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

TEST REPORT

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Test Dates: April 15 – April 23, 2019

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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.