



State of Ohio Environmental Protection Agency

**RE: FINAL PERMIT TO INSTALL CERTIFIED MAIL
HAMILTON COUNTY**

Street Address:

122 S. Front Street

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

Mailing Address:

Lazarus Gov. Center
P.O. Box 1049

**Application No: 14-05636
Fac ID: 1431072038**

DATE: 12/7/2004

Barr Laboratories Inc
Daryl LeSueur
5040 Duramed Drive
Cincinnati, OH 45213

Enclosed please find an Ohio EPA Permit to Install which will allow you to install the described source(s) in a manner indicated in the permit. Because this permit contains several conditions and restrictions, I urge you to read it carefully.

The Ohio EPA is urging companies to investigate pollution prevention and energy conservation. Not only will this reduce pollution and energy consumption, but it can also save you money. If you would like to learn ways you can save money while protecting the environment, please contact our Office of Pollution Prevention at (614) 644-3469.

You are hereby notified that this action by the Director is final and may be appealed to the Ohio Environmental Review Appeals Commission pursuant to Chapter 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. It must be filed within thirty (30) days after the notice of the Directors action. A copy of the appeal must be served on the Director of the Ohio Environmental Protection Agency within three (3) days of filing with the Commission. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission
309 South Fourth Street, Room 222
Columbus, Ohio 43215

Sincerely,

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

CC: USEPA

HCDES



**Permit To Install
Terms and Conditions**

**Issue Date: 12/7/2004
Effective Date: 12/7/2004**

FINAL PERMIT TO INSTALL 14-05636

Application Number: 14-05636
Facility ID: 1431072038
Permit Fee: **\$500**
Name of Facility: Barr Laboratories Inc
Person to Contact: Daryl LeSueur
Address: 5040 Duramed Drive
Cincinnati, OH 45213

Location of proposed air contaminant source(s) [emissions unit(s)]:

**5040 Duramed Drive
Cincinnati, Ohio**

Description of proposed emissions unit(s):

Modification to PTI 14-05334; correction of emissions information for fluidized bed granulator used for manufacturing pharmaceuticals.

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

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Director

Part I - GENERAL TERMS AND CONDITIONS**A. Permit to Install General Terms and Conditions****1. Compliance Requirements**

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

2. Reporting Requirements

The permittee shall submit required reports in the following manner:

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

3. Records Retention Requirements

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

4. Inspections and Information Requests

The Director of the Ohio EPA, or an authorized representative of the Director, may, subject to the safety requirements of the permittee and without undue delay, enter upon the premises of this source at any reasonable time for purposes of making inspections, conducting tests, examining records or reports pertaining to any emission of air contaminants, and determining compliance with any applicable State air pollution laws and regulations and the terms and conditions of this permit. The permittee shall furnish to the Director of the Ohio EPA, or an authorized

representative of the Director, upon receipt of a written request and within a reasonable time, any information that may be requested to determine whether cause exists for modifying, reopening or revoking this permit or to determine compliance with this permit. Upon verbal or written request, the permittee shall also furnish to the Director of the Ohio EPA, or an authorized representative of the Director, copies of records required to be kept by this permit.

5. Scheduled Maintenance/Malfunction Reporting

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

6. Permit Transfers

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

7. Air Pollution Nuisance

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

8. Termination of Permit to Install

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

9. Construction of New Sources(s)

The proposed emissions unit(s) shall be constructed in strict accordance with the plans and application submitted for this permit to the Director of the Ohio Environmental Protection Agency. There may be no deviation from the approved plans without the express, written approval of the Agency. Any deviations from the approved plans or the above conditions may lead to such sanctions and penalties as provided under Ohio law. Approval of these plans does not constitute an assurance that the proposed facilities will operate in compliance with all Ohio laws and regulations. Additional facilities shall be installed upon orders of the Ohio

Environmental Protection Agency if the proposed sources cannot meet the requirements of this permit or cannot meet applicable standards.

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

10. Public Disclosure

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

11. Applicability

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

12. Best Available Technology

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

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

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

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Issued: 12/7/2004

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14. Construction Compliance Certification

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

15. Fees

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

B. Permit to Install Summary of Allowable Emissions

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

Barr Laboratories Inc
PTI Application: 14-05636
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SUMMARY (for informational purposes only)
TOTAL PERMIT TO INSTALL ALLOWABLE EMISSIONS

<u>Pollutant</u>	<u>Tons Per Year</u>
PE	0.01
PM ₁₀	0.01
OC	7.24

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. Applicable Emissions Limitations and/or Control Requirements

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

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P007 - Fluidized Bed Granulator with HEPA filter and packed tower scrubber	OAC rule 3745-31-05(A)(3)	Organic Compound (OC) emissions shall not exceed 13.23 lbs/hr and 7.24 TPY. Particulate Emissions (PE) and Emissions of Particulate Matter less than 10 microns (PM ₁₀) shall not exceed 0.001 lb/hr and 0.01 TPY. See terms and conditions A.2.b, A.2.c and B.1 through B.4.
	OAC rule 3745-17-07 (A)(1)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05 (A)(3).
	OAC rule 3745-17-11	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05 (A)(3).
	OAC rule 3745-21-07(G)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05

(A)(3).

2. Additional Terms and Conditions

- 2.a** Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by the use of HEPA filter and packed-bed scrubber, and compliance with the visible and mass emissions limitations.
- 2.b** The permittee shall control the OC emissions from this emissions unit by use of a packed-bed scrubber capable of maintaining a minimum overall OC control efficiency of 90% by weight.
- 2.c** Visible particulate emissions from this emissions unit shall not exceed 10% opacity, as a six- minute average.

B. Operational Restrictions

- 1.** The scrubber water supply pressure shall be continuously maintained at a value not less than that established during the most recent emission test that demonstrated compliance while the emissions unit is in operation.
- 2.** The scrubber water flow rate shall be continuously maintained at a value not less than that established during the most recent emission test that demonstrated compliance while the emissions unit is in operation.
- 3.** The number of batches processed in this emissions unit shall not exceed 3 batches per day.
- 4.** The material usage in this emissions unit shall not exceed 60 kg (132.3 lbs.) OC per batch.

C. Monitoring and/or Record keeping Requirements

- 1.** The permittee shall properly install, operate and maintain equipment to continuously monitor the scrubber water supply pressure and scrubber water flow rate while the emissions unit is in operation. The monitoring devices shall be installed, calibrated, operated, and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals, with deviations as deemed necessary by the permittee.

The permittee shall collect and record the following information each day that the emissions unit

is operating:

- a. The scrubber water flow rate, in gallons per minute.
 - b. The scrubber water supply pressure, in psig.
 - c. A log of the downtime for the capture (collection) system, control device and monitoring equipment when the associated emissions unit was in operation.
2. The permittee shall collect and record the following information for each batch:
- a. Date the batch was produced.
 - b. The total OC usage (amount of solvent used) in kilograms per batch.
 - c. The monthly OC emissions calculated as follows:
Monthly OC emissions (lbs/month)
= total solvent sprayed during a month (pounds) * (1- the control efficiency determined during the most recent performance test)

These records shall be summarized at the end of each calendar year to determine the annual OC emissions.

3. The permit to install for this emissions unit was evaluated based on the actual materials (typically coatings and cleanup materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Ground-Level Concentration (MAGLC).

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

Pollutant: Ethanol

TLV (ug/m³): 1,880,000

Maximum Hourly Emission Rate (lbs/hr): 13.23 (Emissions units P007)

Predicted 1-Hour Maximum Ground-Level
Concentration (ug/m³): 1377.24

MAGLC (ug/m³): 44,863

Pollutant: Methanol

TLV (ug/m³): 262,000

Maximum Hourly Emission Rate (lbs/hr): 0.66

Predicted 1-Hour Maximum Ground-Level
Concentration (ug/m³): 68.71

MAGLC (ug/m³): 6,240

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

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

If the permittee determines that the "Air Toxic Policy" will be satisfied for the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01 solely due to the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant

emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) is (are) defined as a modification under other provisions of the modification definition, then the permittee shall obtain a final permit to install prior to the change.

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

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

D. Reporting Requirements

1. The permittee shall submit deviation (excursion) reports that identify all periods of time during which the following scrubber parameters were not maintained at or above the required levels:
 - a. The scrubber water flow rate; and
 - b. The scrubber water supply pressure.
2. The permittee shall submit deviation (excursion) reports that identify all exceedances of the following:
 - a. Three batches per day limitation; and
 - b. 60 kg (132.3 lbs) of OC per batch limitation
3. The deviation reports shall be submitted in accordance with the General Terms and Conditions of this permit.

E. Testing Requirements

1. Compliance with the emission limitations specified in Section A.1 shall be determined by the

following methods:

a. Emission limitation:

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

Applicable Compliance Method:

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

b. Emission limitation:

0.001 lb PM/PM₁₀/hr and 0.01 TPY

Applicable Compliance Method:

Compliance shall be determined utilizing the total dry material throughput (in lbs/hr) multiplied by the minimum HEPA control efficiency of 99.97%. The annual emission rate is obtained by multiplying the hourly emission rate by 8760 hours per year and dividing by 2000 lbs/ton.

c. Emission limitation :

13.23 lbs OC/hr

Applicable Compliance Method:

Compliance shall be demonstrated by utilizing the total OC throughput (in lbs/batch) multiplied by the overall control efficiency for OC, as determined by the latest scrubber OC control efficiency test.

d. Emission limitation:

7.24 TPY OC

Applicable Compliance Method:

Compliance shall be determined by the record keeping in term and condition C.2.

2. The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:
 - a. The emission testing shall be conducted within three months of startup of the emissions unit.
 - b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emissions rate and overall control efficiency for OC.
 - c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s): for OC, Method 25 of 40 CFR Part 60, Appendix A- if applicable. Alternative U.S. EPA approved test methods may be used with prior approval from the Hamilton County Department of Environmental Services.
 - d. The test(s) shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the Hamilton County Department of Environmental Services.

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

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

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

3. Compliance with the requirement to maintain a minimum overall OC control efficiency of 90% by

Emissions Unit ID: **P007**

weight at the scrubber, per term and condition A.2.b, shall be demonstrated by the latest scrubber OC control efficiency test and compliance with the scrubber operating requirements in terms and conditions B.1 and B.2.

4. Compliance with the scrubber water supply pressure limitation in term and condition B.1 shall be demonstrated by the record keeping in term and condition C.1.
5. Compliance with the scrubber water flow rate limitation in term and condition B.2 shall be demonstrated by the record keeping in term and condition C.1.
6. Compliance with the daily batch production limitation in term and condition B.3 shall be demonstrated by the record keeping in term and condition C.2.
7. Compliance with the OC material limitation in term and condition B.4 shall be demonstrated by the record keeping in term and condition C.2.

F. Miscellaneous Requirements

1. The terms and conditions in this permit to install supersede Permit to Install 14-05334, as issued on October 1, 2002.
2. The operation of the control equipment outside of the restrictions established in the Special Terms and Conditions may or may not indicate a mass emission violation. If required by the Ohio EPA, compliance with the mass emission limitations shall be determined by performing concurrent mass emission tests and parameter readings, using US EPA-approved methods and procedures. The results of any required emission tests and parameter readings shall be used in determining whether or not the operation of the control equipment outside of the restrictions specified in the Special Terms and Conditions is indicative of a possible violation of the mass emission limitations.
3. Any malfunction, as defined in OAC rule 3745-15-06(B)(1), shall be reported to the local air agency in accordance with OAC rule 3745-15-06(B). Parameter deviations due to such malfunctions, that comply with the requirements of OAC rule 3745-15-06(B), do not constitute violations of the operational restrictions for these emissions units.

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Emissions Unit ID: **P007**

SIC CODE 2834 SCC CODE 3-01-060-12 EMISSIONS UNIT ID P007
 EMISSIONS UNIT DESCRIPTION Fluidized Bed Granulator with HEPA filter and packed tower scrubber

DATE INSTALLED 12/03

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

Pollutants	Air Quality Description	Actual Emissions Rate		PTI Allowable	
		Short Term Rate	Tons Per Year	Short Term Rate	Tons Per Year
Particulate Matter	attainment	0.001 lb/hr	0.01	0.001 lb/hr	0.01
PM ₁₀	attainment	0.001 lb/hr	0.01	0.001 lb/hr	0.01
Sulfur Dioxide	attainment				
Organic Compounds	nonattainment	13.23 lb/hr	7.24	13.23 lb/hr	7.24
Nitrogen Oxides	attainment				
Carbon Monoxide	attainment				
Lead	attainment				
Other: Air Toxics					

APPLICABLE FEDERAL RULES:

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

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

Enter Determination Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by the use of HEPA filter and packed-bed scrubber, and compliance with the visible and mass emissions limitations.

IS THIS SOURCE SUBJECT TO THE AIR TOXICS POLICY? Yes

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

\$ _____

TOXIC AIR CONTAMINANTS

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

AIR TOXICS MODELING PERFORMED*? X YES _____ NO _____

IDENTIFY THE AIR CONTAMINANTS: Ethanol, methanol