



State of Ohio Environmental Protection Agency

**RE: FINAL PERMIT TO INSTALL
FRANKLIN COUNTY**

CERTIFIED MAIL

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: 01-12044

Fac ID: 0125041763

DATE: 10/12/2006

Boehringer Ingelheim Roxane, Inc.
Mark Slaiman
1809 Wilson Rd
Columbus, OH 43216

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 of the Director is final 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 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
309 South Fourth Street, Room 222
Columbus, OH 43215

Sincerely,

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

CC: USEPA

CDO



**Permit To Install
Terms and Conditions**

**Issue Date: 10/12/2006
Effective Date: 10/12/2006**

FINAL PERMIT TO INSTALL 01-12044

Application Number: 01-12044
Facility ID: 0125041763
Permit Fee: **\$200**
Name of Facility: Boehringer Ingelheim Roxane, Inc.
Person to Contact: Mark Slaiman
Address: 1809 Wilson Rd
Columbus, OH 43216

Location of proposed air contaminant source(s) [emissions unit(s)]:
**1809 Wilson Road
Columbus, Ohio**

Description of proposed emissions unit(s):
Fluid bed/granulator dryer.

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

Boehringer Ingelheim Roxane, Inc.
PTI Application: 01-12044
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Part I - GENERAL TERMS AND CONDITIONS

A. Permit to Install General Terms and Conditions

1. Compliance Requirements

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

2. Reporting Requirements

The permittee shall submit required reports in the following manner:

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

3. Records Retention Requirements

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

4. Inspections and Information Requests

The Director of the Ohio EPA, or an authorized representative of the Director, may, subject to the safety requirements of the permittee and without undue delay, enter upon

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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)

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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.

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

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

14. Construction Compliance Certification

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

15. Fees

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

B. Permit to Install Summary of Allowable Emissions

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

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

<u>Pollutant</u>	<u>Tons Per Year</u>
OC	8.28
PM	<10

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

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

Operations, Property, and/or Equipment - (P017) - 600L Fluidized Bed / Granulator Dryer

Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
OAC rule 3745-35-07(B)(1) (synthetic minor to avoid Title V)	Organic Compound (OC) emissions shall not exceed 8.28 tons per year based upon a rolling 12-month summation of the monthly emissions. (see B.1 below).
OAC rule 3745-21-07(G)(9)	Exempt from the requirements of OAC rule 3745-21-07(G)(2) by using non-photochemically reactive materials. (see A.2.a below).
OAC rule 3745-31-02(A)	PE emissions from the stack shall be less than 10.0 tons per year (see A.2.b below).
OAC rule 3745-17-07(A)(1)	Visible particulate emissions from any stack shall not exceed 20 percent opacity as a six-minute average, except as specified by rule.
OAC rule 3745-17-11(B)	Particulate Emissions (PE) shall not exceed 2.01 pounds per hour based on Table I.

2. Additional Terms and Conditions

- 2.a The permittee shall not use any photochemically reactive materials as defined in OAC rule 3745-21-01(C)
- 2.b Permit to Install 01-12044 for this air contaminant source takes into account the following voluntary restrictions (including the use of any applicable air pollution control equipment) as proposed by the permittee for the purpose of avoiding Best Available Technology (BAT) requirements under OAC rule 3745-31-05(A)(3) for particulate emissions:
 - i. The emissions unit shall use a fabric filter with 95% efficiency and a HEPA (high-efficiency particulate air) filter with 99.97% efficiency in series. This control equipment is considered an inherent physical limitation since the filtration system is used to ensure that the company

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can account for the pharmaceutical powder utilized in each batch, by weight.

B. Operational Restrictions

1. The maximum annual production rate for this emissions unit shall not exceed 240 batches that utilize OC, based upon a rolling, 12 month summation of the production rates.

To ensure enforceability during the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, the permittee shall not exceed the production levels specified in the following table for batches that utilize OC:

<u>Month</u>	<u>Maximum Allowable Cumulative Production</u>
1	100
1-2	200
1-3	240
1-4	240
1-5	240
1-6	240
1-7	240
1-8	240
1-9	240
1-10	240
1-11	240
1-12	240

After the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, compliance with the annual production rate limitation shall be based upon a rolling, 12 month summation of the production rates of batches that utilize OC.

C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall maintain monthly records of the following information for this emissions unit:
 - a. the number of pounds of OC per batch;

- b. whether the OC employed was photochemically reactive;
- c. the number of batches that utilize OC per month;
- d. the rolling, 12 month summation of the number of batches that utilize OC;
- e. the rolling, 12 month summation of OC emissions (a X d); and
- f. beginning after the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, the rolling, 12 month summation of the production rate for batches that utilize OC.

Also, during the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, the permittee shall record the cumulative production rate for batches that utilize OC for each calendar month.

2. The permittee shall properly install, operate, and maintain equipment to continuously monitor and record the pressure drop, in inches of water, across the baghouse and the HEPA filter during operation of this emissions unit, including periods of startup and shutdown. The monitoring equipment shall be installed, calibrated, operated, and maintained in accordance with the manufacturer's recommendations, instructions, and operating manual(s). The permittee shall record the pressure drop, in inches of water, across the baghouse on daily basis. The permittee shall record the pressure drop, in inches of water, across the HEPA filter on weekly basis.

Whenever the monitored value for the pressure drop across the baghouse and/or the HEPA filter deviates from the range specified below, the permittee shall promptly investigate the cause of the deviation. The permittee shall maintain records of the following information for each investigation: the date and time the deviation began and the magnitude of the deviation at that time, the date(s) the investigation was conducted, the names of the personnel who conducted the investigation, and the findings and recommendations.

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

Emissions Unit ID: **P017**

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

The acceptable range for the pressure drop across the baghouse and across the HEPA filter shall be based upon the manufacturer's specifications until such time as any required emission testing is required

This range is effective for the duration of this permit, unless revisions are requested by the permittee and approved in writing by the appropriate Ohio EPA District Office or local air agency. The permittee may request revisions to the ranges based upon information obtained during future particulate emission tests that demonstrate compliance with the allowable particulate emission rate for this emissions unit. In addition, approved revisions to the ranges 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.

3. The permit to install for this emissions unit (P017) was evaluated based on the actual 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 to this emissions unit for each toxic pollutant, using data from the permit to install application (01-12044), and modeling was performed for the toxic pollutant emitted at over a ton per year using the SCREEN 3.0 model or other Ohio EPA approved model. The predicted 1-hour maximum ground-level concentration result from the use of the SCREEN 3.0 (or other approved) model, was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC), calculated as required in Engineering Guide #70. The following summarizes the results of the modeling for the "worst case" pollutant:

Pollutant: Ethanol

TLV (mg/m³): 1883

Maximum Hourly Emission Rate (lbs/hr): 69

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m³): 785.0

MAGLC (ug/m³): 44833.3

4. Physical changes to or changes 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 Toxic Policy" is satisfied. Consequently, prior to making a change that

Emissions Unit ID: **P017**

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 applying the "Air Toxic Policy" include the following:

- a. changes in the composition of the materials used or the use of new materials, that would result in the emission of a compound or chemical with a lower Threshold Limit Value (TLV) than the lowest TLV previously modeled, as documented in the most current version of the American Conference of Governmental Industrial Hygienists' (ACGIH's) handbook entitled "TLVs and BEIs" ("Threshold Limit Values for Chemical Substances and Physical Agents, Biological Exposure Indices");
 - 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.).
5. 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) meet(s) the definition of a "modification" under other provisions of the rule, 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 still 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 the evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and

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- c. where 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 quarterly deviation (excursion) reports that identify all exceedances of the rolling, 12 month production rate limitation; and for the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, all exceedances of the maximum allowable cumulative production rate levels.
2. The permittee shall submit quarterly reports that identify the following information concerning the operation of the control equipment during the operation of this emissions unit:
 - a. each period of time when the pressure drop across the baghouse and/or HEPA filter was outside of the range specified by the manufacturer;
 - b. an identification of each incident of deviation described in (a) where a prompt investigation was not conducted;
 - c. an identification of each incident of deviation described in (a) where prompt corrective action, that would bring the pressure drop into compliance with the acceptable range, was determined to be necessary and was not taken; and
 - d. an identification of each incident of deviation described in (a) where proper records were not maintained for the investigation and/or the corrective action

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

3. The permittee shall submit deviation (excursion) reports that identify all periods of time when a photochemically reactive material was employed in this emissions unit. These reports shall be submitted within 30 days after the occurrence.

E. Testing Requirements

1. Compliance with the emission limitations in Section A.I of these terms and conditions

Emissions Unit ID: **P017**

shall be determined in accordance with the following methods:

a. Emission Limitation:

OC emissions shall not exceed 8.28 tons per year based upon a rolling 12-month summation of the monthly emissions.

Applicable Compliance Method:

Compliance shall be demonstrated by through record keeping as required in section C.e. above.

b. Emission Limitation:

Particulate Emissions (PE) shall not exceed 2.01 pounds per hour based on Table I.

Applicable Compliance Method:

This emission limitation is established pursuant to the requirement specified in OAC rule 3745-17-11(A). Per Table I, the calculated State Implementation Plan (SIP) allowable is:

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$$E=4.10(P)^{0.67}$$

Where:

P is the process weight rate falling within 0.05 ton/hour < P < 30 tons per hour.

P = 0.346 ton /hour.

E = 2.01 lbs/hour.

Taking into account the efficiency of the intrinsic control devices (95% for the fabric filter and 99.97% for the HEPA filter):

$$2.01 \text{ lbs/hour} * (1-0.95) * (1-0.9997) = 0.0000301 \text{ lb/hour.}$$

If required, compliance shall be demonstrated by emission stack test employing methods 1-5 of 40 CFR Part 60, Appendix A.

c. Emission Limitation:

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

Applicable Compliance Method:

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

F. Miscellaneous Requirements

None