



# INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

*We Protect Hoosiers and Our Environment.*

*Mitchell E. Daniels Jr.*  
Governor

*Thomas W. Easterly*  
Commissioner

100 North Senate Avenue  
Indianapolis, Indiana 46204  
(317) 232-8603  
Toll Free (800) 451-6027  
[www.idem.IN.gov](http://www.idem.IN.gov)

TO: Interested Parties / Applicant

DATE: April 25, 2012

RE: JLM Pharmatech / 071-31699-00049

FROM: Matthew Stuckey, Branch Chief  
Permits Branch  
Office of Air Quality

## Notice of Decision: Approval - Registration

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 IC 4-21.5-3-4(d) this order is effective when it is served. When served by U.S. mail, the order is effective three (3) calendar days from the mailing of this notice pursuant to IC 4-21.5-3-2(e).

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, Suite N 501E, Indianapolis, IN 46204, **within eighteen (18) calendar days of 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  
FN-REGIS.dot 1/2/08



# INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

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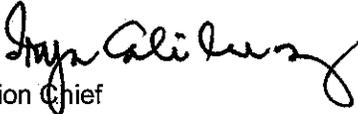
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## REGISTRATION OFFICE OF AIR QUALITY

**JLM Pharmatech  
2223 Killion Ave.  
Seymour, IN 47274**

Pursuant to 326 IAC 2-5.1 (Construction of New Sources: Registrations) and 326 IAC 2-5.5 (Registrations), (herein known as the Registrant) is hereby authorized to construct and operate subject to the conditions contained herein, the source described in Section A (Source Summary) of this registration.

Registration No. R071-31699-00049	
Issued by:  Iryn Calilung, Section Chief Permits Branch Office of Air Quality	Issuance Date: April 25, 2012

## SECTION A

## SOURCE SUMMARY

This registration is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 and A.2 is descriptive information and does not constitute enforceable conditions. However, the Registrant should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Registrant to obtain additional permits pursuant to 326 IAC 2.

### A.1 General Information

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The Registrant owns and operates a stationary nutraceutical and pharmaceutical manufacturing and packaging facility. There is no chemical manufacturing at this source.

Source Address:	2223 Killion Ave., Seymour, IN 47274
General Source Phone Number:	(314) 968-2376
SIC Code:	2834 (Pharmaceutical Preparations), 2833 (Medicinal Chemicals and Botanical Products)
County Location:	Jackson County
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Registration Not 1 of 28 Source Categories

### A.2 Emission Units and Pollution Control Equipment Summary

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This stationary source consists of the following emission units and pollution control devices:

- (a) One (1) polysaccharide iron complex (PIC) spray drying process, mixing a solution of ferric chloride, USP water, and a binder to produce particles used in the pharmaceutical industry for pill and tablet manufacturing, constructed in 1992, consisting of:
  - (1) One (1) cylindrical drying chamber, identified as Spray Dryer #1, with a maximum throughput capacity of 0.048 tons per hour, using an integral cyclone primary product recovery collector, identified as CD-1, and an integral wet venturi scrubber, identified as CD-2, as controls in series, and exhausting to Stack S-1;
  - (2) One (1) natural gas-fired process air heater, identified as Process Heater #1 with a maximum heat input capacity of 0.92 MMBtu/hr, using no control, and exhausting to Stack S-2;
  - (3) One (1) product packaging hopper system.
- (b) One (1) spray drying process, mixing a slurry of calcium carbonate or magnesium carbonate, USP water, and a binder to produce particles used in the pharmaceutical industry for pill and tablet manufacturing, approved for construction in 2012, consisting of:
  - (1) One (1) cylindrical drying chamber, identified as Spray Dryer #2, with a maximum throughput capacity of 0.88 tons per hour, using an integral product recovery cyclone, identified as CD-3, and an integral pulse jet type baghouse, identified as CD-4, as controls in series, and exhausting to Stack S-10;
  - (2) One (1) natural gas-fired process air heater, identified as Process Heater #2, with a maximum heat input capacity of 8.0 MMBtu/hr, using no control, and exhausting to Stack S-11;
  - (3) One (1) natural gas-fired boiler, identified as Boiler #2, with a maximum heat input capacity of 8.4 MMBtu/hr, providing process steam to the Spray Dryer #2,

using no control, and exhausting to Stack S-12; and

- (4) One (1) product hopper with bagging station. The product from the Spray Dryer #2 passes to a vibrating fluid bed dryer before moving to the bagging station through a vibro screen.
- (c) One (1) tablet press process, identified as EU-4, converting polysaccharide iron complex particles created in the spray drying process into pill and tablet blanks, constructed in 1992, with a maximum capacity of 0.017 tons per hour, using a dust collection system, identified as CD-5, as control, and exhausting to Stack S-4. The tablet press process includes a series of hoppers and dies that are used depending on the final product.
- (d) One (1) natural gas-fired boiler, identified as Boiler #1, constructed in 2004, with a maximum heat input capacity of 1.26 MMBtu/hr, using no control, and exhausting to Stack S-3.
- (e) One (1) equipment sanitization process, identified as EU-5, using hand application methods, constructed in 1992, with a maximum capacity of 150 gallons per year, using no control, and exhausting indoors.
- (f) Five (5) natural gas-fired space heaters, identified as Unit Heater #1 through #5, constructed in 1992, with a maximum heat capacity of 0.20 MMBtu/hr, each, using no control, and each exhausting to individual Stacks S-5 through S-9.
- (g) Four (4) natural gas-fired space heaters, identified as Unit Heater #6 through #9, approved for construction in 2012, with a maximum total heat input capacity of 1.55 MMBtu/hr, using no control, with Unit Heater #6 and #7 exhausting outdoors, Unit Heater #8 exhausting to Stack S-13, and Unit Heater #9 exhausting to Stack S-14.

## SECTION B

## GENERAL CONDITIONS

### B.1 Definitions [326 IAC 2-1.1-1]

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Terms in this registration shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2 and 326 IAC 2-1.1-1) shall prevail.

### B.2 Effective Date of Registration [IC 13-15-5-3]

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Pursuant to IC 13-15-5-3, this registration is effective immediately, unless a petition for stay of effectiveness is filed and granted according to IC 13-15-6-3, and may be revoked or modified in accordance with the provisions of IC 13-15-7-1.

### B.3 Registration Revocation [326 IAC 2-1.1-9]

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Pursuant to 326 IAC 2-1.1-9 (Revocation), this registration to operate may be revoked for any of the following causes:

- (a) Violation of any conditions of this registration.
- (b) Failure to disclose all the relevant facts, or misrepresentation in obtaining this registration.
- (c) Changes in regulatory requirements that mandate either a temporary or permanent reduction of discharge of contaminants. However, the amendment of appropriate sections of this registration shall not require revocation of this registration.
- (d) For any cause which establishes in the judgment of IDEM the fact that continuance of this registration is not consistent with purposes of this article.

### B.4 Prior Permits Superseded [326 IAC 2-1.1-9.5]

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- (a) All terms and conditions of permits established prior to Registration No. 071-31699-00049 and issued pursuant to permitting programs approved into the state implementation plan have been either:
  - (1) incorporated as originally stated,
  - (2) revised, or
  - (3) deleted.
- (b) All previous registrations and permits are superseded by this registration.

### B.5 Annual Notification [326 IAC 2-5.1-2(f)(3)] [326 IAC 2-5.5-4(a)(3)]

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Pursuant to 326 IAC 2-5.1-2(f)(3) and 326 IAC 2-5.5-4(a)(3):

- (a) An annual notification shall be submitted by an authorized individual to the Office of Air Quality stating whether or not the source is in operation and in compliance with the terms and conditions contained in this registration.
- (b) The annual notice shall be submitted in the format attached no later than March 1 of each year to:

Indiana Department of Environmental Management  
Compliance and Enforcement Branch, Office of Air Quality  
100 North Senate Avenue  
MC 61-53 IGCN 1003

Indianapolis, IN 46204-2251

- (c) The notification shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

**B.6 Source Modification Requirement [326 IAC 2-5.5-6(a)]**

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Pursuant to 326 IAC 2-5.5-6(a), 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.

**B.7 Registrations [326 IAC 2-5.1-2(i)]**

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Pursuant to 326 IAC 2-5.1-2(i), this registration does not limit the source's potential to emit.

**B.8 Preventive Maintenance Plan [326 IAC 1-6-3]**

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- (a) If required by specific condition(s) in Section D of this registration, the Registrant shall prepare and maintain Preventive Maintenance Plans (PMPs) no later than ninety (90) days after issuance of this registration or ninety (90) days after initial start-up, whichever is later, including the following information on each facility:
- (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;
  - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and
  - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If, due to circumstances beyond the Registrant's control, the PMPs cannot be prepared and maintained within the above time frame, the Registrant may extend the date an additional ninety (90) days provided the Registrant notifies:

Indiana Department of Environmental Management  
Compliance and Enforcement Branch, Office of Air Quality  
100 North Senate Avenue  
MC 61-53 IGCN 1003  
Indianapolis, Indiana 46204-2251

The Registrant shall implement the PMPs.

- (b) A copy of the PMPs shall be submitted to IDEM, OAQ upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ may require the Registrant to revise its PMPs whenever lack of proper maintenance causes or is the primary contributor to an exceedance of any limitation on emissions.
- (c) To the extent the Registrant is required by 40 CFR Part 60 or 40 CFR Part 63 to have an Operation Maintenance, and Monitoring (OMM) Plan for a unit, such OMM Plan is deemed to satisfy the PMP requirements of 326 IAC 1-6-3 for that unit.

**SECTION C**

**SOURCE OPERATION CONDITIONS**

Entire Source

**Emission Limitations and Standards [326 IAC 2-5.1-2(g)] [326 IAC 2-5.5-4(b)]**

**C.1 Opacity [326 IAC 5-1]**

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, unless otherwise stated in this registration:

- (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.

**C.2 Fugitive Dust Emissions [326 IAC 6-4]**

The Registrant shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions).

## SECTION D.1

## OPERATION CONDITIONS

Facility Description [326 IAC 2-5.1-2(f)(2)] [326 IAC 2-5.5-4(a)(2)]:

- (a) One (1) polysaccharide iron complex (PIC) spray drying process, mixing a solution of ferric chloride, USP water, and a binder to produce particles used in the pharmaceutical industry for pill and tablet manufacturing, constructed in 1992, consisting of:
  - (1) One (1) cylindrical drying chamber, identified as Spray Dryer #1, with a maximum throughput capacity of 0.048 tons per hour, using an integral cyclone primary product recovery collector, identified as CD-1, and an integral wet venturi scrubber, identified as CD-2, as controls in series, and exhausting to Stack S-1;
  - (2) One (1) natural gas-fired process air heater, identified as Process Heater #1 with a maximum heat input capacity of 0.92 MMBtu/hr, using no control, and exhausting to Stack S-2;
  - (3) One (1) product packaging hopper system.
- (b) One (1) spray drying process, mixing a slurry of calcium carbonate or magnesium carbonate, USP water, and a binder to produce particles used in the pharmaceutical industry for pill and tablet manufacturing, approved for construction in 2012, consisting of:
  - (1) One (1) cylindrical drying chamber, identified as Spray Dryer #2, with a maximum throughput capacity of 0.88 tons per hour, using an integral product recovery cyclone, identified as CD-3, and an integral pulse jet type baghouse, identified as CD-4, as controls in series, and exhausting to Stack S-10;
  - (2) One (1) natural gas-fired process air heater, identified as Process Heater #2, with a maximum heat input capacity of 8.0 MMBtu/hr, using no control, and exhausting to Stack S-11;
  - (3) One (1) natural gas-fired boiler, identified as Boiler #2, with a maximum heat input capacity of 8.4 MMBtu/hr, providing process steam to the Spray Dryer #2, using no control, and exhausting to Stack S-12; and
  - (4) One (1) product hopper with bagging station. The product from the Spray Dryer #2 passes to a vibrating fluid bed dryer before moving to the bagging station through a vibro screen.
- (c) One (1) tablet press process, identified as EU-4, converting polysaccharide iron complex particles created in the spray drying process into pill and tablet blanks, constructed in 1992, with a maximum capacity of 0.017 tons per hour, using a dust collection system, identified as CD-5, as control, and exhausting to Stack S-4. The tablet press process includes a series of hoppers and dies that are used depending on the final product.
- (d) One (1) natural gas-fired boiler, identified as Boiler #1, constructed in 2004, with a maximum heat input capacity of 1.26 MMBtu/hr, using no control, and exhausting to Stack S-3.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

**Emission Limitations and Standards [326 IAC 2-5.1-2(f)(1)] [326 IAC 2-5.5-4(a)(1)]**

**D.1.1 Particulate Emissions [326 IAC 6-2-4]**

- (a) Pursuant to 326 IAC 6-2-4 (Particulate Emission Limitations for Sources of Indirect Heating), particulate emissions from Boiler #1 shall be limited to 0.6 pounds per MMBtu heat input.
- (b) Pursuant to 326 IAC 6-2-4 (Particulate Emission Limitations for Sources of Indirect Heating), particulate emissions from the Boiler #2 shall be limited to 0.6 pounds per MMBtu heat input.

**D.1.2 Particulate Emissions Limitations [326 IAC 6-3-2]**

Pursuant to 326 IAC 6-3-2, the particulate emissions from each of the following processes shall not exceed the pound per hour limitations specified in the following table:

Emission Unit	Control ID	Process Weight Rate (tons/hr)	Allowable PM Emissions (lb/hr)
Spray Dryer #1	CD-1 cyclone and CD-2 wet venturi scrubber	0.048	0.551
Spray Dryer #2	CD-3 cyclone and CD-4 baghouse	0.880	3.76
Tablet Press Process	CD-5 dust collector	0.017	0.551

Interpolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67} \quad \text{where } E = \text{rate of emission in pounds per hour; and } P = \text{process weight rate in tons per hour}$$

**D.1.3 Preventive Maintenance Plan [326 IAC 1-6-3]**

A Preventive Maintenance Plan is required for the Spray Dryer #1, Spray Dryer #2 and the corresponding control devices. Section B - Preventive Maintenance Plan contains the Registrant's obligation with regard to the preventive maintenance plan required by this condition.

**Compliance Determination Requirements [326 IAC 2-5.1-2(g)] [326 IAC 2-5.5-4(b)]**

**D.1.4 Particulate Control**

- (a) In order to comply with Condition D.1.2 and to maintain the Registration status of the source, the integral control devices, identified as CD-1 and CD-2 for Spray Dryer #1 and CD-3 and CD-4 for Spray Dryer #2, for particulate control shall be in operation and control emissions at all times that the spray drying processes are in operation.
- (b) In the event that bag failure is observed in a multi-compartment baghouse, if operations will continue for ten (10) days or more after the failure is observed before the failed units will be repaired or replaced, the Permittee shall promptly notify the IDEM, OAQ of the expected date the failed units will be repaired or replaced. The notification shall also include the status of the applicable compliance monitoring parameters with respect to normal, and the results of any response actions taken up to the time of notification.

**Compliance Monitoring Requirements [326 IAC 2-5.1-2(g)] [326 IAC 2-5.5-4(b)]**

**D.1.5 Broken or Failed Bag Detection**

In the event that bag failure has been observed:

- (a) For a single compartment baghouses controlling emissions from a process operated continuously, a failed unit and the associated process shall be shut down immediately until the failed unit has been repaired or replaced.
- (b) For a single compartment baghouse controlling emissions from a batch process, the feed to the process shall be shut down immediately until the failed unit has been repaired or replaced. The emissions unit shall be shut down no later than the completion of the processing of the material in the emissions unit.

Bag failure can be indicated by a significant drop in the baghouse's pressure reading with abnormal visible emissions, by an opacity violation, or by other means such as gas temperature, flow rate, air infiltration, leaks, dust traces or triboflows.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
OFFICE OF AIR QUALITY  
COMPLIANCE AND ENFORCEMENT BRANCH**

**REGISTRATION  
ANNUAL NOTIFICATION**

This form should be used to comply with the notification requirements under 326 IAC 2-5.1-2(f)(3) and 326 IAC 2-5.5-4(a)(3).

<b>Company Name:</b>	JLM Pharmatech
<b>Address:</b>	2223 Killion Ave.
<b>City:</b>	Seymour, IN 47274
<b>Phone Number:</b>	(314) 968-2376
<b>Registration No.:</b>	071-31699-00049

I hereby certify that JLM Pharmatech is:

- still in operation.
- no longer in operation.

I hereby certify that JLM Pharmatech is:

- in compliance with the requirements of Registration No. 071-31699-00049.
- not in compliance with the requirements of Registration No. 071-31699-00049.

<b>Authorized Individual (typed):</b>
<b>Title:</b>
<b>Signature:</b>
<b>Phone Number:</b>
<b>Date:</b>

If there are any conditions or requirements for which the source is not in compliance, provide a narrative description of how the source did or will achieve compliance and the date compliance was, or will be achieved.

<b>Noncompliance:</b>

**Indiana Department of Environmental Management  
Office of Air Quality**

Technical Support Document (TSD) for a Registration

**Source Description and Location**

**Source Name:** JLM Pharmatech  
**Source Location:** 2223 Killion Ave., Seymour, IN 47274  
**County:** Jackson  
**SIC Code:** 2834 (Pharmaceutical Preparations), 2833 (Medicinal Chemicals and Botanical Products)  
**Registration No.:** R071-31699-00049  
**Permit Reviewer:** Sarah Street

On April 3, 2012, the Office of Air Quality (OAQ) received an application from JLM Pharmatech related to the construction and operation of new emission units and the continued operation of an existing stationary nutraceutical and pharmaceutical manufacturing and packaging facility.

**Existing Approvals**

There have been no previous approvals issued to this source.

**County Attainment Status**

The source is located in Jackson County.

<b>Pollutant</b>	<b>Designation</b>
SO <sub>2</sub>	Better than national standards.
CO	Unclassifiable or attainment effective November 15, 1990.
O <sub>3</sub>	Attainment effective December 29, 2005, for the 8-hour ozone standard. <sup>1</sup>
PM <sub>10</sub>	Unclassifiable effective November 15, 1990.
NO <sub>2</sub>	Cannot be classified or better than national standards.
Pb	Not designated.
<sup>1</sup> Unclassifiable or attainment effective October 18, 2000, for the 1-hour ozone standard which was revoked effective June 15, 2005. Unclassifiable or attainment effective April 5, 2005, for PM <sub>2.5</sub> .	

- (a) **Ozone Standards**  
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 and NOx emissions are considered when evaluating the rule applicability relating to ozone. Jackson County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NOx emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.
- (b) **PM<sub>2.5</sub>**  
Jackson County has been classified as attainment for PM<sub>2.5</sub>. On May 8, 2008 U.S. EPA promulgated the requirements for Prevention of Significant Deterioration (PSD) for PM<sub>2.5</sub> emissions. These rules became effective on July 15, 2008. Indiana has three years from the publication of these rules to revise its PSD rules, 326 IAC 2-2, to include those requirements. The May 8, 2008 rule revisions require IDEM to regulate PM<sub>10</sub> emissions as a surrogate for PM<sub>2.5</sub> emissions until 326 IAC 2-2 is revised.

- (c) Other Criteria Pollutants  
Jackson County has been classified as attainment or unclassifiable in Indiana for all criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

### **Fugitive Emissions**

The fugitive emissions of criteria pollutants, hazardous air pollutants, and greenhouse gases are counted toward the determination of 326 IAC 2-5.1-2 (Registrations) applicability.

Since there is no chemical manufacturing at this source, this source is not one of the twenty-eight (28) listed source categories under 326 IAC 2-2, 326 IAC 2-3, or 326 IAC 2-7.

### **Background and Description of Emission Units and Pollution Control Equipment**

The Office of Air Quality (OAQ) has reviewed an application, submitted by JLM Pharmatech on April 3, 2012, relating to the construction of new emissions units at an existing facility. The emissions units at the existing facility were exempt from air pollution permit requirements (based on the data submitted and the provisions in 326 IAC 2-1.1-3), and so there have been no previous approvals issued at the source. With the addition of the new emission units, the source has applied for a Registration approval from IDEM, OAQ.

The source consists of the following existing emission unit(s):

- (a) One (1) polysaccharide iron complex (PIC) spray drying process, mixing a solution of ferric chloride, USP water, and a binder to produce particles used in the pharmaceutical industry for pill and tablet manufacturing, constructed in 1992, consisting of:
- (1) One (1) cylindrical drying chamber, identified as Spray Dryer #1, with a maximum throughput capacity of 0.048 tons per hour, using an integral cyclone primary product recovery collector, identified as CD-1, and an integral wet venturi scrubber, identified as CD-2, as controls in series, and exhausting to Stack S-1;
  - (2) One (1) natural gas-fired process air heater, identified as Process Heater #1 with a maximum heat input capacity of 0.92 MMBtu/hr, using no control, and exhausting to Stack S-2;
  - (3) One (1) product packaging hopper system.
- (b) One (1) tablet press process, identified as EU-4, converting polysaccharide iron complex particles created in the spray drying process into pill and tablet blanks, constructed in 1992, with a maximum capacity of 0.017 tons per hour, using a dust collection system, identified as CD-5, as control, and exhausting to Stack S-4. The tablet press process includes a series of hoppers and dies that are used depending on the final product.
- Note: No combustion equipment is used in the tablet press process.
- (c) One (1) natural gas-fired boiler, identified as Boiler #1, constructed in 2004, with a maximum heat input capacity of 1.26 MMBtu/hr, using no control, and exhausting to Stack S-3.
- (d) One (1) equipment sanitization process, identified as EU-5, using hand application methods, constructed in 1992, with a maximum capacity of 150 gallons per year, using no control, and exhausting indoors.
- (e) Five (5) natural gas-fired space heaters, identified as Unit Heater #1 through #5, constructed in 1992, with a maximum heat capacity of 0.20 MMBtu/hr, each, using no control, and each

exhausting to individual Stacks S-5 through S-9.

Note: The emissions from the above existing equipment fall below IDEM's permitting thresholds and therefore there have been no previous air approvals at the source.

The following is a list of the new emission unit(s) and pollution control device(s):

- (a) One (1) spray drying process, mixing a slurry of calcium carbonate or magnesium carbonate, USP water, and a binder to produce particles used in the pharmaceutical industry for pill and tablet manufacturing, approved for construction in 2012, consisting of:
  - (1) One (1) cylindrical drying chamber, identified as Spray Dryer #2, with a maximum throughput capacity of 0.88 tons per hour, using an integral product recovery cyclone, identified as CD-3, and an integral pulse jet type baghouse, identified as CD-4, as controls in series, and exhausting to Stack S-10;
  - (2) One (1) natural gas-fired process air heater, identified as Process Heater #2, with a maximum heat input capacity of 8.0 MMBtu/hr, using no control, and exhausting to Stack S-11;
  - (3) One (1) natural gas-fired boiler, identified as Boiler #2, with a maximum heat input capacity of 8.4 MMBtu/hr, providing process steam to the Spray Dryer #2, using no control, and exhausting to Stack S-12; and
  - (4) One (1) product hopper with bagging station. The product from the Spray Dryer #2 passes to a vibrating fluid bed dryer before moving to the bagging station through a vibro screen.
- (b) Four (4) natural gas-fired space heaters, identified as Unit Heater #6 through #9, approved for construction in 2012, with a maximum total heat input capacity of 1.55 MMBtu/hr, using no control, with Unit Heater #6 and #7 exhausting outdoors, Unit Heater #8 exhausting to Stack S-13, and Unit Heater #9 exhausting to Stack S-14.

Note: There is no chemical manufacturing at this source.

<b>"Integral Part of the Process" Determination</b>
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The applicant has submitted the following information to justify why the controls (the cyclone primary product recovery collector, identified as CD-1, and wet venturi scrubber, identified as CD-2, for Spray Dryer #1; and, the product recovery cyclone, identified as CD-3, and pulse jet type baghouse, identified as CD-4, for Spray Dryer #2) should be considered an integral part of the spray drying process.

- (a) Spray drying is a method of producing a dry powder from a liquid or slurry by rapidly drying with a hot gas. The cyclone on each dryer is considered an integral part of the entire spray drying operation since the cyclone is used to recover product.
- (b) The wet venturi scrubber CD-2 is used in sequence with the CD-1 product recovery cyclone for Spray Dryer #1. Similarly, the baghouse CD-4 is used in sequence with the CD3 product recovery cyclone for Spray Dryer #2. These controls should be considered integral to the process as well.
- (c) The controls are required to operate according to pharmaceutical industry's good manufacturing practices outlined in the following: CFR 21 Part 210 "Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General", CFR 21 Part 211 "Current Good Manufacturing Practice for Finished Pharmaceuticals", and ICH-Q7A "Good Manufacturing Practice guidance for Active Pharmaceutical Ingredients." The control equipment must be fully operational per the Food and Drug Administration (FDA) validation requirements for this operation.

IDEM, OAQ has evaluated the information submitted and agrees that, based on (a) and (b) above, the controls should be considered an integral part of the spray drying process (Spray Dryer #1 and #2). This determination is based on the fact that the cyclones are used for product recovery and the venturi scrubber and baghouse are in series with the cyclone devices; the spray drying process cannot operate without the control equipment. Therefore, the permitting level will be determined using the potential to emit after the controls for the spray drying processes. Operating conditions in the proposed permit will specify that this control equipment shall operate at all times when the spray drying processes are in operation.

<b>Enforcement Issues</b>
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There are no pending enforcement actions related to this source.

<b>Emission Calculations</b>
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See Appendix A of this TSD for detailed emission calculations.

No AP-42 emission factors exist for the spray drying processes in a pharmaceutical application. The best available conservative alternate emission factors used in these emission calculations are from AP-42 Table 9.9.7-1 (Corn Wet Milling: Starch Drying - Spray Dryers). These factors are for a spray drying process in a food (e.g. starch) application. IDEM, OAQ has evaluated the alternative emission factors and determined that stack testing is not necessary to verify the emission factors.

<b>Permit Level Determination – Registration</b>
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The following table reflects the unlimited potential to emit (PTE) of the entire source before controls. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Process/ Emission Unit	Potential To Emit of the Entire Source (tons/year)									
	PM	PM10*	PM2.5	SO <sub>2</sub>	NO <sub>x</sub>	VOC	CO	GHGs as CO <sub>2</sub> e**	Total HAPs	Worst Single HAP
Spray Dryer #1 and Spray Dryer #2 ***	0.001	0.005	0.048	-	-	-	-	-	-	
Tablet Press Process (EU-4)	1.49	1.49	1.49	-	-	-	-	-	-	
Natural Gas Combustion (Boilers #1 and #2, Process Heaters #1 and #2, Space Heaters)	0.18	0.70	0.70	0.06	9.25	0.51	7.77	11,174	0.17	0.17 Hexane
Equipment Sanitization (EU-5)	-	-	-	-	-	0.49	-	-	-	
<b>Total PTE of Entire Source</b>	<b>1.67</b>	<b>2.20</b>	<b>2.24</b>	<b>0.06</b>	<b>9.25</b>	<b>1.00</b>	<b>7.77</b>	<b>11,174</b>	<b>0.17</b>	<b>0.17 Hexane</b>
Exemptions Levels**	5	5	5	10	10	10	25	100,000	25	10
Registration Levels**	25	25	25	25	25	25	100	100,000	25	10
*Under the Part 70 Permit program (40 CFR 70), particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM10), not particulate matter (PM), is considered as a "regulated air pollutant". **The 100,000 CO <sub>2</sub> e threshold represents the Title V and PSD subject to regulation thresholds for GHGs in order to determine whether a source's emissions are a regulated NSR pollutant under Title V and PSD. *** The controls for Spray Dryer #1 and #2 are integral to the process; therefore, permit level is determined after control. The uncontrolled source-wide emissions of all criteria pollutants are under PSD (326 IAC 2-2) thresholds.										

- (a) The potential to emit (PTE) (as defined in 326 IAC 2-1.1-1) of all regulated criteria pollutants are less than the levels listed in 326 IAC 2-1.1-3(e)(1) (Exemptions). However, the source has applied for a Registration. The PTE of all regulated criteria pollutants are less than the ranges listed in 326 IAC 2-5.1-2(a)(1). Therefore, the source is subject to the provisions of 326 IAC 2-5.1-2 (Registrations). A Registration will be issued.
- (b) The potential to emit (PTE) (as defined in 326 IAC 2-1.1-1) of any single HAP is less than ten (10) tons per year and the PTE of a combination of HAPs is less than twenty-five (25) tons per year. Therefore, this source is an area source under Section 112 of the Clean Air Act (CAA) and not subject to the provisions of 326 IAC 2-7.
- (c) The potential to emit (PTE) (as defined in 326 IAC 2-1.1-1) greenhouse gases (GHGs) is less than the Title V subject to regulation threshold of one hundred thousand (100,000) tons of CO<sub>2</sub> equivalent emissions (CO<sub>2</sub>e) per year. Therefore, the source is not subject to the provisions of 326 IAC 2-7.

**Federal Rule Applicability Determination**

New Source Performance Standards (NSPS)

- (a) The requirements of the New Source Performance Standard for Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units, 40 CFR 60, Subpart Dc (326 IAC 12), are not included in the permit, since the two boilers, identified as Boiler #1 and Boiler #2, each have a maximum design heat input capacity of less than ten (10) million Btu per hour.
- (b) There are no New Source Performance Standards (NSPS) (326 IAC 12 and 40 CFR Part 60) included in the permit.

National Emission Standards for Hazardous Air Pollutants (NESHAP)

- (c) The requirements of the National Emission Standards for Hazardous Air Pollutants (NESHAPs) for National Emission Standards for Pharmaceuticals Production, 40 CFR 63, Subpart GGG, are not included in the permit for this source, since this plant site is not a major source of HAPs as defined in section 112(a) of the Clean Air Act and it does not process, use, or produce HAP in the manufacturing of a pharmaceutical product.
- (d) The requirements of the National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Industrial, Commercial, and Institutional Boilers Area Sources, 40 CFR 63, Subpart JJJJJ (6J), are not included in the permit for the natural gas-fired boilers, identified as Boiler #1 and Boiler #2, since gas-fired boilers, as defined in 40 CFR 63.11237, are specifically exempted from this rule as indicated in 40 CFR 63.11195(e). Further, the process heaters (Process Heater #1 and #2) do not meet the definition of a boiler, as defined in 40 CFR 63.11237.
- (e) The requirements of the National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Chemical Manufacturing Area Sources are not included in this permit because this source does not have any chemical manufacturing process units (CMPU) - which would include, but is not limited to any, all, or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a product or isolated intermediate, as defined in 40 CFR 63.11502.
- (f) There are no National Emission Standards for Hazardous Air Pollutants (NESHAPs) (326 IAC 14, 326 IAC 20 and 40 CFR Part 63) included in the permit.

Compliance Assurance Monitoring (CAM)

- (g) Pursuant to 40 CFR 64.2, Compliance Assurance Monitoring (CAM) is not included in the permit, because the unlimited potential to emit of the source is less than the Title V major source thresholds and the source is not required to obtain a Part 70 or Part 71 permit.

<b>State Rule Applicability Determination</b>
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The following state rules are applicable to the source:

- (a) 326 IAC 2-5.1-2 (Registrations)  
Registration applicability is discussed under the Permit Level Determination – Registration section above.
- (b) 326 IAC 2-4.1 (Major Sources of Hazardous Air Pollutants (HAP))  
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, this source is an area source under Section 112 of the Clean Air Act (CAA) and not subject to the provisions of 326 IAC 2-4.1.
- (c) 326 IAC 1-6-3 (Preventive Maintenance Plan)  
Any person responsible for operating any facility required to obtain a permit under the 326 IAC 2-5.1 (Construction of New Sources), shall prepare and maintain a preventive maintenance plan, in accordance with 326 IAC 1-6-3(a), whenever a control device is required for compliance with any applicable emission limitations and/or air pollution control regulations.

The spray dryers (#1 and #2) use a control device to limit the particulate emissions of PM, PM10 and PM2.5 to less than PSD and TV thresholds (see 326 IAC 6-3-2 below). Therefore, a PMP is required for these units and their associated control devices.

- (d) 326 IAC 1-7 (Stack Height)  
The requirements of 326 IAC 1-7 (Stack Height) are not included in the permit because the unlimited potential to emit is less than 25 tons per year of PM and less than 25 tons per year SO<sub>2</sub> through any exhaust gas stack at the source.
- (e) 326 IAC 2-6 (Emission Reporting)  
Pursuant to 326 IAC 2-6-1, this source is not subject to this rule, because it is not required to have an operating permit under 326 IAC 2-7 (Part 70), it is not located in Lake, Porter, or LaPorte County, and it 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.
- (f) 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 this permit:
- (1) 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.
  - (2) 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.
- (g) 326 IAC 6-2-4 (Particulate Emission Limitations for Sources of Indirect Heating)  
Pursuant to 326 IAC 6-2-4 (Particulate Matter Emission Limitations for Sources of Indirect Heating), indirect heating units constructed after September 21, 1983 shall be limited using the following equation:

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

where: Pt = Pounds of particulate matter emitted per million British thermal units (lb/mmBtu) heat input

Q = Total source maximum operating capacity rating in million British thermal units per hour (mmBtu/hr) heat input. The maximum operating capacity rating is defined as the maximum capacity at which the facility is operated or the nameplate capacity, whichever is specified in the facility's permit application, except when some lower capacity is contained in the facility's operation permit; in which case, the capacity specified in the operation permit shall be used.

For Q less than 10 mmBtu/hr, Pt shall not exceed 0.6.

- (1) For Boiler #1 (installed in 1992)  
Q= 1.26  
Pt = 0.60 lbs PM/mmBtu heat input
- (2) For Boiler #2 (installed in 2012)  
Q= 9.66 = 8.4 + 1.26  
Pt = 0.60 lbs PM/mmBtu heat input

Based on Appendix A, the potential to emit of PM from the two (2) boilers identified as Boiler #1 and Boiler #2, both constructed after September 21, 1983, is:

- (1) For Boiler #1 (installed in 1992)  
 $PM = 0.01 \text{ tons/yr} \times (2000 \text{ lbs/ton} / 8760 \text{ hrs/yr}) = 0.0023 \text{ lbs/hr}$   
 $PM = (0.0023 \text{ lbs/hr} / 1.26 \text{ mmBtu/hr}) = 0.0018 \text{ lbs PM/mmBtu}$
- (2) For Boiler #2 (installed in 2012)  
 $PM = 0.07 \text{ tons/yr} \times (2000 \text{ lbs/ton} / 8760 \text{ hrs/yr}) = 0.016 \text{ lbs/hr}$   
 $PM = (0.016 \text{ lbs/hr} / 9.66 \text{ mmBtu/hr}) = 0.0017 \text{ lbs PM/mmBtu}$

Therefore, the two (2) boilers, identified as Boiler #1 and Boiler #2, will be able to comply with this rule without a control device.

Note: The natural gas-fired process air heaters (Process Heater #1 and #2), and the natural gas-fired space heaters are not subject to 326 IAC 6-2 (Particulate Emission Limitations for Sources of Indirect Heating), because, pursuant to 326 IAC 1-2-19, these emission units do not meet the definition of an indirect heating unit.

- (h) 326 IAC 6-3 (Particulate Emission Limitations for Manufacturing Processes)  
 Pursuant to 326 IAC 6-3-2 (Particulate Emissions Limitations), the particulate matter (PM) emissions from the following processes shall be limited by the following equation:

Interpolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67} \quad \text{where } E = \text{rate of emission in pounds per hour and} \\ P = \text{process weight rate in tons per hour}$$

When the process weight rate is less than one hundred (100) pounds per hour, the allowable rate of emission is five hundred fifty-one thousandths (0.551) pound per hour.

Emission Unit	Control ID	Process Weight Rate (tons/hr)	Allowable PM Emissions Pursuant to 326 IAC 6-3-2 (lb/hr)	Potential PM Emissions (lb/hr) *	Able to Comply
Spray Dryer #1	CD-1 cyclone and CD-2 wet venturi scrubber	0.048	0.551	9.216E-05	yes
Spray Dryer #2	CD-3 cyclone and CD-4 baghouse	0.880	3.76	7.04E-05	yes
Tablet Press Process	CD-5 dust collector	0.017	0.551	0.34	yes

\*IDEM, OAQ has evaluated the justifications and agreed that the controls (product recovery cyclones and scrubber/baghouse) will be considered as an integral part of Spray Dryer #1 and Spray Dryer #2, so potential PM emissions for Spray Dryer #1 and #2 are after control. Potential emissions for the Tablet Press Process is the PTE of PM before control; the Tablet Press Process is able to comply with these requirements before control.

Note: The boilers, identified as Boiler #1 and Boiler #2, are each exempt from the requirements of 326 IAC 6-3, pursuant to 326 IAC 6-3-1(b)(1) since they are sources of indirect heating. The natural gas-fired process heaters (Process Heater #1 and #2) and space heaters are exempt from the requirements of 326 IAC 6-3, because, pursuant to 326 IAC 1-2-59, liquid and gaseous fuels and combustion air are not considered as part of the process weight.

- (i) 326 IAC 6-4 (Fugitive Dust Emissions Limitations)  
 Pursuant to 326 IAC 6-4 (Fugitive Dust Emissions Limitations), the source shall not allow fugitive

dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4.

- (j) 326 IAC 6-5 (Fugitive Particulate Matter Emission Limitations)  
The source is not subject to the requirements of 326 IAC 6-5, because, pursuant to 326 IAC 6-5(b), while this source is a new source located anywhere in the state, the source does not have potential fugitive particulate emissions greater than 25 tons per year.
- (k) 326 IAC 8-1-6 (VOC Rules: General Reduction Requirements for New Facilities)  
Each of the emission units at this source is not subject to the requirements of 326 IAC 8-1-6, since the unlimited VOC potential emissions from each emission unit is less than twenty-five (25) tons per year.
- (l) 326 IAC 8 (VOC Rules)  
There are no applicable 326 IAC 8 (VOC) requirements included in this permit. The only source of VOC emissions are from natural gas combustion units and the equipment sanitization (EU-5) process, which uses hand application methods and uses less than 150 gallons of isopropyl alcohol per year. The potential to emit VOCs from the equipment sanitization is 0.49 tons per year.

#### **Compliance Determination, Monitoring and Testing Requirements**

- (a) The compliance determination and monitoring requirements applicable to this source are as follows:
  - (1) In order to comply with the particulate limitations specified under 326 IAC 6-3 and to maintain the registration status of the source, the integral control devices, identified as CD-1 and CD-2 for Spray Dryer #1, and CD-3 and CD-4 for Spray Dryer #2, for particulate control shall be in operation and control emissions at all times that the spray drying processes are in operation.

Note: The two natural gas-fired boilers are able to comply with the emissions limitations required by 326 IAC 6-2-4 without control. The Tablet Press Process is able to comply with the emissions limitations required in 326 IAC 6-3 before control.
- (b) There are no testing requirements applicable in this Registration.

No AP-42 emission factors exist for the spray drying processes in a pharmaceutical application. The best available conservative alternate emission factors used in these emission calculations are from AP-42 Table 9.9.7-1 (Corn Wet Milling: Starch Drying - Spray Dryers). These factors are for a spray drying process in a food application (e.g. starch drying). IDEM, OAQ has evaluated the alternative emission factors and determined that stack testing is not necessary to verify the emission factors.

The emission factor for the Tablet Press Process (EU-4) was determined using a mass balance approach. In the tablet press process, particles created in the spray drying process are loaded into a hopper and then converted into pill and tablet blanks using the tablet press. This process is performed in an enclosed room with no direct emissions to the atmosphere. No combustion equipment (or heating process) is used in this process. Particulate emissions created in this process travel through the dust collection system CD-5 before exhausting to the atmosphere.

#### **Conclusion and Recommendation**

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 April 3, 2012.

The construction and operation of this source shall be subject to the conditions of the attached proposed Registration No. R071-31699-00049. The staff recommends to the Commissioner that this Registration be approved.

<b>IDEM Contact</b>
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- (a) Questions regarding this proposed permit can be directed to Sarah Street at the Indiana Department Environmental Management, Office of Air Quality, Permits Branch, 100 North Senate Avenue, MC 61-53 IGCM 1003, Indianapolis, Indiana 46204-2251 or by telephone at (317) 232-8427 or toll free at 1-800-451-6027 extension 2-8427.
- (b) A copy of the findings is available on the Internet at: <http://www.in.gov/ai/appfiles/idem-caats/>
- (c) For additional information about air permits and how the public and interested parties can participate, refer to the IDEM's Guide for Citizen Participation and Permit Guide on the Internet at: [www.in.gov/idem](http://www.in.gov/idem)

**Appendix A: Emissions Calculations  
Source-wide Summary**

**Company Name:** JLM Pharmatech  
**Address City IN Zip:** 2223 Killion Ave., Seymour, IN 47274  
**Permit Number:** R071-31699-00049  
**Plt ID:** 071-00049  
**Reviewer:** Sarah Street  
**Date:** 4/10/2012

Process/ Emission Units	Unlimited Potential to Emit (tons/yr)									
	PM	PM10*	PM2.5	SO2	NOx	VOC	CO	GHGs as CO2e	Worst Single HAP	Total HAP
Spray Dryer #1 and Spray Dryer #2	0.001	0.005	0.048	-	-	-	-	-	-	-
Tablet Press Process (EU-4)	1.49	1.49	1.49	-	-	-	-	-	-	-
Natural Gas Combustion (Boilers #1 and #2, Process Heaters #1 and #2,	0.18	0.70	0.70	0.06	9.25	0.51	7.77	11,174	0.17 Hexane	0.17
Equipment Sanitization (EU-5)	-	-	-	-	-	0.49	-	-	-	-
<b>Total PTE</b>	<b>1.67</b>	<b>2.20</b>	<b>2.24</b>	<b>0.06</b>	<b>9.25</b>	<b>1.00</b>	<b>7.77</b>	<b>11,174</b>	<b>0.17 Hexane</b>	<b>0.17</b>
Exemptions Levels**	5	5	5	10	10	10	25	100,000	10	25
Registration Levels**	25	25	25	25	25	25	100	100,000	10	25

\*Under the Part 70 Permit program (40 CFR 70), particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM10), not particulate matter (PM), is considered as a "regulated air pollutant".

\*\*The 100,000 CO<sub>2</sub>e threshold represents the Title V and PSD subject to regulation thresholds for GHGs in order to determine whether a source's emissions are a regulated NSR pollutant under Title V and PSD.

**Appendix A: Emissions Calculations  
Spray Drying Process**

**Company Name:** JLM Pharmatech  
**Address City IN Zip:** 2223 Killion Ave., Seymour, IN 47274  
**Permit Number:** R071-31699-00049  
**Pit ID:** 071-00049  
**Reviewer:** Sarah Street  
**Date:** 4/10/2012

Emission Unit I.D.	Source Description	Control Device Efficiency <sup>(1)</sup>								Maximum Hourly Design Rate	Max. Annual Hours of Operation	Max. Annual Production Rate	Emission Factor* (Lbs/Tons of Product)	PM		PM10		PM2.5	
		For Spray Dryer #1				For Spray Dryer #2								Uncontrolled PM Emissions	Controlled PM Emissions	Uncontrolled PM-10 Emissions	Controlled PM-10 Emissions	Uncontrolled PM-2.5 Emissions	Controlled PM-2.5 Emissions
		CD-1 Product Recovery Cyclone	CD-2 Wet Venturi Scrubber	CD-3 Product Recovery Cyclone			CD-4 Baghouse												
		PM, PM-10, and PM-2.5	PM/PM-10/PM-2.5	PM	PM-10	PM-2.5	PM	PM-10	PM-2.5										
(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(Tons/Hr)	(Hrs/Yr)	(Tons/Yr)	(Tons/Yr)	(Tons/Yr)	(Tons/Yr)	(Tons/Yr)	(Tons/Yr)				
EU-1	Spray Dryer #1	98.8	99 /99 / 90	-	-	-	-	-	-	0.048	8,760	420.48	16	0.040	0.00040	0.040	0.00040	0.040	0.004
EU-11	Spray Dryer #2	-	-	99.5	92.5	28.3	99.9	99.9	99.9	0.880	8,760	7,708.80	16	0.308	0.00031	4.625	0.005	44.218	0.044
<b>TOTAL (Tons/Yr)</b>														0.349	0.001	4.666	0.005	44.258	0.048

**Notes:**

\*Emission Factor Source:

AP-42, Section 9.9.7, Corn Wet Milling

Table 9.9.7-1

Starch Drying - Spray Dryers with fabric filter: EF (with controls) = 0.16 lbs/ton product

EF is based on weight of PM regardless of size

Uncontrolled EF was back calculated assuming 99% control efficiency of the baghouse: Thus, 0.16 lbs/ton / (1-.99) = 16 lbs/ton

\*This alternate emission factor has been approved by IDEM, OAQ as a conservative estimate of particulate emissions from spray drying in a pharmaceutical application. No testing will be required in this Permit to verify these emission factors.

(1) Control device efficiency supplied by the source, with the permit application received by IDEM on April 3, 2012

The cyclone on each dryer is considered an integral part of the entire spray drying operation since the cyclone is used to recover product.

Thus, the uncontrolled emission rates include the cyclone control efficiency of each spray drying operation.

The wet scrubber CD-2 and baghouse CD-4 are in series with the cyclone and are considered an integral part of the process. Part 70 permit level determination is considered after control for Spray Dryer #1 and Spray Dryer #2.

PSD Applicability is determined before control:

Uncontrolled PM/PM10/PM2.5 (tons/yr) =	Spray Dryer #1	Spray Dryer #2
	3.36384	61.6704

Sourcewide total PM/PM10/PM2.5 = <250 tons/yr

**Methodology**

Uncontrolled Emission Rate (Tons/Yr):

Max. Annual Production Rate (Tons Product/Yr) \* Emission Factor (Lbs/Ton Product) \* [(1-Control Eff. of Cyclone/100)] / 2000 (Lbs/Ton)

Controlled Emission Rate (Tons/Yr):

Max. Annual Production Rate (Tons Product/Yr) \* Emission Factor (Lbs/Ton Product) \* [(1-Control Eff. of Cyclone/100)] \* [(1-Control Efficiency of Baghouse or Scrubber/100)] / 2000 (Lbs/Ton)

**Appendix A: Emissions Calculations  
Tablet Press Process**

**Company Name:** JLM Pharmatech  
**Address City IN Zip:** 2223 Killion Ave., Seymour, IN 47274  
**Permit Number:** R071-31699-00049  
**Plt ID:** 071-00049  
**Reviewer:** Sarah Street  
**Date:** 4/10/2012

Emission Unit I.D.	Source Description	CD-5		Maximum Hourly Design Rate	Annual Hours of Operation	Annual Production Rate	Emission Factor PM / PM-10/ PM2.5 (Lbs/Tons of Product)	Annual Uncontrolled PM / PM-10 Emissions (Tons/Yr)	Annual Controlled PM / PM-10 Emissions (Tons/Yr)	Annual Uncontrolled PM-2.5 Emissions (Tons/Yr)	Annual Controlled PM-2.5 Emissions (Tons/Yr)
		Dust Collector <sup>(1)</sup>									
		Control Efficiency									
		PM / PM-10	PM-2.5								
EU-4	Tablet Press Process	(%)	(%)	(Tons/Hr)	(Hrs/Yr)	(Tons/Yr)					
		99.8	99.8	0.017	8,760	148.92	20	1.489	0.003	1.489	0.003

(1) Control device efficiency supplied by the source, with the permit application received by IDEM on April 3, 2012.  
Baghouse grain loading is unknown.

**Note:**  
In this process, particles are loaded into a hopper and pressed into pill or tablet blanks. This process is performed in an enclosed room with no direct emissions to atmosphere. Fugitive emissions from the tablet press operation include airborne dust that is processed through a dust collection system (CD-5) prior to being exhausted to atmosphere. Dust particles too large to be entrained in the airstream and collected by the dust collection equipment settle on the exposed surfaces of the tablet press equipment and other surfaces in the contained tablet press area. These surfaces are then washed down with water creating a solution that is then wasted to drain with no fugitive emissions to atmosphere.

**Emission Factor Source: Mass Balance**

The emission factor for this process was developed based on the assumption that 1% of the particulate matter becomes airborne, is captured, and sent to the dust collector. Thus, for every ton of material pressed into tablets, there are 20 lbs of particulate emissions in the form of PM, PM-10 and PM-2.5 that are emitted.

**Methodology**

Uncontrolled Emissions Rate (Tons/Yr):

Annual Production Rate (Tons Product/Yr) \* Emission Factor (Lbs/Ton Product) / 2000 (Lbs/Ton)

Controlled Emissions Rate (Tons/Yr):

Annual Production Rate (Tons Product/Yr) \* Emission Factor (Lbs/Ton Product) \* (1-Control Efficiency/100) / 2000 (Lbs/Ton)

**Appendix A: Emissions Calculations****Equipment Sanitization****Isopropyl Alcohol Solvent**

**Company Name:** JLM Pharmatech  
**Address City IN Zip:** 2223 Killion Ave., Seymour, IN 47274  
**Permit Number:** R071-31699-00049  
**Plt ID:** 071-00049  
**Reviewer:** Sarah Street  
**Date:** 4/10/2012

Solvent:	Isopropyl Alcohol	
Specific Gravity	0.787	
VOC Content	6.56	lbs/gal
Maximum Annual Amount Used (gallons/yr)	Amt. removed as waste (gallons/yr)	Difference (gallons/yr)
150	0	150

<b>TOTAL VOC EMISSIONS</b>	
	<b>Potential</b>
<b>Lbs/Yr</b>	984.00
<b>Tons/Yr</b>	0.49

**Note: There are no HAP emissions from this operation.**

**Methodology**

VOC content (lbs/gal)\* [no. of gallons used - waste gallons] / (2000 lbs/ton)

**Appendix A: Emissions Calculations  
 Natural Gas Combustion Only  
 MM BTU/HR <10**

**Company Name:** JLM Pharmatech  
**Address City IN Zip:** 2223 Killion Ave., Seymour, IN 47274  
**Permit Number:** R071-31699-00049  
**Plt ID:** 071-00049  
**Reviewer:** Sarah Street  
**Date:** 4/10/2012

<b>Emission Unit ID</b>	<b>Emission Unit Description</b>	<b>Max Heat Input Rating (MMBtu/Hr)</b>
EU-2	Process Heater #1	0.920
EU-12	Process Heater #2	8.000
EU-3	Boiler #1	1.260
EU-13	Boiler #2	8.400
EU-6	Unit Heater #1 (space heating)	0.200
EU-7	Unit Heater #2 (space heating)	0.200
EU-8	Unit Heater #3 (space heating)	0.200
EU-9	Unit Heater #4 (space heating)	0.200
EU-10	Unit Heater #5 (space heating)	0.200
EU-14	Unit Heater #6 (space heating)	0.400
EU-15	Unit Heater #7 (space heating)	0.400
EU-16	Unit Heater #8 (space heating)	0.500
EU-17	Unit Heater #9 (space heating)	0.250

**Total                      21.13**

**Appendix A: Emissions Calculations**

**Natural Gas Combustion Only**

**MM BTU/HR <10**

**Company Name: JLM Pharmatech**

**Address City IN Zip: 2223 Killion Ave., Seymour, IN 47274**

**Permit Number: R071-31699-00049**

**Plt ID: 071-00049**

**Reviewer: Sarah Street**

**Date: 4/10/2012**

Heat Input Capacity MMBtu/hr	HHV mmBtu	Potential Throughput MMCF/yr
21.13	mmscf 1000	185.1

Emission Factor in lb/MMCF	Pollutant						
	PM*	PM10*	direct PM2.5*	SO2	NOx	VOC	CO
	1.9	7.6	7.6	0.6	100 **see below	5.5	84
Potential Emission in tons/yr	0.18	0.70	0.70	0.06	9.25	0.51	7.77

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

PM2.5 emission factor is filterable and condensable PM2.5 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

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

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

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

See following page for HAPs emissions calculations.

**Appendix A: Emissions Calculations**

**Natural Gas Combustion Only**

**MM BTU/HR <10**

**HAPs Emissions**

**Company Name: JLM Pharmatech**

**Address City IN Zip: 2223 Killion Ave., Seymour, IN 47274**

**Permit Number: R071-31699-00049**

**Plt ID: 071-00049**

**Reviewer: Sarah Street**

**Date: 4/10/2012**

HAPs - Organics					
Emission Factor in lb/MMcf	Benzene 2.1E-03	Dichlorobenzene 1.2E-03	Formaldehyde 7.5E-02	Hexane 1.8E+00	Toluene 3.4E-03
Potential Emission in tons/yr	1.944E-04	1.111E-04	6.941E-03	1.666E-01	3.147E-04

HAPs - Metals					
Emission Factor in lb/MMcf	Lead 5.0E-04	Cadmium 1.1E-03	Chromium 1.4E-03	Manganese 3.8E-04	Nickel 2.1E-03
Potential Emission in tons/yr	4.627E-05	1.018E-04	1.296E-04	3.517E-05	1.944E-04

Methodology is the same as previous page.

The five highest organic and metal HAPs emission factors are provided above. Additional HAPs emission factors are available in AP-42, Chapter 1.4, Table 1.4. See following page for Greenhouse Gas calculations.

**Appendix A: Emissions Calculations**

**Natural Gas Combustion Only**

**MM BTU/HR <100**

**Greenhouse Gas Emissions**

**Company Name: JLM Pharmatech**

**Address City IN Zip: 2223 Killion Ave., Seymour, IN 47274**

**Permit Number: R071-31699-00049**

**Plt ID: 071-00049**

**Reviewer: Sarah Street**

**Date: 4/10/2012**

	Greenhouse Gas		
	CO2	CH4	N2O
Emission Factor in lb/MMcf	120,000	2.3	2.2
Potential Emission in tons/yr	11,106	0.2	0.2
Summed Potential Emissions in tons/yr	11,106		
CO2e Total in tons/yr	11,174		

**Methodology**

The N2O Emission Factor for uncontrolled is 2.2. The N2O Emission Factor for low Nox burner is 0.64.

Emission Factors are from AP 42, Table 1.4-2 SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03.

Global Warming Potentials (GWP) from Table A-1 of 40 CFR Part 98 Subpart A.

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

CO2e (tons/yr) = CO2 Potential Emission ton/yr x CO2 GWP (1) + CH4 Potential Emission ton/yr x CH4 GWP (21) + N2O Potential Emission ton/yr x N2O GWP (310).

**Appendix A: Emissions Calculations  
Allowable Particulate Emissions**

**Company Name:** JLM Pharmatech  
**Address City IN Zip:** 2223 Killion Ave., Seymour, IN 47274  
**Permit Number:** R071-31699-00049  
**Pit ID:** 071-00049  
**Reviewer:** Sarah Street  
**Date:** 4/10/2012

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

<b>Emission Unit</b>	<b>Process Weight Rate (tons/hr)</b>	<b>Allowable PM Emissions Pursuant to 326 IAC 6-3-2 (lb/hr)</b>	<b>Potential PM Emissions (lb/hr)*</b>	<b>Able to Comply</b>
Spray Dryer #1	0.048	0.551	9.216E-05	yes
Spray Dryer #2	0.880	3.76	7.04E-05	yes
Tablet Press Process	0.017	0.551	0.34	yes

E = 4.10 P<sup>0.67</sup> where E = rate of emission in pounds per hour and  
P = process weight rate in tons per hour

\*Potential PM Emissions for Spray Dryer #1 and Spray Dryer #2 are after integral controls.  
Potential PM Emissions for Tablet Press Process is before controls. The Tablet Press Process is able to comply before controls with this limitation.



# INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

*We Protect Hoosiers and Our Environment.*

*Mitchell E. Daniels Jr.*  
**Governor**

*Thomas W. Easterly*  
**Commissioner**

100 North Senate Avenue  
Indianapolis, Indiana 46204  
(317) 232-8603  
Toll Free (800) 451-6027  
[www.idem.IN.gov](http://www.idem.IN.gov)

## **SENT VIA U.S. MAIL: CONFIRMED DELIVERY AND SIGNATURE REQUESTED**

**TO:** James A Crook  
JLM Pharmatech  
2629 S Hanley Rd  
St Louis, MO 63144

**DATE:** April 25, 2012

**FROM:** Matt Stuckey, Branch Chief  
Permits Branch  
Office of Air Quality

**SUBJECT:** Final Decision  
Registration  
071-31699-00049

Enclosed is the final decision and supporting materials for the air permit application referenced above. Please note that this packet contains the original, signed, permit documents.

The final decision is being sent to you because our records indicate that you are the contact person for this application. However, if you are not the appropriate person within your company to receive this document, please forward it to the correct person.

A copy of the final decision and supporting materials has also been sent via standard mail to:  
Thomas Tod (Burns & McDonnell Engineering Company)  
OAQ Permits Branch Interested Parties List

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178, or toll-free at 1-800-451-6027 (ext. 3-0178), and ask to speak to the permit reviewer who prepared the permit. If you think you have received this document in error, please contact Joanne Smiddie-Brush of my staff at 1-800-451-6027 (ext 3-0185), or via e-mail at [jbrush@idem.IN.gov](mailto:jbrush@idem.IN.gov).

Final Applicant Cover letter.dot 11/30/07

# Mail Code 61-53

IDEM Staff	CDENNY 4/25/2012 JLM Pharmatech 071-31699-00049 (final)		AFFIX STAMP HERE IF USED AS CERTIFICATE OF MAILING	
Name and address of Sender		Indiana Department of Environmental Management Office of Air Quality – Permits Branch 100 N. Senate Indianapolis, IN 46204	Type of Mail:  <b>CERTIFICATE OF MAILING ONLY</b>	

Line	Article Number	Name, Address, Street and Post Office Address	Postage	Handing Charges	Act. Value (If Registered)	Insured Value	Due Send if COD	R.R. Fee	S.D. Fee	S.H. Fee	Rest. Del. Fee	Remarks
1		James A Crook JLM Pharmatech 2629 S Hanley Rd St Louis MO 63144 (Source CAATS)										
2		Jackson County Commissioner Jackson County Courthouse Brownstown IN 47220 (Local Official)										
3		Mr. Wendell Hibdon Plumbers & Steam Fitters Union, Local 136 2300 St. Joe Industrial Park Dr Evansville IN 47720 (Affected Party)										
4		Mr. Tome Earnhart 3960 N. CR 300 W. North Vernon IN 47265 (Affected Party)										
5		Seymour City Council and Mayors Office 301 North Chestnut Street Seymour IN 47274 (Local Official)										
6		Jackson County Health Department 801 West 2nd Street Seymour IN 47274-2711 (Health Department)										
7		Thomas Tod Burns & McDonnell Engineering Company, Inc. 425 South Woods Mill Road, Suite 300 Chesterfield MO 63017 (Consultant)										
8		Beacon Seymour, LLC 912 Walnut Street Edinburgh IN 46124 (Affected Party)										
9		Aisin USA Manufacturing, Inc. 1700 East Fourth Street Road Seymour IN 47274 (Affected Party)										
10		Excel Manufacturing, Inc. 1705 East Fourth Street Road Seymour IN 47274 (Affected Party)										
11		Bradley J Albright 2245 Killion Avenue Seymour IN 47274 (Affected Party)										
12		DFD Industrial Services, Inc. 7989 East County Raod 50 North Seymour IN 47274 (Affected Party)										
13		Seymour Industrial Corporation 105 South Chestnut Street Seymour IN 47274 (Affected Party)										
14		W. Wayne & Rosellen B. Weihe 6670 N County Raod 1075 East Seymour IN 47 (Affected Party)										
15		Donald & Shelby Pardieck 6693 N. County Road 1000 East Seymour IN 47274 (Affected Party)										

Total number of pieces Listed by Sender	Total number of Pieces Received at Post Office	Postmaster, Per (Name of Receiving employee)	The full declaration of value is required on all domestic and international registered mail. The maximum indemnity payable for the reconstruction of nonnegotiable documents under Express Mail document reconstructing insurance is \$50,000 per piece subject to a limit of \$50, 000 per occurrence. The maximum indemnity payable on Express mil merchandise insurance is \$500. The maximum indemnity payable is \$25,000 for registered mail, sent with optional postal insurance. See <b>Domestic Mail Manual R900, S913, and S921</b> for limitations of coverage on inured and COD mail. See <b>International Mail Manual</b> for limitations o coverage on international mail. Special handling charges apply only to Standard Mail (A) and Standard Mail (B) parcels.
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											Remarks
1		James C & Ruthann M 6678 N. County Road 1000 East Seymour IN 47274 (Affected Party)									
2		Kevin & Lisa Imlay 6636 North County Road 1000 East Seymour IN 47274 (Affected Party)									
3		Richard L. & Marilyn Mellencamp 2300 North Ewing Street Seymour IN 47274 (Affected Party)									
4		Joseph E. & Rita Jo Schepman 1443 Killion Avenue Seymour IN 47274 (Affected Party)									
5		Whittymore, LLC 1585 North County Road 180 East Brownstown IN 47220 (Affected Party)									
6											
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