



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

9/26/2013

Certified Mail

Mr. Duane Smith
BOEHRINGER INGELHEIM ROXANE INC
PO Box 16532
Columbus, OH 43216

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: FINALAIR POLLUTION PERMIT-TO-INSTALL AND OPERATE
Facility ID: 0125041763
Permit Number: P0083005
Permit Type: Renewal
County: Franklin

Dear Permit Holder:

Enclosed please find a final Ohio Environmental Protection Agency (EPA) Air Pollution Permit-to-Install and Operate (PTIO) which will allow you to install, modify, and/or operate the described emissions unit(s) in the manner indicated in the permit. Because this permit contains conditions and restrictions, please read it very carefully. In this letter you will find the information on the following topics:

- **How to appeal this permit**
- **How to save money, reduce pollution and reduce energy consumption**
- **How to give us feedback on your permitting experience**
- **How to get an electronic copy of your permit**

How to appeal this permit

The issuance of this PTIO is a final action of the Director and may be appealed to the Environmental Review Appeals Commission pursuant to Section 3745.04 of the Ohio Revised Code. The appeal must be in writing and set forth the action complained of and the grounds upon which the appeal is based. The appeal must be filed with the Commission within thirty (30) days after notice of the Director's action. The appeal must be accompanied by a filing fee of \$70.00, made payable to "Ohio Treasurer Josh Mandel," which the Commission, in its discretion, may reduce if by affidavit you demonstrate that payment of the full amount of the fee would cause extreme hardship. Notice of the filing of the appeal shall be filed with the Director within three (3) days of filing with the Commission. Ohio EPA requests that a copy of the appeal be served upon the Ohio Attorney General's Office, Environmental Enforcement Section. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission
77 South High Street, 17th Floor
Columbus, OH 43215

How to save money, reduce pollution and reduce energy consumption

The Ohio EPA is encouraging 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 Compliance Assistance and Pollution Prevention at (614) 644-3469. Additionally, all or a portion of the capital expenditures related to installing air pollution control equipment under this permit may be eligible for financing and State tax exemptions through the Ohio Air Quality Development Authority (OAQDA) under Ohio Revised Code Section 3706. For more information, see the OAQDA website: www.ohioairquality.org/clean_air

How to give us feedback on your permitting experience

Please complete a survey at www.epa.ohio.gov/survey.aspx and give us feedback on your permitting experience. We value your opinion.

How to get an electronic copy of your permit

This permit can be accessed electronically via the eBusiness Center: Air Services in Microsoft Word format or in Adobe PDF 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.

If you have any questions, please contact Ohio EPA DAPC, Central District Office at (614)728-3778 or the Office of Compliance Assistance and Pollution Prevention at (614) 644-3469.

Sincerely,



Michael W. Ahern, Manager

Permit Issuance and Data Management Section, DAPC

Cc: Ohio EPA-CDO



FINAL

**Division of Air Pollution Control
Permit-to-Install and Operate
for
BOEHRINGER INGELHEIM ROXANE INC**

Facility ID:	0125041763
Permit Number:	P0083005
Permit Type:	Renewal
Issued:	9/26/2013
Effective:	9/26/2013
Expiration:	9/25/2018



Division of Air Pollution Control
Permit-to-Install and Operate
for
BOEHRINGER INGELHEIM ROXANE INC

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Authorization

Facility ID: 0125041763
Application Number(s): A0046927, A0046924, A0044108, A0048373, A0048344, A0013368, A0013363, A0046958, A0013365, A0013366, A0046979, A0013369, A0013367, A0047294, A0013364
Permit Number: P0083005
Permit Description: Renewal FEPTIO for emissions units associated with the manufacturing of pharmaceuticals.
Permit Type: Renewal
Permit Fee: \$0.00
Issue Date: 9/26/2013
Effective Date: 9/26/2013
Expiration Date: 9/25/2018
Permit Evaluation Report (PER) Annual Date: Oct 1 - Sept 30, Due Nov 15

This document constitutes issuance to:

BOEHRINGER INGELHEIM ROXANE INC
1809 WILSON RD
COLUMBUS, OH 43216

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

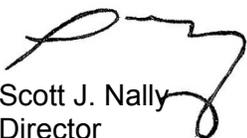
Ohio Environmental Protection Agency (EPA) District Office or local air agency responsible for processing and administering your permit:

Ohio EPA DAPC, Central District Office
50 West Town Street, 6th Floor
P.O. Box 1049
Columbus, OH 43216-1049
(614)728-3778

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



Authorization (continued)

Permit Number: P0083005
Permit Description: Renewal FEPTIO for emissions units associated with the manufacturing of pharmaceuticals.

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

Emissions Unit ID:	P001
Company Equipment ID:	Liquids Area Formation
Superseded Permit Number:	01-06309
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	P002
Company Equipment ID:	Solids Area Formation/Granulation
Superseded Permit Number:	P0083012
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	P005
Company Equipment ID:	Cleaning Process
Superseded Permit Number:	01-06309
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	P008
Company Equipment ID:	600 L Granulation
Superseded Permit Number:	01-06309
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	P010
Company Equipment ID:	Fluid Bed Dryer/Granulator
Superseded Permit Number:	01-06309
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	P013
Company Equipment ID:	Capsule Machine (2)
Superseded Permit Number:	01-06309
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	P014
Company Equipment ID:	Tablet Presses (6)
Superseded Permit Number:	01-06309
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	P016
Company Equipment ID:	Fluid Bed Dryer
Superseded Permit Number:	01-08638
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	P017
Company Equipment ID:	Granulator and Dryer
Superseded Permit Number:	01-12044
General Permit Category and Type:	Not Applicable



Final Permit-to-Install and Operate
BOEHRINGER INGELHEIM ROXANE INC
Permit Number: P0083005
Facility ID: 0125041763
Effective Date: 9/26/2013

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 Ohio EPA DAPC, Central District Office 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.

¹ Permittees 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.



Final Permit-to-Install and Operate
BOEHRINGER INGELHEIM ROXANE INC
Permit Number: P0083005
Facility ID: 0125041763
Effective Date: 9/26/2013

B. Facility-Wide Terms and Conditions



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.



Final Permit-to-Install and Operate
BOEHRINGER INGELHEIM ROXANE INC
Permit Number: P0083005
Facility ID: 0125041763
Effective Date: 9/26/2013

C. Emissions Unit Terms and Conditions



1. P001, Liquids Area Formation

Operations, Property and/or Equipment Description:

Liquids manufacturing

- 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 3745-17-07(A)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
b.	OAC rule 3745-17-11(B)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
c.	OAC rule 3745-31-05(A)(3) (PTI No. 01-06309, as issued 2/26/2002)	Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 7.4 pounds per day and 1.4 tons per year. Particulate emissions (PE) shall not exceed 2.5 pounds per day and 0.46 tons per year. There shall be no visible emissions from this emissions unit.



	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		<p>The requirements of this rule also include compliance with the requirements of OAC rule 3745-17-07(A) and OAC rule 3745-17-11(B) .</p> <p>See b)(2)a., b)(2)b. and b)(2)c. below.</p>

(2) Additional Terms and Conditions

- a. The OC/VOC limitations were established to reflect the potentials to emit for this emissions unit in accordance with the information provided in the application. It is not necessary to develop recordkeeping and/or reporting requirements to ensure compliance with these limitations.
- b. The emissions from the emissions unit shall vent to a dust collector with a control efficiency of 95%. This control device is used to ensure that the company can account for the total volume of powder use in the process, by weight. The FDA and the DEA require total accountability for the manufactured pharmaceuticals. Due to this limitation, monitoring for visible emissions is unnecessary.
- c. The PE limitations were established to reflect the potential to emit for this emissions unit as vented to the dust collector taking into consideration the maximum batch throughput of 1,922 pounds of solids. The monitoring, recordkeeping and testing requirements that ensure PE from this emissions unit are captured and directed to the dust collector are sufficient to ensure compliance with these limitations.

c) Operational Restrictions

- (1) None.

d) Monitoring and/or Recordkeeping Requirements

- (1) The permittee shall maintain daily records that document any time when the emissions from the emissions unit were not captured and controlled by the dust collector while the emissions unit was in operation.

e) Reporting Requirements

- (1) Unless other arrangements have been approved by the director, all notifications and reports shall be submitted through the Ohio EPA's eBusiness Center: Air Services online web portal.
- (2) The permittee shall notify the director (the Central District Office) in writing of any daily record showing the emissions were not captured and controlled by the dust collector



while the emissions unit was in operation. The notification shall include a copy of such record and shall be submitted within 30 days after the event occurs.

- (3) 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 e-Business 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.

f) Testing Requirements

- (1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:

- a. Emissions Limitations

Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 7.4 pounds per day and 1.4 tons per year.

Applicable Compliance Method

Compliance with the daily OC/VOC emissions limitation shall be determined using the following equation.

$$\text{OC/VOC} = (\text{Alcohol}) \times (\text{Batches}) \times (\text{Lines}) \times (\% \text{ OC/VOC}) \times (\text{EF}), \text{ where}$$

Alcohol = Maximum alcohol usage per batch (30 gal)

Batches = Maximum number of batches per day (3)

Lines = Maximum number of process lines (7)

% OC/VOC = Maximum OC/VOC content of alcohol (92.5% by volume)

EF = Emission factor based on emissions testing of a similar source (0.0127 lb OC/VOC per gal OC/VOC mixed)

The annual OC/VOC limitation was developed by multiplying the daily OC/VOC limitation by 365 day/yr and then dividing by 2,000 lb/ton. Therefore, if compliance is shown with the daily OC/VOC limitation, compliance shall also be shown with the annual OC/VOC limitation.

If the composition of the alcohol changes, or a new alcohol is applied in this emissions unit, then the above calculations should be adjusted to account for the properties of the new alcohol.

- b. Emissions Limitations

Particulate emissions (PE) shall not exceed 2.5 pounds per day and 0.46 ton per year.



Applicable Compliance Method

Compliance with the daily PE limitation shall be determined using the following equation.

$PE = (\text{Solids}) \times (\text{Batches}) \times (\text{Lines}) \times (\text{EF}) \times (1 - \text{CE})$, where

Solids = Maximum solids processed per batch (1,922 lb)

Batches = Maximum number of batches per day (3)

Lines = Maximum number of process lines (7)

EF = Emission factor based on emissions testing of a similar source (0.00125 lb PE per lb solids)

CE = Control efficiency of dust collector (95%)

The annual PE limitation was developed by multiplying the daily PE limitation by 365 day/yr and then dividing by 2,000 lb/ton. Therefore, if compliance is shown with the daily PE limitation, compliance shall also be shown with the annual PE limitation.

c. Emissions Limitation

There shall be no visible emissions from this emissions unit.

Applicable Compliance Method

If required, compliance with the stack visible particulate emissions limitation shall be determined through visible emissions observations performed in accordance with U.S. EPA Method 9.

g) Miscellaneous Requirements

- (1) None.



2. P002, Solids Area Formation/Granulation

Operations, Property and/or Equipment Description:

Granulators and Tablet Presses

- 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. b)(1)d., c)(1), d)(1), e)(3) and f)(1)d.
- 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 3745-17-07(A)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
b.	OAC rule 3745-17-11(B)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
c.	OAC rule 3745-31-05(A)(3) (PTI No. 01-08002, as issued 3/15/2000)	Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 59.6 pounds per hour. Particulate emissions (PE) shall not exceed 0.06 pound per hour and 0.25 ton per year. There shall be no visible emissions from this emissions unit.



	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		The requirements of this rule also include compliance with the requirements of OAC rule 3745-17-07(A), OAC rule 3745-17-11(B) and OAC rule 3745-31-05(D). See b)(2)a., b)(2)b. and b)(2)c. below.
d.	OAC rule 3745-31-05(D) (Federally enforceable limitations to avoid Title V)	Volatile organic compound (VOC) emissions shall not exceed 6.4 tons per rolling 12-month period. See c)(1) below.

(2) Additional Terms and Conditions

- a. The hourly OC/VOC limitation was established to reflect the potential to emit for this emissions unit. It is not necessary to develop recordkeeping and/or reporting requirements to ensure compliance with this limitation.
- b. The emissions from the emissions unit shall vent to a dust collector with a control efficiency of 99.9%. This control device is used to ensure that the company can account for the total volume of powder use in the process, by weight. The FDA and the DEA require total accountability for the manufactured pharmaceuticals. Due to this limitation, monitoring for visible emissions is unnecessary.
- c. The PE limitations were established to reflect the potential to emit for this emissions unit as vented to the dust collector taking into consideration the maximum hourly throughputs of 1,110 pounds of solids in granulation and 2,302 pounds of solids in tablet compression. The monitoring, recordkeeping and testing requirements that ensure PE from this emissions unit are captured and directed to the dust collector are sufficient to ensure compliance with these limitations.

c) Operational Restrictions

- (1) The usage of alcohol shall not exceed 2,000 gallons per rolling, 12-month period.

d) Monitoring and/or Recordkeeping Requirements

- (1) The permittee shall maintain monthly records of the following information:
 - a. the number of gallons of alcohol employed;
 - b. the density of the alcohol, in pounds per gallon;
 - c. the percent of volatile organic compounds, by weight;
 - d. the VOC emissions, in pounds;



- e. the rolling, 12-month summation of alcohol usage, in gallons; and
 - f. the rolling, 12-month summation of VOC emissions, in tons.
- (2) The permittee shall maintain daily records that document any time when the emissions from the emissions unit were not captured and controlled by the dust collector while the emissions unit was in operation.
- e) Reporting Requirements
- (1) Unless other arrangements have been approved by the director, all notifications and reports shall be submitted through the Ohio EPA's e-Business Center: Air Services online web portal.
 - (2) The permittee shall notify the director (Central District Office) in writing of any daily record showing the emissions were not captured and controlled by the dust collector while the emissions unit was in operation. The notification shall include a copy of such record and shall be submitted within 30 days after the event occurs.
 - (3) The permittee shall submit quarterly deviation (excursion) reports that identify:
 - a. all deviations (excursions) of the following emission limitations, operational restrictions and/or control device operating parameter limitations that restrict the potential to emit (PTE) of any regulated air pollutant and have been detected by the monitoring, record keeping and/or testing requirements in this permit:
 - i. all exceedances of the rolling, 12-month alcohol usage limitation; and
 - ii. all exceedances of the rolling, 12-month VOC emission limitation.
 - b. the probable cause of each deviation (excursion);
 - c. any corrective actions that were taken to remedy the deviations (excursions) or prevent future deviations (excursions); and
 - d. the magnitude and duration of each deviation (excursion).
- If no deviations (excursions) occurred during a calendar quarter, the permittee shall submit a report that states that no deviations (excursions) occurred during the quarter.
- The quarterly reports shall be submitted electronically through Ohio EPA's e-Business Center: 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 (Central District Office).
- (4) 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 e-Business 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.



f) Testing Requirements

(1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:

a. Emissions Limitation

Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 59.6 pounds per hour.

Applicable Compliance Method

Compliance with the hourly OC/VOC emissions limitation shall be determined using the following equation.

$OC/VOC = (Alcohol) \times (Density) \times (\% OC/VOC) \times (Granulators) / (Dry Time)$, where

Alcohol = Maximum alcohol usage per batch per granulator (9.24 gal)

Density = Density of alcohol (6.79 lb/gal)

% OC/VOC = Maximum OC/VOC content of alcohol (95% by weight)

Granulators = Maximum number of granulators (3)

Dry Time = Minimum drying time per batch (3 hr)

If the composition of the alcohol changes, or a new alcohol is applied in this emissions unit, then the above calculations should be adjusted to account for the properties of the new alcohol.

b. Emissions Limitations

Particulate emissions (PE) shall not exceed 0.06 pound per hour and 0.25 tons per year.

Applicable Compliance Method

Compliance with the hourly PE limitation shall be determined by summing the total PE from the granulators and tablet presses associated with this emissions unit using the following equations.

$$PE = PE_{\text{granulators}} + PE_{\text{tablet presses}}$$

$$PE_{\text{granulators}} = (\text{Solids}) \times (EF) \times (1 - CE), \text{ where}$$

Solids = Maximum solids processed in all granulators (1,110 lb/hr)

EF = Emission factor based on facility mass balance (0.05 lb PE/lb solids)

CE = Control efficiency of dust collector (99.9%)

$$PE_{\text{tablet presses}} = (\text{solids}) \times (EF) \times (1 - CE), \text{ where}$$

Solids = Maximum solids processed in all tablet presses (2,302 lb/hr)



EF = Emission factor based on facility mass balance (0.0005 lb PE/lb solids)
CE = Control efficiency of dust collector (99.9%)

The annual PE limitation was developed by multiplying the hourly PE limitation by 8,760 hr/yr and then dividing by 2,000 lb/ton. Therefore, if compliance is shown with the hourly PE limitation, compliance shall also be shown with the annual PE limitation.

c. Emissions Limitation

There shall be no visible emissions from this emissions unit.

Applicable Compliance Method

If required, compliance with the stack visible particulate emissions limitation shall be determined through visible emissions observations performed in accordance with U.S. EPA Method 9..

d. Emissions Limitation

Volatile organic compound (VOC) emissions shall not exceed 6.4 tons per rolling 12-month period.

Applicable Compliance Method

Compliance shall be determined by the monitoring and recordkeeping established in d)(1).

g) Miscellaneous Requirements

(1) None.



3. P005, Cleaning Process

Operations, Property and/or Equipment Description:

Cleaning process

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) (PTI No. 01-06309, as issued 2/26/2002)	Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 3.7 pounds per hour and 8.11 tons per year. See b)(2)a. below.

(2) Additional Terms and Conditions

a. The hourly OC/VOC limitation was established to reflect the potential to emit for this emissions unit. It is not necessary to develop recordkeeping and/or reporting requirements to ensure compliance with this limitation.

c) Operational Restrictions

(1) None.



d) Monitoring and/or Recordkeeping Requirements

(1) The permittee shall maintain monthly records of the following information:

- a. the number of gallons of cleanup material employed;
- b. the density of the cleanup material, in pounds per gallon;
- c. the percent of OC/VOC, by weight;
- d. the OC/VOC emissions, in pounds; and
- e. the total OC/VOC emissions for the calendar year, in tons.

e) Reporting Requirements

(1) The permittee shall submit an annual Permit Evaluation Report (PER) to Ohio EPA. The PER must be completed electronically and submitted via the Ohio EPA's e-Business 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.

f) Testing Requirements

(1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:

a. Emissions Limitation

Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 3.7 pounds per hour.

Applicable Compliance Method

Compliance with the hourly OC/VOC emissions limitation shall be determined using the following equation.

$OC/VOC = (\text{Cleanup Material}) \times (\text{Density}) \times (\% \text{ OC/VOC}) \times (\text{EF})$, where

Cleanup Material = Maximum cleanup material usage (3.8 gal)

Density = Density of cleanup material (6.55 lb/gal)

% OC/VOC = Maximum OC/VOC content of cleanup material (30% by volume)

EF = Emission factor based on facility mass balance (50%)

If the composition of the cleanup material changes or a new cleanup material is applied in this emissions unit, then the above calculations should be adjusted to account for the properties of the new cleanup material.



b. Emissions Limitations

Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 8.11 tons per year.

Applicable Compliance Method

Compliance shall be determined by the monitoring and recordkeeping established in d)(1).

g) Miscellaneous Requirements

(1) None.



4. P008, 600 L Granulation

Operations, Property and/or Equipment Description:

600 Liter one pot granulation

- 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. b)(1)d., c)(1), d)(1), e)(3) and f)(1)d.
- 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 3745-17-07(A)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
b.	OAC rule 3745-17-11(B)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
c.	OAC rule 3745-31-05(A)(3) (PTI No. 01-06309, as issued 2/26/2002)	Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 49.6 pounds per hour. Particulate emissions (PE) shall not exceed 0.22 pound per hour and 0.97 ton per year. There shall be no visible emissions from this emissions unit.



	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		The requirements of this rule also include compliance with the requirements of OAC rule 3745-17-07(A), OAC rule 3745-17-11(B) and OAC rule 3745-31-05(D). See b)(2)a., b)(2)b. and b)(2)c. below.
d.	OAC rule 3745-31-05(D) (Federally enforceable limitations to avoid Title V)	Volatile organic compound (VOC) emissions shall not exceed 7.81 tons per rolling 12-month period. See c)(1) below.

(2) Additional Terms and Conditions

- a. The hourly OC/VOC limitation was established to reflect the potential to emit for this emissions unit. It is not necessary to develop recordkeeping and/or reporting requirements to ensure compliance with this limitation.
- b. The emissions from the emissions unit shall vent to a dust collector with a control efficiency of 99%. This control device is used to ensure that the company can account for the total volume of powder use in the process, by weight. The FDA and the DEA require total accountability for the manufactured pharmaceuticals. Due to this limitation, monitoring for visible emissions is unnecessary.
- c. The PE limitations were established to reflect the potential to emit for this emissions unit as vented to the dust collector taking into consideration the maximum hourly throughput of 445 pounds of solids. The monitoring, recordkeeping and testing requirements that ensure PE from this emissions unit are captured and directed to the dust collector are sufficient to ensure compliance with these limitations.

c) Operational Restrictions

- (1) The usage of alcohol shall not exceed 2,574 gallons per rolling, 12-month period.

d) Monitoring and/or Recordkeeping Requirements

- (1) The permittee shall maintain monthly records of the following information:
 - a. the number of gallons of alcohol employed;
 - b. the density of the alcohol, in pounds per gallon;
 - c. the percent of volatile organic compounds, by weight;
 - d. the VOC emissions, in pounds;
 - e. the rolling, 12-month summation of alcohol usage, in gallons; and



- f. the rolling, 12-month summation of VOC emissions, in tons.
- (2) The permittee shall maintain daily records that document any time when the emissions from the emissions unit were not captured and controlled by the dust collector while the emissions unit was in operation.
- e) Reporting Requirements
- (1) Unless other arrangements have been approved by the director, all notifications and reports shall be submitted through the Ohio EPA's eBusiness Center: Air Services online web portal.
 - (2) The permittee shall notify the director (the Central District Office) in writing of any daily record showing the emissions were not captured and controlled by the dust collector while the emissions unit was in operation. The notification shall include a copy of such record and shall be submitted within 30 days after the event occurs.
 - (3) The permittee shall submit quarterly deviation (excursion) reports that identify:
 - a. all deviations (excursions) of the following emission limitations, operational restrictions and/or control device operating parameter limitations that restrict the potential to emit (PTE) of any regulated air pollutant and have been detected by the monitoring, record keeping and/or testing requirements in this permit:
 - i. all exceedances of the rolling, 12-month alcohol usage limitation; and
 - ii. all exceedances of the rolling, 12-month VOC emission limitation.
 - b. the probable cause of each deviation (excursion);
 - c. any corrective actions that were taken to remedy the deviations (excursions) or prevent future deviations (excursions); and
 - d. the magnitude and duration of each deviation (excursion).
- If no deviations (excursions) occurred during a calendar quarter, the permittee shall submit a report that states that no deviations (excursions) 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 Central District Office).
- (4) 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 e-Business 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.



f) Testing Requirements

(1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:

a. Emissions Limitation

Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 49.6 pounds per hour.

Applicable Compliance Method

Compliance with the hourly OC/VOC emissions limitation shall be determined using the following equation.

$OC/VOC = (\text{Alcohol}) \times (\text{Density}) \times (\% \text{ OC/VOC})$, where

Alcohol = Maximum alcohol usage per hour (8.17 gal)

Density = Density of alcohol (6.66 lb/gal)

% OC/VOC = Maximum OC/VOC content of alcohol (91.1% by weight)

If the composition of the alcohol changes, or a new alcohol is applied in this emissions unit, then the above calculations should be adjusted to account for the properties of the new alcohol.

b. Emissions Limitations

Particulate emissions (PE) shall not exceed 0.22 pound per hour and 0.97 ton per year.

Applicable Compliance Method

Compliance with the hourly PE limitation shall be determined using the following equation.

$PE = (\text{Solids}) \times (EF) \times (1 - CE)$, where

Solids = Maximum solids processed (445 lb/hr)

EF = Emission factor based on facility mass balance (0.05 lb PE/lb solids)

CE = Control efficiency of dust collector (99%)

The annual PE limitation was developed by multiplying the hourly PE limitation by 8,760 hr/yr and then dividing by 2,000 lb/ton. Therefore, if compliance is shown with the hourly PE limitation, compliance shall also be shown with the annual PE limitation.

c. Emissions Limitation

There shall be no visible emissions from this emissions unit.



Applicable Compliance Method

If required, compliance with the stack visible particulate emissions limitation shall be determined through visible emissions observations performed in accordance with U.S. EPA Method 9.

d. Emissions Limitation

Volatile organic compound (VOC) emissions shall not exceed 7.81 tons per rolling 12-month period.

Applicable Compliance Method

Compliance shall be determined by the monitoring and recordkeeping established in d)(1).

g) Miscellaneous Requirements

(1) None.



5. P010, Fluid Bed Dryer/Granulator

Operations, Property and/or Equipment Description:

Fluid bed dryer/granulator

- 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. b)(1)d., c)(1), d)(1), e)(3) and f)(1)d.
- 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 3745-17-07(A)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
b.	OAC rule 3745-17-11(B)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
c.	OAC rule 3745-31-05(A)(3) (PTI No. 01-06687, as issued 12/17/1997)	Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 66 pounds per hour. Particulate emissions (PE) shall not exceed 0.35 pound per hour and 1.52 tons per year. There shall be no visible emissions from this emissions unit.



	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		The requirements of this rule also include compliance with the requirements of OAC rule 3745-17-07(A), OAC rule 3745-17-11(B) and OAC rule 3745-31-05(D). See b)(2)a., b)(2)b. and b)(2)c. below.
d.	OAC rule 3745-31-05(D) (Federally enforceable limitations to avoid Title V)	Volatile organic compound (VOC) emissions shall not exceed 7.92 tons per rolling 12-month period. See c)(1) below.

(2) Additional Terms and Conditions

- a. The hourly OC/VOC limitation was established to reflect the potential to emit for this emissions unit. It is not necessary to develop recordkeeping and/or reporting requirements to ensure compliance with this limitation.
- b. The emissions from the emissions unit shall vent to a dust collector with a control efficiency of 99%. This control device is used to ensure that the company can account for the total volume of powder use in the process, by weight. The FDA and the DEA require total accountability for the manufactured pharmaceuticals. Due to this limitation, monitoring for visible emissions is unnecessary.
- c. The PE limitations were established to reflect the potential to emit for this emissions unit as vented to the dust collector taking into consideration the maximum hourly throughput of 693 pounds of solids. The monitoring, recordkeeping and testing requirements that ensure PE from this emissions unit are captured and directed to the dust collector are sufficient to ensure compliance with these limitations.

c) Operational Restrictions

- (1) The usage of alcohol shall not exceed 2,336 gallons per rolling, 12-month period.

d) Monitoring and/or Recordkeeping Requirements

- (1) The permittee shall maintain monthly records of the following information:
 - a. the number of gallons of alcohol employed;
 - b. the density of the alcohol, in pounds per gallon;
 - c. the percent of volatile organic compounds, by weight;
 - d. the VOC emissions, in pounds;
 - e. the rolling, 12-month summation of alcohol usage, in gallons; and



- f. the rolling, 12-month summation of VOC emissions, in tons.
- (2) The permittee shall maintain daily records that document any time when the emissions from the emissions unit were not captured and controlled by the dust collector while the emissions unit was in operation.
- e) Reporting Requirements
- (1) Unless other arrangements have been approved by the director, all notifications and reports shall be submitted through the Ohio EPA's eBusiness Center: Air Services online web portal.
 - (2) The permittee shall notify the director (the Central District Office) in writing of any daily record showing the emissions were not captured and controlled by the dust collector while the emissions unit was in operation. The notification shall include a copy of such record and shall be submitted within 30 days after the event occurs.
 - (3) The permittee shall submit quarterly deviation (excursion) reports that identify:
 - a. all deviations (excursions) of the following emission limitations, operational restrictions and/or control device operating parameter limitations that restrict the potential to emit (PTE) of any regulated air pollutant and have been detected by the monitoring, record keeping and/or testing requirements in this permit:
 - i. all exceedances of the rolling, 12-month alcohol usage limitation; and
 - ii. all exceedances of the rolling, 12-month VOC emission limitation.
 - b. the probable cause of each deviation (excursion);
 - c. any corrective actions that were taken to remedy the deviations (excursions) or prevent future deviations (excursions); and
 - d. the magnitude and duration of each deviation (excursion).
- If no deviations (excursions) occurred during a calendar quarter, the permittee shall submit a report that states that no deviations (excursions) 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 Central District Office).
- (4) 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 e-Business 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.



f) Testing Requirements

(1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:

a. Emissions Limitation

Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 66 pounds per hour.

Applicable Compliance Method

Compliance with the hourly OC/VOC emissions limitation shall be determined using the following equation.

$OC/VOC = (\text{Alcohol}) \times (\text{Density}) \times (\% \text{ OC/VOC})$, where

Alcohol = Maximum alcohol usage per hour (9.73 gal)

Density = Density of alcohol (6.781 lb/gal)

% OC/VOC = Maximum OC/VOC content of alcohol (100% by weight)

If the composition of the alcohol changes, or a new alcohol is applied in this emissions unit, then the above calculations should be adjusted to account for the properties of the new alcohol.

b. Emissions Limitations

Particulate emissions (PE) shall not exceed 0.35 pound per hour and 1.52 tons per year.

Applicable Compliance Method

Compliance with the hourly PE limitation shall be determined using the following equation.

$PE = (\text{Solids}) \times (EF) \times (1 - CE)$, where

Solids = Maximum solids processed (693 lb/hr)

EF = Emission factor based on facility mass balance (0.05 lb PE/lb solids)

CE = Control efficiency of dust collector (99%)

The annual PE limitation was developed by multiplying the hourly PE limitation by 8,760 hr/yr and then dividing by 2,000 lb/ton. Therefore, if compliance is shown with the hourly PE limitation, compliance shall also be shown with the annual PE limitation.

c. Emissions Limitation

There shall be no visible emissions from this emissions unit.



Applicable Compliance Method

If required, compliance with the stack visible particulate emissions limitation shall be determined through visible emissions observations performed in accordance with U.S. EPA Method 9.

d. Emissions Limitation

Volatile organic compound (VOC) emissions shall not exceed 7.92 tons per rolling 12-month period.

Applicable Compliance Method

Compliance shall be determined by the monitoring and recordkeeping established in d)(1).

g) Miscellaneous Requirements

(1) None.



6. P013, Capsule Machine (2)

Operations, Property and/or Equipment Description:

Capsule machine (2)

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 3745-17-07(A)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
b.	OAC rule 3745-17-11(B)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
c.	OAC rule 3745-31-05(A)(3) (PTI No. 01-06309, as issued 2/26/2002)	<p>Particulate emissions (PE) shall not exceed 0.0003 pound per hour and 0.002 ton per year.</p> <p>There shall be no visible emissions from this emissions unit.</p> <p>The requirements of this rule also include compliance with the requirements of OAC rule 3745-17-07(A) and OAC rule 3745-17-11(B).</p>



	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		See b)(2)a. and b)(2)b. below.

(2) Additional Terms and Conditions

- a. The emissions from the emissions unit shall vent to a dust collector with a control efficiency of 99.99%. This control device is used to ensure that the company can account for the total volume of powder use in the process, by weight. The FDA and the DEA require total accountability for the manufactured pharmaceuticals. Due to this limitation, monitoring for visible emissions is unnecessary.
- b. The PE limitations were established to reflect the potential to emit for this emissions unit as vented to the dust collector taking into consideration the maximum hourly throughput of 115.71 pounds of solids. The monitoring, recordkeeping and testing requirements that ensure PE from this emissions unit are captured and directed to the dust collector are sufficient to ensure compliance with these limitations.

c) Operational Restrictions

- (1) None.

d) Monitoring and/or Recordkeeping Requirements

- (1) The permittee shall maintain daily records that document any time when the emissions from the emissions unit were not captured and controlled by the dust collector while the emissions unit was in operation.

e) Reporting Requirements

- (1) Unless other arrangements have been approved by the director, all notifications and reports shall be submitted through the Ohio EPA's e-Business Center: Air Services online web portal.
- (2) The permittee shall notify the director (Central District Office) in writing of any daily record showing the emissions were not captured and controlled by the dust collector while the emissions unit was in operation. The notification shall include a copy of such record and shall be submitted within 30 days after the event occurs.
- (3) 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 e-Business 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.



f) Testing Requirements

- (1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:

a. Emissions Limitations

Particulate emissions (PE) shall not exceed 0.0003 pound per hour and 0.002 ton per year.

Applicable Compliance Method

Compliance with the hourly PE limitation shall be determined using the following equation.

$PE = (\text{Solids}) \times (EF) \times (1 - CE)$, where

Solids = Maximum solids processed (115.71 lb/hr)

EF = Emission factor based on facility mass balance (0.03 lb PE/lb solids)

CE = Control efficiency of dust collector (99.99%)

The annual PE limitation was developed by multiplying the hourly PE limitation by 8,760 hr/yr and then dividing by 2,000 lb/ton. Therefore, if compliance is shown with the hourly PE limitation, compliance shall also be shown with the annual PE limitation.

b. Emissions Limitation

There shall be no visible emissions from this emissions unit.

Applicable Compliance Method

If required, compliance with the stack visible particulate emissions limitation shall be determined through visible emissions observations performed in accordance with U.S. EPA Method 9.

g) Miscellaneous Requirements

- (1) None.



7. P014, Tablet Presses (8)

Operations, Property and/or Equipment Description:

Tablet presses (8)

- 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 3745-17-07(A)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
b.	OAC rule 3745-17-11(B)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
c.	OAC rule 3745-31-05(A)(3) (PTI No. 01-06309, as issued 2/26/2002)	<p>Particulate emissions (PE) shall not exceed 0.002 pound per hour and 0.008 ton per year.</p> <p>There shall be no visible emissions from this emissions unit.</p> <p>The requirements of this rule also include compliance with the requirements of OAC rule 3745-17-07(A) and OAC rule 3745-17-11(B).</p>



	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		See b)(2)a. and b)(2)b. below.

(2) Additional Terms and Conditions

- a. The emissions from the emissions unit shall vent to a dust collector with a control efficiency of 99.99%. This control device is used to ensure that the company can account for the total volume of powder use in the process, by weight. The FDA and the DEA require total accountability for the manufactured pharmaceuticals. Due to this limitation, monitoring for visible emissions is unnecessary.
- b. The PE limitations were established to reflect the potential to emit for this emissions unit as vented to the dust collector taking into consideration the maximum hourly throughput of 600 pounds of solids. The monitoring, recordkeeping and testing requirements that ensure PE from this emissions unit are captured and directed to the dust collector are sufficient to ensure compliance with these limitations.

c) Operational Restrictions

- (1) None.

d) Monitoring and/or Recordkeeping Requirements

- (1) The permittee shall maintain daily records that document any time when the emissions from the emissions unit were not captured and controlled by the dust collector while the emissions unit was in operation.

e) Reporting Requirements

- (1) Unless other arrangements have been approved by the director, all notifications and reports shall be submitted through the Ohio EPA e-Business Center: Air Services online web portal.
- (2) The permittee shall notify the director (Central District Office) in writing of any daily record showing the emissions were not captured and controlled by the dust collector while the emissions unit was in operation. The notification shall include a copy of such record and shall be submitted within 30 days after the event occurs.
- (3) 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 e-Business 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.



f) Testing Requirements

(1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:

a. Emissions Limitations

Particulate emissions (PE) shall not exceed 0.002 pound per hour and 0.008 ton per year.

Applicable Compliance Method

Compliance with the hourly PE limitation shall be determined using the following equation.

$PE = (\text{Solids}) \times (EF) \times (1 - CE)$, where

Solids = Maximum solids processed (600 lb/hr)

EF = Emission factor based on facility mass balance (0.03 lb PE/lb solids)

CE = Control efficiency of dust collector (99.99%)

The annual PE limitation was developed by multiplying the hourly PE limitation by 8,760 hr/yr and then dividing by 2,000 lb/ton. Therefore, if compliance is shown with the hourly PE limitation, compliance shall also be shown with the annual PE limitation.

b. Emissions Limitation

There shall be no visible emissions from this emissions unit.

Applicable Compliance Method

If required, compliance with the stack visible particulate emissions limitation shall be determined through visible emissions observations performed in accordance with U.S. EPA Method 9.

g) Miscellaneous Requirements

(1) None.



8. P016, Fluid Bed Dryer

Operations, Property and/or Equipment Description:

Product development 100L Fluid Bed Dryer and Granulator

- 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 3745-17-07(A)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
b.	OAC rule 3745-17-11(B)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
c.	OAC rule 3745-31-05(A)(3) (PTI No. 01-08638, as issued 11/21/2002)	Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 11.0 pounds per batch and 5.35 tons per year. Particulate emissions (PE) shall not exceed 0.000010 pound per hour and 0.000005 ton per year. There shall be no visible emissions from this emissions unit.



	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		See b)(2)a., b)(2)b. and b)(2)c. below.

(2) Additional Terms and Conditions

- a. The OC/VOC limitations were established to reflect the potentials to emit for this emissions unit in accordance with the information provided in the application. It is not necessary to develop recordkeeping and/or reporting requirements to ensure compliance with these limitations.
- b. The emissions from the emissions unit shall vent to a fabric pre-filter with a control efficiency of 99%. This control device is used to ensure that the company can account for the total volume of powder use in the process, by weight. The FDA and the DEA require total accountability for the manufactured pharmaceuticals. Due to this limitation, monitoring for visible emissions is unnecessary.
- c. The PE limitations were established to reflect the potential to emit for this emissions unit as vented to the fabric pre-filter in addition to a HEPA post-filter taking into consideration the maximum hourly throughput of 66 pounds of solids and the maximum annual number of batches of 973. The monitoring, recordkeeping and testing requirements for the fabric pre-filter and HEPA post-filter are sufficient to ensure compliance with these limitations.

c) Operational Restrictions

- (1) None.

d) Monitoring and/or Recordkeeping Requirements

- (1) The permittee shall maintain daily records that document any time when the emissions from the emissions unit were not captured and controlled by the fabric pre-filter and/or HEPA post-filter while the emissions unit was in operation.
- (2) The pressure drop across the fabric pre-filter shall be maintained between 1.0 and 6.0 inches of water while the emissions unit is in operation.
- (3) The pressure drop across the HEPA post-filter shall be maintained between 0.50 and 3.0 inches of water while the emissions unit is in operation.
- (4) The permittee shall properly install, operate, and maintain equipment to monitor the pressure drops across the fabric pre-filter and HEPA post-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).



- (5) The permittee shall record on a daily basis when the unit is in operation:
- a. the pressure drop across the fabric filter; and
 - b. the pressure drop across the HEPA filter.
- e) Reporting Requirements
- (1) Unless other arrangements have been approved by the director, all notifications and reports shall be submitted through the Ohio EPA e-Business Center: Air Services online web portal.
 - (2) The permittee shall notify the director (Central District Office) in writing of any daily record showing the emissions were not captured and controlled by the dust collector while the emissions unit was in operation. The notification shall include a copy of such record and shall be submitted within 30 days after the event occurs.
 - (3) The permittee shall submit an annual Permit Evaluation Report (PER) to Ohio EPA. The PER must be completed electronically and submitted via the Ohio EPA e-Business 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.
- f) Testing Requirements
- (1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:
 - a. Emissions Limitations

Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 11.0 pounds per batch and 5.35 tons per year.

Applicable Compliance Method

Compliance with the hourly OC/VOC emissions limitation shall be determined using the following equation.

$$\text{OC/VOC} = (\text{Alcohol}) \times (\text{Density}) \times (\% \text{ OC/VOC}), \text{ where}$$

Alcohol = Maximum alcohol usage per batch (1.62 gal)
Density = Density of alcohol (6.781 lb/gal)
% OC/VOC = Maximum OC/VOC content of alcohol (100% by weight)

Compliance with the annual OC/VOC limitation shall be determined by multiplying the individual batch limitation by the maximum potential number of batches per year (973 batch/yr) and then dividing by 2,000 lb/ton.



If the composition of the alcohol changes, or a new alcohol is applied in this emissions unit, then the above calculations should be adjusted to account for the properties of the new alcohol.

b. Emissions Limitations

Particulate emissions (PE) shall not exceed 0.000010 pound per hour and 0.000005 ton per year.

Applicable Compliance Method

Compliance with the hourly PE limitation shall be determined using the following equation.

$$PE = (\text{Solids}) \times (EF) \times (1 - CE_{\text{fabric filter}}) \times (1 - CE_{\text{HEPA filter}}), \text{ where}$$

Solids = Maximum solids processed (66lb/hr)

EF = Emission factor based on facility mass balance (0.05 lb PE/lb solids)

$CE_{\text{fabric filter}}$ = Control efficiency of fabric filter (99%)

$CE_{\text{HEPA filter}}$ = Control efficiency of HEPA filter (99.97%)

Compliance with the annual PE limitation shall be determined by multiplying the hourly PE limitation by the batch time (1 hr/batch) and the maximum potential number of batches per year (973 batch/yr) and then dividing by 2,000 lb/ton.

Emissions Limitation

There shall be no visible emissions from this emissions unit.

Applicable Compliance Method

If required, compliance with the stack visible particulate emissions limitation shall be determined through visible emissions observations performed in accordance with U.S. EPA Method 9.

g) Miscellaneous Requirements

- (1) None.



9. P017, Granulator and Dryer

Operations, Property and/or Equipment Description:

600L Fluidized Bed / Granulator Dryer

- 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. b)(1)e., c)(1), d)(1), e)(3) and f)(1)e.
- 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 3745-17-07(A)	Visible particulate emissions from the stack serving this emissions unit shall not exceed 20 percent opacity as a six-minute average, except as provided by rule.
b.	OAC rule 3745-17-11(B)	Particulate emissions (PE) shall not exceed 1.4 pounds per hour, based upon Table I of OAC rule 3745-17-11.
c.	OAC rule 3745-31-05(A)(3), as effective 11/30/01	Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 69 pounds per hour. Particulate emissions (PE) shall not exceed 0.0003 pound per hour and 0.001 ton per year. See b)(2)a. and b)(2)c. below.
d.	OAC rule 3745-31-05(A)(3)(a)(ii), as effective 12/01/06	See b)(2)b. below.



	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
e.	OAC rule 3745-31-05(D) (Federally enforceable limitations to avoid Title V)	Volatile organic compound (VOC) emissions shall not exceed 8.28 tons per rolling 12-month period. See c)(1) below.

(2) Additional Terms and Conditions

- a. 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.
- b. The following rule paragraphs will apply once U.S. EPA approves the December 1, 2006 version of OAC rule 3745-31-05 as part of the State Implementation Plan:
 - i. The Best Available Technology (BAT) requirements under OAC rule 3745-31-05(A)(3) do not apply to the OC/VOC emissions from this air contaminant source since the potential to emit is less than 10 tons per year taking into consideration the federally enforceable limitation established under OAC rule 3745-31-05(D).
 - ii. The Best Available Technology (BAT) requirements under OAC rule 3745-31-05(A)(3) do not apply to the PE from this air contaminant source since the potential to emit is less than 10 tons per year taking into consideration the limitation established under OAC rule 3745-17-11(B).
- c. The OC/VOC limitation was established to reflect the potential to emit for this emissions unit in accordance with the information provided in the application. It is not necessary to develop recordkeeping and/or reporting requirements to ensure compliance with these limitations.
- d. The emissions from the emissions unit shall vent to a fabric pre-filter with a control efficiency of 95%. This control device is used to ensure that the company can account for the total volume of powder use in the process, by weight. The FDA and the DEA require total accountability for the manufactured



pharmaceuticals. Due to this limitation, monitoring for visible emissions is unnecessary.

- e. The PE limitations were established to reflect the potential to emit for this emissions unit as vented to the fabric pre-filter in addition to a HEPA post-filter taking into consideration the maximum hourly throughput of 400 pounds of solids. The monitoring, recordkeeping and testing requirements for the fabric pre-filter and HEPA post-filter are sufficient to ensure compliance with these limitations.

c) Operational Restrictions

- (1) The usage of alcohol shall not exceed 2,636 gallons per rolling, 12-month period.

d) Monitoring and/or Recordkeeping Requirements

- (1) The permittee shall maintain monthly records of the following information:
 - a. the number of gallons of alcohol employed;
 - b. the density of the alcohol, in pounds per gallon;
 - c. the percent of volatile organic compounds, by weight;
 - d. the VOC emissions, in pounds;
 - e. the rolling, 12-month summation of alcohol usage, in gallons; and
 - f. the rolling, 12-month summation of VOC emissions, in tons.
- (2) The permittee shall maintain daily records that document any time when the emissions from the emissions unit were not captured and controlled by the fabric pre-filter and/or HEPA post-filter while the emissions unit was in operation.
- (3) The acceptable range for the pressure drops across the fabric pre-filter and HEPA post-filter shall be based upon the manufacturer's specifications, until such time as any required performance testing is conducted and an alternative pressure drop range and/or limit is established.
- (4) The permittee shall properly install, operate, and maintain equipment to monitor the pressure drops across the fabric pre-filter and HEPA post-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).
- (5) The permittee shall record the pressure drop across the fabric filter on a daily basis when the unit is in operation.
- (6) The permittee shall record the pressure drop across the HEPA filter on a weekly basis when the unit is in operation.



- (7) Whenever the monitored value for the pressure drop deviates from the limit or range 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 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 pressure drop readings 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.

This range or limit on the pressure drop across the baghouse is effective for the duration of this permit, unless revisions are requested by the permittee and approved in writing by Ohio EPA, Central District Office. The permittee may request revisions to the permitted limit or range for the pressure drop based upon information obtained during future testing that demonstrate compliance with the allowable particulate emission rate for the controlled emissions unit(s). In addition, approved revisions to the range or limit 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.



e) Reporting Requirements

- (1) Unless other arrangements have been approved by the director, all notifications and reports shall be submitted through the Ohio EPA's e-Business Center: Air Services online web portal.
- (2) The permittee shall notify the director (Central District Office) in writing of any daily record showing the emissions were not captured and controlled by the dust collector while the emissions unit was in operation. The notification shall include a copy of such record and shall be submitted within 30 days after the event occurs.
- (3) The permittee shall submit quarterly deviation (excursion) reports that identify:
 - a. all deviations (excursions) of the following emission limitations, operational restrictions and/or control device operating parameter limitations that restrict the potential to emit (PTE) of any regulated air pollutant and have been detected by the monitoring, record keeping and/or testing requirements in this permit:
 - i. all exceedances of the rolling, 12-month alcohol usage limitation; and
 - ii. all exceedances of the rolling, 12-month VOC emission limitation.
 - b. the probable cause of each deviation (excursion);
 - c. any corrective actions that were taken to remedy the deviations (excursions) or prevent future deviations (excursions); and
 - d. the magnitude and duration of each deviation (excursion).

If no deviations (excursions) occurred during a calendar quarter, the permittee shall submit a report that states that no deviations (excursions) 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 (Central District Office).

- (4) The permittee shall submit an annual Permit Evaluation Report (PER) to Ohio EPA. The PER must be completed electronically and submitted via the Ohio EPA e-Business 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.

f) Testing Requirements

- (1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:



a. Emission Limitation

Visible particulate emissions from the stack shall not exceed 20 percent opacity as a six-minute average, except as provided by rule.

Applicable Compliance Method

If required, compliance with the stack visible particulate emissions limitation shall be determined through visible emissions observations performed in accordance with U.S. EPA Method 9.

b. Emission Limitation

Particulate emissions (PE) from the stack serving this emissions unit shall not exceed 1.4 pounds per hour, based upon Table I of OAC rule 3745-17-11.

Applicable Compliance Method

If required, compliance with this emission limitation shall be determined in accordance with 40 CFR Part 60, Appendix A, Methods 1 through 5.

c. Emissions Limitation

Organic compound and volatile organic compound (OC/VOC) emissions shall not exceed 69 pounds per hour.

Applicable Compliance Method

Compliance with the hourly OC/VOC emissions limitation shall be determined using the following equation.

$OC/VOC = (\text{Alcohol}) \times (\text{Density}) \times (\% \text{ OC/VOC})$, where

Alcohol = Maximum alcohol usage per hour (11 gal)

Density = Density of alcohol (6.80 lb/gal)

% OC/VOC = Maximum OC/VOC content of alcohol (92.4% by weight)

If the composition of the alcohol changes, or a new alcohol is applied in this emissions unit, then the above calculations should be adjusted to account for the properties of the new alcohol.

d. Emissions Limitations

Particulate emissions (PE) shall not exceed 0.0003 pound per hour and 0.001 ton per year.

Applicable Compliance Method

Compliance with the hourly PE limitation shall be determined using the following equation.



$PE = (\text{Solids}) \times (EF) \times (1 - CE_{\text{fabric filter}}) \times (1 - CE_{\text{HEPA filter}})$, where

Solids = Maximum solids processed (400lb/hr)

EF = Emission factor based on facility mass balance (0.05 lb PE/lb solids)

$CE_{\text{fabric filter}}$ = Control efficiency of fabric filter (95%)

$CE_{\text{HEPA filter}}$ = Control efficiency of HEPA filter (99.97%)

The annual PE limitation was developed by multiplying the hourly PE limitation by 8,760 hr/yr and then dividing by 2,000 lb/ton. Therefore, if compliance is shown with the hourly PE limitation, compliance shall also be shown with the annual PE limitation.

e. Emissions Limitation

Volatile organic compound (VOC) emissions shall not exceed 8.28 tons per rolling 12-month period.

Applicable Compliance Method

Compliance shall be determined by the monitoring and recordkeeping established in d)(1).

g) Miscellaneous Requirements

(1) None.