



Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
(800) 451-6027
www.IN.gov/idem

TO: Interested Parties / Applicant
DATE: May 09, 2006
RE: Acura Pharmaceuticals, Inc. / 099-22715-00039
FROM: Nisha Sizemore
Chief, Permits Branch
Office of Air Quality

Notice of Decision – Approval

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the enclosed matter. Pursuant to 326 IAC 2, this approval was effective immediately upon submittal of the application.

If you wish to challenge this decision, IC 4-21.5-3-7 requires that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room 1049, Indianapolis, IN 46204, **within eighteen (18) calendar days from the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

- (1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
- (2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
- (3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

- (1) the name and address of the person making the request;
- (2) the interest of the person making the request;
- (3) identification of any persons represented by the person making the request;
- (4) the reasons, with particularity, for the request;
- (5) the issues, with particularity, proposed for considerations at any hearing; and
- (6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

Enclosures
FNPER-AM.dot 03/23/06



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Mr. John Gilkay
Director of EHS
Acura Pharmaceuticals, Inc.
16235 State Road 17
Culver, Indiana 46511

May 09, 2006

Dear Mr. Gilkay:

Re: Exempt Operation Status,
099-22715-00039

The application from Acura Pharmaceuticals, Inc., received on February 28, 2006, has been reviewed. Based on the data submitted and the provisions in 326 IAC 2-1.1-3, it has been determined that the following pharmaceutical products manufacturing and packaging source, located at 16235 State Road 17, Culver, Indiana, 46511, is classified as exempt from air pollution permit requirements:

- (a) One (1) natural gas-fired boiler, identified as 67479, constructed in 1993 and exhausting through vent V-10, capacity: 2.2 million British thermal units per hour;
- (b) One (1) tablet press, equipped with dust collector exhausting through stack V-7A, capacity: 40 pounds per hour, each, based on the unit capacity and 7 pounds per hour, each, based on the source capacity.
- (c) One (1) natural gas-fired emergency generator, 25 kVA (33.5 hp), exhausting through vent V-11.

The following conditions shall be applicable:

1. Pursuant to 326 IAC 5-1-2 (Opacity Limitations) except as provided in 326 IAC 5-1-3 (Temporary alternative opacity limitations), opacity shall meet the following:
 - (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
 - (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of 15 minutes (60 readings in a 6-hour period as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.
2. Pursuant to 326 IAC 6-2-4 (Particulate Emissions Limitations for Sources of Indirect Heating), the PM from the one (1) boiler, identified as 67479, shall not exceed 0.6 pound per million British thermal units.
3. Pursuant to 326 IAC 6-3-2, (Particulate Emission Limitations for Manufacturing Processes), the particulate matter (PM) emissions from the one (1) tablet press shall not exceed 0.551 pounds per hour, when operating at a process weight rate of less than 100 pounds per hour. The dust collector shall be in operation and control emissions from the tablet press at all times when the tablet press is in operation.

This source has been operating under registration 099-13728-00039, issued on July 3, 2001.
The registration is being revoked concurrently with this exemption.

An application or notification shall be submitted in accordance with 326 IAC 2 to the Office of Air Quality (OAQ) if the source proposes to construct new emission units, modify existing emission units, or otherwise modify the source.

Sincerely,

Original signed by
Nysa L. James, Section Chief
Permits Branch
Office of Air Quality

NLJ/clb

cc: File - Marshall County
Marshall County Health Department
Air Compliance - Rick Reynolds
Northern Regional Office
Permit Tracking – Cynthia Bymaster
Office of Enforcement
Air Programs Section - Michele Boner
Compliance Data Section

Indiana Department of Environmental Management Office of Air Quality

Technical Support Document (TSD) for an Exemption

Source Background and Description

Source Name:	Acura Pharmaceuticals, Inc.
Source Location:	16235 State Road 17, Culver, Indiana, 46511
County:	Marshall
SIC Code:	2834
Exemption No.:	099-22715-00039
Permit Reviewer:	Cynthia Bymaster

The Office of Air Quality (OAQ) has reviewed an application from Acura Pharmaceuticals, Inc. relating to the operation of pharmaceutical products manufacturing and packaging source.

Unpermitted Emission Units and Pollution Control Equipment

The source consists of the following unpermitted emission unit:

- (a) One (1) natural gas-fired emergency generator, 25 kVA (33.5 hp), exhausting through vent V-11;

Permitted Emission Units and Pollution Control Equipment

The source consists of the following permitted emission units and pollution control devices:

- (a) One (1) natural gas-fired boiler, identified as 67479, constructed in 1993 and exhausting through vent V-10, capacity: 2.2 million British thermal units per hour;
- (b) One (1) tablet press, equipped with dust collector exhausting through stack V-7A, capacity: 40 pounds per hour, each, based on the unit capacity and 7 pounds per hour, each, based on the source capacity.

Existing Approvals

The source has been operating under a previous approval including, but not limited to, the following:

- (a) Construction Exemption, 099-3259-00039, issued December 14, 1993
- (b) Construction Registration, 099-4316-00039, issued April 6, 1995
- (c) Re-Registration, 099-13728-00039, issued July 3, 2001.

All conditions from previous approvals were incorporated into this permit except for conditions relating to the following emission units which have been removed from the source:

- (a) The following equipment used in the processing and manufacture of Doxycycline hyclate:
 - (1) One (1) natural gas-fired boiler, identified as 63042, constructed in September 1991 and exhausting through stack V-9, capacity: 0.69 million British thermal units per hour.
 - (2) Two (2) stainless steel vessels, identified as RE102 and TA109, capacities: 600 and 300 gallons, respectively.

- (3) Four (4) glass-lined vessels, identified as RE101, RE103, RE105 and RE107, capacities: 500, 500, 500, and 300 gallons, respectively.
 - (4) One (1) plastic vessel, identified as TA108, capacity: 250 gallons.
 - (5) Four (4) forced air drying ovens, identified as DY103, DY104, DY111 and DY112, exhausting through stack V-2, with steam originating from boiler 63042. There is no combustion at these ovens.
 - (6) Three (3) forced air drying ovens, identified as DY106, DY107 and DY108, exhausting through stack V-3, with steam originating from boiler 63042. There is no combustion at these ovens.
 - (7) Three (3) methanol storage tanks, identified as ST102, ST103 and ST104, constructed in 1986, capacity: 1,000 gallons, each.
 - (8) Two (2) electric vacuum pumps, identified as VP101 and VP102, with VP101 exhausting through stack V-1.
 - (9) Two (2) plastic filter boxes, identified as FB106 and FB107.
 - (10) Three (3) sparkler filters, identified as SF101, SF102 and SF103, capacities: 3, 3 and 1 cubic feet, respectively.
- (b) The following equipment used in the processing and manufacture of Doxycycline monohydrate:
- (1) Three (3) glass-lined vessels, identified as RE203, RE206 and RE208, capacities: 300, 300, and 100 gallons, respectively.
 - (2) Two (2) vacuum drying ovens, identified as VD201 and VD202, with steam originating from boilers 63042 and 67479. There is no combustion at these ovens.
 - (3) Two (2) electric vacuum pumps, identified as VP201 and VP202, exhausting through stack V-8.
 - (4) One (1) plastic filter box, identified as FB201.
- (c) The following process equipment used in the processing and manufacture of both Doxycycline hyclate and Doxycycline monohydrate (the individual unit capacities are greater than the capacities based on the source capacity due to the batch nature of the operations):
- (1) One (1) Fitzmill, equipped with a dust collector exhausting through stack V-4, capacity: 330 pounds per hour based on the unit capacity and 7 pounds per hour based on the source capacity.
 - (2) One (1) encapsulator, equipped with a dust collector exhausting through stack V-6, capacity: 80 pounds per hour based on the unit capacity and 7 pounds per hour based on the source capacity.
 - (3) One (1) oscillator, equipped with a dust collector exhausting through stack V-5, capacity: 880 pounds per hour based on the unit capacity and 7 pounds per hour based on the source capacity.
 - (4) One (1) tablet press, equipped with dust collector exhausting through stack V-7B, capacity: 40 pounds per hour, each, based on the unit capacity and 7 pounds per hour, each, based on the source capacity.

- (5) One (1) packaging line, capacity: 175 pounds per hour based on the unit capacity and 7 pounds per hour based on the source capacity.
- (d) One (1) acetone storage tank, identified as ST101, constructed in 1986, capacity: 1,000 gallons.

Enforcement Issue

There are no enforcement actions pending.

Recommendation

The staff recommends to the Commissioner that the operation be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on February 28, 2006, with additional information received on March 11, 2006.

Emission Calculations

See Appendix A, pages 1-2, of this document for detailed emission calculations.

Potential to Emit of the Source Before Controls

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as “the maximum capacity of a stationary source or emissions unit to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U.S. EPA, the department, or the appropriate local air pollution control agency.”

Pollutant	Potential to Emit (tons/yr)
PM	3.8
PM-10	3.8
SO ₂	negligible
VOC	negligible
CO	0.8
NO _x	1
Single HAP	negligible
Combined HAP	negligible

- (a) The potential to emit of all criteria pollutants is less than the levels listed in 326 IAC 2-1.1-3(d)(1). Therefore, the source is subject to the provisions of 326 IAC 2-1.1-3. An exemption will be issued.
- (b) The potential to emit of any single HAP is less than ten (10) tons per year and the potential to emit of a combination of HAPs is less than twenty-five (25) tons per year. Therefore, the source is subject to the provisions of 326 IAC 2-1.1-3. An exemption will be issued.

County Attainment Status

The source is located in Marshall County.

Pollutant	Status
PM-10	attainment
PM 2.5	attainment
SO ₂	attainment
NO ₂	attainment
1-hr Ozone	attainment
8-hr Ozone	attainment
CO	attainment
Lead	attainment

- (a) Volatile organic compounds (VOC) and Nitrogen Oxides (NOx) are regulated under the Clean Air Act (CAA) for the purposes of attaining and maintaining the National Ambient Air Quality Standards (NAAQS) for ozone. Therefore, VOC emissions and NOx are considered when evaluating the rule applicability relating to ozone. Marshall County has been designated as attainment or unclassifiable for ozone. Therefore, VOC emissions and NOx were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2. See the State Rule Applicability for the source section.
- (b) Marshall County has been classified as attainment or unclassifiable for PM2.5. U.S. EPA has not yet established the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 for PM 2.5 emissions. Therefore, until the U.S.EPA adopts specific provisions for PSD review for PM2.5 emissions, it has directed states to regulate PM10 emissions as surrogate for PM2.5 emissions. See the State Rule Applicability – Entire Source section.
- (c) Marshall County has been classified as attainment or unclassifiable for all other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2. See the State Rule Applicability for the source section.
- (d) Fugitive Emissions
 Since this type of operation is not one of the 28 listed source categories under 326 IAC 2-2 or 2-3 and since there are no applicable New Source Performance Standards that were in effect on August 7, 1980, the fugitive particulate matter (PM) and volatile organic compound (VOC) emissions are not counted toward determination of PSD and Emission Offset applicability.

Source Status

Existing Source PSD, Part 70, or FESOP Definition (emissions after controls, based on 8760 hours of operation per year at rated capacity and/or as otherwise limited):

Pollutant	Potential to Emit (tons/yr)
PM	3.8
PM-10	3.8
SO ₂	negligible
VOC	negligible
CO	0.8
NO _x	1
Single HAP	negligible
Combined HAP	negligible

This existing source is **not** a major stationary source because no attainment regulated pollutant is emitted at a rate of 250 tons per year or greater and it is not in one of the 28 listed source categories.

Part 70 Permit Determination

326 IAC 2-7 (Part 70 Permit Program)

This existing source, including the emissions from this exemption **099-22715-00039**, is still not subject to the Part 70 Permit requirements because the potential to emit (PTE) of:

- (a) each criteria pollutant is less than 100 tons per year,
- (b) a single hazardous air pollutant (HAP) is less than 10 tons per year, and
- (c) any combination of HAPs is less than 25 tons per year.

This status is based on all the air approvals issued to the source. This status has been verified by the OAQ inspector assigned to the source.

Federal Rule Applicability

- (a) There are no New Source Performance Standards (NSPS) (326 IAC 12 and 40 CFR Part 60) included in this exemption. 40 CFR 60, Subpart Dc is not included in this exemption for the boiler identified as 67479, because the maximum heat input capacity is less than 10 MMBtu/hr.
- (b) There are no National Emission Standards for Hazardous Air Pollutants (NESHAP)(326 IAC 14, 20 and 40 CFR Part 61, 63) included in this exemption. 40 CFR 63, Subpart DDDDD is not included in this exemption for the boiler identified as 67479, because this is not a major source of HAPs.

State Rule Applicability – Entire Source

326 IAC 2-2 (Prevention of Significant Deteriorations (PSD) Requirements)

This source is not subject to the requirements of 326 IAC 2-2 (PSD) because the potential to emit of all criteria pollutants is less than 250 tons per year and it is not one of 28 listed source categories.

326 IAC 2-4.1 (Major Sources of Hazardous Air Pollutants (HAP))

This source will emit less than 10 tons per year of a single HAP and less than 25 tons per year of a combination of HAPs. Therefore, 326 IAC 2-4.1 does not apply.

326 IAC 2-6 (Emission Reporting)

This source is located in Marshall County and is not required to have a permit under 326 IAC 2-7 and does not emit lead into the ambient air at levels equal to or greater than 5 tons per year. Therefore, 326 IAC 2-6 does not apply.

326 IAC 5-1 (Opacity Limitations)

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in the permit:

- (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

- (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

State Rule Applicability – Individual Facilities

326 IAC 6-2 (Emission Limitations)

Particulate emissions from indirect heating facilities constructed after September 21, 1983 shall be limited by the following equation:

$$Pt = \frac{1.09}{Q^{0.26}}$$

Where:

Pt = Pounds of particulae matter emitted per million Btu (lb/mmBtu) heat input

Q = Total source maximum operating capacity rating in million Btu Per Hour (mmBtu/hr) heat input.

For Q < 10 mmBtu/hr, Pt shall not exceed 0.6. Therefore the particulate matter emissions from the boiler, identified as 67479, shall not exceed 0.6 lb/mmBtu.

The emergency generator is not a surce of indirect heating and is therefore not subject to the requirements of 326 IAC 6-2.

326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes):

Pursuant to 326 IAC 6-3-2(e), the particulate matter (PM) emissions from the one (1) tablet press shall not exceed 0.551 pounds per hour, when operating at a process weight rate of less than 100 pounds per hour. The dust collector shall be in operation and control emissions from the tablet press at all times when the tablet press is in operation.

Conclusion

The operation of this pharmaceutical products manufacturing and packaging source shall be subject to the conditions of the Exemption 099-22715-00039.

**Appendix A: Emissions Calculations
 Natural Gas Combustion Only
 MM BTU/HR <100
 Small Industrial Boiler**

Company Name: Acura Pharmaceuticals, Inc.
Address City IN Zip: 16235 State Road 17, Culver, Indiana 46511
Exemption: 099-22715
Plt ID: 099-00039
Reviewer: Cynthia Bymaster
Date: May 1, 2006

Heat Input Capacity	Potential Throughput	
MMBtu/hr	MMCF/yr	
<table border="1"><tr><td>2.300</td></tr></table>	2.300	20.15
2.300		

	Pollutant					
	PM*	PM10*	SO2	NOx	VOC	CO
Emission Factor in lb/MMCF	1.9	7.6	0.6	100.0 **see below	5.5	84.0
Potential Emission in tons/yr	0.019	0.077	0.006	1.007	0.055	0.846

*PM emission factor is filterable PM only. PM10 emission factor is filterable and condensable PM10 combined.

**Emission Factors for NOx: Uncontrolled = 100, Low NOx Burner = 50, Low NOx Burners/Flue gas recirculation = 32

Methodology

All emission factors are based on normal firing.

MMBtu = 1,000,000 Btu

MMCF = 1,000,000 Cubic Feet of Gas

Potential Throughput (MMCF) = Heat Input Capacity (MMBtu/hr) x 8,760 hrs/yr x 1 MMCF/1,000 MMBtu

Emission Factors are from AP 42, Chapter 1.4, Tables 1.4-1, 1.4-2, 1.4-3, SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03 (SUPPLEMENT D 3/98)

Emission (tons/yr) = Throughput (MMCF/yr) x Emission Factor (lb/MMCF)/2,000 lb/ton

**Appendix A: Emission Calculations
Process Operations**

Company Name: Acura Pharmaceuticals, Inc.
Address City IN Zip: 16235 State Road 17, Culver, Indiana 46511
Exemption: 099-22715
Pit ID: 099-00039
Reviewer: Cynthia Bymaster
Date: May 1, 2006

Unit ID	Control Efficiency (%)	Grain Loading per Actual Cubic foot of Inlet Air (grains/cub. ft.)	Gas or Air Flow Rate (acfm.)	Emission Rate before Controls (lb/hr)	Emission Rate before Controls (tons/yr)	Emission Rate after Controls (lb/hr)	Emission Rate after Controls (tons/yr)
V-7A	99.9%	0.340	300.0	0.874	3.83	0.0009	0.0038
Totals:				0.87	3.8	0.001	0.004

Methodology

Emission Rate in lbs/hr (before controls) = (grains/cub. ft. inlet air) x (acfm) x (60 min/hr) x (lb/7000 grains)

Emission Rate in lbs/hr (after controls) = Emission Rate (before controls) x (1-control efficiency)

Emission Rate in tons/yr = (lbs/hr) x (8760 hrs/yr) x (1 ton/2000 lbs)