



State of Ohio Environmental Protection Agency

Street Address:

Mailing Address:

TELE: (614) 644-3020 FAX: (614) 644-2329

09/24/98

CERTIFIED MAIL

01-25-04-1763

RE: Final Chapter 3745-35 Permit To Operate

Roxane Laboratories, Inc.
Mark S. Slaiman
1809 Wilson Road
P.O. Box 16532
Columbus, OH 43216-6532

Dear Mark S. Slaiman:

The enclosed Permit(s) to Operate allow you to operate the described emissions unit(s) in the manner indicated in the Permit(s). Because each permit contains several terms and conditions, I urge you to read them 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. It must be filed with the Environmental Review Appeals Commission within thirty (30) days after notice of the Director's 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. It is also requested by the Director that a copy of the appeal be served upon the Environmental Enforcement Section of the Office of the Attorney General. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission
236 East Town Street
Room 300
Columbus, Ohio 43215

If you have any questions, please contact the Central District Office at (614) 728-3778.

Very truly yours,

Thomas G. Rigo, Manager
Field Operations and Permit Section
Division of Air Pollution Control

cc: Central District Office
Jim Orlemann, DAPC Engineering
Becky Castle, DAPC PMU



PERMIT TO OPERATE AN EMISSIONS UNIT

Effective Date: 09/24/98

Facility ID: 01-25-04-1763

Expiration Date: 09/24/03

FINAL ISSUE

This document constitutes issuance for:

Roxane Laboratories, Inc.
1809 Wilson Road
Columbus, OH 43228

of a permit to operate for:

P007 (200 L Granulation)
Solid Dosage Pharmaceutical Granulation Process - Mixing, granulating, and drying of solid pharmaceutical powders.

PART I General Terms & Conditions

1 Compliance Requirements

The above-described emissions unit is and shall remain in full compliance with all applicable State and federal laws and regulations and the terms and conditions of this permit.

2. Permit to Install Requirement

Prior to the "installation" or "modification" of any "air contaminant source," as those terms are defined in OAC rule 3745-31-01, a permit to install must be obtained from the Ohio EPA pursuant to OAC Chapter 3745-31.

3. Reporting Requirements Related to Monitoring and Recordkeeping 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.)

4. 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 three 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 the permit. Such records may be maintained in computerized form.

5. 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 and federal 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.

6. 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 unit 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 this emissions unit(s) that is (are) served by such control system(s).

7. Permit Transfers

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

8. 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.

9. Permit Renewal

Approximately six months prior to the expiration date of this permit, a notice regarding the renewal of this permit will be sent to the permittee's designated facility contact. If you are not contacted, please contact the appropriate Ohio EPA District Office or local air agency. It is the permittee's responsibility to renew this permit even if no notice of its expiration is received.

The following Ohio EPA District Office or local air agency has jurisdiction in the area in which the facility is located:

Central District Office
3232 Alum Creek Drive
PO Box 1049
Columbus, OH 43216-1049
(614) 728-3778

You will be contacted approximately six months prior to expiration-date regarding the renewal of this permit. If you are not contacted, please contact the Central District Office.

10. The permittee is also subject to the attached special terms and conditions.

OHIO ENVIRONMENTAL PROTECTION AGENCY

Director 

Part II: Special Terms and Conditions

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operation(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 employed. Additional applicable emissions limitations and/or control measures (if any) may be specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/ Requirements	Applicable Emissions Limitations/Control Measures
200-Liter One Pot Granulation - Mixing, granulating and drying for solid dosage pharmaceutical granulation process	OAC rule 3745-21-07(G)(9)	Exempt from the requirements of OAC rule 3745-21-07(G)(2) by using nonphotochemically reactive materials.
	OAC rule 3745-17-07(A)(1)	This limitation is less restrictive than A.2.f.
	OAC rule 3745-17-11(C)	This limitation is less restrictive than A.2.g. and OAC rule 3745-31-05.
	OAC rule 3745-35-07	Total organic compound emissions shall not exceed 7.81 tons per year for sources P006, P007, P008 and P009 as a rolling 12-month summation.
	OAC rule 3745-31-05 (PTI 01-6309)	Particulate emissions shall not exceed 0.1 lb/hr and 0.15 ton/yr. See A.2.d.

2. Additional Terms and Conditions

- 2.a. The permittee shall not use any photochemically reactive material as defined in OAC rule 3745-21-01(C).
- 2.b. Organic compound emissions shall not exceed 7.76 lbs/hr from P007.
- 2.c. There shall be no visible emissions from the emissions unit.
- 2.d. The emissions unit shall use a dust collector with a 99% control efficiency. This control equipment is considered an inherent physical limitation since the fabric filter is used to ensure that the company can account for the total volume of powder used in the process, by weight. The FDA and DEA require total accountability of the pharmaceuticals manufactured by Roxane Laboratories. Due to this inherent physical limitation, monitoring for visible emissions is unnecessary.

B. Operational Restrictions

1. The maximum annual alcohol usage for P006, P007, P008 and P009 shall not exceed 17,146 pounds, based upon a rolling, 12-month summation of the alcohol usage figures. To ensure enforceability during the first twelve calendar months of operation after issuance of this permit to operate, emissions units P006, P007, P008 and P009 shall not exceed the following alcohol usage limitations:

Maximum Allowable Cumulative Usage For:
Month(s) Alcohol (pounds)

1	2,744
1-2	4,061
1-3	5,379
1-4	6,696
1-5	8,013
1-6	9,330
1-7	10,648
1-8	11,965
1-9	13,282
1-10	13,721
1-11	15,917
1-12	17,146

After the first twelve calendar months of operation following the issuance of this permit, compliance with the annual alcohol usage limitation shall be based upon rolling, 12-month summations of the alcohol usage amounts.

2. The permittee shall not employ an alcohol with an organic compound content greater than 95%, by weight.

C. Monitoring and/or Record Keeping Requirements

1. The permittee shall maintain daily records of the following information for P007:
 - a. the number of gallons of alcohol employed per day;
 - b. the density of the alcohol, in pounds per gallon;
 - c. the percent of organic compounds, by weight;
 - d. the total number of hours the emissions unit was in operation;
 - e. the total uncontrolled organic compound emissions, in pounds per day; and
 - f. the average hourly uncontrolled organic compound emission rate for alcohol, in pounds per hour (average).
2. The permittee shall maintain monthly records of the following information:
 - a. the total alcohol usage in pounds;
 - b. beginning after the first 12 calendar months of operation following the issuance of this permit, the rolling, 12-month summation of the alcohol usage figures; and
 - c. during the first 12 calendar months of operation following the issuance of this permit, the cumulative alcohol usage for each calendar month.
3. The permittee shall maintain daily records that document any time when the dust collector was not in service while the emissions unit was in operation.

D. Reporting Requirements

1. Excursion Reporting Requirements

The permittee shall submit deviation (excursion) reports which identify all exceedances of the rolling, 12-month alcohol usage limitation and, for the first 12 calendar months of operation following the issuance of this permit, all alcohol usage exceedances of the maximum allowable cumulative alcohol usage levels.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

D. Reporting Requirements (continued)

2. The permittee shall submit deviation (excursion) reports which identify each day during which the average hourly total organic compound emissions exceeded 7.76 pounds per hour, and the actual average hourly organic compound emissions for each such day.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

3. The permittee shall also submit annual reports which specify the total alcohol usage and organic compound emissions from emissions units P006 - P009 combined for the previous calendar year. These reports shall be submitted by January 31 of each year.
4. The permittee shall notify the Director (the appropriate District office or local air agency) in writing of any daily record showing that the dust collector was not in service when the emissions unit was in operation. The notification shall include a copy of such record and shall be sent to the Director (the appropriate District Office or local air agency) within 30 days after the event occurs.
5. The permittee shall submit deviation (excursion) reports which identify each day during which any photochemically reactive materials were employed in P007.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

E. Testing Requirements

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

- 1.a. Emission Limitation -
7.76 lbs/hr of organic compounds

Applicable Compliance Method -

Compliance shall be demonstrated by multiplying the density of the alcohol by the daily alcohol usage (in gallons) and the percent of organic compounds, by weight, and then dividing by the hours of operation.

Formulation data derived from MSDS or USEPA Method 24 shall be used to determine the organic compound content of the alcohol.

- 1.b. Emission Limitation -
7.81 tons per year of organic compounds

Applicable Compliance Method -

Compliance shall be demonstrated by summing the daily organic compound emissions from P006 - P009 for each month and then adding the emissions from the previous eleven months.

- 1.c. Emission Limitation:
no visible emissions

Applicable Compliance Method -

If required, compliance shall be determined through visible emissions observations performed in accordance with 40CFR Part 60, Method 22 and the procedures specified in OAC rule 3745-17-03(B)(4).

- 1.d. Emission Limitation -
particulate emissions shall not exceed 0.1 lb/hr and 0.15 ton/yr

Applicable Compliance Method -

Compliance with the hourly emission limitation shall be demonstrated by multiplying the maximum hourly solids usage of 200 lbs/hr by 0.05 lb/lb (emissions factor determined by company mass balance) and 0.01 (control factor). This value represents the potential-to-emit.

F. Miscellaneous Requirements

1. Sections A,B,C,D,E and F of these terms and conditions constitute the federally enforceable portions of this permit.



PERMIT TO OPERATE AN EMISSIONS UNIT

Effective Date: 09/24/98

Facility ID: 01-25-04-1763

Expiration Date: 09/24/03

FINAL ISSUE

This document constitutes issuance for:

Roxane Laboratories, Inc.
1809 Wilson Road
Columbus, OH 43228

of a permit to operate for:

P008 (600 L Granulation)
Solid Dosage Pharmaceutical Granulation Process - Mixing, granulating, and drying of solid pharmaceutical powders.

PART I General Terms & Conditions

Compliance Requirements

The above-described emissions unit is and shall remain in full compliance with all applicable State and federal laws and regulations and the terms and conditions of this permit.

Permit to Install Requirement

Prior to the "installation" or "modification" of any "air contaminant source," as those terms are defined in OAC rule 3745-31-01, a permit to install must be obtained from the Ohio EPA pursuant to OAC Chapter 3745-31.

3. Reporting Requirements Related to Monitoring and Recordkeeping 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.)

4. 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 three 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 the permit. Such records may be maintained in computerized form.

5. 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 and federal 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.

6. 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 unit 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 this emissions unit(s) that is (are) served by such control system(s).

7. Permit Transfers

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

8. 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.

9. Permit Renewal

Approximately six months prior to the expiration date of this permit, a notice regarding the renewal of this permit will be sent to the permittee's designated facility contact. If you are not contacted, please contact the appropriate Ohio EPA District Office or local air agency. It is the permittee's responsibility to renew this permit even if no notice of its expiration is received.

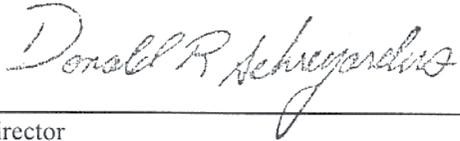
The following Ohio EPA District Office or local air agency has jurisdiction in the area in which the facility is located:

Central District Office
3232 Alum Creek Drive
PO Box 1049
Columbus, OH 43216-1049
(614) 728-3778

You will be contacted approximately six months prior to expiration date regarding the renewal of this permit. If you are not contacted, please contact the Central District Office.

10. The permittee is also subject to the attached special terms and conditions.

OHIO ENVIRONMENTAL PROTECTION AGENCY



Director

Part II: Special Terms and Conditions

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operation(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 employed. Additional applicable emissions limitations and/or control measures (if any) may be specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/ Requirements	Applicable Emissions Limitations/Control Measures
600-Liter One Pot Granulation - Mixing, granulating and drying for solid dosage pharmaceutical granulation process	OAC rule 3745-21-07(G)(9)	Exempt from the requirements of OAC rule 3745-21-07(G)(2) by using nonphotochemically reactive materials.
	OAC rule 3745-17-07(A)(1)	This limitation is less restrictive than A.2.f.
	OAC rule 3745-17-11(C)	This limitation is less restrictive than A.2.g. and OAC rule 3745-31-05.
	OAC rule 3745-35-07	Total organic compound emissions shall not exceed 7.81 tons per year for sources P006, P007, P008 and P009 as a rolling 12-month summation.
	OAC rule 3745-31-05 (PTI 01-6309)	Particulate emissions shall not exceed 0.22 lb/hr and 0.42 ton/yr. (See A.2.d.)

2. Additional Terms and Conditions

- 2.a. The permittee shall not use any photochemically reactive material as defined in OAC rule 3745-21-01(C).

Organic compound emissions shall not exceed 49.6 lbs/hr from P008.

- 2.c There shall be no visible emissions from the emissions unit.

The emissions unit shall use a dust collector with a 99% control efficiency. This control equipment is considered an inherent physical limitation since the fabric filter is used to ensure that the company can account for the total volume of powder used in the process, by weight. The FDA and DEA require total accountability of the pharmaceuticals manufactured by Roxane Laboratories. Due to this inherent physical limitation, monitoring for visible emissions is unnecessary.

B. Operational Restrictions

1. The maximum annual alcohol usage for P006, P007, P008 and P009 shall not exceed 17,146 pounds, based upon a rolling, 12-month summation of the alcohol usage figures. To ensure enforceability during the first twelve calendar months of operation after issuance of this permit to operate, emissions units P006, P007, P008 and P009 shall not exceed the following alcohol usage limitations:

Maximum Allowable Cumulative Usage For:
Month(s) Alcohol (pounds)

	2,744
1-2	4,061
1-3	5,379
1-4	6,696
1-5	8,013
1-6	9,330
1-7	10,648
1-8	11,965
1-9	13,282
1-10	13,721
1-11	15,917
1-12	17,146

After the first twelve calendar months of operation following the issuance of this permit, compliance with the annual alcohol usage limitation shall be based upon rolling, 12-month summations of the alcohol usage amounts.

2. The permittee shall not employ an alcohol with an organic compound content greater than 95%, by weight.

C Monitoring and/or Record Keeping Requirements

1. The permittee shall maintain daily records of the following information for P008.
 - a. the number of gallons of alcohol employed;
 - b. the density of the alcohol, in pounds per gallon;
 - c. the percent of organic compounds, by weight;
 - d. the total number of hours the emissions unit was in operation;
 - e. the total uncontrolled organic compound emissions, in pounds per day; and
 - f. the average hourly uncontrolled organic compound emission rate for alcohol, in pounds per hour (average).
2. The permittee shall maintain monthly records of the following information:
 - a. the total alcohol usage in pounds;
 - b. beginning after the first 12 calendar months of operation following the issuance of this permit, the rolling, 12-month summation of the alcohol usage figures; and
 - c. during the first 12 calendar months of operation following the issuance of this permit, the cumulative alcohol usage for each calendar month.
3. The permittee shall maintain daily records that document any time when the dust collector was not in service while the emissions unit was in operation.

D. Reporting Requirements

1. Excursion Reporting Requirements

The permittee shall submit deviation (excursion) reports which identify all exceedances of the rolling, 12-month alcohol usage limitation and, for the first 12 calendar months of operation following the issuance of this permit, all exceedances of the maximum allowable cumulative alcohol usage levels.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

D. Reporting Requirements (continued)

2. The permittee shall submit deviation (excursion) reports which identify each day during which the average hourly total organic compound emissions exceeded 49.6 pounds per hour, and the actual average hourly organic compound emissions for each such day.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

3. The permittee shall also submit annual reports which specify the total alcohol usage and organic compound emissions from emissions units P006 - P009 combined for the previous calendar year. These reports shall be submitted by January 31 of each year.

4. The permittee shall notify the Director (the appropriate District office or local air agency) in writing of any daily record showing that the dust collector was not in service when the emissions unit was in operation. The notification shall include a copy of such record and shall be sent to the Director (the appropriate District Office or local air agency) within 30 days after the event occurs.

5. The permittee shall submit deviation (excursion) reports which identify each day during which any photochemically reactive materials were employed in P008.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

E. Testing Requirements

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

- 1.a. Emission Limitation -
49.6 lbs/hr of organic compounds

Applicable Compliance Method -

Compliance shall be demonstrated by multiplying the density of the alcohol by the daily alcohol usage (in gallons) and the percent of organic compounds, by weight, and then dividing by the hours of operation.

Formulation data derived from MSDS or USEPA Method 24 shall be used to determine the organic compound content of the alcohol.

- 1.b. Emission Limitation -
7.81 tons per year of organic compounds

Applicable Compliance Method -

Compliance shall be demonstrated by summing the daily organic compound emissions from P006 - P009 for each month and then adding the emissions from the previous eleven months.

Emission Limitation:
no visible emissions

Applicable Compliance Method -

If required, compliance shall be determined through visible emissions observations performed in accordance with 40CFR Part 60, Method 22 and the procedures specified in OAC rule 3745-17-03(B)(4).

Emission Limitation -
particulate emissions shall not exceed 0.22 lb/hr and 0.42 ton/yr

Applicable Compliance Method -

Compliance with the hourly emission limitation shall be demonstrated by multiplying the maximum hourly solids usage of 445 lbs/hr by 0.05 lb/lb (emissions factor determined by company mass balance) and 0.01 (control factor). This value represents the potential-to-emit.

F. Miscellaneous Requirements

1. Sections A, B, C, D, E and F of these terms and conditions constitute the federally enforceable portions of this permit.



PERMIT TO OPERATE AN EMISSIONS UNIT

Effective Date: 09/24/98

Facility ID: 01-25-04-1763

Expiration Date: 09/24/03

FINAL ISSUE

This document constitutes issuance for:

Roxane Laboratories, Inc.
1809 Wilson Road
Columbus, OH 43228

of a permit to operate for:

P009 (2000 L Granulation)
Solid Dosage Pharmaceutical Granulation Process - Mixing, granulating, and drying of solid pharmaceutical powders.

PART I General Terms & Conditions

Compliance Requirements

The above-described emissions unit is and shall remain in full compliance with all applicable State and federal laws and regulations and the terms and conditions of this permit.

Permit to Install Requirement

Prior to the "installation" or "modification" of any "air contaminant source," as those terms are defined in OAC rule 3745-31-01, a permit to install must be obtained from the Ohio EPA pursuant to OAC Chapter 3745-31.

Reporting Requirements Related to Monitoring and Recordkeeping 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.)

4. 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 three 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 the permit. Such records may be maintained in computerized form.

5. 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 and federal 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.

6. 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 unit 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 this emissions unit(s) that is (are) served by such control system(s).

7. Permit Transfers

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

8. 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.

9. Permit Renewal

Approximately six months prior to the expiration date of this permit, a notice regarding the renewal of this permit will be sent to the permittee's designated facility contact. If you are not contacted, please contact the appropriate Ohio EPA District Office or local air agency. It is the permittee's responsibility to renew this permit even if no notice of its expiration is received.

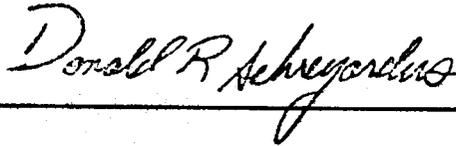
The following Ohio EPA District Office or local air agency has jurisdiction in the area in which the facility is located:

Central District Office
3232 Alum Creek Drive
PO Box 1049
Columbus, OH 43216-1049
(614) 728-3778

You will be contacted approximately six months prior to expiration date regarding the renewal of this permit. If you are not contacted, please contact the Central District Office.

10. The permittee is also subject to the attached special terms and conditions.

OHIO ENVIRONMENTAL PROTECTION AGENCY



Director

Part II: Special Terms and Conditions

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operation(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 employed. Additional applicable emissions limitations and/or control measures (if any) may be specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/ Requirements	Applicable Emissions Limitations/Control Measures
2000-Liter One Pot Granulation - Mixing, granulating and drying for solid dosage pharmaceutical granulation process	OAC rule 3745-21-07(G)(9)	Exempt from the requirements of OAC rule 3745-21-07(G)(2) by using nonphotochemically reactive materials.
	OAC rule 3745-17-07(A)(1)	This limitation is less restrictive than A.2.f.
	OAC rule 3745-17-11(C)	This limitation is less restrictive than A.2.g. and OAC rule 3745-31-05.
	OAC rule 3745-35-07	Total organic compound emissions shall not exceed 7.81 tons per year for sources P006, P007, P008 and P009 as a rolling 12-month summation.
	OAC rule 3745-31-05 (PTI 01-6309)	Particulate emissions shall not exceed 0.8 lb/hr and 1.5 ton/yr. See A.2.d. below.

2. Additional Terms and Conditions

The permittee shall not use any photochemically reactive material as defined in OAC rule 3745-21-01(C).

- 2.b. Organic compound emissions shall not exceed 161.87 lbs/hr from P009.

There shall be no visible emissions from the emissions unit.

- 2.d The emissions unit shall use a dust collector with a 99% control efficiency. This control equipment is considered an inherent physical limitation since the fabric filter is used to ensure that the company can account for the total volume of powder used in the process, by weight. The FDA and DEA require total accountability of the pharmaceuticals manufactured by Roxane Laboratories. Due to this inherent physical limitation, monitoring for visible emissions is unnecessary.

B. Operational Restrictions

1. The maximum annual alcohol usage for P006, P007, P008 and P009 shall not exceed 17,146 pounds, based upon a rolling, 12-month summation of the alcohol usage figures. To ensure enforceability during the first twelve calendar months of operation after issuance of this permit to operate, emissions units P006, P007, P008 and P009 shall not exceed the following alcohol usage limitations:

Maximum Allowable Cumulative Usage For:
Month(s) Alcohol (pounds)

1	2,744
1-2	4,061
1-3	5,379
1-4	6,696
1-5	8,013
1-6	9,330
1-7	10,648
1-8	11,965
1-9	13,282
1-10	13,721
1-11	15,917
1-12	17,146

After the first twelve calendar months of operation following the issuance of this permit, compliance with the annual alcohol usage limitation shall be based upon rolling, 12-month summations of the alcohol usage amounts.

2. The permittee shall not employ an alcohol with a volatile organic compound content greater than 95%, by weight.

C. Monitoring and/or Record Keeping Requirements

1. The permittee shall maintain daily records of the following information for P009:
 - a. the number of gallons of alcohol employed;
 - b. the density of the alcohol, in pounds per gallon;
 - c. the percent of organic compounds, by weight;
 - d. the total number of hours the emissions unit was in operation;
 - e. the total uncontrolled organic compound emissions, in pounds per day; and
 - f. the average hourly uncontrolled organic compound emission rate for alcohol, in pounds per hour (average).
2. The permittee shall maintain monthly records of the following information:
 - a. the total alcohol usage in pounds;
 - b. beginning after the first 12 calendar months of operation following the issuance of this permit, the rolling, 12-month summation of the alcohol usage figures; and
 - c. during the first 12 calendar months of operation following the issuance of this permit, the cumulative alcohol usage for each calendar month.
3. The permittee shall maintain daily records that document any time when the dust collector was not in service while the emissions unit was in operation.

D. Reporting Requirements

1. Excursion Reporting Requirements

The permittee shall submit deviation (excursion) reports which identify all exceedances of the rolling, 12-month alcohol usage limitation and, for the first 12 calendar months of operation following the issuance of this permit, all exceedances of the maximum allowable cumulative alcohol usage levels.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

D. Reporting Requirements (continued)

2. The permittee shall submit deviation (excursion) reports which identify each day during which the average hourly total organic compound emissions exceeded 161.87 pounds per hour, and the actual average hourly organic compound emissions for each such day.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

3. The permittee shall also submit annual reports which specify the total alcohol usage and organic compound emissions from emissions units P006 - P009 combined for the previous calendar year. These reports shall be submitted by January 31 of each year.
4. The permittee shall notify the Director (the appropriate District office or local air agency) in writing of any daily record showing that the dust collector was not in service when the emissions unit was in operation. The notification shall include a copy of such record and shall be sent to the Director (the appropriate District Office or local air agency) within 30 days after the event occurs.
5. The permittee shall submit deviation (excursion) reports which identify each day during which any photochemically reactive materials were employed in P009.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

E. Testing Requirements

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

- 1.a. Emission Limitation -
161.87 lbs/hr of organic compounds

Applicable Compliance Method -

Compliance shall be demonstrated by multiplying the density of the alcohol by the daily alcohol usage (in gallons) and the percent of organic compounds, by weight, and then dividing by the hours of operation.

Formulation data derived from MSDS or USEPA Method 24 shall be used to determine the organic compound content of the alcohol.

- 1.b. Emission Limitation -
7.81 tons per year of organic compounds

Applicable Compliance Method -

Compliance shall be demonstrated by the summing the daily organic compound emissions from P006 - P009 for each month and then adding the emissions from the previous eleven months.

- 1.c. Emission Limitation:
no visible emissions

Applicable Compliance Method -

If required, compliance shall be determined through visible emissions observations performed in accordance with 40CFR Part 60, Method 22 and the procedures specified in OAC rule 3745-17-03(B)(4).

- 1.d. Emission Limitation -
particulate emissions shall not exceed 0.8 lb/hr and 1.5 ton/yr

Applicable Compliance Method -

Compliance with the hourly emission limitation shall be demonstrated by multiplying the maximum hourly solids usage of 1600 lbs/hr by 0.05 lb/lb (emissions factor determined by company mass balance) and 0.01 (control factor). This value represents the potential-to-emit.

F. Miscellaneous Requirements

1. Sections A,B,C,D,E and F of these terms and conditions constitute the federally enforceable portions of this permit.



PERMIT TO OPERATE AN EMISSIONS UNIT

Effective Date: 09/24/98

Facility ID: 01-25-04-1763

Expiration Date: 09/24/03

FINAL ISSUE

This document constitutes issuance for:

Roxane Laboratories, Inc.
1809 Wilson Road
Columbus, OH 43228

of a permit to operate for:

P006 (50 L Granulation)

Solid Dosage Pharmaceutical Granulation Process - Mixing, granulating, and drying of solid pharmaceutical powders.

PART I General Terms & Conditions

1. Compliance Requirements

The above-described emissions unit is and shall remain in full compliance with all applicable State and federal laws and regulations and the terms and conditions of this permit.

2. Permit to Install Requirement

Prior to the "installation" or "modification" of any "air contaminant source," as those terms are defined in OAC rule 3745-31-01, a permit to install must be obtained from the Ohio EPA pursuant to OAC Chapter 3745-31.

3. Reporting Requirements Related to Monitoring and Recordkeeping 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.)

4. 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 three 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 the permit. Such records may be maintained in computerized form.

5. 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 and federal 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.

6. 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 unit 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 this emissions unit(s) that is (are) served by such control system(s).

7. Permit Transfers

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

8. 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.

9. Permit Renewal

Approximately six months prior to the expiration date of this permit, a notice regarding the renewal of this permit will be sent to the permittee's designated facility contact. If you are not contacted, please contact the appropriate Ohio EPA District Office or local air agency. It is the permittee's responsibility to renew this permit even if no notice of its expiration is received.

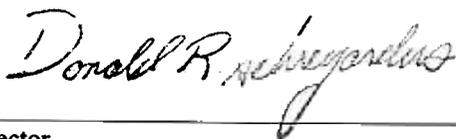
The following Ohio EPA District Office or local air agency has jurisdiction in the area in which the facility is located:

Central District Office
3232 Alum Creek Drive
PO Box 1049
Columbus, OH 43216-1049
(614) 728-3778

You will be contacted approximately six months prior to expiration date regarding the renewal of this permit. If you are not contacted, please contact the Central District Office.

10. The permittee is also subject to the attached special terms and conditions.

OHIO ENVIRONMENTAL PROTECTION AGENCY

A handwritten signature in cursive script that reads "Donald R. Schreyer". The signature is written in black ink and is positioned above a horizontal line.

Director

Part II: Special Terms and Conditions

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operation(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 employed. Additional applicable emissions limitations and/or control measures (if any) may be specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/ Requirements	Applicable Emissions Limitations/Control Measures
50-Liter One Pot Granulation - Mixing, granulating and drying for solid dosage pharmaceutical granulation process	OAC rule 3745-21-07(G)(9)	Exempt from the requirements of OAC rule 3745-21-07(G)(2) by using nonphotochemically reactive materials.
	OAC rule 3745-17-07(A)(1)	This limitation is less restrictive than A.2.f.
	OAC rule 3745-17-11(C)	This limitation is less restrictive than A.2.g. and OAC rule 3745-31-05.
	OAC rule 3745-35-07	Total organic compound emissions shall not exceed 7.81 tons per year for sources P006, P007, P008 and P009 as a rolling 12-month summation.
	OAC rule 3745-31-05 (PTI 01-6309)	Particulate emissions shall not exceed 0.1 lb/hr and 0.1 ton/yr. See A.2.d.

2. Additional Terms and Conditions

The permittee shall not use any photochemically reactive material as defined in OAC rule 3745-21-01(C).

Organic compound emissions shall not exceed 14.5 lbs/hr from P006.

- 2.c There shall be no visible emissions from the emissions unit.

The emissions unit shall use a dust collector with a 99% control efficiency. This control equipment is considered an inherent physical limitation since the fabric filter is used to ensure that the company can account for the total volume of powder used in the process, by weight. The FDA and DEA require total accountability of the pharmaceuticals manufactured by Roxane Laboratories. Due to this inherent physical limitation, monitoring for visible emissions is unnecessary.

B. Operational Restrictions

1. The maximum annual alcohol usage for P006, P007, P008 and P009 shall not exceed 17,146 pounds, based upon a rolling, 12-month summation of the alcohol usage figures. To ensure enforceability during the first twelve calendar months of operation after issuance of this permit to operate, emissions units P006, P007, P008 and P009 shall not exceed the following alcohol usage limitations:

Maximum Allowable Cumulative Usage For:
Month(s) Alcohol (pounds)

1	2,744
1-2	4,061
1-3	5,379
1-4	6,696
1-5	8,013
1-6	9,330
1-7	10,648
1-8	11,965
1-9	13,282
1-10	13,721
1-11	15,917
1-12	17,146

After the first twelve calendar months of operation following the issuance of this permit, compliance with the annual alcohol usage limitation shall be based upon rolling, 12-month summations of the alcohol usage amounts.

2. The permittee shall not employ an alcohol with a organic compound content greater than 95%, by weight.

C. Monitoring and/or Record Keeping Requirements

1. The permittee shall maintain daily records of the following information for P006:
 - a. the number of gallons of alcohol employed;
 - b. the density of the alcohol, in pounds per gallon;
 - c. the percent of organic compounds, by weight;
 - d. the total number of hours the emissions units was in operation;
 - e. the total uncontrolled organic compound emissions, in pounds per day; and
the average hourly uncontrolled organic compound emission rate for alcohol, in pounds per hour (average).
2. The permittee shall maintain monthly records of the following information:
 - a. the total alcohol usage in pounds;
 - b. beginning after the first 12 calendar months of operation following the issuance of this permit, the rolling, 12-month summation of the alcohol usage figures; and
 - c. during the first 12 calendar months of operation following the issuance of this permit, the cumulative alcohol usage for each calendar month.
3. The permittee shall maintain daily records that document any time when the dust collector was not in service while the emissions unit was in operation.

D. Reporting Requirements

1. Excursion Reporting Requirements

The permittee shall submit deviation (excursion) reports which identify all exceedances of the rolling, 12-month alcohol usage limitation and, for the first 12 calendar months of operation following the issuance of this permit, all exceedances of the maximum allowable cumulative alcohol usage levels.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

D. Reporting Requirements (continued)

2. The permittee shall submit deviation (excursion) reports which identify each day during which the average hourly total organic compound emissions exceeded 14.5 pounds per hour, and the actual average hourly organic compound emissions for each such day.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

3. The permittee shall also submit annual reports which specify the total alcohol usage and organic compound emissions from emissions units P006 - P009 combined for the previous calendar year. These reports shall be submitted by January 31 of each year.
4. The permittee shall notify the Director (the appropriate District Office or local air agency) in writing of any daily record showing that the dust collector was not in service when the emissions unit was in operation. The notification shall include a copy of such record and shall be sent to the Director (the appropriate District Office or local air agency) within 30 days after the event occurs.
5. The permittee shall submit deviation (excursion) reports which identify each day during which any photochemically reactive materials were employed in P006.

These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit under Section A.1.

E. Testing Requirements

Compliance with the emissions limitation(s) in Section A of these terms and conditions shall be determined in accordance with the following method(s):

- 1.a. Emission Limitation -
14.5 lbs/hr of organic compounds

Applicable Compliance Method -

Compliance shall be demonstrated by multiplying the density of the alcohol by the daily alcohol usage (in gallons) and the percent of organic compounds, by weight, and then dividing by the hours of operation.

Formulation data derived from MSDS or USEPA Method 24 shall be used to determine the organic compound content of the alcohol.

- 1.b. Emission Limitation -
7.81 tons per year of organic compounds

Applicable Compliance Method -

Compliance shall be demonstrated by summing the daily organic compound emissions from P006 - P009 for each month and then adding the emissions from the previous eleven months.

- 1.c. Emission Limitation:
no visible emissions

Applicable Compliance Method -

If required, compliance shall be determined through visible emissions observations performed in accordance with 40CFRPart60, Method 22 and the procedures specified in OAC rule 3745-17-03(B)(4).

- 1.d. Emission Limitation -
particulate emissions shall not exceed 0.1 lb/hr and 0.1 ton/yr

Applicable Compliance Method -

Compliance with the hourly emission limitation shall be demonstrated by multiplying the maximum hourly solids usage of 50 lbs/hr by 0.05 lb/lb (emissions factor determined by company mass balance) and 0.01 (control factor). This value represents the potential-to-emit.

Facility Name: Roxane Laboratories, Inc.

Facility ID: 01-25-04-1763

Emissions Unit: 50 L Granulation (P006)

F. Miscellaneous Requirements

1. Sections A,B,C,D,E and F of these terms and conditions constitute the federally enforceable portions of this permit.

