



John R. Kasich, Governor
Mary Taylor, Lt. Governor
Scott J. Nally, Director

6/6/2013

Certified Mail

Mr. Dane Marsee
Aptalis Pharmatech, Inc.
845 CENTER DR.
VANDALIA, OH 45377

| | |
|-----|------------------------------------|
| No | TOXIC REVIEW |
| No | SYNTHETIC MINOR TO AVOID MAJOR NSR |
| No | CEMS |
| No | MACT/GACT |
| No | NSPS |
| No | NESHAPS |
| No | NETTING |
| No | MODELING SUBMITTED |
| Yes | SYNTHETIC MINOR TO AVOID TITLE V |
| Yes | FEDERALLY ENFORCABLE PTIO (FEPTIO) |
| No | SYNTHETIC MINOR TO AVOID MAJOR GHG |

RE: DRAFT AIR POLLUTION PERMIT-TO-INSTALL AND OPERATE

Facility ID: 0857171794
Permit Number: P0113893
Permit Type: Initial Installation
County: Montgomery

Dear Permit Holder:

A draft of the Ohio Administrative Code (OAC) Chapter 3745-31 Air Pollution Permit-to-Install and Operate (PTIO) for the referenced facility has been issued for the emissions unit(s) listed in the Authorization section of 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 permit. A public notice will appear in the Ohio Environmental Protection Agency (EPA) Weekly Review and the local newspaper, Dayton Daily News. A copy of the public notice and the draft permit are enclosed. This permit can be accessed electronically on the Division of Air Pollution Control (DAPC) Web page, www.epa.ohio.gov/dapc by clicking the "Search for Permits" link under the Permitting topic on the Programs tab. Comments will be accepted as a marked-up copy of the draft permit or in narrative format. Any comments must be sent to the following:

Andrew Hall
Permit Review/Development Section
Ohio EPA, DAPC
122 South Front Street
Columbus, Ohio 43215

and Regional Air Pollution Control Agency
117 South Main Street
Dayton, OH 45422-1280

Comments and/or a request for a public hearing will be accepted within 30 days of the date the notice is published in the newspaper. You will be notified if a public hearing is scheduled. A decision on issuing a final permit-to-install will be made after consideration of comments received and oral testimony if a public hearing is conducted. Any permit fee that will be due upon issuance of a final Permit-to-Install is indicated in the Authorization section. Please do not submit any payment now. If you have any questions, please contact Regional Air Pollution Control Agency at (937)225-4435.

Sincerely,

Michael W. Ahern
Michael W. Ahern, Manager
Permit Issuance and Data Management Section, DAPC

Cc: U.S. EPA Region 5 Via E-Mail Notification
RAPCA; Indiana; Kentucky



Permit Strategy Write-Up

1. Check all that apply:

Synthetic Minor Determination

Netting Determination

2. Source Description:

AptalisPharmatech, Inc. (Aptalis) is a facility that specializes in the coating and microencapsulation of active pharmaceuticals. Aptalis plans to install two research and development operations.

- Emissions Unit P021 is a Biorise Process used to modify the morphology of active pharmaceuticals for the purpose of enhancing the bioavailability. The process involves mixing and heating the active pharmaceutical, polymers and solvent in a high shear granulator/mixer followed by transfer to drying in a vacuum oven; and
- Emissions Unit P022 is a spray dryer, the MS35 Spray Dryer is used for particle formation and drying.

The VOC emissions (except for negligible fugitive VOC emissions during manual transfer of material from the granulator/mixer to the vacuum drying oven during the Biorise process) from both emissions units will be captured and vented to the Megtec catalytic oxidizer common to emission units P001, P014, P015, P017, P019 and P020. The catalytic oxidizer is required to achieve a volatile organic compound (VOC) destruction efficiency of at least 98%.

3. Facility Emissions and Attainment Status:

Aptalis is located in Montgomery County which is currently in attainment for all criteria pollutants except the annual PM 2.5 standard, which is classified as basic nonattainment. With the issuance of this PTIO the allowable VOC emissions facility wide will increase from 74.1 to 75.2 tons on a rolling 12-month basis.

4. Source Emissions:

Uncontrolled potential VOC emissions from the biorise process (emissions unit P021) are 42 pounds per day and 7.67 tons per year. The VOC emissions from will be captured and vented to a catalytic oxidizer capable of a VOC destruction efficiency greater than 98% by weight. This permit will be issued as a federally enforceable PTIO and have a 0.45 ton VOC emissions limitation on a rolling 12-month basis.

Uncontrolled potential VOC emissions from the spray dryer (emissions unit P022) are 170 pounds per day and 31.1 tons per year. The VOC emissions will be captured and vented to a catalytic oxidizer capable of a VOC destruction efficiency greater than 98% by weight. This permit will be issued as a federally enforceable PTIO and have a 0.62 ton VOC emissions limitation on a rolling 12-month basis.



This permit represents a 1.07 tons increase in the rolling 12-month emissions limitations in VOC emissions for the Aptalis facility as a whole.

5. Conclusion:

Aptalis is a synthetic minor facility by recovering liquid solvents and controlling VOC emissions with a catalytic oxidizer limiting the annual potential VOC emissions below the Title V permitting threshold (100 tons per year). Continuous temperature monitoring and periodic catalyst testing for the catalytic oxidizer, monthly record keeping for VOC use and reporting requirements are required to ensure compliance. Therefore, by limiting VOC emissions from emissions units P021 to less than 0.45 ton and P022 to less than 0.62 ton on a rolling 12-month basis potential VOC emissions from Aptalis will not exceed the Title V permitting threshold.

6. Please provide additional notes or comments as necessary:

None

7. Total Permit Allowable Emissions Summary (for informational purposes only):

| <u>Pollutant</u> | <u>Tons Per Year</u> |
|------------------|----------------------|
| <u>VOC</u> | <u>1.07</u> |

PUBLIC NOTICE
6/6/2013 Issuance of Draft Air Pollution Permit-To-Install and Operate

Aptalis Pharmatech, Inc.
845 CENTER DR.,
VANDALIA, OH 45377

Montgomery County

FACILITY DESC.: Pharmaceutical Preparation Manufacturing

PERMIT #: P0113893

PERMIT TYPE: Initial Installation

PERMIT DESC: Initial installation permit for a new granulator/vacuum dryer and a spray dryer that vent to an existing catalytic oxidizer.

The Director of the Ohio Environmental Protection Agency issued the draft permit above. The permit and complete instructions for requesting information or submitting comments may be obtained at: <http://epa.ohio.gov/dapc/permitsonline.aspx> by entering the permit # or: Andrew Weisman, Regional Air Pollution Control Agency, 117 South Main Street, Dayton, OH 45422-1280. Ph: (937)225-4435



DRAFT

**Division of Air Pollution Control
Permit-to-Install and Operate
for
Aptalis Pharmatech, Inc.**

| | |
|----------------|-----------------------------------|
| Facility ID: | 0857171794 |
| Permit Number: | P0113893 |
| Permit Type: | Initial Installation |
| Issued: | 6/6/2013 |
| Effective: | To be entered upon final issuance |
| Expiration: | To be entered upon final issuance |



Division of Air Pollution Control
Permit-to-Install and Operate
for
Aptalis Pharmatech, Inc.

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Draft Permit-to-Install and Operate

Aptalis Pharmatech, Inc.

Permit Number: P0113893

Facility ID: 0857171794

Effective Date: To be entered upon final issuance

Authorization

Facility ID: 0857171794
Application Number(s): A0047447
Permit Number: P0113893
Permit Description: Initial installation permit for a new granulator/vacuum dryer and a spray dryer that vent to an existing catalytic oxidizer.
Permit Type: Initial Installation
Permit Fee: \$400.00 *DO NOT send payment at this time, subject to change before final issuance*
Issue Date: 6/6/2013
Effective Date: To be entered upon final issuance
Expiration Date: To be entered upon final issuance
Permit Evaluation Report (PER) Annual Date: To be entered upon final issuance

This document constitutes issuance to:

Aptalis Pharmatech, Inc.
845 CENTER DR.
VANDALIA, OH 45377

of a Permit-to-Install and Operate for the emissions unit(s) identified on the following page.

Ohio Environmental Protection Agency (EPA) District Office or local air agency responsible for processing and administering your permit:

Regional Air Pollution Control Agency
117 South Main Street
Dayton, OH 45422-1280
(937)225-4435

The above named entity is hereby granted this Permit-to-Install and Operate for the air contaminant source(s) (emissions unit(s)) listed in this section 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 described emissions unit(s) will operate in compliance with applicable State and Federal laws and regulations.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Scott J. Nally
Director



Draft Permit-to-Install and Operate

Aptalis Pharmatech, Inc.

Permit Number: P0113893

Facility ID: 0857171794

Effective Date: To be entered upon final issuance

Authorization (continued)

Permit Number: P0113893

Permit Description: Initial installation permit for a new granulator/vacuum dryer and a spray dryer that vent to an existing catalytic oxidizer.

Permits for the following Emissions Unit(s) or groups of Emissions Units are in this document as indicated below:

Group Name: Research & Development Units

| | |
|-----------------------------------|---------------------|
| Emissions Unit ID: | P021 |
| Company Equipment ID: | RDF Biorise Process |
| Superseded Permit Number: | |
| General Permit Category and Type: | Not Applicable |
| Emissions Unit ID: | P022 |
| Company Equipment ID: | MS35 Spray Dryer |
| Superseded Permit Number: | |
| General Permit Category and Type: | Not Applicable |



Draft Permit-to-Install and Operate

Aptalis Pharmatech, Inc.

Permit Number: P0113893

Facility ID: 0857171794

Effective Date: To be entered upon final issuance

A. Standard Terms and Conditions



1. What does this permit-to-install and operate ("PTIO") allow me to do?

This permit allows you to install and operate the emissions unit(s) identified in this PTIO. You must install and operate the unit(s) in accordance with the application you submitted and all the terms and conditions contained in this PTIO, including emission limits and those terms that ensure compliance with the emission limits (for example, operating, recordkeeping and monitoring requirements).

2. Who is responsible for complying with this permit?

The person identified on the "Authorization" page, above, is responsible for complying with this permit until the permit is revoked, terminated, or transferred. "Person" means a person, firm, corporation, association, or partnership. The words "you," "your," or "permittee" refer to the "person" identified on the "Authorization" page above.

The permit applies only to the emissions unit(s) identified in the permit. If you install or modify any other equipment that requires an air permit, you must apply for an additional PTIO(s) for these sources.

3. What records must I keep under this permit?

You must keep all records required by this permit, including monitoring data, test results, strip-chart recordings, calibration data, maintenance records, and any other record required by this permit for five years from the date the record was created. You can keep these records electronically, provided they can be made available to Ohio EPA during an inspection at the facility. Failure to make requested records available to Ohio EPA upon request is a violation of this permit requirement.

4. What are my permit fees and when do I pay them?

There are two fees associated with permitted air contaminant sources in Ohio:

PTIO fee. This one-time fee is based on a fee schedule in accordance with Ohio Revised Code (ORC) section 3745.11, or based on a time and materials charge for permit application review and permit processing if required by the Director.

You will be sent an invoice for this fee after you receive this PTIO and payment is due within 30 days of the invoice date. You are required to pay the fee for this PTIO even if you do not install or modify your operations as authorized by this permit.

Annual emissions fee. Ohio EPA will assess a separate fee based on the total annual emissions from your facility. You self-report your emissions in accordance with Ohio Administrative Code (OAC) Chapter 3745-78. This fee assessed is based on a fee schedule in ORC section 3745.11 and funds Ohio EPA's permit compliance oversight activities. Unless otherwise specified, facilities subject to one or more synthetic minor restrictions must use Ohio EPA's "Air Services" to submit annual emissions associated with this permit requirement. Ohio EPA will notify you when it is time to report your emissions and to pay your annual emission fees.

5. When does my PTIO expire, and when do I need to submit my renewal application?

This permit expires on the date identified at the beginning of this permit document (see "Authorization" page above) and you must submit a renewal application to renew the permit. Ohio EPA will send a renewal notice to you approximately six months prior to the expiration date of this permit. However, it is



very important that you submit a complete renewal permit application (postmarked prior to expiration of this permit) even if you do not receive the renewal notice.

If a complete renewal application is submitted before the expiration date, Ohio EPA considers this a timely application for purposes of ORC section 119.06, and you are authorized to continue operating the emissions unit(s) covered by this permit beyond the expiration date of this permit until final action is taken by Ohio EPA on the renewal application.

6. What happens to this permit if my project is delayed or I do not install or modify my source?

This PTIO expires 18 months after the issue date identified on the "Authorization" page above unless otherwise specified if you have not (1) started constructing the new or modified emission sources identified in this permit, or (2) entered into a binding contract to undertake such construction. This deadline can be extended by up to 12 months, provided you apply to Ohio EPA for this extension within a reasonable time before the 18-month period has ended and you can show good cause for any such extension.

7. What reports must I submit under this permit?

An annual permit evaluation report (PER) is required in addition to any malfunction reporting required by OAC rule 3745-15-06 or other specific rule-based reporting requirement identified in this permit. Your PER due date is identified in the Authorization section of this permit.

8. If I am required to obtain a Title V operating permit in the future, what happens to the operating provisions and PER obligations under this permit?

If you are required to obtain a Title V permit under OAC Chapter 3745-77 in the future, the permit-to-operate portion of this permit will be superseded by the issued Title V permit. From the effective date of the Title V permit forward, this PTIO will effectively become a PTI (permit-to-install) in accordance with OAC rule 3745-31-02(B). The following terms and conditions will no longer be applicable after issuance of the Title V permit: Section B, Term 1.b) and Section C, for each emissions unit, Term a)(2).

The PER requirements in this permit remain effective until the date the Title V permit is issued and is effective, and cease to apply after the effective date of the Title V permit. The final PER obligation will cover operations up to the effective date of the Title V permit and must be submitted on or before the submission deadline identified in this permit on the last day prior to the effective date of the Title V permit.

9. What are my obligations when I perform scheduled maintenance on air pollution control equipment?

You must perform scheduled maintenance of air pollution control equipment in accordance with OAC rule 3745-15-06(A). If scheduled maintenance requires shutting down or bypassing any air pollution control equipment, you must also shut down the emissions unit(s) served by the air pollution control equipment during maintenance, unless the conditions of OAC rule 3745-15-06(A)(3) are met. Any emissions that exceed permitted amount(s) under this permit (unless specifically exempted by rule) must be reported as deviations in the annual permit evaluation report (PER), including nonexempt excess emissions that occur during approved scheduled maintenance.



10. Do I have to report malfunctions of emissions units or air pollution control equipment? If so, how must I report?

If you have a reportable malfunction of any emissions unit(s) or any associated air pollution control system, you must report this to the Regional Air Pollution Control Agency in accordance with OAC rule 3745-15-06(B). Malfunctions that must be reported are those that result in emissions that exceed permitted emission levels. It is your responsibility to evaluate control equipment breakdowns and operational upsets to determine if a reportable malfunction has occurred.

If you have a malfunction, but determine that it is not a reportable malfunction under OAC rule 3745-15-06(B), it is recommended that you maintain records associated with control equipment breakdown or process upsets. Although it is not a requirement of this permit, Ohio EPA recommends that you maintain records for non-reportable malfunctions.

11. Can Ohio EPA or my local air agency inspect the facility where the emission unit(s) is/are located?

Yes. Under Ohio law, the Director or his authorized representative may inspect the facility, conduct tests, examine records or reports to determine compliance with air pollution laws and regulations and the terms and conditions of this permit. You must provide, within a reasonable time, any information Ohio EPA requests either verbally or in writing.

12. What happens if one or more emissions units operated under this permit is/are shut down permanently?

Ohio EPA can terminate the permit terms associated with any permanently shut down emissions unit. "Shut down" means the emissions unit has been physically removed from service or has been altered in such a way that it can no longer operate without a subsequent "modification" or "installation" as defined in OAC Chapter 3745-31.

You should notify Ohio EPA of any emissions unit that is permanently shut down by submitting¹ a certification that identifies the date on which the emissions unit was permanently shut down. The certification must be submitted by an authorized official from the facility. You cannot continue to operate an emissions unit once the certification has been submitted to Ohio EPA by the authorized official.

You must comply with all recordkeeping and reporting for any permanently shut down emissions unit in accordance with the provisions of the permit, regulations or laws that were enforceable during the period of operation, such as the requirement to submit a PER, air fee emission report, or malfunction report. You must also keep all records relating to any permanently shutdown emissions unit, generated while the emissions unit was in operation, for at least five years from the date the record was generated.

Again, you cannot resume operation of any emissions unit certified by the authorized official as being permanently shut down without first applying for and obtaining a permit pursuant to OAC Chapter 3745-31.

¹Permittees that use Ohio EPA's "Air Services" can mark the affected emissions unit(s) as "permanently shutdown" in the facility profile along with the date the emissions unit(s) was permanently removed and/or disabled. Submitting the facility profile update will constitute notifying of the permanent shutdown of the affected emissions unit(s).



13. Can I transfer this permit to a new owner or operator?

You can transfer this permit to a new owner or operator. If you transfer the permit, you must follow the procedures in OAC Chapter 3745-31, including notifying Ohio EPA or the local air agency of the change in ownership or operator. Any transferee of this permit must assume the responsibilities of the transferor permit holder.

14. Does compliance with this permit constitute compliance with OAC rule 3745-15-07, "air pollution nuisance"?

This permit and OAC rule 3745-15-07 prohibit operation of the air contaminant source(s) regulated under this permit in a manner that causes a nuisance. Ohio EPA can require additional controls or modification of the requirements of this permit through enforcement orders or judicial enforcement action if, upon investigation, Ohio EPA determines existing operations are causing a nuisance.

15. What happens if a portion of this permit is determined to be invalid?

If a portion of this permit is determined to be invalid, the remainder of the terms and conditions remain valid and enforceable. The exception is where the enforceability of terms and conditions are dependent on the term or condition that was declared invalid.



Draft Permit-to-Install and Operate

Aptalis Pharmatech, Inc.

Permit Number: P0113893

Facility ID: 0857171794

Effective Date: To be entered upon final issuance

B. Facility-Wide Terms and Conditions



Draft Permit-to-Install and Operate

Aptalis Pharmatech, Inc.

Permit Number: P0113893

Facility ID: 0857171794

Effective Date: To be entered upon final issuance

1. This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).
 - a) For the purpose of a permit-to-install document, the facility-wide terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.
 - (1) None.
 - b) For the purpose of a permit-to-operate document, the facility-wide terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.
 - (1) None.



Draft Permit-to-Install and Operate

Aptalis Pharmatech, Inc.

Permit Number: P0113893

Facility ID: 0857171794

Effective Date: To be entered upon final issuance

C. Emissions Unit Terms and Conditions



1. Emissions Unit Group -Research & Development Units: P021,P022,

| EU ID | Operations, Property and/or Equipment Description |
|--------------|--|
| P021 | Biorise Process with catalytic oxidizer |
| P022 | MS35 Spray Dryer with catalytic oxidizer |

a) This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

(1) For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.

a. None.

(2) For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

a. None.

b) Applicable Emissions Limitations and/or Control Requirements

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

| | Applicable Rules/Requirements | Applicable Emissions Limitations/Control Measures |
|----|--|--|
| a. | OAC rule 3745-31-05(A)(3) As effective 11/30/01 | The BAT determination for each emissions unit includes the use of a catalytic oxidizer to reduce volatile organic compound (VOC) emissions by at least 98%, on a dry weight basis, excluding methane. See b)(2)a. and b)(2)b. |
| b. | OAC rule 3745-31-05(A)(3)(b) As effective 12/01/06 | See b)(2)c. |
| c. | OAC rule 3745-31-05(D) (Synthetic Minor to avoid Title V) | <u>Emissions Unit P021:</u> The VOC emissions from this emissions unit shall not exceed 0.45 ton on a rolling 12-month basis. |



| | Applicable Rules/Requirements | Applicable Emissions Limitations/Control Measures |
|--|-------------------------------|---|
| | | <u>Emissions Unit P022:</u> The VOC emissions from this emissions unit shall not exceed 0.62 ton on a rolling 12-month basis. |

(2) Additional Terms and Conditions

- a. All of the VOC emissions* from each emissions unit shall be vented to a catalytic oxidizer that shall meet the operational, monitoring, and record keeping requirements of this permit, when one or more of the emissions units are in operation. The Megtec catalytic oxidizer system is a common VOC control device for emissions units P001, P008, P014, P015, P017, P019, P020, P021 and P022.

*The biorise process includes a manual transfer of VOC laden material from the mixer to a vacuum dryer when VOC emissions will not be captured and vented to the catalytic oxidizer. The fugitive VOC emissions from this transfer were evaluated as part of this PTIO and are considered negligible.

- b. The permittee has satisfied the Best Available Technology (BAT) requirements pursuant to Ohio Administrative Code (OAC) paragraph 3745-31-05(A)(3), as effective November 30, 2001, in this permit. On December 1, 2006, paragraph (A)(3) of OAC rule 3745-31-05 was revised to conform to the Ohio Revised Code (ORC) changes effective August 3, 2006 (Senate Bill 265 changes), such that BAT is no longer required by State regulations for National Ambient Air Quality Standards (NAAQS) pollutant(s) less than ten tons per year. However, that rule revision has not yet been approved by 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 3745-31-05, the requirement to satisfy BAT still exists as part of the federally-approved SIP for Ohio. Once U.S. EPA approves the December 1, 2006 version of OAC rule 3745-31-05, then these emission limitations/control measures no longer apply.
- c. This rule paragraph applies once U.S. EPA approves the December 1, 2006 version of OAC rule 3745-31-05 as part of the State Implementation Plan.

This PTIO takes into account the voluntary use of a catalytic oxidizer to control VOC emissions as proposed by the permittee. The use of a catalytic oxidizer to reduce VOC emissions to less than 10 tons per year precludes compliance with the Best Available Technology (BAT) requirements of OAC rule 3745-31-05(A)(3).

c) Operational Restrictions

- (1) The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals. The conversion efficiency of the catalyst, as determined by an annual (once per calendar year) inspection and catalyst activity test, shall be sufficient to meet the destruction and control



efficiency requirements of this permit at a test temperature that is equal to that temperature at which the inlet to the catalyst bed is set. Solvent loading during the catalyst activity test shall be consistent with the test laboratory's normal testing protocol and the (Megtec/CSM) "Catalyst Sampling and Catalyst Testing" protocol. An Intent to Test (ITT) notification is not required for catalyst testing activity or catalyst replacement.

d) **Monitoring and/or Recordkeeping Requirements**

- (1) The permittee shall properly install, operate, and maintain continuous temperature monitors that measure and record, on a continuous basis (at least every 15 minutes), the temperature, in degrees Fahrenheit, immediately upstream and downstream of the oxidizers catalyst bed when the emissions unit is in operation, including periods of startup and shutdown. The monitoring equipment shall be installed, calibrated, operated, and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals, with any modifications deemed necessary by the permittee. The permittee may use a temperature chart recorder or equivalent recording device as the log that documents the temperature differential across the catalyst bed. These records shall be maintained at the facility for a period of no less than 3 years.
- (2) In order to maintain compliance with the applicable emission limitations contained in this permit, the acceptable temperature of the exhaust gases immediately before the catalyst bed, during any period of time when the emissions unit controlled by the catalytic oxidizer is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature measured during the most recent performance test that demonstrated the emissions unit was in compliance.
- (3) The permittee shall perform a preventative maintenance inspection of the catalytic oxidizer on an annual basis to evaluate the performance of the catalyst bed. Each inspection shall consist of internal and visual inspections in accordance with the manufacturer's recommendations, and shall include a physical inspection of the unit and all of the associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and recording equipment. Repair and replacement of equipment and the catalyst shall be performed as determined by the inspection. During each annual inspection a sample of the catalyst material shall be collected from the catalyst bed and used to perform a catalyst activity test. The permittee shall maintain a record of the results of each annual inspection, the results of each annual catalyst activity test, and the date(s) of catalyst replacement, and if only partial replacement, the amount or percent of the total catalyst replaced.
- (4) Whenever the monitored average temperature of the exhaust gases immediately before the catalyst bed deviates from the range or limit established in accordance with this permit, the permittee shall promptly investigate the cause of the deviation. The permittee shall maintain records of the following information for each investigation:
 - a. the date and time the deviation began;
 - b. the magnitude of the deviation at that time;
 - c. the date the investigation was conducted;



- d. the name(s) of the personnel who conducted the investigation; and
- e. the findings and recommendations.

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

- f. a description of the corrective action;
- g. the date corrective action was completed;
- h. the date and time the deviation ended;
- i. the total period of time (in minutes) during which there was a deviation;
- j. the temperature of the exhaust gases immediately before the catalyst bed immediately after the corrective action was implemented; and
- k. the name(s) of the personnel who performed the work.

Investigation and records required by this paragraph do not eliminate the need to comply with the requirements of OAC rule 3745-15-06 if it is determined that a malfunction has occurred.

The temperature ranges are effective for the duration of this permit, unless revisions are requested by the permittee and approved in writing by the appropriate Ohio EPA district office or local air agency. The permittee may request revisions to the permitted temperature range(s) based upon information obtained during future performance tests that demonstrate compliance with the allowable emission rate(s) of the controlled pollutant(s). In addition, approved revisions to the temperature range(s) will not constitute a relaxation of the monitoring requirements of this permit and may be incorporated into this permit by means of an administrative modification.

- (5) The permittee shall collect and record the following information each month:
 - a. The number of batches.
 - b. The volume, in gallons, of each VOC material employed in each batch.
 - c. The density of each VOC material employed, in pounds per gallon.
 - d. The weight, in pounds, of VOC material employed in each batch, {d)(5)b. X d)(5)c}.
 - e. The monthly uncontrolled VOC emission rate, in pounds per month, (the sum of all the VOC materials employed from d)(5)d. for all batches combined).



- f. The monthly controlled VOC emission rate for all VOC solvent materials, in pounds per month, (the monthly VOC emissions rate from d)(5)e. multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance).
- g. The rolling 12-month emissions of VOC, in tons per rolling 12-month period (the sum of the monthly emissions rates from d)(5)f. for the previous 12-month period, in pounds, divided by 2000 pounds per ton).

e) Reporting Requirements

(1) The permittee shall submit quarterly deviation reports that identify:

- a. each period of time (start time and date, and end time and date) when the average temperature of the exhaust gases immediately before the catalyst bed was outside of the acceptable range;
- b. any period of time (start time and date, and end time and date) when the emissions unit was in operation and the process emissions were not vented to the catalytic oxidizer;
- c. the probable cause of each deviation;
- d. any corrective actions that were taken to remedy the deviations or prevent future deviations; and
- e. the magnitude and duration of each deviation.

If no deviations occurred during a calendar quarter, the permittee shall submit a report that states that no deviations occurred during the quarter.

The quarterly reports shall be submitted, electronically through Ohio EPA Air Services, each year by January 31 (covering October to December), April 30 (covering January to March), July 31 (covering April to June), and October 31 (covering July to September), unless an alternative schedule has been established and approved by the Director (the appropriate district office or local air agency).

(2) The permittee shall submit an annual Permit Evaluation Report (PER) to the Ohio EPA. The PER must be completed electronically and submitted via the Ohio EPA eBusiness Center: Air Services by the due date identified in the Authorization section of this permit. The permit evaluation report shall cover a reporting period of no more than twelve-months for each air contaminant source identified in this permit.

The permittee shall identify in the annual permit evaluation report the following information concerning the operations of the catalytic oxidizer during the 12-month reporting period for these emissions units:

- a. the results of any catalyst activity test(s) along with a summary of the results of the annual inspection of the internal integrity of the catalytic oxidizer.



f) Testing Requirements

a. Emission Limitation

The use of a closed vent system ducted to a catalytic oxidizer to reduce VOC emissions by at least 98%, on a dry weight basis, excluding methane.

Applicable Compliance Method

Compliance shall be determined according to the record keeping requirements of d)(1) through d)(4) and performance testing.

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

The emissions testing shall be conducted on a five year recurring schedule to measure the VOC destruction efficiency of the catalytic oxidizer. The last stack test that showed the catalytic oxidizer on this emissions unit was in compliance was completed on December 15, 2009. The next emissions test shall be conducted no later than December 15, 2014 and every five years thereafter for VOC destruction efficiency.

Method 25 or 25A and/or Method 18 of 40 CFR Part 60, Appendix A, as appropriate, must be employed to demonstrate compliance with the overall control efficiency limitation for VOC. Alternative U.S. EPA approved test methods may be used with prior approval from the appropriate Ohio EPA district office or local air agency.

The control efficiency (i.e., the percent reduction in emissions, by weight, 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 of the approved alternative test protocol (e.g., "the mass balance protocol approved on 10/25/95").

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 appropriate Ohio EPA district office or local air agency.

Not later than 60 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the appropriate Ohio EPA district office or local air agency. 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 Ohio EPA district office's or local air agency's refusal to accept the results of the emission test(s).

Personnel from the appropriate Ohio EPA district office or local air agency 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.



Draft Permit-to-Install and Operate

Aptalis Pharmatech, Inc.

Permit Number: P0113893

Facility ID: 0857171794

Effective Date: To be entered upon final issuance

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 appropriate Ohio EPA district office or local air agency 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 appropriate Ohio EPA district office or local air agency.

b. Emission Limitation -

Emissions Unit P021: The VOC emissions from this emissions unit shall not exceed 0.45 ton on a rolling 12-month basis.

Emissions Unit P022: The VOC emissions from this emissions unit shall not exceed 0.62 ton on a rolling 12-month basis. .

Applicable Compliance Method

Compliance shall be determined according to the record keeping requirements specified in d)(5).

g) Miscellaneous Requirements

(1) None.