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

TEST REPORT

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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: May 3 – 5, 2017

Report Date: May 31, 2017

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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 on May 3, 4, and 5, 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,"* dated February 17, 2017.

The test plan was acknowledged and the test methods and process parameters were confirmed by the MDEQ in their letter dated April 24, 2017 (see Appendix A). The test program was performed by Blake Ericson of Prism Analytical Technologies, Inc., and coordinated by John Ring of Pfizer, and Mark Horne of Environmental Partners, Inc. The test on May 4th was witnessed by Dennis Dunlap, Monica Brothers, and David Patterson of the Michigan Department of Environmental Quality Air Quality Division.

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 a pilot scale fermentation process, identified as OCA. The average total HAPs concentration data from the three test runs 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 45 to 100 standard liters per minute (slpm) over the test 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 08:00 May 2, 2017. The glucose (feed) for the process began 24 hours after inoculation, and was shut down on May 7, 2017 at about 02:00. The batch was completed at 13:00 May 11, 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.

Three 1-hour USEPA Method 320 tests were performed using an MKS Multigas Model 2030 extractive Fourier Transform Infrared (FTIR) spectrometer. The FTIR sample gas flow rate was approximately 10 liters per minute throughout the duration of the three test runs. The exhaust vent pressure was maintained at approximately 5 psig throughout the duration of the three tests.

The three test runs were performed on three different days for the purpose of characterizing representative periods of the batch process. The three periods included increasing OUR, peak OUR, and a sustained period of elevated OUR. The three test run times were as follows:

Test Run Number	Date	Time
1	May 3, 2017	14:00 – 15:00
2	May 4, 2017	09:00 – 10:00
3	May 5, 2017	08:45 – 09:45

The field test data sheets, process parameters, and Method 320 concentration summary tables are included in Appendix B. The complete Method 320 Prism Analytical test report is included in Appendix C.

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 Run	Date	Time	Total HAPs Actual Readings (ppmv)	Total HAPs Using Detection Limits (ppmv)
1	May 3, 2017	14:00 – 15:00	6.42	7.94
2	May 4, 2017	09:00 – 10:00	40.86	42.26
3	May 5, 2017	08:45 – 09:45	62.15	62.46
		3 Run Average	36.48	37.55

The results shown above under the heading, "Total HAPs Actual Readings" reflect the actual FTIR instrument readings as shown in the full data summary tables.

The results shown above under the heading, "Total HAPs Using Detection Limits" reflect the method detection limits for the respective analytes, as shown in the Table 4 summary of the Prism test report.

Summary tables of the actual FTIR readings for the three test runs are included in Appendix B. Field test data sheets and process parameters are also included in Appendix B. The complete Method 320 Prism Analytical test report is included in Appendix C.

6.0 CONCLUSION

Based on the three run method detection limit adjusted average total HAP concentration (37.55 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.