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

TEST REPORT

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AIR QUALITY DIVISION

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: July 13 – July 22, 2017

Report Date: August 7, 2017

Prepared by:

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

EPI
Environmental Partners Inc.

1.0 INTRODUCTION

Hazardous Air Pollutant (HAP) emission testing was conducted on the OCA pilot scale fermentation process at the Pharmacia & Upjohn Company (a subsidiary of Pfizer Inc) facility located in Kalamazoo, Michigan. The tests were performed over the entire batch starting July 13, 2017, and ending July 22, 2017. Testing was conducted in accordance with the test plan titled, *"Test Plan for the Determination of Applicability of the Pharmaceutical NESHAP to a Fermentation Process,"* as originally issued on February 17, 2017, and as amended June 2017 consistent with the June 22, 2017 e-mail communication from John Ring of Pfizer to Dennis Dunlap and Dave Patterson of the Michigan DEQ (MDEQ) Air Quality Division (AQD), a copy of which is included in Appendix A.

The test plan was acknowledged and the test methods and process parameters were confirmed by the MDEQ in their letter dated July 5, 2017 (see Appendix A). The test program was performed by Phil Kauppi and Blake Ericson of Prism Analytical Technologies, Inc., and coordinated by John Ring of Pfizer, and Mark Horne of Environmental Partners, Inc. The test was observed by David Patterson, Dennis Dunlap, and Monica Brothers of the MDEQ 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 fermentation batch process, identified as OCA. The average total HAPs concentration will be utilized 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" (≥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 OCA batch volume was approximately 250 liters. The aeration rate ranged from 5 to 100 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 OCA fermentation batch was inoculated at 08:30 on July 13, 2017, and the batch was completed at 08:00 on July 22, 2017.

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 at 11:37 on July 13, 2017, and was completed at 08:00 on July 22, 2017 upon completion of the batch. The FTIR was operated continuously around the clock. Daily calibrations required the instrument to be taken off line for about an hour each day. As a result, just over 23 hours of monitoring data was obtained each day.

5.0 RESULTS OF THE TEST PROGRAM

The results of the test program are summarized below. The HAPs that were detected include formaldehyde, methanol, and acetaldehyde. No other HAPs were detected. Total HAP concentrations are summarized below:

Test Started	Test Completed	Total HAPs Incl Detection Limits, Averaged Over the Test Period (ppmv)
July 13, 2017 08:30	July 22, 2017 08:00	42.35

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 (42.35 ppmv) measured in the exhaust from the OCA 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.