DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
**ACTIVITY REPORT: Self Initiated Inspection**

N340146207

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| **FACILITY:** SPI PHARMA | | **SRN / ID:** N3401 |
| **LOCATION:** 1711 TILES COURT, GRAND HAVEN | | **DISTRICT:** Grand Rapids |
| **CITY:** GRAND HAVEN | | **COUNTY:** OTTAWA |
| **CONTACT:** Mindi Harmon , Safety and Health Manager | | **ACTIVITY DATE:** 07/26/2018 |
| **STAFF:** Tyler Salamasick | **COMPLIANCE STATUS:** Compliance | **SOURCE CLASS:** MINOR |
| **SUBJECT:** FY 2018 Unannounced inspection. | | |
| **RESOLVED COMPLAINTS:** | | |

*Clean Air Act Inspection report for* SPI Pharma, Grand Haven, Michigan

***Overview***

SPI Pharma is a bulk manufacturer of pharmaceutical expedients. The facility receives materials in bulk and performs a combination of the following, blending, drying, grinding, screening and fluid bed granulation.

On July 26, 2018 Tyler Salamasick, Environmental Quality Analyst of the Michigan Department of Environmental Quality, Air Quality Division conducted an unannounce, scheduled inspection of SPI Pharma The MDEQ inspected the facility located at 1711 Tiles Court, Grand Haven, Michigan. The purpose of the inspection was to determine the facility's compliance with the requirements of the federal Clean Air Act; Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Act 451); the Air Pollution Control Rules; and Rule 201.

***Compliance History***

SPI Pharma has not received any recent complaints or violation notices.

***Observations and facility processes***

Prior to entering the facility, AQD staff drove around the area and made observations of the facility. I did not detect any odors or visible emissions coming from the facility.

AQD staff met with Mindi Harmon, Environmental Health and Safety Manager, Bob Kayler, Production Manager, Todd Lumbert, Site General Manager, Sonya Warber, Human Resource Manager. AQD staff presented their identification and informed the representatives of the intent of the inspection. The facility representative agreed to show the MDEQ the facility and its processes.

SPI Pharma produces and blends bulk pharmaceutical excipients. The excipients are the inactive or inert substances that act as a medium for the delivery of drugs or active components of a medication. The facility utilizes multiple suites, with varying arrangements to blend, dry, grind, screen and granulate the materials. Each of the suites has its own HVAC system and associated baghouse (dust collector).

AQD staff walked through the facility and inspected the suites. While inspecting the suites, staff observed the associated baghouses and pressure drop gauges. While observing suit 7 it was noted that the process was operating, yet the baghouse did not indicate a pressure drop. AQD staff along with the facility representatives inspected the outside area and the exhaust point of the baghouse. I did not observe visible emissions at the exhaust point. A maintenance manager indicated that there was a possibility that they baghouse was operating correctly but they might just have a plugged line.

The facility's 9 production suites can produce the same product anywhere from 3 days to 120 days, depending on order size and production rate. The facility's processes are currently exempt from requiring a permit pursuant to Rule 290.

***Regulatory analysis and compliance evaluation***

*Facility emission category*

SPI Pharma is a minor source of particulate matter (PM). The facility does not currently have any air quality permits but instead demonstrates their exemption from requiring permits. Mindi Harmon provided the MDEQ AQD with a detailed exemption demonstration that included the facility wide potential to emit calculation. The facility has the potential to emit 48.63 tons of PM per year. This is below the 100 ton per year major source threshold. The facility's actual emissions were exceptionally low, between approximately 3 to 10 kg (6.6 to 22 lbs) per month. This would total a maximum of 264 pounds of emissions per year, or 0.13 tons. The facility's

actual emissions and their potential to emit (50% of major source threshold) is likely due to the conservative emission calculations based upon federally enforceable emission limits. The facility's filtration system is more efficient than included in the PTE calculation.

*Rule 290*
The provided records indicate that the facility uses Rule 290(2)(a)(iii) to demonstrate that the baghouses are exempt from the requirements of Rule 201, which would require a permit. The facility's largest dust collector is 7500 SCFM with a 99.99% control efficiency. This complies with the 30,000 SCFM limit set by Rule 290. The filters on the varying models include a 99.99% HEPA filters, 99.5% 0.5 micron filters and 99.99% 1 micron filters. The facility also maintains an associated monthly material usage spreadsheet and a chemical inventory. The inventory includes associated ITSL and IRSL value, which demonstrate the materials meet the requirements of Rule 290.

Rule 282(2)(a)
The facility has five (5) boilers/ heaters at the facility. The largest boiler is 4.5 MMBtu/Hr. The boilers are under the 10 Mmbtu size restriction as detailed in Rule 282 and appear to not require a permit because they meet the exemption from Rule 201.

***Discussion***
**Concerns:** During the inspection, AQD staff indicated that the baghouse pressure drop should register on the gauge. SPI should frequently inspect the pressure drops on the equipment as it is operating to ensure the filtration system is working properly.

**Compliance statement**: It appears that SPI Pharma is in compliance with the requirements of the federal Clean Air Act; Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Act 451); the Air Pollution Control Rules; and Rule 201.

NAME _____ DATE 9/21/18 SUPERVISOR _____