Monica

Pfizer Inc
7000 Portage Road
Kalamazoo, Michigan 49001

Ms. Karen Kajiya-Mills
Supervisor, Technical Programs Unit
Air Quality Division
Michigan Department of Environment, Great Lakes, and Energy
Constitution Hall, 3rd Floor
525 W. Allegan Street
Lansing, Michigan 48933

via **FedEx**

Subject: Applicability of Pharmaceutical NESHAP for VCF Process Final Test Report

Dear Ms. Kajiya-Mills:

A performance test was conducted April 15-23, 2019 on a pilot scale batch fermentation process at the Pharmacia & Upjohn Company LLC, a subsidiary of Pfizer Inc, pharmaceutical manufacturing facility in Kalamazoo, Michigan. The purpose of this performance test was to determine the applicability of the Pharmaceuticals NESHAP (40 CFR 63 Subpart GGG) to a new batch fermentation process called VCF by monitoring HAPs continuously throughout the entire process. The test plan was reviewed and approved by the Michigan Department of Environment, Great Lakes, and Energy on February 22, 2019.

A copy of the performance test report from EPI is enclosed with this letter. The average total HAP concentration from the process run was 45.80 ppmv, which is below the process vent criteria of 50 ppmv. As noted in the report, this is a conservative calculation as it includes the method detection limit for non-detect readings.

Based on the test results, we conclude that the VCF process emissions do not meet the Pharmaceutical NESHAP definition of a process vent.

If you should have any questions, please call me at (269) 833-2007.

Sincerely,

Nathan Lucas
EHS Specialist
PGS Kalamazoo Site

Enclosure

c EGLE AQD Monica Brothers, Kalamazoo District Office

DEQ

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION

RENEWABLE OPERATING PERMIT REPORT CERTIFICATION

Authorized by 1994 P.A. 451, as amended. Failure to provide this information may result in civil and/or criminal penalties.

Reports submitted pursuant to R 336.1213 (Rule 213), subrules (3)(c) and/or (4)(c), of Michigan's Renewable Operating Permit (ROP) program must be certified by a responsible official. Additional information regarding the reports and documentation listed below must be kept on file for at least 5 years, as specified in Rule 213(3)(b)(ii), and be made available to the Department of Environmental Quality, Air Quality Division upon request.

Source Name: Pharmacia & Upjohn LLC, a subsidiary of Pfizer Inc County: Kalamazoo

Source Address: 7000 Portage Rd. City: Kalamazoo

AQD Source ID (SRN): B3610 ROP No.: MI-ROP-B3610-2014 ROP Section No.: 3

Please check the appropriate box(es):

☐ **Annual Compliance Certification (Pursuant to Rule 213(4)(c))**

Reporting period (provide inclusive dates): From _____ To _____

☐ 1. During the entire reporting period, this source was in compliance with **ALL** terms and conditions contained in the ROP, each term and condition of which is identified and included by this reference. The method(s) used to determine compliance is/are the method(s) specified in the ROP.

☐ 2. During the entire reporting period this source was in compliance with all terms and conditions contained in the ROP, each term and condition of which is identified and included by this reference, **EXCEPT** for the deviations identified on the enclosed deviation report(s). The method used to determine compliance for each term and condition is the method specified in the ROP, unless otherwise indicated and described on the enclosed deviation report(s).

☐ **Semi-Annual (or More Frequent) Report Certification (Pursuant to Rule 213(3)(c))**

Reporting period (provide inclusive dates): From _____ To _____

☐ 1. During the entire reporting period, **ALL** monitoring and associated recordkeeping requirements in the ROP were met and no deviations from these requirements or any other terms or conditions occurred.

☐ 2. During the entire reporting period, all monitoring and associated recordkeeping requirements in the ROP were met and no deviations from these requirements or any other terms or conditions occurred, **EXCEPT** for the deviations identified on the enclosed deviation report(s).

☒ **Other Report Certification**

Reporting period (provide inclusive dates): From 4/15/2019 To 4/23/2019

Additional monitoring reports or other applicable documents required by the ROP are attached as described:

Determinaition of Pharmaceutical NESHAP for VCF Process, per 40 CFR 63 Subpart GGG

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in this report and the supporting enclosures are true, accurate and complete

Ron Perry	Site Leader	269-833-0196
Name of Responsible Official (print or type)	Title	Phone Number
Signature of Responsible Official		16 MAY 2019 Date

* Photocopy this form as needed

EQP 5736 (Rev 11-04)

DETERMINATION OF APPLICABILITY OF THE PHARMACEUTICALS NESHAP TO THE VCF FERMENTATION PROCESS

TEST REPORT

The Pharmacia & Upjohn Company LLC
A Subsidiary of Pfizer Inc
7000 Portage Road
Kalamazoo, Michigan 49001

A Subsidiary of Pfizer Inc
Kalamazoo, Michigan

Test Dates: April 15 – April 23, 2019

Report Date: May 10, 2019

Prepared by:

Environmental Partners, Inc.
305 Hoover Boulevard, Suite 200
Holland, Michigan 49423

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EPI
Environmental Partners Inc.

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1.0 INTRODUCTION

Hazardous Air Pollutant (HAP) emission testing was conducted on the VCF pilot scale fermentation process at the Pharmacia & Upjohn Company (a subsidiary of Pfizer Inc) facility located in Kalamazoo, Michigan. The tests were performed on the batch which started on April 15, 2019, and was completed on April 23, 2019. FTIR test data was collected continuously over the entire batch period, with the exception of brief periods during which the FTIR was down for purposes of daily QA/QC, a brief power outage, and a period during which the FTIR liquid nitrogen was depleted.

Testing was conducted in accordance with the test plan submitted by Pfizer to the DEQ on February 8, 2019. The test plan was titled, *"Test Plan for Determination of Applicability of the Pharmaceuticals NESHAP to a Fermentation Process – VCF Fermentation Process,"* and was dated February 2019. A copy of the DEQ test plan approval letter dated February 22, 2019 is included in Appendix A.

The test program was performed by Phil Kauppi and Blake Ericson of Prism Analytical Technologies, Inc., and coordinated by Nathan Lucas of Pfizer, and Mark Horne of Environmental Partners, Inc. The test was observed by Tom Gasloli and Monica Brothers of the DEQ AQD (now EGLE AQD).

2.0 PURPOSE OF THE TEST PROGRAM

The purpose of the test program was to characterize the concentration of total organic HAPs present in the exhaust stream of the pilot scale VCF fermentation batch process. The average total HAPs concentration is to be used for purposes of determining whether the OCA process is subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production Operations (40 CFR 63 Subpart GGG). To be subject to the NESHAP, the fermentation process exhaust must meet the definition of a "process vent" ($\geq$50 ppmv undiluted total HAPs, per 40 CFR 63.1251).

3.0 PROCESS DESCRIPTION

The emission test was performed on the exhaust from Fermenter No. 429. The VCF batch volume was approximately 250 liters. The aeration rate ranged from 200 to 250 standard liters per minute (slpm) over the batch period. The fermenter was maintained under a positive static pressure of 5 psig. The FTIR sampling test port was located on the fermenter exhaust vent which discharges directly to atmosphere undiluted & uncontrolled.

The VCF fermentation batch was inoculated at 15:00 on April 15, 2019, and the batch was completed at 15:00 on April 23, 2019.

4.0 DESCRIPTION OF THE TEST PROGRAM

The USEPA OAQPS approved Method 320 as a valid alternative to Method 18 for purposes of demonstrating whether a pharmaceutical process vent is to be considered a NESHAP subject process vent as defined in 40 CFR 63.1251. Accordingly, Method 320 was utilized for the on-site sampling and analysis for this test program.

USEPA Method 320 testing was performed using an MKS Multigas Model 2030 extractive Fourier Transform Infrared (FTIR) spectrometer. The fermenter exhaust vent pressure was maintained at 5 psig throughout the duration of the batch. M320 testing commenced just after the batch was inoculated, and was completed just prior to completion of the batch. The VCF fermentation batch was inoculated at 15:00 on April 15, 2019, and was completed at 15:00 on April 23, 2019, for a total batch length of 192 hours.

The FTIR continuously monitored the fermenter exhaust around the clock. Daily calibrations required the instrument to be taken off line for less than an hour each day. As a result, over 23 hours of monitoring data was obtained each day, with the exception of the days that encompassed the building power outage and the period during which the FTIR was low on liquid nitrogen.

On April 15, 2019, FTIR data was not collected from 16:26 to 17:40 due to a power loss to the fermentation building. Also, from 17:39 on 04/20/19 to 09:32 on 04/21/19, FTIR readings were not collected due to the liquid nitrogen having not been replenished. These two periods resulted in a total of just over 17 hours of data not being collected.

When accounting for the periods the FTIR was offline due to the scheduled calibrations and unscheduled outages, a total of just over 173 hours of FTIR data was collected over the course of the 192 hour VCF batch, which represents over 90% of the batch time.

5.0 *RESULTS OF THE TEST PROGRAM*

The result of the test program is summarized below. The HAPs that were detected were formaldehyde, methanol, and acetaldehyde. The average concentrations of formaldehyde and methanol were below their respective method detection limits. The total HAP concentration over the course of the batch reflects the average acetaldehyde concentration, plus the respective method detection limits for formaldehyde and methanol. The test result is summarized below:

Test Started	Test Completed	Total HAPs Incl Detection Limits, Averaged Over the Test Period (ppmv)
April 15, 2019 15:17	April 23, 2019 15:00	< 45.80

The results shown above reflect the inclusion of method detection limits for the respective analytes for those minutes where an analyte was not detected, as shown in the Table 4 summary of the Prism test report. Therefore, the above is a worst case result for total organic HAPs.

Process parameters are included in Appendix B. The complete Method 320 Prism Analytical test report is included in Appendix C.

6.0 CONCLUSION

Based on the average total HAP concentration (< 45.80 ppmv) measured in the exhaust from the VCF pilot fermentation process, it is concluded that this process exhaust does not meet the process vent definition as described under 40 CFR 63.1251 of the Pharmaceuticals NESHAP (40 CFR 63 Subpart GGG) since it contains less than 50 ppmv total HAP.