

**U.S. Environmental Protection Agency  
Region 5**

**Purpose:** Industrial User Compliance Evaluation Inspection

**Facility:** Catalent Pharma Solutions, Inc., ILP000396  
2010 Lake Shore Drive  
Woodstock, Illinois 60098 (815) 388-9500

**Inspection Date:** December 4, 2020

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## **PURPOSE OF INSPECTION**

The purpose of this announced inspection at the Catalent Pharma Solutions, Inc., (Catalent) Facility ILP000396, located at 2210 Lake Shore Drive, Woodstock, Illinois 60098 was to describe, evaluate, and document compliance with the Clean Water Act (CWA) and associated pretreatment regulations.

## **COVID-19 PRECAUTIONS**

COVID-19 precautions included inspectors driving to and departing from the Catalent facility in separate vehicles. During the Catalent inspection, EPA inspectors wore face masks, and were provided with face shields to be worn in addition to masks. We read and confirmed conformance to the requirements of Catalent’s “Visitor Health Statement (COVID-19)” (Attachment IX), and had individual temperatures taken before entry into the facility. All participants maintained a 6-foot distance from persons throughout the inspection. Upon finishing introductions, presenting credentials and donning face shields, the inspectors followed Mr. Carter, the Environmental Health and Safety (EHS) Manager and Mr. Reget, the EHS Specialist to the auditorium conference room for a Catalent operations presentation and the opening conference.

## **BACKGROUND**

Catalent 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 Street, Woodstock, Illinois within the Kishwaukee River Watershed. EPA is the control authority (CA) for the industry as the City currently does not administer an approved pretreatment program. It was found that the City is currently developing its pretreatment program as required by its NPDES permit effective April 1, 2020 for the north wastewater treatment plant (Attachment I). Catalent is tributary to the south WWTP whose NPDES permit also was effective April 1, 2020 (Attachment II). The City has decided to include both north and south service areas as subject to its new pretreatment program once approved, since both plants accept wastewater from industrial users. The proposed pretreatment program being developed by the City is due to EPA on April 1, 2022 (within 24 months of the notification date (effective) date of the permit).

“Catalent” became the official name for the facility in June 2007. Production was started in 1982 under a previous owner “Automatic Liquid Packaging” (ALP) with four (4) Blow-Fill & Seal (BFS) operations at the current location and constructed in 1980. Catalent now operates 34 BFS operations on site.

The Catalent 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 (Attachment III). Catalent’s Standard Industrial Classification (SIC) is #2834, “Pharmaceutical Preparations”, and its NAICS is #325412 “Pharmaceutical Preparation Manufacturing”.

Catalent utilizes incoming raw materials received including polypropylene resin, active pharmaceutical ingredients (APIs) which are proprietary, and isopropyl alcohol which are shipped to location and then stored in the warehouse areas for quality control activities including sampling and cataloguing before manufacturing. Storage of these commodities takes place in secured quarantined areas.

Catalent's processing operations consist of aseptic custom packaging of drugs focusing on respiratory care formulations utilizing BFS technology. The sterile packaging operations also includes biological, topical and ophthalmic applications. Catalent's BFS operations provide batch sizes of product from 5 to 2,000 liters and fill volumes from 0.25 to 125 milliliters in single and multi-dose quantities within sterile and non-sterile settings as needed. Catalent now utilizes 34 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 and de-ionized) sterile water, raw materials and APIs. Except for emergencies, all water treated is sourced from two private wells owned and operated by Catalent. A third well is used solely for grounds irrigation. This formulated product is sterilized and filtered during the formulation process and directed through piping to the BFS operation. The BFS operation utilizes a combination of injection molding, and extrusion technology in conjunction with a vacuum operation using compressed air to create a "tear, twist, open" container in which the drug product is introduced. Excess plastic is then trimmed from the drug-filled product vials, labels are affixed as needed, the product is foil pouched, packaged and then placed in on-site warehouse storage. Storage includes controlled temperature storage as needed including room temperature, refrigerated storage or freezer storage. Product sampling is periodically conducted prior to shipment.

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

### Catalent Wastewaters

Although water is also sourced from the municipal public water supply for fire suppression and minimal domestic use, process water is primarily obtained from two private wells owned by Catalent on-site. Process wastewater as generated on-site includes rinse (wash) water from tank cleaning within each of the 34 suites. This wash water is collected and stored in 55-gallon drums on pallets and is hauled from the site by a licensed waste hauler as non-hazardous waste. These wastewaters are not continuous, but batch discharges as a result of facility pharmaceutical operations. The volume of wash water is estimated to be a daily average volume of 1,350 gallons per day (gpd).

Other wastewater discharges which are directed to the South Woodstock Publicly Owned Treatment Works (POTW) include:

- |  |           |
|--|-----------|
| 1. Reverse Osmosis (RO) reject:                | 8,309 gpd |
| 2. Water softener backwash and regeneration:   | 7,250 gpd |
| 3. Other ion exchange (DI) system wastestream: | 1,752 gpd |
| 4. Boilers blow down discharge:                | 1,718 gpd |

5. Steam condensate:	1,258 gpd
6. Floor wash water:	24 gpd
7. Air compressor condensate:	10 gpd
8. Domestic wastewater:	125 gpd

Catalent sent a letter from Region V, EPA Water Division dated July 7, 2020 inquiring as to the manner in which their waste is disposed. Catalent responded with its first submitted semi-annual IU report (baseline monitoring report) to EPA, the current control authority, on August 14, 2020 and informed EPA that its wastewater is collected and hauled offsite. (Attachment IV).

Catalent does not own and operate a pretreatment system but collects all wastewater which is wash down water from the blending tanks and pipelines in each of the 34 formulation suites in 55-gallons drums which are palletized and hauled as non-hazardous waste by a licensed hauler. Hauling manifests are maintained by Catalent. EPA requested and received hauling manifests for wastewater hauling operations for 2018, 2019, and 2020 (Attachment V) in addition to municipal water bills (Attachment VI) for these three years. Sewer bills are based on municipal water usage.

Catalent provided a copy of the facilities' U.S.EPA Tier I SPCC Plan (Attachment VII) and Catalent filed a "No Exposure Certification for Exclusion from NPDES Storm Water Permitting" with IEPA on December 11, 2019. IEPA responded with a letter of acknowledgement dated December 12, 2019 (IEPA Log No. ILRX1247), (Attachment VIII).

Catalent conducted sampling and sent a report to EPA on August 14, 2020. In its report, Catalent cited 40 CFR 439 – Pharmaceutical Manufacturing Point Source Category and reported the results of wastewater sample analyses taken July 30, 2020. In reviewing the results, EPA noted that the results were based on grab or time proportional samples and the categorical standard establishes flow proportioned composite samples. EPA also noted that the Chain-of-Custody form did not specify the type of container (glass, plastic) used for collection.

### **ON-SITE INSPECTION**

EPA inspectors drove to the Catalent location in separate vehicles and met at 8:45AM in the parking lot to jointly enter the facility lobby at 9:00AM to meet with Dow Carter, the Environmental Health and Safety Manager. Upon entering the lobby, introductions and credentials were presented as well as the intent of the visit. EPA inspectors signed the visitor's log while introductions were made. Mr. Carter explained Catalent's COVID policy to us as visitors. During the Catalent inspection, EPA inspectors wore face masks, and were provided with face shields to be worn in addition to the masks. We read and confirmed conformance to the requirements of Catalent's "Visitor Health Statement (COVID-19)" (Attachment IX), and had individual temperatures taken before entry into the facility. All participants maintained a 6-foot distance from persons throughout the inspection. Upon acknowledging an understanding of Catalent's COVID policy, the inspectors followed Mr. Carter, the Environmental Health and Safety (EHS) Manager and Mr. Reget, the EHS Specialist to the auditorium conference room for a Catalent operations presentation and the opening conference.

## Catalent Opening Conference

At 9:08 AM, upon EPA inspectors and Jerry Reget of Catalent being seated in the conference auditorium, Mr. Carter stated he would begin a power point presentation describing Catalent's history and pharmaceutical operations. The presentation was preceded by introductions of many Catalent remotely-located employees who participated in the opening meeting via video "Zoom" conferencing.

After introductions were made, I stated that the purpose of the EPA's inspection at the Catalent facility was to conduct an announced inspection to describe, evaluate, and document compliance with the Clean Water Act (CWA) and associated pretreatment regulations. I stated that the inspection would include the opening conference meeting to discuss Catalent's operations, to respond to interview questions that were previously sent to Catalent with a CBI and Personal Privacy Information (PPI) information sheet (Attachment X), to conduct a facility operations tour and inspection which will result in the preparation of a final inspection report to be provided to Catalent following management approval of today's findings and to conduct a closing conference.

I stated that the opening conference will entail an interview to secure detailed information on the manufacturing process at the Catalent facility, a succinct discussion regarding pretreatment activities if any, and a records review of requested materials related to Catalent operations as an industrial user discharging to a publicly owned wastewater treatment works (POTW) located in the City of Woodstock and owned and operated by the City.

I mentioned that we would be finished by the end of the day. I asked if there were any confidential business information (CBI) restrictions or concerns. Mr. Carter responded there were no CBI concerns.

Following CBI discussion, I stated that the inspection team would take photographs during the course of inspection and Mr. Carter stated it was acceptable to do so and that Catalent would take in-kind photographs in concert with those as taken by EPA.

### **Catalent Opening Meeting Attendees:**

- Chris Cronin; Sr. Director - Operations
- Todd Larson; Sr. Director – Engineering & Facilities
- Natasha Hults; Director – CI & Technology
- Wendy Khine; Director – Project Management / Product Development
- Sandy Cantwell; Director – Commercial Operations
- Kareen Nunnally; Manager - Operations
- Matt Logue; Manager – Manufacturing Engineering
- Larry Thompson; Director – Sterility Assurance
- Robin Richards; Environmental Consultant
- Jeremy Hirst; Site Security Lead
- Jerry Reget; Specialist - EHS
- Colleen Taylor; Supervisor – Quality Assurance
- Dow Carter; Manager - EHS

After setting the foundation for the inspection, the inspection team began to ask questions regarding Catalent's operations and watched a power point presentation conducted by Mr. Carter. The presentation experienced certain technical difficulties and Mr. Carter provided an in-depth description of Catalent's operations and responded to specific pharmaceutical manufacturing IU and general questions regarding operations.

Specific pharmaceutical categorical questions and responses were as follows:

- What type of processes are used to manufacture product(s)? (Fermentation, biological and natural extraction, chemical synthesis, mixing/compounding, and formulation.) *The process involves mixing/compounding, and formulation.*
- If processes include fermentation and/or chemical synthesis, are these continuous or batch-type operations? *Batch -type operations are employed within 34 suites.*
- If chemical synthesis is involved, what processing steps (crystallization, distillation, filtration, centrifugation, vacuum filtration, solvent extract, etc.) produce wastewaters? *Chemical synthesis is not involved. Catalent blends and mixes third party proprietary pharmaceutical with treated water and blows, fills and seals the pharmaceutical products in vials. Are these wastewaters discharged to the sewer system? All wastewaters generated by the production processes involve wash water from the mixing tanks and lines. Those wastewaters are collected in 55-gallon drums and hauled off for proper disposal as non-hazardous waste by a licensed hauler. Manifests are maintained.*
- Are any of the "regulated organics" used or generated in the manufacturing process? *No.*
- What types of solvents are used, if any? How are spent solvents disposed of? How are they stored? Are there any floor drains nearby? *Yes. Solvents are used for cleaning. They are removed in washing operations and disposed of in 55-gallon drums. They are stored in designated warehouse areas with no floor drains present.*
- Do you employ any detergent cleaning or acid cleaning of tanks or vessels? *Yes, all 34 suites utilize tanks for batch-type production runs of varying volumes and each suit utilizes one stainless steel tank that is cleaned following the production run.*
- Are any disinfectants used and discharged to the sewer? *Bleach is used in minimal cleaning applications.*
- Is the raw water intake purified? If yes, by what method - ion exchange, reverse osmosis, water softening, etc.? *Raw water is purified by ion exchange (deionization), reverse osmosis, conventional water softening and ultraviolet disinfection processes.*

Mr. Carter stated that Catalent operates four alternating 12 hour shifts per day “round the clock”, seven days a week if needed. Catalent currently has 600 employees down from a previous 700.

I asked Mr. Carter how long the facility has been operating. He stated that the facility was started with 4 lines (suites) in 1982. I asked if a slug control plan was available. Mr. Carter indicated that the facility was working on a plan but did not have one available.

Catalent does not have a pretreatment system for its pharmaceutical operation but captures this wastewater consisting of only tank wash water and stores it in 55-gallon drums for proper manifested nonhazardous waste by a licensed hauler as the number of drums warrants to complete a workable shipment. All domestic and other waste streams not associated with pharmaceutical operations are discharged to one discharge point. There is a control manhole located on the southwest corner of the facility from which sampling is conducted by a contractor who takes custody from that point of sample collection to the certified laboratory for analysis. The City additionally collects wastewater samples from this location.

Catalent forwarded a report to EPA with a certification statement on August 14, 2020 with laboratory sampling results in Section 3 of the report for 40 CFR 439 Subpart D. Catalent conducts activities defined in 40 CFR Part 439, – Pharmaceutical Manufacturing Point Source Category, Subpart D, mixing, compounding and formulation, pretreatment Standards. Catalent represented that the process wastewaters from those processes are collected in 55-gallon drums and hauled off for proper disposal.

### Catalent Facility Inspection

Before the facility production area and pretreatment inspection tour began, EPA asked Mr. Carter if we were required to view any safety presentation or read any safety policy and what particular personal protective equipment the inspection team is to wear before entry into the production area. Mr. Carter replied that there was no safety presentation to view before the inspection, but we were to maintain COVID masks, face shields and to maintain six-foot distances throughout the facility as designated by floor decals throughout the facility (Photo #1). Safety glasses and hairnets, (beard nets, as appropriate) and several changing intervals of the use of foot coverings (booties) were mandatory and used in certain production areas as the inspection team toured various facility areas of operation.

The facility inspection began at 11:26 AM during which time we walked to the water treatment area of Catalent accompanied by both Mr. Carter and other Catalent representatives.

The water used in the blending and formulation process is treated with a conventional ion exchange water softener process, a reverse osmosis process, a de-ionization process and an ultraviolet sterilization application. The RO treatment area and reject water discharge piping to a floor drain is pictured in Photo #2. In addition to the three private water wells on site, the facility is serviced with City water through an incoming line that provides for cross-connection control with a reduced pressure zone (RPZ) backflow preventer (Photo #3) and master water meter (Photo #4). The discharged backwash and regeneration water from the water softener, DI system water reject (Photo #5) and steam condensate wastewater (Photo #6) are all discharged into floor

drains and directed to the City sewer. The combined daily average of these discharges is approximately 20,269 gallons per day (gpd).

The inspection team continued to see the boilers at their respective locations in the facility. These units contribute an estimated 1.718 gpd discharge to the floor drain to the City sewer. The floor drain for boilers #1 & #2 is shown in Photo #7. The facilities' boilers are shown in Photo #8.

As the inspection team passed through the RO water treatment area to inspect the chiller units, we noticed bleach containers stored on the floor adjacent to a floor drain without spill prevention (Photo #9). The floor drain (missed in the photo) was immediately to the left of the bleach containers on the floor.

The inspection team then proceeded to the chiller units to locate any additional wastewater discharges and viewed the chiller system floor drain (Photo #10). This discharge was minimal and not estimated by Catalent.

We proceeded to walk through the facility to the lower basement area and observed the lift station (Photo #11) that pumps non-process wastewater to the City sewer. We also observed the fire suppression manifold (Photo #12). The fire system utilizes City water as a direct connection with backflow protection and directs the flow to distal locations of the Catalent facility via victaulic piping connections separate from the main water system. A reduced pressure zone (RPZ) backflow prevention device provides backflow protection to the City's main water system.

After inspecting the water treatment areas and other areas with potential wastewater discharges and connections, the inspection team went to the main production area consisting of 34 separate and sterile formulation suites (Photo #13) and (Photo #14).

Catalent advised us that all tank wash water is collected in 55-gallon plastic drums from any of the 34 suites following a product run. Product batch run times vary considerably based on volume. The drums are removed from the suites as filled and are palletized (Photo #15) in a warehouse-designated area and held until a haul volume is warranted. At that time, a licensed waste hauler accepts the wastewater as non-hazardous waste and transports the wastewater for proper disposal. We secured waste manifests for the last three years of operations. It was noted that the containers of wastewater were not provided with spill containment.

Photo #16 and Photo #17 are of the sampling manhole located outside of the Catalent building on the southwest corner from which all grab and time composite samples are collected by a private contractor to deliver to the certified laboratory and by the City for industrial user sampling activities. Photo #16 is an interior shot of the manhole bench and Photo #17 shows the location.

#### Catalent Closing Conference

The closing conference was conducted as we finished our facility tour. The inspection team from EPA returned to the conference room at 3:15PM for a closing conference with Mr. Carter

and Mr. Reget. Once again, remotely-located Catalent employees participated in the closing meeting including:

**Catalent Closing Meeting Attendees:**

- Oliver Vogt; General Manager
- Chris Cronin; Sr. Director - Operations
- Todd Larson; Sr. Director – Engineering & Facilities
- Natasha Hults; Director – CI & Technology
- Sandy Cantwell; Director – Commercial Operations
- Kareen Nunnally; Manager - Operations
- Matt Logue; Manager – Manufacturing Engineering
- Robin Richards; Environmental Consultant
- Jeremy Hirst; Site Security Lead
- Jerry Reget; Specialist - EHS
- Danielle Carpenter; Engineer - Quality Assurance
- Dow Carter; Manager - EHS

During the closing conference, after I thanked Mr. Carter and those present for their participation and courtesy rendered throughout the inspection, I briefly reviewed and discussed the information and documents we received and commented on our observations. I also shared the preliminary areas of concern below, noting that these would be finalized when we sent our inspection report to them. Mr. Carter asked if we found any immediate concerns and I responded that we were concerned with the storage of liquid bleach on the RO floor near a floor drain, that Catalent needs to develop and provide a slug control plan per 40 CFR403.8(F)(2)(vi), and were concerned about their sampling methodology. We advised Mr. Carter and Mr. Reget who were present, and those Catalent representatives as listed above who conferenced remotely, that our inspection and findings will be described in an inspection report and would be sent to their attention for their review and comment following our management’s review and approval of the report. I asked if Catalent had any further questions and hearing none, I then ended the closing conference and the inspection team departed the facility at 3:40 PM. Catalent required a sign in-sign out log for visitors.

**OBSERVATIONS AND AREAS OF CONCERN**

EPA has the following areas of concern following the review of information gathered during the inspection.

- The team noticed improper storage of bleach containers near a floor drain in the RO area (Photo #9).
- The 55-gallon palletized drums containing the process wastewater did not have secondary containment while being stored in the warehouse awaiting shipment.

- The composite sampler utilized by the contractor for sampling is time proportional and not flow proportional as is established for this category of industry.
- The chain of custody for samples collected does not clearly specify the type of containers utilized for certain samples. (i.e. Cyanide samples are to be grab samples collected in a glass container, VOCs are to be grab samples collected in amber containers with no head space for volatilization of the sample.)
- The facility did not have a “Slug Discharge Plan” according to 40 CFR403.8(F)(2)(vi) to advise the POTW of any accidental spills or slug loads that may be introduced into the sanitary sewer system. Catalent needs to develop a plan to provide notification requirements or contact information to the POTW in the case of emergency slug discharge incidents.

### **LIST OF ATTACHMENTS**

- I.** IL0031861 North POTW NPDES permit.
- II.** IL0034282 South POTW NPDES permit.
- III.** Catalent floor layout.
- IV.** Catalent’s first EPA report.
- V.** Typical wastewater hauling manifest (2018-2010).
- VI.** Typical wastewater hauling manifest (2018-2010).
- VII.** USEPA SPCC plan, Tier I.
- VIII.** IEPA No-Exposure recertification letter.
- IX.** Catalent visitor health statement.
- X.** Interview question list, CBI & PPI information sheet.