	non attainment	1.82 lbs/hr	8.0	1.82 lbs/hr	8.0
Nitrogen Oxides					
Carbon Monoxide					
Lead					
Other: Air Toxics					

APPLICABLE FEDERAL RULES:

NSPS? _____ NESHAP? _____ PSD? _____ OFFSET POLICY? _____

WHAT IS THE BAT DETERMINATION, AND WHAT IS THE BASIS FOR THE DETERMINATION?

Enter Determination OC emissions vented to 98% efficient thermal oxidizer and emission limitations.

IS THIS SOURCE SUBJECT TO THE AIR TOXICS POLICY? Yes

OPTIONAL: WHAT IS THE CAPITAL COST OF CONTROL EQUIPMENT? \$ _____

TOXIC AIR CONTAMINANTS

Ohio EPA's air toxics policy applies to contaminants for which the American Conference of Governmental Industrial Hygienists (ACGIH) has a listed threshold limit value.

AIR TOXICS MODELING PERFORMED*? X YES _____ NO _____

IDENTIFY THE AIR CONTAMINANTS: methanol