

Synthetic Minor Determination and/or Netting Determination

Permit To Install 14-05727

A. Source Description

Pantheon is a manufacturer of pharmaceutical products, including tablets and capsules. Emissions units P003, P005, P006, and P048 are coating pans where tablets are coated with aqueous and solvent based coatings. Only aqueous coatings are used in the coating pans associated with P004. This permit also includes two new drying ovens, P049 and P050.

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 will be a synthetic minor organic compound (OC) source. Facility-wide controlled OC* emissions are 60.5 tons per year (TPY) for this permit plus 29.0 TPY from other sources that results in 89.5 TPY. Facility-wide controlled PM emissions are 16.7 TPY.

This permit will limit the facility-wide hazardous air pollutant (HAP) emissions to 9.9 TPY for a single HAP and 24.9 TPY for the combined facility-wide emissions. This permit application requests federally enforceable limits to avoid Title V status and major source status under the MACT rules for HAPs and to avoid Title V and Non-attainment New Source Review for the OC.

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

C. Source Emissions

This permit application will include the installation of a thermal oxidizer that will control OC emissions from emissions units P003, P048, P049, and P050. Uncontrolled OC emissions are also generated from emissions units P005 and P006, which are coating pans. These emissions units are controlled by particulate filters (rotoclones, cartridge filters or HEPA filters). Total OC emissions will be limited to 60.5 TPY OC and 13.1 TPY PM. The permit terms and conditions will limit the OC and HAP emissions to below major source thresholds.

D. Conclusion

This permit modification includes Operational Restrictions, Record keeping and Monitoring Requirements, Reporting Requirements, and emissions compliance demonstration requirements which will allow the facility to determine compliance with the HAPs and OC Synthetic Minor limitations. As a result of the permit being issued in draft and incorporating federally enforceable terms, Patheon will be a Synthetic Minor facility with respect to the Part 70 Title V requirements and the MACT provisions. Also the facility will not trigger Non-Attainment New Source Review due to the limitations on the OC emissions.



State of Ohio Environmental Protection Agency

**RE: DRAFT PERMIT TO INSTALL
HAMILTON COUNTY**

CERTIFIED MAIL

Street Address:

Lazarus Gov. Center TELE: (614) 644-3020 FAX: (614) 644-2329

Mailing Address:
Lazarus Gov.
Center

Application No: 14-05727

Fac ID: 1431380503

DATE: 8/25/2005

Patheon Pharmaceuticals, Inc.
Teresa Turnbow
2110 Galbraith Road
Cincinnati, OH 452156300

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, 43266-0149.

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 **\$1400** 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

CC: USEPA HCDES OH-KY-IN Regional Council Governments KY IN

HAMILTON COUNTY

PUBLIC NOTICE

ISSUANCE OF DRAFT PERMIT TO INSTALL **14-05727** FOR AN AIR CONTAMINANT SOURCE FOR **Patheon Pharmaceuticals, Inc.**

On 8/25/2005 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 14-05727:

Installation of two tray drying ovens, No. 1 and 2; modification of PTI 14-1267, issued 9/23/87, for P003, P004, P005, P006; modification of PTI 14-05576, issued July 15, 2004.

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 14-05727

Application Number: 14-05727
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 452156300

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

Description of proposed emissions unit(s):
Installation of two tray drying ovens, No. 1 and 2; modification of PTI 14-1267, issued 9/23/87, for P003, P004, P005, P006; modification of PTI 14-05576, issued July 15, 2004.

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

Director

Patheon Pharmaceuticals, Inc.

Facility ID: 1431380503

PTI Application: 14-05727

Issued: To be entered upon final issuance

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 quarterly, i.e., 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,

Patheon Pharmaceuticals, Inc.

Facility ID: 1431380503

PTI Application: 14-05727

Issued: To be entered upon final issuance

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

Patheon Pharmaceuticals, Inc.

Facility ID: 1431380503

PTI Application: 14-05727

Issued: To be entered upon final issuance

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

Patheon Pharmaceuticals, Inc.

Facility ID: 1431380503

PTI Application: 14-05727

Issued: To be entered upon final issuance

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	60.48
Single HAP	9.9
Combined HAPs	24.9
PM/PM10/PM2.5	13.12
SO2	0.01
NOx	0.70
CO	0.59

Patheon Pharmaceuticals, Inc.

PTI Application: 14-05727

Issued: To be entered upon final issuance

Facility ID: 1431380503

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.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>
P003 - 48-inch tablet coating pan (TT-23) using aqueous and solvent coatings with cartridge filter and thermal oxidizer; modification of PTI 14-1267, issued September 23, 1987.	OAC rule 3745-31-05(A)(3)

Issued: To be entered upon final issuance

	<p style="text-align: center;"><u>Applicable Emissions Limitations/Control Measures</u></p>	<p>controls emissions units P003, P048, P049, and P050.)</p>
<p>OAC rule 3745-17-07(A)(1)</p>	<p>Organic Compound (OC) emissions from the process shall not exceed 1.94 lbs OC/hour.</p>	<p>The hourly emissions limitations for PE, PM10, PM2.5, SO2, NOx, CO and OC and the annual PE, PM10, PM2.5, SO2, NOx, and CO emissions limits are based upon the emissions unit's potential to emit. Therefore, no records are required to demonstrate compliance with these limits.</p>
<p>OAC rule 3745-17-11(B)</p>	<p>OC* emissions from the process shall not exceed 11.0 tons per year (TPY), as a rolling 12-month summation, for emissions units P003 and P048 combined.</p>	<p>The requirements of this rule also include compliance with the requirements of OAC rule 3745-21-08(B), OAC rule 3745-23-06(B) and OAC rule 3745-31-05(C).</p>
<p>OAC rule 3745-21-07(G)</p>	<p>Particulate emissions (PE) from the process shall not exceed 0.53 lb/hour and 2.33 TPY.</p>	<p>Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a six-minute average.</p>
<p>OAC rule 3745-31-05(C)</p>	<p>Particulate matter emissions 10 microns and less in diameter (PM10) and particulate matter emissions 2.5 microns and less in diameter (PM2.5) from the process shall not exceed 0.53 lb/hour and 2.33 TPY.</p>	<p>See terms and conditions B.1. and B.3.</p>
<p>OAC rule 3745-21-08(B)</p>	<p>Emissions from the combustion of natural gas in the regenerative thermal oxidizer shall not exceed the following:</p>	<p>The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).</p>
<p>OAC rule 3745-23-06(B)</p>	<p>0.01 lb/hr and 0.05 TPY PE; 0.01 lb/hr and 0.05 TPY PM10; 0.01 lb/hr and 0.05 TPY PM2.5; 0.001 lb/hr and 0.01 TPY SO2; 0.16 lb/hr and 0.70 TPY NOx; 0.13 lb/hr and 0.59 TPY CO; and 0.02 lb/hr and 0.08 TPY OC. (These emissions are from the one thermal oxidizer which</p>	<p>The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).</p>

Pathe**PTI A**Emissions Unit ID: **P003****Issued: To be entered upon final issuance**

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

See terms and conditions A.2.b, A.2.c. and B.2.

See term and condition A.2.d.

See term and condition A.2.e.

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

2. Additional Terms and Conditions

- 2.a** Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by emissions limitations, the use of a particulate filter with a particulate emissions control efficiency of at least 95 percent 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 materials.
- 2.c** 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 P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009(quality control lab), P010 (dry packaging), P012(lozenge manufacturing), P014(granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), any de minimis emissions units as defined in OAC rule 3745-15-05, 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

Emissions Unit ID: P003

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.c. upon permit issuance.

- 2.d** The permittee has satisfied the "best available control techniques and operating practices" required pursuant to OAC rule 3745-21-08(B) by committing to comply with the best available technology requirements established pursuant to OAC rule 3745-31-05(A)(3) in Permit to Install 14-05727.

On November 5, 2002, OAC rule 3745-21-08 was revised to delete paragraph (B); therefore, paragraph (B) is no longer part of the State regulations. However, that rule revision has not yet been submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revision occurs and the U.S. EPA approves the revisions to OAC rule 3745-21-08, the requirement to satisfy the "best available control techniques and operating practices" still exists as part of the federally-approved SIP for Ohio.

- 2.e** The permittee has satisfied the "latest available control techniques and operating practices" required pursuant to OAC rule 3745-23-06(B) by committing to comply with the best available technology requirements established pursuant to OAC rule 3745-31-05(A)(3) in Permit to Install 14-05727.

On February 15, 2005, OAC rule 3745-23-06 was rescinded and therefore no longer a part of the State regulations. However, that rule revision has not yet been submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revision occurs and the U.S. EPA approves the revisions to OAC rule 3745-23-06, the requirement to satisfy "latest available control techniques and operating practices" still exists as part of the federally-approved SIP for Ohio.

B. Operational Restrictions

1. The pressure drop across the particulate filter (cartridge filter) while the emissions unit is in operation shall be maintained either within the range of 0.25 to 4 inches of water or that range which was established during the most recent emission test that demonstrated the emissions unit was in compliance.
2. The organic solvent usage rate shall not exceed 1,100,000 pounds per year, based on

Pathe**PTI A**Emissions Unit ID: **P003****Issued: To be entered upon final issuance**

a rolling, 12-month summation for emissions units P003 and P048 combined. The organic solvent usage rate, in pounds, equates to the assumption that 100% of the all the organic solvent is emitted.

3. The average combustion temperature within the chamber within the thermal oxidizer, for any 3-hour block of time when the emissions unit is in operation, shall be maintained above 1450 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.

C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall collect and record the following information each month for emissions unit P003 and P048:
 - 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; and
 - d. the updated, rolling 12-month summation of the organic solvent usage rate for P003 and P048 combined, in pounds. This shall include the information for the current month and the preceding eleven months.
 - e. the updated, rolling 12-month summation of the OC emissions for P003 and P048, 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 P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), 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;

Issued: To be entered upon final issuance

- 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 operate and maintain a continuous temperature monitor and recorder which measures and records the combustion temperature within the thermal oxidizer when the emissions unit is in operation. Units shall be in degrees Fahrenheit.

Issued: To be entered upon final issuance

The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitor and recorder shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

The permittee shall collect and record the following information for each day:

- a. All 3-hour blocks of time during which the average combustion temperature within the thermal oxidizer, when the emissions unit was in operation, was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
- b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.

The control device downtime is defined as any time when the emissions unit is operating, is employing organic compounds, and the thermal oxidizer is not in operation. Monitoring device downtime is defined as any time when the emissions unit is operating, is employing organic compounds, and the temperature monitoring equipment is not in operation.

4. The permittee shall properly install, operate, and maintain equipment to monitor the pressure drop across the cartridge filter while the emissions unit is in operation. 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 pressure drop across the cartridge filter on weekly basis.
5. The permit to install for this emissions unit (P003) was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN3 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN3 model was compared to the Maximum Ground-Level Concentration (MAGLC).

The following summarizes the results of the modeling for the "worst case" pollutant(s) for the emissions from P003, P005, P006, P048, P049, and P050 combined:

Patheon Pharmaceuticals, Inc.
PTI Application: 14-05727
Issue

Facility ID: 1431380503

Emissions Unit ID: P003

Pollutant: methanol

TLV (ug/m3): 262,086

Maximum Hourly Emission Rate (lbs/hr): 75.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 5,756

MAGLC (ug/m3): 6,240

Pollutant: isopropanol

TLV (ug/m3): 491,534

Maximum Hourly Emission Rate (lbs/hr): 103.6

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Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 8,194

MAGLC (ug/m3): 11,703

Physical changes to or in the method of operation of the emissions unit after it's installation or modification could affect the parameters used to determine whether or not the "Air Toxics Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in the "Air Toxic Policy" include the following:

- a. changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value 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 pollutant with a listed TLV that was proposed in the application and modeled; and
- c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" 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 the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) is (are) defined as a modification under other provisions of the modification definition, then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will satisfy the Air Toxic Policy:"

- a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
- b. documentation of it's evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
- c. when the computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

D. Reporting Requirements

1. The permittee shall submit written quarterly deviation reports to the Hamilton County Department of Environmental Services that include the following:
 - a. an identification of all 3-hour blocks of time during which the average combustion temperature within the thermal oxidizer, when the emissions unit was in operation, was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance; and
 - b. pressure drop deviation (excursion) reports that identify all periods of time during which the pressure drop across the particulate filter did not comply with the allowable range specified in term B.1.

If no exceedances occurred during the reporting period than a report is required stating so.
2. The permittee shall submit quarterly deviation reports to the Hamilton County Department of Environmental Services that include a log of the downtime for the particulate filter, and/or thermal oxidizer and/or monitoring equipment when this emissions unit was in operation.
3. The deviation (excursion) reports shall be submitted in accordance with the reporting requirements of the General Terms and Conditions of this permit.
4. 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.c. 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

Pathe**PTI A**Emissions Unit ID: **P003****Issued: To be entered upon final issuance**

year and shall cover the previous calendar quarters (October through December, January through March, April through June and July through September, respectively.)

5. The permittee shall submit written reports to the Hamilton County Department of Environmental Services which identify the amount of organic compounds (solvent) employed per month and the updated rolling, 12-month summation of the amount of organic compounds employed for emissions unit P003 and P048 combined. The reports shall also include the monthly OC emissions rate and the updated rolling, 12-month OC emissions rate. 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.)

E. Testing Requirements

1. Compliance with the emission limitations in Section A. of these terms and conditions shall be determined in accordance with the following method(s):

- a. Emissions limitations:

1.94 lbs OC/hour for P003; and 11.0 TPY OC combined for P003 and P048

Applicable Compliance Method:

The hourly OC emissions rate shall be determined by multiplying the maximum coating material throughput (pounds OC per batch divided by the hours per batch) multiplied by the efficiency of the thermal oxidizer (1- 0.98), as provided in PTI application 14-05727 submitted on May 23, 2005. 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 times one minus 0.98 and dividing by 2000 lbs/ton to obtain tons OC per year.

- b. Emissions limitations:

0.53 lb PE/PM10/PM2.5 per hour and 2.33 TPY PE/PM10/PM2.5

Applicable Compliance Method:

PE, PM10 and PM2.5 emissions rates shall be determined by multiplying the total coating material throughput (pounds per batch divided by the hours per batch) by the percent solids in the coating (25%), times the solids transfer factor of the tablet coating (1-0.67), times the particulate not controlled by the 95% efficient cartridge filter (1- 0.95), as provided in PTI application 14-05727 submitted on May 23, 2005. The hourly coating material emissions shall be multiplied by 8760 hours per year and divided by 2000 lbs/ton to obtain the annual emissions.

- c. Emissions limitation:

The total allowable emissions of Hazardous Air Pollutants (HAPs) from the emissions units identified in term and condition A.2.c. 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 HAPs emissions limitations shall be based on the record keeping requirements established in term and condition C.2.

d. Emissions limitations:

0.01 lb per hour and 0.05 TPY PE/PM10/PM2.5 from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

PE/PM10/PM2.5 emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (7.6 lb PM/MMft³). The emissions factor 7.6 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton. All PM10 and PM2.5 was assumed equal to the PE rate.

e. Emissions limitations:

0.001 lb per hour and 0.01 TPY SO₂ from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

SO₂emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (0.6 lb SO₂/MMft³). The emissions factor 0.6 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

f. Emissions limitations:

0.16 lb per hour and 0.70 TPY NO_x from natural gas combustion in the regenerative thermal oxidizer

Pathe**PTI A****Issued: To be entered upon final issuance**Emissions Unit ID: **P003**

Applicable Compliance Method:

NOx emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (100 lb NOx/MMft³). The emissions factor 100 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

Issued: To be entered upon final issuance

g. Emissions limitations:

0.13 lb per hour and 0.59 TPY CO from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

CO emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (84 lb CO/MMft³). The emissions factor 84 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

h. Emissions limitations:

0.02 lb per hour and 0.08 TPY OC from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

OC emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (11 lb OC/MMft³). The emissions factor 11 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

i. Emissions limitation:

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a 6-minute average.

Applicable Compliance Method:

Compliance with the visible particulate emission limitation shall be demonstrated by the methods outlined in 40 CFR Part 60, Appendix A, Method 9.

2. Compliance with the particulate control device pressure differential requirements of

Issued: To be entered upon final issuance

term and condition B.1. shall be demonstrated by the recordkeeping in term and condition C.4.

3. Compliance with the organic material usage limitations of term and condition B.2. shall be demonstrated by the recordkeeping in term and condition C.1.
4. Compliance with the minimum temperature within the regenerative thermal oxidizer requirements of term and condition B.3. shall be demonstrated by the recordkeeping in term and condition C.3.
5. Emission testing requirements

The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

- a. The emissions testing shall be performed within six months of the start up of this emissions unit.
- b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emissions rate for OC and the 98% OC overall control efficiency for the thermal oxidizer.
- c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s):
for OC, Method 25 or 25 A as per 40 CFR Part 60, Subpart A.

Alternative U.S. EPA approved test methods may be used with prior approval from the Hamilton County Department of Environmental Services.

The test method(s) which must be employed to demonstrate compliance with the destruction efficiency for the thermal oxidizer are specified below.

- d. The test(s) shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the Hamilton County Department of Environmental Services.

The control efficiency (i.e., the percent reduction in mass emissions between the inlet and outlet of the control system) shall be determined in accordance with the test methods and procedures specified in OAC rule 3745-21-10 or an approved alternative test protocol. The test methods and procedures selected shall be based on a consideration of the diversity of the organic species present and

Patheon Pharmaceuticals, Inc.
PTI Application: 14-05727
Issue

Facility ID: 1431380503

Emissions Unit ID: P003

their total concentration, and on a consideration of the potential presence of interfering gases.

Not later than 30 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the Hamilton County Department of Environmental Services. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Hamilton County Department of Environmental Services refusal to accept the results of the emission test(s).

Personnel from the Hamilton County Department of Environmental Services shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the Hamilton County Department of Environmental Services within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the Hamilton County Department of Environmental Services.

F. Miscellaneous Requirements

1. The requirements of this permit to install shall supercede the terms and conditions in PTI 14-1267, as issued on September 23, 1987.
2. The following terms and conditions in this permit are federally enforceable: Sections A., B., C.1 - C.4., D. and E.

Pathe
PTI A

Emissions Unit ID: P004

Issued: To be entered upon final issuance

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.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>
P004 - Coating pan w/ water based materials and rotoclone (TT-22), modification of PTI 14-1267, issued September 23, 1987	<p>OAC rule 3745-31-05(A)(3)</p> <p>OAC rule 3745-17-07(A)(1)</p> <p>OAC rule 3745-17-11(B)</p> <p>OAC rule 3745-31-05(C)</p>

Applicable Emissions
Limitations/Control Measures

Particulate emissions (PE) from the process shall not exceed 0.60 lb/hour and 2.63 TPY.

Particulate matter emissions 10 microns and less in diameter (PM10) and Particulate matter emissions 2.5 microns and less in diameter (PM2.5) from the process shall not exceed 0.60 lb/hour and 2.63 TPY.

The hourly emissions limitations for PE, PM10, PM2.5 and the annual PE, PM10, PM2.5 emissions limits are based upon the emissions unit's potential to emit. Therefore, no records are required to demonstrate compliance with these limits.

The requirements of this rule also include compliance with the requirements of OAC rule 3745-31-05(C).

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a six-minute average.

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant

to OAC rule 3745-31-05(A)(3).

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

See term and condition A.2.b.

**Pathe
PTI A**

Emissions Unit ID: **P004**

Issued: To be entered upon final issuance

2. Additional Terms and Conditions

- 2.a** Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by emissions limitations and the use of a rotoclone with a particulate emissions control efficiency of at least 95 percent.
- 2.b** 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 P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), any de minimis emissions units as defined in OAC rule 3745-15-05, 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.b. upon permit issuance.

B. Operational Restrictions

None.

C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall collect and record the following information each month for emissions units P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), and any de minimis emissions units as 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

Issued: To be entered upon final issuance

- 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.

D. Reporting Requirements

1. 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.b. 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.).

E. Testing Requirements

1. Compliance with the emission limitations in Section A. of these terms and conditions shall be determined in accordance with the following method(s):

- a. Emissions limitations:

0.60 lb PE/PM10/PM2.5 per hour and 2.63 TPY PE/PM10/PM2.5

Applicable Compliance Method:

PE, PM10 and PM2.5 emissions rates shall be determined by multiplying the total coating material throughput (pounds per batch divided by the hours per batch) by the solids transfer factor of the tablet coating (1-0.67), times the particulate not controlled by the 95% efficient rotoclone particulate control device (1- 0.95), as provided in PTI application 14-05727 submitted on May 23, 2005. The hourly coating material emissions shall be multiplied by 8760 hours per year and divided by 2000 lbs/ton to obtain the annual emissions.

- b. Emissions limitation:

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

Pathe**PTI A**Emissions Unit ID: **P004****Issued: To be entered upon final issuance**

Applicable Compliance Method:

Compliance with the HAPs emissions limitations in term A.2.b shall be based on the record keeping requirements established in term and condition C.1.

c. Emissions limitation:

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a 6-minute average.

Applicable Compliance Method:

Compliance with the visible particulate emission limitation shall be demonstrated by the methods outlined in 40 CFR Part 60, Appendix A, Method 9.

F. Miscellaneous Requirements

1. The requirements of this permit to install shall supercede the terms and conditions in PTI 14-1267, as issued on September 23, 1987.
2. The following terms and conditions in this permit are federally enforceable: Sections A., B., C., D. and E.

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.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>
P005 - Coating pan for aqueous and solvent material w/ rotoclone (TT-28) - modification of PTI 14-1267, issued September 23, 1987	OAC rule 3745-31-05(A)(3)
	OAC rule 3745-17-07(A)(1)
	OAC rule 3745-17-11(B)

Pathe

PTI A

Emissions Unit ID: P005

Issued: To be entered upon final issuance

OAC rule 3745-21-07(G)

Applicable Emissions Limitations/Control Measures

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a six-minute average.

OAC rule 3745-31-05(C)

Organic Compound (OC) emissions from the process shall not exceed 88.0 lbs OC/hour.

See terms and conditions A.2.c. and A.2.d.

OC emissions from the process shall not exceed 40.0 tons per year (TPY), as a rolling 12-month summation, for P005 and P006 combined.

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

Particulate emissions (PE) from the process shall not exceed 0.48 lb/hour and 2.12 TPY.

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

Particulate matter emissions 10 microns and less in diameter (PM10) and Particulate matter emissions 2.5 microns and less in diameter (PM2.5) from the process shall not exceed 0.48 lb/hour and 2.12 TPY.

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3). See term B.2.

The hourly OC, PE, PM10, and PM2.5 and annual emissions limitations for PE, PM10, and PM2.5, are based upon the emissions unit's potential to emit. Therefore, no records are required to demonstrate compliance with these limits.

See terms and condition A.2.b. and B.1.

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

The requirements of this rule also include compliance with the requirements of OAC rule 3745-31-05(C).

Issued: To be entered upon final issuance**2. Additional Terms and Conditions**

- 2.a** Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by emissions limitations, the use of a rotoclone to control particulate emissions and the limited solvent usage rate.
- 2.b** 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 P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), any de minimis emissions units as defined in OAC rule 3745-15-05, 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.b. upon permit issuance.
- 2.c** Isopropyl alcohol emissions from emissions units P005 and P006 combined shall not exceed 88.0 lbs/hour.
- 2.d** Methyl alcohol emissions from emissions units P005 and P006 combined shall not exceed 60.0 lbs/hour.

B. Operational Restrictions

1. The organic solvent usage rate shall not exceed 157,691 pounds per year, based on a rolling, 12-month summation for emissions units P005 and P006 combined. The organic solvent usage rate, in pounds, equates to the assumption that 100% of the all the organic solvent is emitted.
2. The use of photochemically reactive materials as defined in OAC rule 3745-21-01(C)(5) is prohibited in this emissions unit.

C. Monitoring and/or Recordkeeping Requirements

Emissions Unit ID: **P005**

1. The permittee shall collect and record the following information each month for emissions unit P005 and P006:
 - 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 organic solvent usage rate for P005 and P006, in pounds. This shall include the information for the current month and the preceding eleven months;
 - e. the updated, rolling 12-month summation of the OC emissions for P005 and P006, in tons. This shall include the information for the current month and the preceding eleven months; and
 - f. documentation on whether or not each coating/solvent and organic cleanup material is a photochemically reactive material as defined in OAC rule 3745-21-01(C)(5).

2. The permittee shall collect and record the following information each month for emissions units P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), and any de minimis emissions units as 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)];

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- 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 permit to install for this emissions unit (P005) was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the

Emissions Unit ID: **P005**

emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN3 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN3 model was compared to the Maximum Ground-Level Concentration (MAGLC).

The following summarizes the results of the modeling for the "worst case" pollutant(s) for the emissions from P003, P005, P006, P048, P049, and P050 combined:

Pollutant: methanol (methyl alcohol)

TLV (ug/m3): 262,086

Maximum Hourly Emission Rate (lbs/hr): 75.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 5,756

MAGLC (ug/m3): 6,240

Pollutant: isopropanol

TLV (ug/m3): 491,534

Maximum Hourly Emission Rate (lbs/hr): 103.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 8,194

MAGLC (ug/m3): 11,703

Physical changes to or in the method of operation of the emissions unit after it's installation or modification could affect the parameters used to determine whether or not the "Air Toxics Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in the "Air Toxic Policy" include the following:

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- a. changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value 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 pollutant with a listed TLV that was proposed in the application and modeled; and
- c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" 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 the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) is (are) defined as a modification under other provisions of the modification definition, then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will satisfy the Air Toxic Policy:"

- a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
 - b. documentation of it's evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
 - c. when the computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.
4. The permittee shall collect and record the following information each day for emissions unit P005 and P006:

Patheon Pharmaceuticals, Inc.
PTI Application: 14-05727
Issue:

Facility ID: 1431380503

Emissions Unit ID: P005

- a. the company identification of each coating and cleanup material employed that contains isopropyl alcohol and/or methyl alcohol in these emissions units;
- b. the amount of isopropyl alcohol and/or methyl alcohol materials employed, in pounds per day;
- c. the hours of operation during which isopropyl alcohol and/or methyl alcohol was employed in both P005 and P006; and
- d. the isopropyl alcohol and methyl alcohol emissions, in lbs/hr for emissions unit P005 and P006 combined (b/c).

D. Reporting Requirements

1. 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.b. 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 submit written reports to the Hamilton County Department of Environmental Services which identify the amount of organic compounds (solvent) employed per month and the updated rolling, 12-month summation of the amount of organic compounds employed for emissions units P005 and P006, combined. The reports shall also include the monthly OC emissions rate and the updated rolling, 12-month OC emissions rate. 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 written quarterly deviation reports to the Hamilton County Department of Environmental Services that include the following:
 - a. an identification of all hourly exceedances of the isopropyl alcohol and methyl alcohol emissions limitations.

If no exceedances occurred during the reporting period than a report is required stating so. 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,

Pathe**PTI A**Emissions Unit ID: **P005****Issued: To be entered upon final issuance**

January through March, April through June and July through September, respectively.)

4. The permittee shall notify the Hamilton County Department of Environmental Services in writing of any record showing the use of noncomplying coatings/solvents (i.e., photochemically reactive material restriction in term B.2). The notification shall include a copy of such records and shall be sent to the Hamilton County Department of Environmental Services within 45 days of the occurrence.

E. Testing Requirements

1. Compliance with the emission limitations in Section A. of these terms and conditions shall be determined in accordance with the following method(s):

- a. Emissions limitations:

88.0 lbs OC/hour and 40.0 TPY OC combined for P005 and P006

Applicable Compliance Method:

The hourly OC emissions rate shall be determined by multiplying the maximum coating material throughput (pounds OC per batch divided by the hours per batch) as provided in PTI application 14-05727 submitted on May 23, 2005. The annual OC emissions shall be reported to the Hamilton County Department of Environmental Services and determined by summing the amount of OC material employed per month over the preceding 12 month period and dividing by 2000 lbs/ton to obtain tons OC per year.

- b. Emissions limitations:

0.48 lb PE/PM10/PM2.5 per hour and 2.12TPY PE/PM10/PM2.5

Applicable Compliance Method:

PE, PM10 and PM2.5 emissions rates shall be determined by multiplying the total coating material throughput (pounds per batch divided by the hours per batch) by the percent solids in the coating (25%), times the solids transfer factor of the tablet coating (1-0.67), times the particulate not controlled by the 95% efficient rotoclone (1- 0.95), as provided in PTI application 14-05727 submitted on May 23, 2005. The hourly coating material emissions shall be multiplied by 8760 hours per year and divided by 2000 lbs/ton to obtain the annual emissions.

Patheon Pharmaceuticals, Inc.
PTI Application: 14-05727
Issue

Facility ID: 1431380503

Emissions Unit ID: P005

c. Emissions limitation:

The total allowable emissions of Hazardous Air Pollutants (HAPs) from the emissions units identified in term and condition A.2.b. 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 HAPs emissions limitations shall be based on the record keeping requirements established in term and condition C.2.

d. Emissions limitation:

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a 6-minute average.

Applicable Compliance Method:

Compliance with the visible particulate emission limitation shall be demonstrated by the methods outlined in 40 CFR Part 60, Appendix A, Method 9.

2. Compliance with the organic material usage limitation in term and condition B.1. shall be demonstrated by the recordkeeping in term and condition C.1.
3. Compliance with the isopropyl alcohol and methyl alcohol emissions limitations of terms and conditions A.2.c. and A.2.d. shall be demonstrated by the record keeping in term and condition C.4.
4. Compliance with the limitation in term B.2 shall be demonstrated by the record keeping in term C.1.

F. Miscellaneous Requirements

1. The requirements of this permit to install shall supercede the terms and conditions in PTI 14-1267, as issued on September 23, 1987.
2. The following terms and conditions in this permit are federally enforceable: Sections A.1., A.2.a., A.2.b., B., C.1, C.2., D.1., D.2., D.4., E.1, E.2, and E.4.

**Pathe
PTI A**

Emissions Unit ID: **P006**

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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.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>
P006 - Coating pan for aqueous and solvent materials w/ rotoclone (TT-29) - modification of PTI 14-1267, issued September 23, 1987	OAC rule 3745-31-05(A)(3)
	OAC rule 3745-17-07(A)(1)
	OAC rule 3745-17-11(B)

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OAC rule 3745-21-07(G)

Applicable Emissions
Limitations/Control Measures

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a six-minute average.

OAC rule 3745-31-05(C)

Organic Compound (OC) emissions from the process shall not exceed 88.0 lbs OC/hour.

See terms and conditions A.2.c.and A.2.d.

OC emissions from the process shall not exceed 40.0 tons per year (TPY), as a rolling 12-month summation, for P005 and P006 combined.

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

Particulate emissions (PE) from the process shall not exceed 0.48 lb/hour and 2.12 TPY.

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

Particulate matter emissions 10 microns and less in diameter (PM10) and Particulate matter emissions 2.5 microns and less in diameter (PM2.5) from the process shall not exceed 0.48 lb/hour and 2.12 TPY.

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

The hourly for OC, PE, PM10, and PM2.5, and the annual emissions limitations for PE, PM10, and PM2.5, are based upon the emissions unit's potential to emit. Therefore, no records are required to demonstrate compliance with these limits.

See terms and condition A.2.b. and B.1.

The requirements of this rule also include compliance with the requirements of OAC rule 3745-31-05(C).

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

**Pathe
PTI A**

Emissions Unit ID: **P006**

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2. Additional Terms and Conditions

- 2.a** Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by emissions limitations, the use of a rotoclone to control particulate emissions and the limited solvent usage rate.
- 2.b** 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 P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), any de minimis emissions units as defined in OAC rule 3745-15-05, 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.b. upon permit issuance.
- 2.c** Isopropyl alcohol emissions from emissions units P005 and P006 combined shall not exceed 88.0 lbs/hour.
- 2.d** Methyl alcohol emissions from emissions units P005 and P006 combined shall not exceed 60.0 lbs/hour.

B. Operational Restrictions

1. The organic solvent usage rate shall not exceed 157,691 pounds per year, based on a rolling, 12-month summation for emissions units P005 and P006 combined. The organic solvent usage rate, in pounds, equates to the assumption that 100% of the all the organic solvent is emitted.
2. The use of photochemically reactive materials as defined in OAC rule 3745-21-01(C)(5) is prohibited in this emissions unit.

C. Monitoring and/or Recordkeeping Requirements

Emissions Unit ID: **P006**

1. The permittee shall collect and record the following information each month for emissions unit P005 and P006:
 - 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 organic solvent usage rate for P005 and P006, in pounds. This shall include the information for the current month and the preceding eleven months;
 - e. the updated, rolling 12-month summation of the OC emissions for P005 and P006, in tons. This shall include the information for the current month and the preceding eleven months; and
 - f. documentation on whether or not each coating/solvent and organic cleanup material is a photochemically reactive material as defined in OAC rule 3745-21-01(C)(5).

2. The permittee shall collect and record the following information each month for emissions units P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), and any de minimis emissions units as 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)];

**Pathe
PTI A**Emissions Unit ID: **P006****Issued: To be entered upon final issuance**

- 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 permit to install for this emissions unit (P006) was evaluated based on the actual

Emissions Unit ID: **P006**

materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN3 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN3 model was compared to the Maximum Ground-Level Concentration (MAGLC).

The following summarizes the results of the modeling for the "worst case" pollutant(s) for the emissions from P003, P005, P006, P048, P049, and P050 combined:

Pollutant: methanol

TLV (ug/m3): 262,086

Maximum Hourly Emission Rate (lbs/hr): 75.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 5,756

MAGLC (ug/m3): 6,240

Pollutant: isopropanol

TLV (ug/m3): 491,534

Maximum Hourly Emission Rate (lbs/hr): 103.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 8,194

MAGLC (ug/m3): 11,703

Physical changes to or in the method of operation of the emissions unit after its installation or modification could affect the parameters used to determine whether or not the "Air Toxics Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in the "Air Toxic Policy" include the following:

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- a. changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value 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 pollutant with a listed TLV that was proposed in the application and modeled; and
- c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" 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 the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) is (are) defined as a modification under other provisions of the modification definition, then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will satisfy the Air Toxic Policy:"

- a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
 - b. documentation of it's evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
 - c. when the computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.
4. The permittee shall collect and record the following information each day for emissions

unit P005 and P006:

- a. the company identification of each coating and cleanup material employed that contains isopropyl alcohol and/or methyl alcohol in these emissions units;
- b. the amount of isopropyl alcohol and/or methyl alcohol materials employed, in pounds per day;
- c. the hours of operation during which isopropyl alcohol and/or methyl alcohol was employed in both P005 and P006; and
- d. the isopropyl alcohol and methyl alcohol emissions, in lbs/hr for emissions unit P005 and P006 combined (b/c).

D. Reporting Requirements

1. 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.b. 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 submit written reports to the Hamilton County Department of Environmental Services which identify the amount of organic compounds (solvent) employed per month and the updated rolling, 12-month summation of the amount of organic compounds employed for emissions units P005 and P006, combined. The reports shall also include the monthly OC emissions rate and the updated rolling, 12-month OC emissions rate. 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 written quarterly deviation reports to the Hamilton County Department of Environmental Services that include the following:
 - a. an identification of all hourly exceedances of the isopropyl alcohol and methyl alcohol emissions limitations.

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

**Pathe
PTI A**

Emissions Unit ID: **P006**

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cover the previous calendar quarters (October through December, January through March, April through June and July through September, respectively.)

4. The permittee shall notify the Hamilton County Department of Environmental Services in writing of any record showing the use of noncomplying coatings/solvents (i.e., photochemically reactive material restriction in term B.2). The notification shall include a copy of such records and shall be sent to the Hamilton County Department of Environmental Services within 45 days of the occurrence.

E. Testing Requirements

1. Compliance with the emission limitations in Section A. of these terms and conditions shall be determined in accordance with the following method(s):

- a. Emissions limitations:

88.0 lbs OC/hour and 40.0 TPY OC combined for P005 and P006

Applicable Compliance Method:

The hourly OC emissions rate shall be determined by multiplying the maximum coating material throughput (pounds OC per batch divided by the hours per batch) as provided in PTI application 14-05727 submitted on May 23, 2005. The annual OC emissions shall be reported to the Hamilton County Department of Environmental Services and determined by summing the amount of OC material employed per month over the preceding 12 month period and dividing by 2000 lbs/ton to obtain tons OC per year.

- b. Emissions limitations:

0.48 lb PE/PM10/PM2.5 per hour and 2.12 TPY PE/PM10/PM2.5

Applicable Compliance Method:

PE, PM10 and PM2.5 emissions rates shall be determined by multiplying the total coating material throughput (pounds per batch divided by the hours per batch) by the percent solids in the coating (25%), times the solids transfer factor of the tablet coating (1-0.67), times the particulate not controlled by the 95% efficient rotoclone (1- 0.95), as provided in PTI application 14-05727 submitted on May 23, 2005. The hourly coating material emissions shall be multiplied by

Emissions Unit ID: **P006**

8760 hours per year and divided by 2000 lbs/ton to obtain the annual emissions.

c. Emissions limitation:

The total allowable emissions of Hazardous Air Pollutants (HAPs) from the emissions units identified in term and condition A.2.b. 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 HAPs emissions limitations shall be based on the record keeping requirements established in term and condition C.2.

d. Emissions limitation:

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a 6-minute average.

Applicable Compliance Method:

Compliance with the visible particulate emission limitation shall be demonstrated by the methods outlined in 40 CFR Part 60, Appendix A, Method 9.

2. Compliance with the organic material usage limitations of term and condition B.1. shall be demonstrated by the record keeping in term and condition C.1.
3. Compliance with the isopropyl alcohol and methyl alcohol emissions limitations of terms and conditions A.2.c. and A.2.d. shall be demonstrated by the record keeping in term and condition C.4.
4. Compliance with the limitation in term B.2 shall be demonstrated by the record keeping in term C.1.

F. Miscellaneous Requirements

1. The requirements of this permit to install shall supercede the terms and conditions in PTI 14-1267, as issued on September 23, 1987.
2. The following terms and conditions in this permit are federally enforceable: Sections A.1., A.2.a., A.2.b., B., C.1, C.2., D.1., D.2., D.4., E.1, E.2, and E.4.

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PTI A

Emissions Unit ID: P048

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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.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>
P048 - 60-inch tablet coating pan using aqueous and solvent coatings w/ cartridge filter and thermal oxidizer - modification of PTI 14-05576, issued July 15, 2004	OAC rule 3745-31-05(A)(3)

Pathe

PTI A

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Emissions Unit ID: **P048**

	<u>Applicable Emissions Limitations/Control Measures</u>	
	Organic Compound (OC) emissions from the process shall not exceed 3.03 lbs OC/hour.	(These emissions are from the one thermal oxidizer which controls emissions units P003, P048, P049, and P050.)
OAC rule 3745-17-07(A)(1)	OC emissions from the process shall not exceed 11.0 tons per year (TPY), as a rolling 12-month summation, for P003 and P048 combined.	The hourly emissions limitations for PE, PM10, PM2.5, SO2, NOx, CO and OC and the annual PE, PM10, PM2.5, SO2, NOx, and CO emissions limits are based upon the emissions unit's potential to emit. Therefore, no records are required to demonstrate compliance with these limits.
OAC rule 3745-17-11(B)	Particulate emissions (PE) from the process shall not exceed 0.83 lb/hour and 3.65 TPY.	The requirements of this rule also include compliance with the requirements of OAC rule 3745-21-08(B), OAC rule 3745-23-06(B) and OAC rule 3745-31-05(C).
OAC rule 3745-21-07(G)	Particulate matter emissions 10 microns and less in diameter (PM10) and Particulate matter emissions 2.5 microns and less in diameter (PM2.5) from the process shall not exceed 0.83 lb/hour and 3.65 TPY.	Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a six-minute average.
OAC rule 3745-31-05(C)	Emissions from the combustion of natural gas in the regenerative thermal oxidizer shall not exceed the following:	See terms and conditions B.1. and B.3.
OAC rule 3745-21-08(B)	0.01 lb/hr and 0.05 TPY PE;	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
OAC rule 3745-23-06(B)	0.01 lb/hr and 0.05 TPY PM10;	
	0.01 lb/hr and 0.05 TPY PM2.5;	
	0.001 lb/hr and 0.01 TPY SO2;	
	0.16 lb/hr and 0.70 TPY NOx;	
	0.13 lb/hr and 0.59 TPY CO;	
	and	
	0.02 lb/hr and 0.08 TPY OC.	The emission limitation specified by this rule is less stringent than the emission limitation established

pursuant to OAC rule
3745-31-05(A)(3).

The emission limitation
specified by this rule is less
stringent than the emission
limitation established pursuant
to OAC rule 3745-31-05(A)(3).

See term and conditions A.2.b,
A.2.c., and B.2.

See term and condition A.2.d.

See term and condition A.2.e.

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

2. Additional Terms and Conditions

- 2.a** Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by emissions limitations, the use of a particulate filter with a particulate emissions control efficiency of at least 95 percent 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 materials.
- 2.c** 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 P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and

Pathe**PTI A**Emissions Unit ID: **P048****Issued: To be entered upon final issuance**

P050 (drying oven), any de minimis emissions units as defined in OAC rule 3745-15-05, 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.c. upon permit issuance.

- 2.d** The permittee has satisfied the "best available control techniques and operating practices" required pursuant to OAC rule 3745-21-08(B) by committing to comply with the best available technology requirements established pursuant to OAC rule 3745-31-05(A)(3) in Permit to Install 14-05727.

On November 5, 2002, OAC rule 3745-21-08 was revised to delete paragraph (B); therefore, paragraph (B) is no longer part of the State regulations. However, that rule revision has not yet been submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revision occurs and the U.S. EPA approves the revisions to OAC rule 3745-21-08, the requirement to satisfy the "best available control techniques and operating practices" still exists as part of the federally-approved SIP for Ohio.

- 2.e** The permittee has satisfied the "latest available control techniques and operating practices" required pursuant to OAC rule 3745-23-06(B) by committing to comply with the best available technology requirements established pursuant to OAC rule 3745-31-05(A)(3) in Permit to Install 14-05727.

On February 15, 2005, OAC rule 3745-23-06 was rescinded and therefore no longer a part of the State regulations. However, that rule revision has not yet been submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revision occurs and the U.S. EPA approves the revisions to OAC rule 3745-23-06, the requirement to satisfy "latest available control techniques and operating practices" still exists as part of the federally-approved SIP for Ohio.

B. Operational Restrictions

1. The pressure drop across the particulate (cartridge) filter while the emissions unit is in operation shall be maintained either within the range of 0.25 to 4 inches of water or that

Patheon Pharmaceuticals, Inc.

PTI Application: 14-05727

Issue

Facility ID: 1431380503

Emissions Unit ID: **P048**

range which was established during the most recent emission test that demonstrated the emissions unit was in compliance.

2. The organic solvent usage rate shall not exceed 1,100,000 pounds per year, based on a rolling, 12-month summation for emissions units P003 and P048 combined. The organic solvent usage rate, in pounds, equates to the assumption that 100% of the all the organic solvent is emitted.
3. The average combustion temperature within the chamber within the thermal oxidizer, for any 3-hour block of time when the emissions unit is in operation, shall be maintained above 1450 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.

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C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall collect and record the following information each month for emissions unit P003 and P048:
 - 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 organic solvent usage rate for P003 and P048 combined, in pounds. This shall include the information for the current month and the preceding eleven months.
 - e. the updated, rolling 12-month summation of the OC emissions for P003 and P048, 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 P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), and any de minimis emissions units as 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)];

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- 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 operate and maintain a continuous temperature monitor and

Emissions Unit ID: **P048**

recorder which measures and records the combustion temperature within the thermal oxidizer when the emissions unit is in operation. Units shall be in degrees Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitor and recorder shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

The permittee shall collect and record the following information for each day:

- a. All 3-hour blocks of time during which the average combustion temperature within the thermal oxidizer, when the emissions unit was in operation, was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
- b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.

The control device downtime is defined as any time when the emissions unit is operating, is employing organic compounds, and the thermal oxidizer is not in operation. Monitoring device downtime is defined as any time when the emissions unit is operating, is employing organic compounds, and the temperature monitoring equipment is not in operation.

4. The permittee shall properly install, operate, and maintain equipment to monitor the pressure drop across the cartridge filter while the emissions unit is in operation. 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 pressure drop across the cartridge filter on daily basis.
5. The permit to install for this emissions unit (P048) was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN3 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN3 model was compared to the Maximum Ground-Level Concentration (MAGLC).

The following summarizes the results of the modeling for the "worst case" pollutant(s)

Emissions Unit ID: P048

for the emissions from P003, P005, P006, P048, P049, and P050 combined:

Pollutant: methanol

TLV (ug/m3): 262,086

Maximum Hourly Emission Rate (lbs/hr): 75.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 5,756

MAGLC (ug/m3): 6,240

Pollutant: isopropanol

TLV (ug/m3): 491,534

Maximum Hourly Emission Rate (lbs/hr): 103.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 8,194

MAGLC (ug/m3): 11,703

Physical changes to or in the method of operation of the emissions unit after it's installation or modification could affect the parameters used to determine whether or not the "Air Toxics Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in the "Air Toxic Policy" include the following:

- a. changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value 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 pollutant with a listed TLV that was

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proposed in the application and modeled; and

- c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" 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 the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) is (are) defined as a modification under other provisions of the modification definition, then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will satisfy the Air Toxic Policy:"

- a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
- b. documentation of it's evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
- c. when the computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

D. Reporting Requirements

1. The permittee shall submit written quarterly deviation reports to the Hamilton County Department of Environmental Services that include the following:
 - a. an identification of all 3-hour blocks of time during which the average combustion temperature within the thermal oxidizer, when the emissions unit was in operation, was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance; and

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- b. pressure drop deviation (excursion) reports that identify all periods of time during which the pressure drop across the particulate filter did not comply with the allowable range specified in term B.1.

If no exceedances occurred during the reporting period than a report is required stating so.

2. The permittee shall submit quarterly deviation reports to the Hamilton County Department of Environmental Services that include a log of the downtime for the particulate filter, and/or thermal oxidizer and/or monitoring equipment when this emissions unit was in operation.
3. The deviation (excursion) reports shall be submitted in accordance with the reporting requirements of the General Terms and Conditions of this permit.
4. 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.c. 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.)
5. The permittee shall submit written reports to the Hamilton County Department of Environmental Services which identify the amount of organic compounds (solvents) employed per month and the updated rolling, 12-month summation of the amount of organic compounds employed for emissions units P003 and P048,combined. The reports shall also include the monthly OC emissions rate and the updated rolling, 12-month OC emissions rate. 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.)

E. Testing Requirements

1. Compliance with the emission limitations in Section A. of these terms and conditions shall be determined in accordance with the following method(s):
 - a. Emissions limitations:

3.03 lbs OC/hour for P048; and 11.0 TPY OC combined for P003 and P048

Applicable Compliance Method:

The hourly OC emissions rate shall be determined by multiplying the maximum coating material throughput (pounds OC per batch divided by the hours per batch) multiplied by the efficiency of the thermal oxidizer (1- 0.98), as provided in PTI application 14-05727 submitted on May 23, 2005. 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 times one minus 0.98 and dividing by 2000 lbs/ton to obtain tons OC per year.

b. Emissions limitations:

0.83 lb PE/PM10/PM2.5 per hour and 3.65 TPY PE/PM10/PM2.5

Applicable Compliance Method:

PE, PM10 and PM2.5 emissions rates shall be determined by multiplying the total coating material throughput (pounds per batch divided by the hours per batch) by the percent solids in the coating (25%), times the solids transfer factor of the tablet coating (1-0.67), times the particulate not controlled by the 95% efficient cartridge filter (1- 0.95), as provided in PTI application 14-05727 submitted on May 23, 2005. The hourly coating material emissions shall be multiplied by 8760 hours per year and divided by 2000 lbs/ton to obtain the annual emissions.

c. Emissions limitation:

The total allowable emissions of Hazardous Air Pollutants (HAPs) from the emissions units identified in term and condition A.2.c. 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 HAPs emissions limitations shall be based on the record keeping requirements established in term and condition C.2.

d. Emissions limitations:

0.01 lb per hour and 0.05 TPY PE/PM10/PM2.5 from natural gas combustion in

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the regenerative thermal oxidizer

Applicable Compliance Method:

PE/PM10/PM2.5 emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (7.6 lb PM/MMft³). The emissions factor 7.6 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton. All PM10 and PM2.5 was assumed equal to the PE rate.

e. Emissions limitations:

0.001 lb per hour and 0.01 TPY SO₂ from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

SO₂emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (0.6 lb SO₂/MMft³). The emissions factor 0.6 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

f. Emissions limitations:

0.16 lb per hour and 0.70 TPY NO_x from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

NO_x emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (100 lb NO_x/MMft³). The emissions factor 100 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by

Patheon Pharmaceuticals, Inc.
PTI Application: 14-05727
Issue

Facility ID: 1431380503

Emissions Unit ID: P048

multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

g. Emissions limitations:

0.13 lb per hour and 0.59 TPY CO from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

CO emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (84 lb CO/MMft³). The emissions factor 84 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

h. Emissions limitations:

0.02 lb per hour and 0.08 TPY OC from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

OC emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (11 lb OC/MMft³). The emissions factor 11 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

i. Emissions limitation:

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a 6-minute average.

Applicable Compliance Method:

Compliance with the visible particulate emission limitation shall be demonstrated by the methods outlined in 40 CFR Part 60, Appendix A, Method 9.

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2. Compliance with the particulate control device pressure differential requirements of term and condition B.1. shall be demonstrated by the recordkeeping in term and condition C.4.
3. Compliance with the organic material usage limitations of term and condition B.2. shall be demonstrated by the record keeping in term and condition C.1.
4. Compliance with the minimum temperature within the regenerative thermal oxidizer requirements of term and condition B.3. shall be demonstrated by the recordkeeping in term and condition C.3.
5. Emission testing requirements

The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

- a. The emissions testing shall be performed within six months of the start up of this emissions unit.
- b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emissions rate for OC and the 98% OC overall control efficiency for the thermal oxidizer.
- c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s):
for OC, Method 25 or 25 A as per 40 CFR Part 60, Subpart A.

Alternative U.S. EPA approved test methods may be used with prior approval from the Hamilton County Department of Environmental Services.

The test method(s) which must be employed to demonstrate compliance with the destruction efficiency for the thermal oxidizer are specified below.

- d. The test(s) shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the Hamilton County Department of Environmental Services.

The control efficiency (i.e., the percent reduction in mass emissions between the inlet and outlet of the control system) shall be determined in accordance with the

Patheon Pharmaceuticals, Inc.
PTI Application: 14-05727
Issue

Facility ID: 1431380503

Emissions Unit ID: **P048**

test methods and procedures specified in OAC rule 3745-21-10 or an approved alternative test protocol. The test methods and procedures selected shall be based on a consideration of the diversity of the organic species present and their total concentration, and on a consideration of the potential presence of interfering gases.

Not later than 30 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the Hamilton County Department of Environmental Services. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Hamilton County Department of Environmental Services refusal to accept the results of the emission test(s).

Personnel from the Hamilton County Department of Environmental Services shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the Hamilton County Department of Environmental Services within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the Hamilton County Department of Environmental Services.

F. Miscellaneous Requirements

1. The requirements of this permit to install shall supercede the terms and conditions in PTI 14-05576, as issued on July 15, 2004.
2. The following terms and conditions in this permit are federally enforceable: Sections A., B., C.1. - C.4., D. and E.

Pathe
PTI A

Emissions Unit ID: P049

Issued: To be entered upon final issuance

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.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>
P049 - Tray drying oven - oven No.1 w/ HEPA filter and thermal oxidizer	OAC rule 3745-31-05(A)(3)

Pathe

PTI A

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Emissions Unit ID: **P049**

	Applicable Emissions <u>Limitations/Control Measures</u>	P048, P049, and P050.)
OAC rule 3745-17-07(A)(1)	Organic Compound (OC) emissions from the process shall not exceed 25.8 lbs OC/day.	The hourly emissions limitations for PE, PM10, PM2.5, SO2, NOx, CO and OC and the annual PE, PM10, PM2.5, SO2, NOx, CO and OC emissions limits are based upon the emissions unit's potential to emit. Therefore, no records are required to demonstrate compliance with these limits.
OAC rule 3745-17-11(B)	OC emissions from the process shall not exceed 4.70 tons per year (TPY).	
	Particulate emissions (PE) from the process shall not exceed 0.03 lb/hour and 0.11 TPY.	The requirements of this rule also include compliance with the requirements of OAC rule 3745-21-08(B), OAC rule 3745-23-06(B) and OAC rule 3745-31-05(C).
OAC rule 3745-21-07(G)	Particulate matter emissions 10 microns and less in diameter (PM10) and Particulate matter emissions 2.5 microns and less in diameter (PM2.5) from the process shall not exceed 0.03 lb/hour and 0.11 TPY.	Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a six-minute average.
OAC rule 3745-31-05(C)	Emissions from the combustion of natural gas in the regenerative thermal oxidizer shall not exceed the following:	See terms and conditions B.1. and B.2.
OAC rule 3745-21-08(B)	0.01 lb/hr and 0.05 TPY PE;	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
OAC rule 3745-23-06(B)	0.01 lb/hr and 0.05 TPY PM10;	
	0.01 lb/hr and 0.05 TPY PM2.5;	
	0.001 lb/hr and 0.01 TPY SO2;	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
	0.16 lb/hr and 0.70 TPY NOx;	
	0.13 lb/hr and 0.59 TPY CO; and 0.02 lb/hr and 0.08 TPY OC. (These emissions are from the one thermal oxidizer which controls emissions units P003,	

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

See terms and condition A.2.b and A.2.c.

See term and condition A.2.d.

See term and condition A.2.e.

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

2. Additional Terms and Conditions

- 2.a** Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by emissions limitations, the use of a particulate filter with a particulate emissions control efficiency of at least 99.9 percent 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 materials.
- 2.c** 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 P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), any de minimis emissions units as defined in OAC rule 3745-15-05, any registration status and/or permit exempt emissions units shall

Pathe**PTI A**Emissions Unit ID: **P049****Issued: To be entered upon final issuance**

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.c. upon permit issuance.

- 2.d** The permittee has satisfied the "best available control techniques and operating practices" required pursuant to OAC rule 3745-21-08(B) by committing to comply with the best available technology requirements established pursuant to OAC rule 3745-31-05(A)(3) in Permit to Install 14-05727.

On November 5, 2002, OAC rule 3745-21-08 was revised to delete paragraph (B); therefore, paragraph (B) is no longer part of the State regulations. However, that rule revision has not yet been submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revision occurs and the U.S. EPA approves the revisions to OAC rule 3745-21-08, the requirement to satisfy the "best available control techniques and operating practices" still exists as part of the federally-approved SIP for Ohio.

- 2.e** The permittee has satisfied the "latest available control techniques and operating practices" required pursuant to OAC rule 3745-23-06(B) by committing to comply with the best available technology requirements established pursuant to OAC rule 3745-31-05(A)(3) in Permit to Install 14-05727.

On February 15, 2005, OAC rule 3745-23-06 was rescinded and therefore no longer a part of the State regulations. However, that rule revision has not yet been submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revision occurs and the U.S. EPA approves the revisions to OAC rule 3745-23-06, the requirement to satisfy "latest available control techniques and operating practices" still exists as part of the federally-approved SIP for Ohio.

B. Operational Restrictions

1. The pressure drop across the particulate filter (HEPA) while the emissions unit is in operation shall be maintained either within the range of 0.25 to 4 inches of water or that range which was established during the most recent emission test that demonstrated the emissions unit was in compliance.

Emissions Unit ID: P049

2. The average combustion temperature within the chamber within the thermal oxidizer, for any 3-hour block of time when the emissions unit is in operation, shall be maintained above 1450 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.

C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall collect and record the following information each month for emissions units P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), and any de minimis emissions units as 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)

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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.

- 2. The permittee shall operate and maintain a continuous temperature monitor and recorder which measures and records the combustion temperature within the thermal oxidizer when the emissions unit is in operation. Units shall be in degrees Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitor and recorder shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

The permittee shall collect and record the following information for each day:

- a. All 3-hour blocks of time during which the average combustion temperature within the thermal oxidizer, when the emissions unit was in operation, was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

Emissions Unit ID: **P049**

- b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.

The control device downtime is defined as any time when the emissions unit is operating, is employing organic compounds, and the thermal oxidizer is not in operation. Monitoring device downtime is defined as any time when the emissions unit is operating, is employing organic compounds, and the temperature monitoring equipment is not in operation.

3. The permittee shall properly install, operate, and maintain equipment to monitor the pressure drop across the particulate control device while the emissions unit is in operation. 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 pressure drop across the control device on weekly basis.
4. The permit to install for this emissions unit (P049) was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN3 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN3 model was compared to the Maximum Ground-Level Concentration (MAGLC).

The following summarizes the results of the modeling for the "worst case" pollutant(s) for the emissions from P003, P005, P006, P048, P049, and P050 combined:

Pollutant: methanol

TLV (ug/m3): 262,086

Maximum Hourly Emission Rate (lbs/hr): 75.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 5,756

MAGLC (ug/m3): 6,240

Pollutant: isopropanol

Pathe**PTI A**Emissions Unit ID: **P049****Issued: To be entered upon final issuance**

TLV (ug/m3): 491,534

Maximum Hourly Emission Rate (lbs/hr): 103.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 8,194

MAGLC (ug/m3): 11,703

Physical changes to or in the method of operation of the emissions unit after its installation or modification could affect the parameters used to determine whether or not the "Air Toxics Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in the "Air Toxic Policy" include the following:

- a. changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value 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 pollutant with a listed TLV that was proposed in the application and modeled; and
- c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" 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 the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) is (are) defined as a modification under other provisions of the modification definition, then the permittee shall obtain a final

permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will satisfy the Air Toxic Policy:"

- a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
- b. documentation of it's evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
- c. when the computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

D. Reporting Requirements

1. The permittee shall submit written quarterly deviation reports to the Hamilton County Department of Environmental Services that include the following:
 - a. an identification of all 3-hour blocks of time during which the average combustion temperature within the thermal oxidizer, when the emissions unit was in operation, was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance; and
 - b. pressure drop deviation (excursion) reports that identify all periods of time during which the pressure drop across the particulate filter did not comply with the allowable range specified in term B.1.

If no exceedances occurred during the reporting period than a report is required stating so.
2. The permittee shall submit quarterly deviation reports to the Hamilton County Department of Environmental Services that include a log of the downtime for the fabric filter, and/or thermal oxidizer and/or monitoring equipment when this emissions unit was in operation.
3. The deviation (excursion) reports shall be submitted in accordance with the reporting requirements of the General Terms and Conditions of this permit.

Pathe**PTI A**Emissions Unit ID: **P049****Issued: To be entered upon final issuance**

4. 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.c. 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.)

E. Testing Requirements

1. Compliance with the emission limitations in Section A. of these terms and conditions shall be determined in accordance with the following method(s):

- a. Emissions limitations:

1.72 lbs OC/hour; and 4.70 TPY OC

Applicable Compliance Method:

The hourly OC emissions rate shall be determined by multiplying the maximum coating material throughput (pounds OC per batch divided by the hours per batch, times a factor of 0.4 to represent the maximum emission rate during the first hour of the batch) multiplied by the efficiency of the thermal oxidizer (1-0.98), as provided in PTI application 14-05727 submitted on May 23, 2005. The annual OC emissions shall be determined by multiplying the maximum coating material throughput (pounds OC per batch divided by the hours per batch) multiplied by the efficiency of the thermal oxidizer (1-0.98), multiplied by 8760 hrs/year, and dividing by 2000 lbs/ton to obtain tons OC per year.

- b. Emissions limitations:

0.03 lb PE/PM10/PM2.5 per hour and 0.11 TPY PE/PM10/PM2.5

Applicable Compliance Method:

PE, PM10 and PM2.5 emissions rates shall be determined by multiplying the total coating material throughput (pounds per batch divided by the hours per batch) by the percent solids in the coating (100%), times the solids transfer factor of the tablet coating (1-0.90), times the particulate not controlled by the 99.9% efficient particulate filter (1-0.999), as provided in PTI application

Emissions Unit ID: **P049**

14-05727 submitted on May 23, 2005. The hourly coating material emissions shall be multiplied by 8760 hours per year and divided by 2000 lbs/ton to obtain the annual emissions.

c. Emissions limitation:

The total allowable emissions of Hazardous Air Pollutants (HAPs) from the emissions units identified in term and condition A.2.c. 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 HAPs emissions limitations shall be based on the record keeping requirements established in term and condition C.1.

d. Emissions limitations:

0.01 lb per hour and 0.05 TPY PE/PM10/PM2.5 from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

PE/PM10/PM2.5 emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (7.6 lb PM/MMft³). The emissions factor 7.6 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton. All PM10 and PM2.5 was assumed equal to the PE rate.

e. Emissions limitations:

0.001 lb per hour and 0.01 TPY SO₂ from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

SO₂emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (0.6 lb SO₂/MMft³). The emissions factor

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0.6 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

f. Emissions limitations:

0.16 lb per hour and 0.70 TPY NO_x from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

NO_x emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (100 lb NO_x/MMft³). The emissions factor 100 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

g. Emissions limitations:

0.13 lb per hour and 0.59 TPY CO from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

CO emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (84 lb CO/MMft³). The emissions factor 84 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

h. Emissions limitations:

0.02 lb per hour and 0.08 TPY OC from natural gas combustion in the regenerative thermal oxidizer

Issued: To be entered upon final issuance

Applicable Compliance Method:

OC emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (11 lb OC/MMft³). The emissions factor 11 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

i. Emissions limitation:

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a 6-minute average.

Applicable Compliance Method:

Compliance with the visible particulate emission limitation shall be demonstrated by the methods outlined in 40 CFR Part 60, Appendix A, Method 9.

2. Compliance with the particulate control device pressure differential requirements of term and condition B.1. shall be demonstrated by the recordkeeping in term and condition C.3.
3. Compliance with the minimum temperature within the regenerative thermal oxidizer requirements of term and condition B.2. shall be demonstrated by the recordkeeping in term and condition C.2.
4. Emission testing requirements

The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

- a. The emissions testing shall be performed within six months of the start up of this emissions unit.
- b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emissions rate for OC and the 98% OC overall control efficiency for the thermal oxidizer.

Emissions Unit ID: **P049**

- c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s):
for OC, Method 25 or 25 A as per 40 CFR Part 60, Subpart A.

Alternative U.S. EPA approved test methods may be used with prior approval from the Hamilton County Department of Environmental Services.

The test method(s) which must be employed to demonstrate compliance with the destruction efficiency for the thermal oxidizer are specified below.

- d. The test(s) shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the Hamilton County Department of Environmental Services.

The control efficiency (i.e., the percent reduction in mass emissions between the inlet and outlet of the control system) shall be determined in accordance with the test methods and procedures specified in OAC rule 3745-21-10 or an approved alternative test protocol. The test methods and procedures selected shall be based on a consideration of the diversity of the organic species present and their total concentration, and on a consideration of the potential presence of interfering gases.

Not later than 30 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the Hamilton County Department of Environmental Services. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Hamilton County Department of Environmental Services refusal to accept the results of the emission test(s).

Personnel from the Hamilton County Department of Environmental Services shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the Hamilton County Department of Environmental Services within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written

Pathe

PTI A

Emissions Unit ID: **P049**

Issued: To be entered upon final issuance

report, where warranted, with prior approval from the Hamilton County Department of Environmental Services.

F. Miscellaneous Requirements

1. The following terms and conditions in this permit are federally enforceable: Sections A., B., C.1 - C.3., D. and E.

Pathe
PTI A

Emissions Unit ID: P050

Issued: To be entered upon final issuance

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.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>
P050 - Tray drying oven - Oven No. 2, w/ HEPA filter and thermal oxidizer	OAC rule 3745-31-05(A)(3)

	<u>Applicable Emissions Limitations/Control Measures</u>	
OAC rule 3745-17-07(A)(1)	Organic Compound (OC) emissions from the process shall not exceed 25.8 lbs OC/day.	
OAC rule 3745-17-11(B)	OC emissions from the process shall not exceed 4.70 tons per year (TPY).	The hourly emissions limitations for PE, PM10, PM2.5, SO2, NOx, CO and OC and the annual PE, PM10, PM2.5, SO2, NOx, CO and OC emissions limits are based upon the emissions unit's potential to emit. Therefore, no records are required to demonstrate compliance with these limits.
OAC rule 3745-21-07(G)	<p>Particulate emissions (PE) from the process shall not exceed 0.03 lb/hour and 0.11 TPY.</p> <p>Particulate matter emissions 10 microns and less in diameter (PM10) and Particulate matter emissions 2.5 microns and less in diameter (PM2.5) from the process shall not exceed 0.03 lb/hour and 0.11 TPY.</p>	<p>The requirements of this rule also include compliance with the requirements of OAC rule 3745-21-08(B), OAC rule 3745-23-06(B) and OAC rule 3745-31-05(C).</p> <p>Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a six-minute average.</p>
OAC rule 3745-31-05(C)	Emissions from the combustion of natural gas in the regenerative thermal oxidizer shall not exceed the following:	See terms and conditions B.1. and B.2.
OAC rule 3745-21-08(B)	0.01 lb/hr and 0.05 TPY PE;	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
OAC rule 3745-23-06(B)	0.01 lb/hr and 0.05 TPY PM10;	
	0.01 lb/hr and 0.05 TPY PM2.5;	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
	0.001 lb/hr and 0.01 TPY SO2;	The emission limitation specified by this rule is less stringent than
	0.16 lb/hr and 0.70 TPY NOx;	
	0.13 lb/hr and 0.59 TPY CO;	
	and 0.02 lb/hr and 0.08 TPY OC.	
	(These emissions are from the one thermal oxidizer which controls emissions units P003, P048, P049, and P050.)	

Pathe**PTI A**Emissions Unit ID: **P050****Issued: To be entered upon final issuance**

the emission limitation
established pursuant to OAC
rule 3745-31-05(A)(3).

See term and condition A.2.b
and A.2.c.

See term and condition A.2.d.

See term and condition A.2.e.

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

2. Additional Terms and Conditions

- 2.a** Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by emissions limitations, the use of a particulate filter with a particulate emissions control efficiency of at least 99.9 percent 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 materials.
- 2.c** 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 P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), any de minimis emissions units as defined in OAC rule 3745-15-05, 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

Pathe

PTI A

Emissions Unit ID: **P050**

Issued: To be entered upon final issuance

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.c. upon permit issuance.

- 2.d** The permittee has satisfied the "best available control techniques and operating practices" required pursuant to OAC rule 3745-21-08(B) by committing to comply with the best available technology requirements established pursuant to OAC rule 3745-31-05(A)(3) in Permit to Install 14-05727.

On November 5, 2002, OAC rule 3745-21-08 was revised to delete paragraph (B); therefore, paragraph (B) is no longer part of the State regulations. However, that rule revision has not yet been submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revision occurs and the U.S. EPA approves the revisions to OAC rule 3745-21-08, the requirement to satisfy the "best available control techniques and operating practices" still exists as part of the federally-approved SIP for Ohio.

- 2.e** The permittee has satisfied the "latest available control techniques and operating practices" required pursuant to OAC rule 3745-23-06(B) by committing to comply with the best available technology requirements established pursuant to OAC rule 3745-31-05(A)(3) in Permit to Install 14-05727.

On February 15, 2005, OAC rule 3745-23-06 was rescinded and therefore no longer a part of the State regulations. However, that rule revision has not yet been submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revision occurs and the U.S. EPA approves the revisions to OAC rule 3745-23-06, the requirement to satisfy "latest available control techniques and operating practices" still exists as part of the federally-approved SIP for Ohio.

B. Operational Restrictions

1. The pressure drop across the particulate (HEPA) filter while the emissions unit is in operation shall be maintained either within the range of 0.25 to 4 inches of water or that range which was established during the most recent emission test that demonstrated the emissions unit was in compliance.
2. The average combustion temperature within the chamber within the thermal oxidizer, for any 3-hour block of time when the emissions unit is in operation, shall be maintained above 1450 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.

Pathe**PTI A**Emissions Unit ID: **P050****Issued: To be entered upon final issuance****C. Monitoring and/or Recordkeeping Requirements**

1. The permittee shall collect and record the following information each month for emissions units P002 (capsule production line), P007 (fluid bed dryer), P008(dry products line), P009 (quality control lab), P010 (dry packaging), P012 (lozenge manufacturing), P014 (granulation processing), P003 (Tablet coating line), P004 (Tablet coating line), P005 (Tablet coating line), P006 (Tablet coating line) and P048 (Tablet coating line), P001 (drying oven), P044-P047 (drying ovens), P049 (drying oven) and P050 (drying oven), and any de minimis emissions units as 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.

- 2. The permittee shall operate and maintain a continuous temperature monitor and recorder which measures and records the combustion temperature within the thermal oxidizer when the emissions unit is in operation. Units shall be in degrees Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitor and recorder shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

The permittee shall collect and record the following information for each day:

- a. All 3-hour blocks of time during which the average combustion temperature within the thermal oxidizer, when the emissions unit was in operation, was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
- b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.

The control device downtime is defined as any time when the emissions unit is operating, is employing organic compounds, and the thermal oxidizer is not in operation. Monitoring device downtime is defined as any time when the emissions unit is operating, is employing organic compounds, and the temperature monitoring

Pathe**PTI A**Emissions Unit ID: **P050****Issued: To be entered upon final issuance**

equipment is not in operation.

3. The permittee shall properly install, operate, and maintain equipment to monitor the pressure drop across the particulate control device while the emissions unit is in operation. 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 pressure drop across the control device on weekly basis.
4. The permit to install for this emissions unit (P050) was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from

Pathe**PTI A**Emissions Unit ID: **P050****Issued: To be entered upon final issuance**

the permit to install application and the SCREEN3 model(or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN3 model was compared to the Maximum Ground-Level Concentration (MAGLC).

The following summarizes the results of the modeling for the "worst case" pollutant(s) for the emissions from P003, P005, P006, P048, P049, and P050 combined:

Pollutant: methanol

TLV (ug/m3): 262,086

Maximum Hourly Emission Rate (lbs/hr): 75.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 5,756

MAGLC (ug/m3): 6,240

Pollutant: isopropanol

TLV (ug/m3): 491,534

Maximum Hourly Emission Rate (lbs/hr): 103.6

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 8,194

MAGLC (ug/m3): 11,703

Physical changes to or in the method of operation of the emissions unit after it's installation or modification could affect the parameters used to determine whether or not the "Air Toxics Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in the "Air Toxic Policy" include the following:

- a. changes in the composition of the materials used (typically for coatings or

Emissions Unit ID: **P050**

cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value 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 pollutant with a listed TLV that was proposed in the application and modeled; and
- c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" 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 the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) is (are) defined as a modification under other provisions of the modification definition, then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will satisfy the Air Toxic Policy:"

- a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
- b. documentation of it's evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
- c. when the computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

D. Reporting Requirements

1. The permittee shall submit written quarterly deviation reports to the Hamilton County Department of Environmental Services that include the following:

Pathe**PTI A**Emissions Unit ID: **P050****Issued: To be entered upon final issuance**

- a. an identification of all 3-hour blocks of time during which the average combustion temperature within the thermal oxidizer, when the emissions unit was in operation, was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance; and
- b. pressure drop deviation (excursion) reports that identify all periods of time during which the pressure drop across the particulate filter did not comply with the allowable range specified in term B.1.

Issued: To be entered upon final issuance

If no exceedances occurred during the reporting period than a report is required stating so.

2. The permittee shall submit quarterly deviation reports to the Hamilton County Department of Environmental Services that include a log of the downtime for the fabric filter, and/or thermal oxidizer and/or monitoring equipment when this emissions unit was in operation.
3. The deviation (excursion) reports shall be submitted in accordance with the reporting requirements of the General Terms and Conditions of this permit.
4. 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.c. 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.)

E. Testing Requirements

1. Compliance with the emission limitations in Section A. of these terms and conditions shall be determined in accordance with the following method(s):

- a. Emissions limitations:

1.72 lbs OC/hour; and 4.70 TPY OC

Applicable Compliance Method:

The hourly OC emissions rate shall be determined by multiplying the maximum coating material throughput (pounds OC per batch divided by the hours per batch, times a factor of 0.4 to represent the maximum emission rate during the first hour of the batch) multiplied by the efficiency of the thermal oxidizer (1- 0.98), as provided in PTI application 14-05727 submitted on May 23, 2005. The annual OC emissions shall be determined by multiplying the maximum coating material throughput (pounds OC per batch divided by the hours per batch) multiplied by the efficiency of the thermal oxidizer (1- 0.98), multiplied by 8760 hrs/year, and dividing by 2000 lbs/ton to obtain tons OC per year.

Patheon Pharmaceuticals, Inc.
PTI Application: 14-05727
Issue

Facility ID: 1431380503

Emissions Unit ID: P050

b. Emissions limitations:

0.03 lb PE/PM10/PM2.5 per hour and 0.11 TPY PE/PM10/PM2.5

Pathe**PTI A****Issued: To be entered upon final issuance**Emissions Unit ID: **P050**

Applicable Compliance Method:

PE, PM10 and PM2.5 emissions rates shall be determined by multiplying the total coating material throughput (pounds per batch divided by the hours per batch) by the percent solids in the coating (100%), times the solids transfer factor of the tablet coating (1-0.90), times the particulate not controlled by the 99.9% efficient particulate filter (1- 0.999), as provided in PTI application 14-05727 submitted on May 23, 2005. The hourly coating material emissions shall be multiplied by 8760 hours per year and divided by 2000 lbs/ton to obtain the annual emissions.

c. Emissions limitation:

The total allowable emissions of Hazardous Air Pollutants (HAPs) from the emissions units identified in term and condition A.2.c. 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 HAPs emissions limitations shall be based on the record keeping requirements established in term and condition C.1.

d. Emissions limitations:

0.01 lb per hour and 0.05 TPY PE/PM10/PM2.5 from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

PE/PM10/PM2.5 emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (7.6 lb PM/MMft³). The emissions factor 7.6 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton. All PM10 and PM2.5 was assumed equal to the PE rate.

e. Emissions limitations:

101

Pathe

PTI A

Issued: To be entered upon final issuance

Emissions Unit ID: **P050**

0.001 lb per hour and 0.01 TPY SO₂ from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

SO₂ emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (0.6 lb SO₂/MMft³). The emissions factor 0.6 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

f. Emissions limitations:

0.16 lb per hour and 0.70 TPY NO_x from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

NO_x emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (100 lb NO_x/MMft³). The emissions factor 100 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

g. Emissions limitations:

0.13 lb per hour and 0.59 TPY CO from natural gas combustion in the regenerative thermal oxidizer

Applicable Compliance Method:

CO emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (84 lb CO/MMft³). The emissions factor 84 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

Patheon Pharmaceuticals, Inc.
PTI Application: 14-05727
Issue

Facility ID: 1431380503

Emissions Unit ID: P050

h. Emissions limitations:

0.02 lb per hour and 0.08 TPY OC from natural gas combustion in the regenerative thermal oxidizer

Issued: To be entered upon final issuance

Applicable Compliance Method:

OC emissions rates shall be determined by multiplying the maximum fuel use for the regenerative thermal oxidizer (1600 cubic feet per hour divided by 1,000,000) times the emission factor (11 lb OC/MMft³). The emissions factor 11 lb/MMft³ was taken from AP-42, Fifth Edition, Chapter 1.4, Natural Gas Combustion (July 1998.) The annual emission rate shall be determined by multiplying the maximum emissions hourly rate by 8760 hours per year and dividing by 2000 lbs per ton.

i. Emissions limitation:

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a 6-minute average.

Applicable Compliance Method:

Compliance with the visible particulate emission limitation shall be demonstrated by the methods outlined in 40 CFR Part 60, Appendix A, Method 9.

2. Compliance with the particulate control device pressure differential requirements of term and condition B.1. shall be demonstrated by the record keeping in term and condition C.3.
3. Compliance with the minimum temperature within the regenerative thermal oxidizer requirements of term and condition B.2. shall be demonstrated by the record keeping in term and condition C.2.
4. Emission testing requirements

The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

- a. The emissions testing shall be performed within six months of the start up of this emissions unit.
- b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emissions rate for OC and the 98% OC overall control efficiency for the thermal oxidizer.

Pathe

PTI A

Issued: To be entered upon final issuance

Emissions Unit ID: **P050**

- c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s):
for OC, Method 25 or 25 A as per 40 CFR Part 60, Subpart A.

Issued: To be entered upon final issuance

Alternative U.S. EPA approved test methods may be used with prior approval from the Hamilton County Department of Environmental Services.

The test method(s) which must be employed to demonstrate compliance with the destruction efficiency for the thermal oxidizer are specified below.

- d. The test(s) shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the Hamilton County Department of Environmental Services.

The control efficiency (i.e., the percent reduction in mass emissions between the inlet and outlet of the control system) shall be determined in accordance with the test methods and procedures specified in OAC rule 3745-21-10 or an approved alternative test protocol. The test methods and procedures selected shall be based on a consideration of the diversity of the organic species present and their total concentration, and on a consideration of the potential presence of interfering gases.

Not later than 30 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the Hamilton County Department of Environmental Services. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Hamilton County Department of Environmental Services refusal to accept the results of the emission test(s).

Personnel from the Hamilton County Department of Environmental Services shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the Hamilton County Department of Environmental Services within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the Hamilton County Department of Environmental Services.

Patheon Pharmaceuticals, Inc.
PTI Application: 14-05727
Issue

Facility ID: 1431380503

Emissions Unit ID: P050

F. Miscellaneous Requirements

1. The following terms and conditions in this permit are federally enforceable: Sections A., B., C.1 - C.3., D. and E.