REGION 3

PHILADELPHIA, PA 19103

Report Title:	Clean Air Act Inspection of Adare Pharma Solutions		
Inspection Date(s):	12/10/2024		
Regulatory Program(s):	SIP, MACT, NSPS		
Company Name:	Adare Pharma Solutions, LLC		
Facility Name:	Adare Pharma Solutions		
Facility Location:	1100 Orthodox St Philadelphia, PA 19124		
Latitude:	40.01863	**Longitude:**	-75.09271
County/Parish:	Philadelphia County		
AFS/ICIS-Air Number:	PAPAM0004210102258		
Permit Number:	P18-000013		
NAICS Code:	325412, 446110	**SIC:**	2834, 5122
DSB ID #:	ECAD-5688		

Facility Representatives: **Point of Contact**

Tyrone Hart, EHS Manager ☒
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EPA Inspectors:

Scott Yanos, Compliance Officer
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Parmatma Adhikari, Compliance Officer
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State/Local Inspectors:

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Phone: 215-685-7575 Email: Duaa.Saleh@phila.gov
Johana Borda-Perez
Phone: Not provided Email: Johana.Borda-Perez@Phila.gov

EPA Lead Inspector Signature	SCOTT YANOS Digitally signed by SCOTT YANOS Date: 2025.01.22 08:56:41 -05'00'	
	Scott Yanos	**Date**
	1600 John F Kennedy Blvd Philadelphia, PA 19103-2852	
Supervisor Signature	KRISTEN HALL Digitally signed by KRISTEN HALL Date: 2025.01.22 10:06:01 -05'00'	
	Kristen Hall	**Date**

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I. Introduction

The United States Environmental Protection Agency (EPA) conducted a Clean Air Act (CAA) inspection at Adare Pharma Solutions (Adare or Facility) to verify compliance with applicable State and Federal regulations. The Air Management Services of Philadelphia (AMS) was notified of the inspection on November 4, 2024 via email. On December 9, 2024, EPA notified the Facility of the planned inspection via phone and email. EPA emailed a list of records for review to Tyrone Hart, EHS Manager, prior to the inspection (see Attachment 1). These records are listed in the Records Review section of the report.

The inspection included an evaluation of the Facility's processes and its compliance with the CAA. All information included in this report is the result of statements by the Facility representatives, materials shown to the inspectors by the Facility representatives, and/or documents provided by the Facility representatives to the inspectors at the time of, or subsequent to, the inspection. In addition, information gathered prior to the inspection from a review of EPA and State records may be included in this report.

A. Summary of the Facility

The Facility is located at 1100 Orthodox St, Philadelphia, PA 19124. Adare Pharma Solutions is a small-scale pharmaceutical manufacturing facility. The facility focuses on producing tablets and capsules for various clients.

The Facility received a Synthetic Minor Permit (OP18-000013) from Philadelphia AMS issued on November 17, 2020.

Adare Pharma Solutions is classified as a synthetic minor source (SM-80) for Volatile Organic Compound (VOC), and Hazardous Air Pollutant (HAP). The Facility is subject to, or potentially subject to the following federal regulations:

- 40 CFR Part 60 Subpart Dc – Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units
- 40 CFR Part 63 Subpart ZZZZ – National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines

B. Inspection Opening Conference

At 09:07 AM on December 10, 2024, EPA inspectors arrived at the Facility for a CAA Inspection and conducted a brief opening conference. Adare Pharma Solutions was represented by Vivek Thapar, Director of Engineering; Tyrone Hart, Environment and Health Safety Manager; and Shawn Watson, Vice President of Quality. Also, Duaa Saleh, Environmental Engineer and Johana Borda-Peres, Specialist Engineer (AMS) were present. EPA inspectors, Scott Yanos and Parmatma Adhikari, presented their credentials and explained the purpose of the visit was to conduct a CAA inspection to determine

compliance with their permit and any applicable regulations. Additionally, EPA informed the Facility representatives of their right to claim any confidential business information (CBI). At that time, Tyrone Hate did not claim any photos or documentation as CBI.

II. Site Activity/Process Description

The Facility that Adare Pharma Solutions was founded under Mutual Pharmaceutical Company in 1984. In 2013, the Facility was acquired by Takeda Pharmaceuticals before being bought out by Frontida BioPharm Inc. in 2016. Adare Pharma Solutions acquired the Facility in 2021. The Facility is open 6 AM to 11 PM, Monday through Friday employing a first and second shift schedule with occasional Saturday shifts needed depending on production and contract obligations. Adare Pharma Solutions has 246 employees with 75 of those employees off site. The entire Facility is 193,000 square feet under roof with the Facility under this permit taking up 26,500 square feet.

Adare Pharma Solutions is a small-scale Good Manufacturing Practices (GMP) Facility providing pharmaceutical tableting and capsule filling to various customers. Ingredients for manufacturing are obtained through venders who go through a qualification process to be certified to sell ingredients for pharmaceutical products. Sometimes, customers provide their own ingredients for the tablets and capsules which they have contracted Adare to produce instead of obtaining the ingredients from venders. All the ingredients and processes in tableting and capsule filling are regulated by the Food and Drug Administration (FDA).

The process of tableting and capsule filling begins with granulation, where fine powder ingredients are made into granules often with the use of alcohol. A dust collector and catalytic oxidizer are used to control the emissions from this process. Once granulation is complete, the granules are sent to the ovens to dry. If alcohol was utilized in the granulation process, catalytic oxidizers are used as an emission control. From here, the granules are placed in drums and sent to milling and blending where the granules are milled down to the desired size and blended with other ingredients. Due to granules ability to still have PM and VOC emissions, the mill and blending processes have dust collector and catalytic oxidizer emission controls. Once milled and blended, the product is sent to tablet pressing which has a dust collector emission control. If desired by the customer, the tablets are sent to coating to be coated. Since the coatings sometimes contain alcohol, these production areas have dust collector and catalytic oxidizer emission controls.

Adare Pharma has eight Dust Collectors in total for these processes and two catalytic oxidizers for emission controls. Every production area has a dust collector emission control. Processes requiring alcohol which includes the alcohol dispensing room, granulation, ovens, milling and blending as well as the coating rooms are split between Catalytic Oxidizer #1 and Catalytic Oxidizer #2 which use natural gas to produce heat the catalyst bed and produce a reaction using the oxidation reaction process maintain a temperature over 650-degree Fahrenheit to accomplish this. Adare Pharma Solutions operates two natural gas boilers used for process heat: a Weil-McLain LGB-23 with a capacity of 2.86

MMBtu/hr and a Weil-McLain LGB-17W/SN with a capacity of 2.08 MMBtu/hr. Adare Parma Solutions has one emergency diesel generator, a Cummins Model DGFB-5704157.

The opening conference concluded at 09:59 AM.

III. Observations

EPA inspectors were led on a walkthrough of the Facility at 11:29 AM by Tyrone Hart, Vivek Thapar and Shawn Watson of Adare Pharma Solutions and Duaa Sale (AMS) and Johana Borda-Perez (AMS) also present for the walkthrough. EPA inspectors noted photos would be taken during the Facility walkthrough (Attachment 2).

The walkthrough began at the alcohol dispensing room where alcohol is dispensed for granulation if needed. We observed the catalytic oxidizer intake for the catalytic oxidizer emission control. Next to this were Rooms #1, #3 and Collette Room #15 H which were granulation rooms. Within these rooms we observed the granulation machinery which is a Glen Mixer used in the granulation process and the intakes for both emission controls, the dust collector and catalytic oxidizer. None of these rooms were being used at the time of inspection.

Next observed were the ovens that dry the granules when water or alcohol is used for granulation. Ovens 9, 10, 11, and 12 are vented to Catalytic Oxidizer 1 and were not being used at the time of inspection. Ovens 18 and 19 are vented to Catalytic Oxidizer 2 and were not being used at the time of the inspection. After the ovens, the walkthrough proceeded to the Coating Room where the coating machine was observed with the intakes for the dust collect and catalytic oxidizer are kept. It was noted by Vivek Thapar that the Coating Room is kept under negative pressure during active production to assist with emissions control.

After the Coating Room, the walkthrough proceeded to Collette #17 which was a room utilized both for granulation, blending and mixing depending on current operational need. It was here that Vivek Thapar that all the milling equipment is wheeled and can be transported to any production area. It is this reason that all production areas at least have an intake to a dust collector.

Once fully blended, the product which is transferred in drums is sent to tableting, which was observed. The drums are loaded onto the tableting machine and a compressor is used to press the granulated mix into pill form. All the tableting press rooms have dust collectors to control emissions which were observed during the inspection.

Once the full process of manufacturing was observed, the walkthrough proceeded to observe the emission controls. Catalytic Oxidizer #1 was shut down for routine maintenance. Catalytic Oxidizer #2 was on with a 700^{o}F internal temperature and 674^{o}F outlet temperature. EPA observed the pressure drop across several dust collectors: Dust Collector 6 had 0.5 inches of water, Dust Collector 4 had 0.8 inches of water, Dust Collector 2 had 0.6 inches of water, Dust Collector 3 had 1.1 inches of water and Dust Collector 1 had 0.6 inches of water. The walkthrough then proceeded to inspect both operating

process natural gas boilers which are a Weil-McLain LGB-23 with a capacity of 2.86 MMBtu/hr and a Weil-McLain LGB-17W/SN with a capacity of 2.08 MMBtu/hr. After, the EPA inspectors inspected the emergency diesel generator, a Cummins Model DGFB-5704157 was recored to have 409.9 hours at the time of inspection and Tyrone Hart said that Foley Caterpillar was contracted to service the emergency generator.

One area not inspected was the high potent processing room due to the need of fully encapsulated suits for personal protection equipment due to use of more potent pharmaceutical ingredients. The EPA inspectors asked Tyrone Hart if all the processes were the same as what was already explained and observed and Tyrone Hart confirmed this. The EPA inspectors were able to observe the granulation, mixing and blending equipment observed in the walkthrough through windows and confirm the intakes for both dust collector and oxidizer emission controls.

The walkthrough concluded at 12:51 PM.

IV. Records Review

The records review commenced immediately after the opening conference before the facility walk through at 10:00 AM. EPA inspectors reviewed documents requested in the December 9, 2024 email to Tyrone Hart (see Attachment 1). Records were provided at the time of the inspection by Tyrone Hart. Below are the records requested and what was provided:

1. Provide a plot plan of the Facility. The plot plan should identify each production process unit to include but not limited to: pharmaceutical preparation and manufacturing
   Provided at the time of inspection

2. Provide a detailed process description of the Facility. This should include a description of each production process unit to include but not limited to: pharmaceutical preparation and manufacturing
   Provided at the time of inspection

3. For each of the pharmaceutical process production unit, provide the following information:
   a. Date of construction, date operation commenced at the Facility;
   b. Date the unit was modified or reconstructed;
   c. Provide the current and historical (as built) production capacity for each unit;
   Was not provided at the time of inspection, Tyrone Hart said the documents will be provided post inspection via secure link.

4. A list of all combustion sources at the Facility such as furnaces, boilers, and/or engines.
   a. For each boiler or engine identified, provide:
      i. Date of installation;
      ii. Type of fuel(s) combusted;
      iii. Maximum heat input rating (MMbtu, HP or kW/hr);

iv. Days each unit operated and hours of operation[1] monthly from January 2022 to the present.

b. Fuel usage on a monthly basis for any combustion equipment at the Facility (boilers, emergency generators, fire pumps, etc.) since January 2022.

c. Records of each tune-up conducted at each unit since January 2022.
Was not provided at the time of inspection, Tyrone Hart said the documents will be provided post inspection via secure link.

5. Provide copies of the emission statements submitted to Philadelphia AMS for the years 2020-2024. These emission statements shall include the emission factors used to determine emissions and the derivation of each factor (stack test, CEMS, AP-42, etc.).
Provided at the time of inspection.

6. Annual emissions calculations (preferably emailed in an unlocked Microsoft Excel format) since 2020, including but not limited to:
   a. Monthly rolling emissions of VOCs, HAPs and NOx for each process unit and facility wide along with supporting calculations for 2020-2024 (lbs/hr).
   Provided at the time of inspection.

7. Provide a list of any and each control device currently in use at Adare Pharma Solutions used to control or reduce emissions from any emission point at the site. The list should include:
   a. The make/model of the control;
   b. Date of installation at the Facility;
   c. Which pollutant(s) are being controlled;
   d. Each source or emission point being controlled;
   e. The capture and destruction efficiency for each control;
   Was not provided at the time of inspection, Tyrone Hart said the documents will be provided post inspection via secure link.

8. Copies of any stack tests conducted on any pharmaceutical process units to determine emission rate, control efficiency, or for compliance demonstrations, etc. conducted at the Facility since 2010.
Provided at the time of inspection.

9. Provide a list of each request for permit determination or permit application submitted to the Philadelphia AMS since January 2020. Also, provide a list of each permit or permitting determination issued to Adare Phama Solutions. This should include the date of the request/permit and the permit number, if applicable.
Provided at the time of inspection.

[1] Hours of operation for each month should identify whether the hours were for testing, emergency, or non-emergency purposes.

10. Provide copies of any initial notifications, compliance reports, and/or periodic reports submitted to either EPA or Philadelphia AMS pursuant to applicable regulations under 40 C.F.R. Part 60 and 63.
    Provided at the time of inspection.

Records review concluded at 11:22 AM.

V. Closing Conference

After the records review, EPA inspectors, Tyrone Hart, Vivek Thapar, and Shawn Watson of Adare Pharma Solutions and Duaa Saleh and Johana Borda-Perez of AMS had a brief closing conference to ask additional questions and discuss observations. The EPA inspectors noted that the investigation is on-going, and any areas of concern identified in the final report do not necessarily reflect a violation or deviation, rather, they are areas that will require further investigation. EPA also noted that they would issue an inspection report within 60 days, with a copy to the State. Simultaneously, EPA will perform a detailed review of records and may have additional questions. The inspection concluded at 01:02 PM.

The following have been identified as potential issues during the inspection. They are issues that require either further investigation by EPA or additional information or explanation by Tyrone Hart.

- According to their Synthetic Minor Operating Permit No. OP18-000013 for Adare Pharma Solutions, Catalytic Oxidizer #1 and #2 shall perform a stack test every five years to demonstrate compliance with the 95% VOC destruction efficiency and it has been 7 years since the last stack test for Catalytic Oxidizer #1 and Catalytic Oxidizer #2's stack test needs to be completed in 2025.
- Adare Pharma Solutions did not have several of the requested records at the time of inspection. Adare Pharma Solutions has stated that they will get the records to the EPA Inspectors post inspection. At the time of this inspection report, those records had not been received by the EPA.

VI. List of Attachments

Attachment 1:	Email correspondence to Tyrone Hart of records requested to review during inspection
Attachment 2:	Photo Log
Attachment 3:	Sign-in Sheet

From: Yanos, Scott (he/they)
To: Tyrone Hart; Denise Richards
Cc: Duaa Saleh; Adhikari, Parmatma
Subject: Upcoming EPA Clean Air Act Inspection at Adare Pharma Solutions
Date: Monday, December 9, 2024 10:41:00 AM
Attachments: image003.png
image004.png
image005.png
Adare Pharma Solutions Inspection Record Request.docx
Importance: High

Dear Mr. Tyrone Hart:

I have tried to contact you via phone but have been unable to get a hold of you so I am following up with this email. I will continue to try and call in case you have any questions or concerns. I am contacting you because EPA Region 3 will be conducting a Clean Air Act (CAA) inspection of Adare Pharma Solutions on December 10, 2024. My colleague, Parmatma Adhikari, and I anticipate arriving at 1100 Orthodox Street, Philadelphia, PA 19124 around 9:00 AM. We would like to begin with an opening meeting that will provide EPA with the current and historical operations at the facility and a brief overview of its process(es).

The scope of the inspection will include, but may not be limited to, a review of all air pollution sources, a facility walk-through (during which photographs will be taken), and a review of records. Philadelphia AMS been notified of the inspection and plans to attend.

To help facilitate the inspection, it would be appreciated if the records in the attached document were made available for review.

Please confirm receipt of this message and don't hesitate to contact me with any questions.

Regards,

Scott Yanos
Life Scientist (Enforcement and Compliance Officer)
Enforcement & Compliance Assurance Division
US EPA Mid-Atlantic Region
Phone 215-814-2128
Email yanos.scott@epa.gov

Attachment 2:
PHOTO LOG

Facility: Adare Pharma Solutions

Location: Philadelphia, PA

Inspection Date: December 10, 2024

EPA Inspector(s): Scott Yanos, Parmatma Adhikari

Photographer: Parmatma Adhikari

Photo Number: 001
Photo Description: Alcohol Room

Photo Number: 002
Photo Description: Glen Mixer with Dust Collector Intake

Photo Number: 003
Photo Description: Controls for the Drying Ovens

Photo Number: 004
Photo Description: Drying Ovens 9, 10 and 11

Photo Number: 005
Photo Description: Coating Room with intake to RTO-2

Photo Number: 006
Photo Description: Milling Equipment

Photo Number: 007
Photo Description: Blending Room

Photo Number: 008
Photo Description: Tablet Pressing Room with Dust Collector Intake

Photo Number: 009
Photo Description: Control Panel for Oxidizer #2

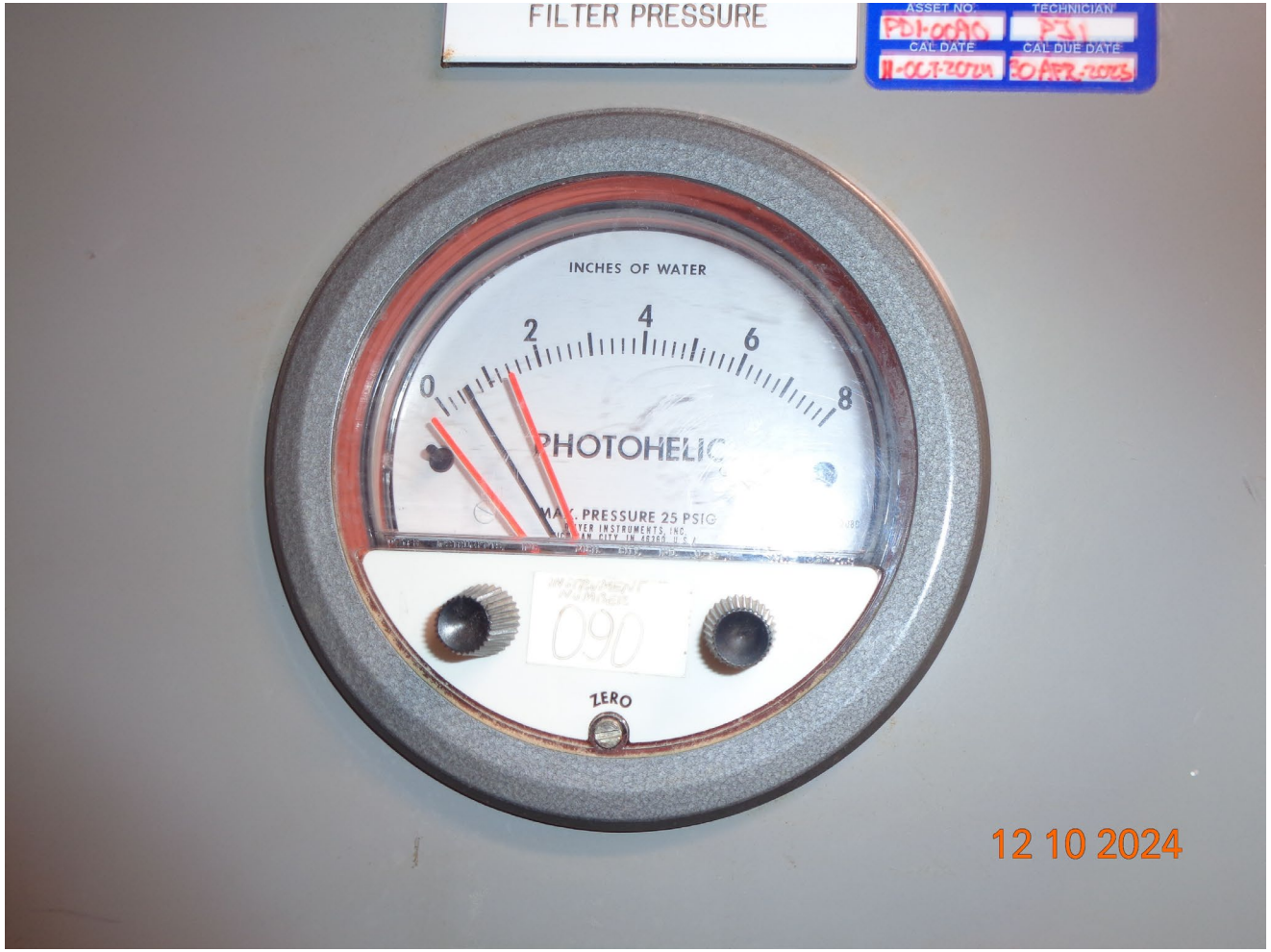

Photo Number: 010
Photo Description: Pressure Gauge for Dust Collector #6

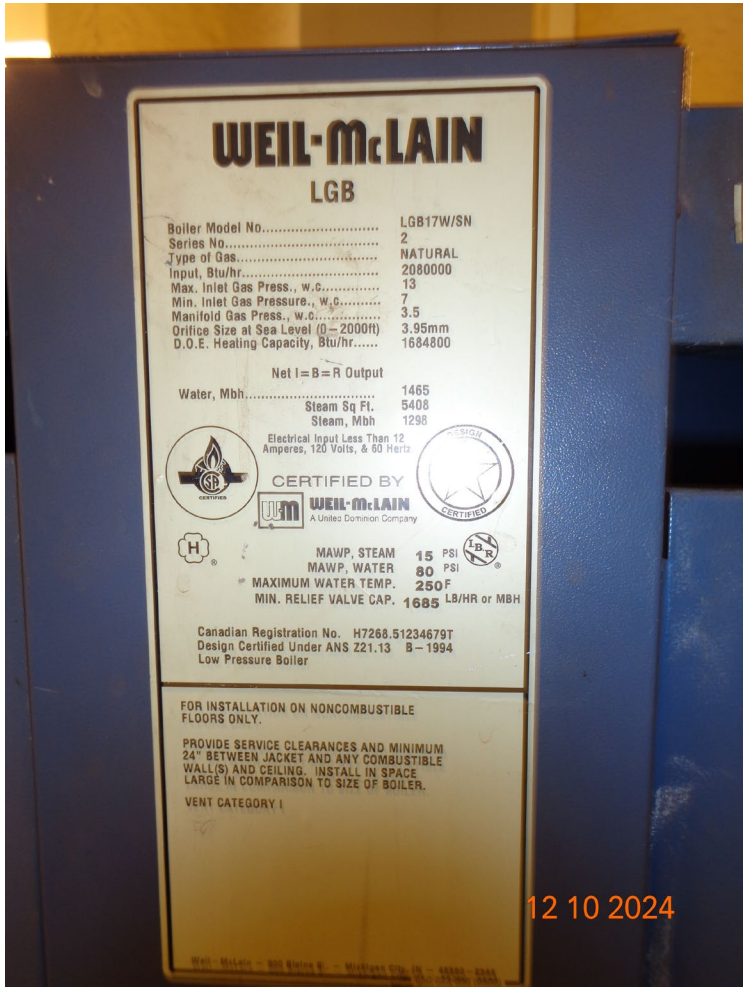

Photo Number: 011
Photo Description: Boiler #1 Information Panel

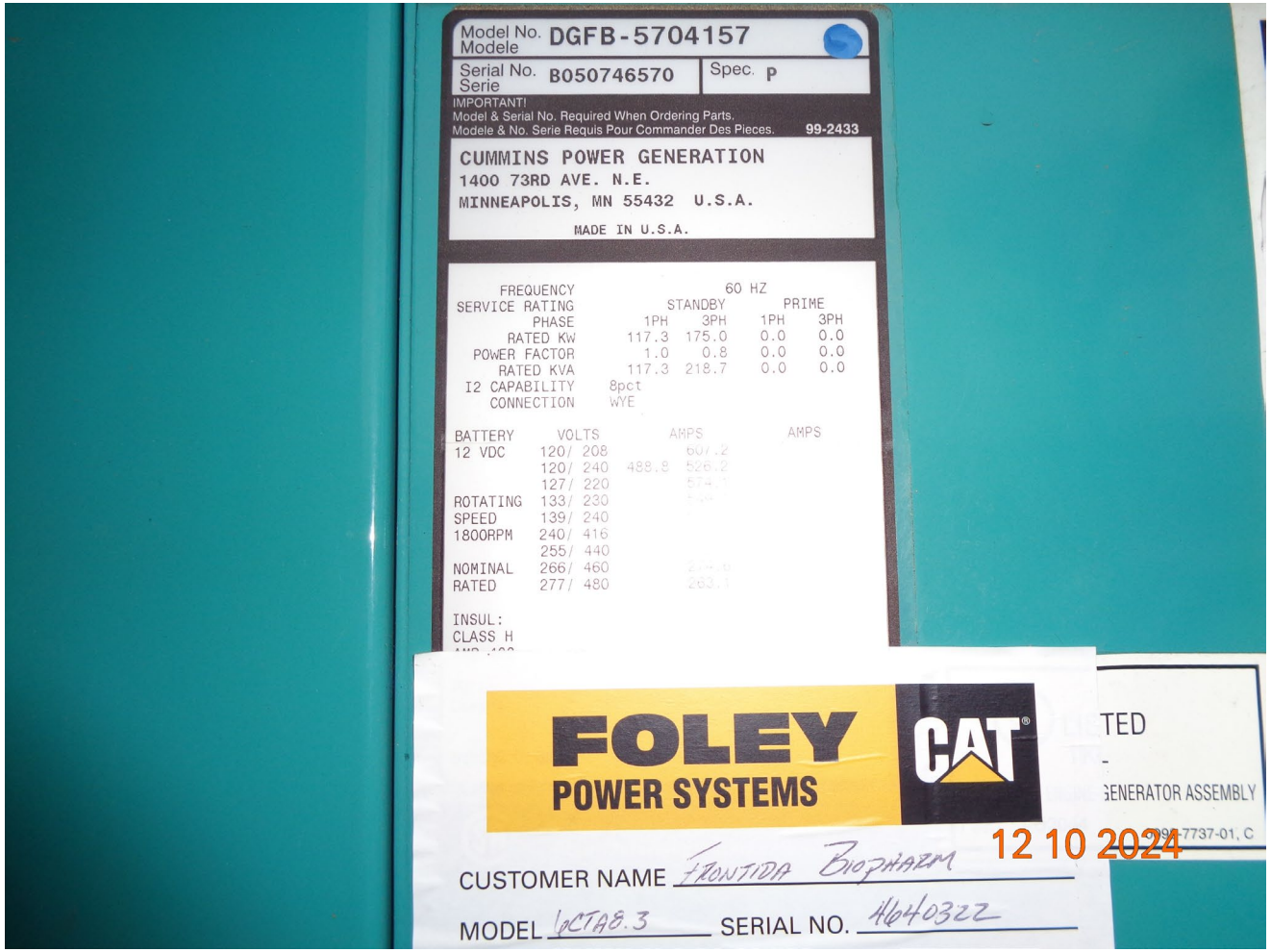

Photo Number: 012

Photo Description: Emergency Generator Information Panel

Inspection Sign-In Sheet

Facility: Adare Pharma Solutions
Date: 12/10/2024

Name	Affiliation	Title	Phone Number	Email
Scott Yanos	US ~~EA~~ EPA	Compliance Officer	215-814-2128	Yanos.Scott@epa.gov
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Johana Borda Perez	AMS Philadelphia	Specialist Engineer		Johana.bordaPerez@Phila.gov
Parmatma Adhikari	EPA	Air Inspector	215-814-2161	Adhikari.parmatma@epa.gov