



CLEAN WATER ACT INSPECTION REPORT
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, ILLINOIS 60604

Purpose: Pretreatment Industrial User (IU) Inspection

Facility: Woodstock Sterile Solutions
2210 Lake Shore Drive
Woodstock, IL 60098

Date of Inspection: April 18, 2025

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Water Enforcement and Compliance Assurance Branch, Section 1

Inspector Signature: JEREMIAH LEGGETT Digitally signed by JEREMIAH LEGGETT
Date: 2025.06.06 12:40:07 -05'00'

Report Date: 6/6/25

Approver Name and Title: Molly Smith, Section 1 Supervisor,
Water Enforcement and Compliance Assurance Branch, Section 1
U.S. EPA Region 5 Enforcement and Compliance Assurance Division

Approver Signature: MOLLY SMITH Digitally signed by MOLLY SMITH
Date: 2025.06.06 13:58:26 -05'00'

Approval Date: 6/6/25

Purpose of Inspection:

The purpose of the inspection performed by the U.S. Environmental Protection Agency (EPA) was to investigate elements of the Clean Water Act (CWA) and associated pretreatment regulations with respect to Woodstock Sterile Solutions, located at 2210 Lake Shore Drive Woodstock, IL 60098.

Background:

Woodstock is an indirect industrial discharger to the City of Woodstock's (City's) south wastewater treatment plant (WWTP) (NPDES No. IL0034282) located at 800 Diekman Road, Woodstock, Illinois. EPA is the control authority for the facility as the City currently does not administer an approved pretreatment program for Woodstock Sterile Solutions. During the inspection it was found that the City is currently in development of a pretreatment program for Woodstock Sterile Solutions. The facility shared the draft wastewater permit drafted by the City.

Woodstock Sterile Solutions became the official name for the facility in March 2021. Prior to that the facility was known as Catalent Pharma Solutions. Production started at the facility in 1982 under a previous owner. The original operations was four Blow-Fill & Seal (BFS) production lines. Woodstock now operates 33 BFS production lines on-site.

The Woodstock facility is approximately 430,000 square feet (sq. ft.) under roof, which includes approximately 146,075 sq. ft. of production, 209,627 sq. ft. of warehouse and 74,268 sq. ft. of utilities and administrative office space. Woodstock's Standard Industrial Classification (SIC) is #2834, "Pharmaceutical Preparations", and its NAICS is #325412 "Pharmaceutical Preparation Manufacturing".

Woodstock's operations consist of aseptic custom packaging of pharmaceutical drugs utilizing BFS technology. Woodstock utilizes 33 processing suites with formulation tank rooms, BFS operations and final packaging. Within each of these suites, third party drug products are blended with treated (softened, reverse osmosis (RO) and de-ionized) sterile water, raw materials and active pharmaceutical ingredients (APIs). All water used in the manufacturing process is treated and sourced from three private wells owned and operated by Woodstock on the facility grounds.

The raw materials used at the facility for pharmaceutical packaging manufacturing include resin, APIs, isopropyl alcohol, and water. Other raw materials used onsite for operations and maintenance include fuels, oils, lubricants, greases, non-chlorinated degreasers, boiler treatment chemicals, refrigerants, sanitizers, bleach and detergents.

Inspection:**Opening Conference**

Lead Inspector Jeremy Leggett, and Matthew Schulte, of EPA arrived at the facility on April 18, 2025, at 10:50 a.m. CST and were met by Kevin Lundborg (C Shift Facility Maintenance Mechanic), Blake Arseneaux (EHS Manager), and Trent Schlesinger (Director Production). The Opening Conference began at 11:14 a.m. CST. During the Opening Conference, EPA staff presented their credentials and confirmed there was no claim of Confidential Business Information (CBI). EPA staff discussed cybersecurity with the facility. The Opening Conference ended at 12:40 p.m. CST. The following information was provided to EPA by Woodstock Sterile Solutions staff.

General Facility Information:

- The facility operates seven days a week, twenty-four hours a day.
- The facility employs around 450 people, who work four different 12-hour shifts across the week.
- The facility operates 33 separate production lines.
- The facility has three on-site wells, water from the wells is used exclusively for production.

Manufacturing Process:

- Facility utilizes raw materials including polypropylene resin, and APIs, which are shipped to the facility and stored in the warehouse for use in production.
- Each BFS batched production line produces batches of API's to meet individual orders.

Waste Generation:

- The facility does not have a pretreatment system for their production. Following batched production runs, the stainless-steel tanks are cleaned. The wash water generated from the cleaning process is stored in 55-gallon drums on pallets. A licensed waste hauler (Veolia) hauls away the material as non-hazardous waste.

Wastewater Sampling:

- Sigma Group Inc. (Facility consultant) performs quarterly sampling for the facility. A facility representative is present for all the samples collected by Sigma. The Facility is in the process of being issued a permit by the City's POTW. According to the facility, the current draft permit only requires semi-annual sampling. During the inspection, the Facility stated that they plan to maintain a quarterly sampling schedule.

Facility Walk-Through

The facility walk-through began at 12:40 p.m. CST. Woodstock Sterile Solutions staff showed EPA inspectors the following during the plant walk-through:

- Production Line

- BFS vials (Photo 1). BFS vials are filled with liquid pharmaceutical products for individual orders.
 - Manufacturing suite three (Photo 2). Each manufacturing suite is designed to operate independent of the other suites.
 - BFS waste storage (Photo 3).
- Incoming Chemical Storage
 - Incoming quality assurance area (Photo 4).
- Dispensary Stock Room
 - Stock Room 1 (Photo 5).
- Water Treatment Process
 - Softened chilled City water used for temperature exchange at process production, molds, stills (Photo 6).
 - Well water chlorine injection process (Photo 7).
 - Well water treatment process. Water passes through a multimedia filter, is softened, and then passes through a carbon filter. Once through the carbon filter, water is treated with a UV treatment (Photo 8) (Photo 9).
 - Within the water treatment RO Room there was a floor drain (Photo 10).
 - RO reject water is returned to the RO Room for reprocessing (Photo 11).
 - Deionization Plates (Photo 12).
 - After RO, water is held and mixed with deionized water in a storage tank (Photo 13).
 - RO water is distilled after deionization (Photo 14).
 - Following deionization, water is stored in water for injection (WFI) tanks for use in BFS manufacturing (Photo 15).
 - Steam is generated using RO water for use around the facility (Photo 16).
- Reject Cage Waste Area
 - Wash water is stored in the storage area until it is hauled from the site by a licensed waste hauler as non-hazardous waste (Photo 17).
- Loading Dock
 - Storm drains receive storm water within the facilities loading dock (Photo 18).

The site walk-through ended at 1:50 p.m. CST.

Closing Conference

EPA and Woodstock Sterile Solutions staff discussed the following:

- EPA requested the following documents be emailed to the Lead Inspector for review:
 - Woodstock Sterile Solutions' 2024 facility sampling data and the associated chain of custody for collected samples.
 - Copy of the proposed draft wastewater permit.
 - Most recent SLUG Plan. Plan was updated in 2025 by facility and found to be effective.
 - Facilities training documents standard operating procedures (SOP).

- Copy of the current and effective stormwater pollution prevention plan (SWPPP).
 - Copy of Woodstock Sterile Solutions' semi-annual wastewater monitoring results for 2024
- At the time of the inspection the storm drain in the loading dock was observed to have debris around and inside the grate of the storm drain (Photo 18). During the closing conference this was discussed as an area of concern.
 - EPA staff reviewed the inspection report timeline, and reconfirmed no CBI was claimed.

EPA staff completed the Closing Conference and left the facility at 2:43 p.m. CST.

Post-Inspection Activities

Blake Arseneaux, EHS Manager, provided the following documents to EPA via email on April 24, 2025:

1. 2024 Sampling Data and Chain of Custody;
2. Copy of proposed Wastewater Draft Permit;
3. Copy of SLUG Plan, updated in 2025 as stated by facility.
4. Training Documents SOP; and
5. Copy of SWPPP, updated in 2025 as stated by facility.
6. Copy of Woodstock Sterile Solutions' semi-annual wastewater monitoring results dated 26 November 2024.

Records Review

After the Inspection, EPA staff reviewed photographs documenting the cleaning of the storm drain in the loading dock provided by Blake Arseneaux. These photos are included as Attachment B.

Attachments

- A. Photo Log: Photos taken during U.S. Environmental Protection Agency Inspection of Woodstock Sterile Solutions (April 18, 2025)
- B. Woodstock Sterile Solutions Post-Inspection Photos (April 22, 2025)

ATTACHMENT A
Woodstock Sterile Solutions
EPA Inspection 18 April 2025
All photos taken by Matthew Schulte, Physical Scientist, U.S. EPA
Camera: Olympus Tough TG-6 SN#BJ5B21169



1: WSS_01

Description: Manufactured Blow-Fill-Vials of Betadine.

Location: Woodstock Sterile Solutions Factory Floor.

Camera Direction: Down

Date/Time: 18 April 2025/12:46 P.M.



2: WSS_02

Description: Production Line manufacturing suite 0003.

Location: Woodstock Sterile Solutions Factory Floor.

Camera Direction: North

Date/Time: 18 April 2025/12:48 P.M.



3: WSS_03

Description: Vial Waste Storage Area.

Location: Woodstock Sterile Solutions Vial Waste Storage Area.

Camera Direction: Factory Floor.

Date/Time: 18 April 2025/12:51 P.M.



4: WSS_04

Description: Incoming Chemical Storage

Location: Incoming Quality Assurance Area.

Camera Direction: Factory Floor.

Date/Time: 18 April 2025/12:53 P.M.



5: WSS_05

Description: Dispensing Stock Room 1.

Location: Woodstock Sterile Solutions Dispensing Stock Room 1.

Camera Direction:

Date/Time: 18 April 2025/12:58 P.M.



6: WSS_06

Description: Softened City Water Used For Temperature Exchange.

Location:

Camera Direction:

Date/Time: 18 April 2025/1:04 P.M.



7: WSS_07

Description: Well Water is Injected With Chlorine Through Pretreatment Pumps.

Location: RO Room

Camera Direction:

Date/Time: 18 April 2025/1:07 P.M.



8: WSS_08

Description: Well Water Multi-Media Treatment Process.

Location: RO Room

Camera Direction:

Date/Time: 18 April 2025/1:08 P.M.



9: WSS_09

Description: UV Treatment Process.

Location: RO Room

Camera Direction:

Date/Time: 18 April 2025/1:08 P.M.



10: WSS_10

Description: Floor Drain in RO Room.

Location: RO Room

Camera Direction: Down

Date/Time: 18 April 2025/1:08 P.M.



11: WSS_11

Description: RO Reject Water – Recycled to Beginning of Treatment Process.

Location:

Camera Direction:

Date/Time: 18 April 2025/1:12 P.M.



12: WSS_12

Description: Ionization Plates

Location:

Camera Direction:

Date/Time: 18 April 2025/1:12 P.M.



13: WSS_13

Description: RO Water after mixing with Ionized Water.

Location:

Camera Direction:

Date/Time: 18 April 2025/1:12 P.M.



14: WSS_14

Description: Still – Water Distillation System.

Location:

Camera Direction:

Date/Time: 18 April 2025/1:14 P.M.



15: WSS_15

Description: Water For Injection Tanks.

Location:

Camera Direction:

Date/Time: 18 April 2025/1:15 P.M.



16: WSS_16

Description: Steam Generation

Location:

Camera Direction:

Date/Time: 18 April 2025/1:16 P.M.



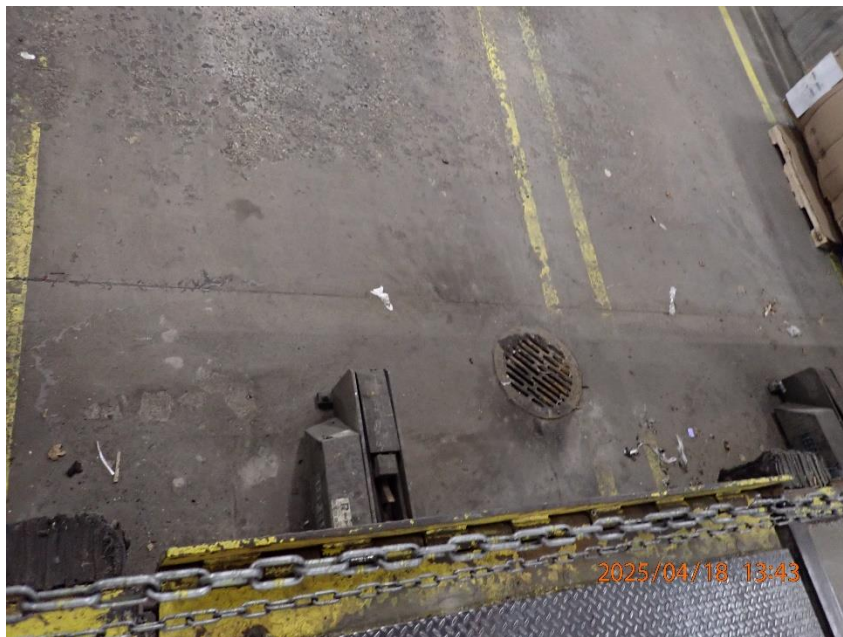
17: WSS_17

Description: Reject Wash Water and Waste Area.

Location: Reject Cage

Camera Direction:

Date/Time: 18 April 2025/1:38 P.M.



18: WSS_18

Description: Storm Drain In Loading Dock.

Location:

Camera Direction: Down

Date/Time: 18 April 2025/1:43 P.M.

ATTACHMENT B
Woodstock Sterile Solutions
EPA Inspection 18 April 2025
Photos Taken on 22 April 2025 by
Blake Arseneaux, EHS Manager at Woodstock Sterile Solutions



Description: Photos provided by facility showing area has been cleaned around storm drains in loading dock.