NPDES Pretreatment Categorical Industrial User Inspection
Pharmaceutical Manufacturing Point Source Category
40 CFR Part 439

National Database Information	
Inspection Type	Pretreatment Categorical Industrial User (CIU)
NPDES ID Number	COPF-000106
Inspection ID	202304_COPF00106
Inspection Date	04/13/2023
Entry Time	04/13/2023 @ 0915
Exit Time	04/13/2023 @ 1300

General	
Inspector Name	Al Garcia
Telephone	303.312.6382
Inspector Type	EPA Region 8
Inspector Name	Stephanie Passarelli
Telephone	303.312.6803
Inspector Type	EPA Region 8

Facility Location Information	
Business Name	Tolmar Inc.
Facility Location	1201 Cornerstone Drive, Windsor CO 80550
Mailing Address	same
Type of Business/Operations	Pharmaceutical Manufacturing
Average Production Rate	NA
Number of Employees	300
Days of Operation	365 days per year, 24 hours per day; except for holiday schedules and planned shutdowns
Type/Number of Shifts	Production Days/Shifts: • A shift (5:30 am through 5:30 pm), B shift (5:30 pm through 5:30 am) - Monday through Wednesday • C shift (5:30 am through 5:30 pm), D shift (5:30 pm through 5:30 am) - Wednesday through Saturday

Facility Representatives		
Name	**Title**	**Contact Information**
Tony Backo	Environmental Health and Safety Specialist	Tony.Backo@tolmar.com; 720.442.1016
Mike Ricks	Associate Director – Maintenance and Facilities	970.212.4515
Charles Mays	VP-Engineering and Facilities	970.212.4515
Chris Banfield	Environmental Health and Safety Manager	970.212.4515

POTW/Receiving Water	
Publicly Owned Treatment Works (POTW) and Permit Number	Town of Windsor, CO-0020320
Ultimate Receiving Water(s)	Cache la Poudre

General Inspection and Facility Information

Inspection Description

The U.S. Environmental Protection Agency (EPA) and the Town of Windsor (Town) conducted a facility inspection at Tolmar Inc. (the facility) on April 13, 2023 at 0915. The facility inspection consisted of an opening interview facility walk-through tour, and a closing conference. Digital photos were taken during the facility tour to document laboratory wastewater sources, purified supply water treatment, the wastewater collection lift stations and the wastewater treatment system/discharge point to the Town. EPA reviewed relevant Pretreatment records provided by the facility electronically prior to the facility inspection.

Al Garcia and Stephanie Passarelli, EPA inspectors, and Mr. Ryne Oniecinski from the Town of Windsor (jointly referred to as inspectors) provided credentials and introductions to all attendees. The inspectors interviewed the facility representatives consisting of Mr. Tony Backo, Mr. Mike Ricks, Mr. Charles May and Mr. Chris Banfield about the facility and the associated unit operations/processes, including raw materials/chemicals and management or treatment of discharged and non-discharged wastestreams. A facility walk-through was performed to visually observe the unit operations, chemical storage/transfer/handling for slug discharge potential, wastewater generation/management/treatment and the discharge/compliance monitoring point. A closing conference was held to discuss the findings and observations of the facility inspection. During the facility inspection, EPA provided outreach regarding the applicable Pretreatment Regulations and projections of the control mechanism that will be issued by the EPA. The EPA and Town inspectors signed out of the facility at 1300.

Chemicals/ Raw Materials Overview

Chemical/Raw Material	Volume/Mass	Storage Location	Process Use
Flammables: (isopropyl alcohol, acetonitrile, acetone, ethanol, methanol)	Various sizes (5-gallon, 55-gallon, 250-gallon}	Raw Materials Waterhouse	Pharmaceutical manufacturing
Cleaner: (sporacide, hydrogen peroxide, para-acetic acid, Vesphene, lysol)	Various sizes	Raw Materials warehouse	Pharmaceutical manufacturing
Sulfuric acid	Two 55-gallons drums	Wastewater treatment skids in spill containment	Wastewater treatment – pH neutralization
Caustic Soda	Two 55-gallons drums	Wastewater treatment skids in spill containment	Wastewater treatment – pH neutralization
Defoamer	10-gallons	Wastewater treatment skids in spill containment	Wastewater treatment

Boiler treatment chemicals (descalant, oxygen scavengers)	35 gallons	Boilers Room– in spill containment	Boiler treatment
Lab pack chemicals	Various sizes	QC labs	Laboratory
Solvents (halogenated and non-halogenated)	various	Labs	Pharmaceutical manufacturing

Description of Chemical Handling/Transfer to Process Operations:

The raw materials, active pharmaceutical ingredients (API) and chemicals are received in shipping docks located on the south side of the facility and stored in the Raw Materials warehouse. The boiler treatment and wastewater treatment chemicals are moved to the in-use areas. The raw materials are stored in the warehouse either on the floor or on shelves of large industrial storage racks. When requested by the various manufacturing areas or labs within the facility, the raw materials are staged in a pickup storage rack and issued to that area or lab.

Certain raw materials may be sampled to ensure quality control. An aliquot is taken from the raw material container and analyzed in the QA area, located in the Raw Materials warehouse. **Note**: the facility is decommissioning the dermatological products manufacturing (Derms East and Derms West areas and will be moving large manufacturing equipment (mixing/bulking) and quantities of chemicals used in this larger scale manufacturing out of the facility.

Potential for Spills or Slug Discharges from Chemical Storage/Handling/Transfer to reach Sanitary Sewer?

☒yes ☐no

Describe Spill or Slug Discharge Potential:

Minimal, the facility is transitioning to smaller quantities of mixing, compounding and formulating of API and pharmaceutical products. The current slug discharge control plan adequately addresses slug discharge potential and measures, equipment and procedures to eliminate or minimize slug discharges to the sanitary sewer.

Process/Unit Operations

Describe the facility industrial process.

The facility organizes its pharmaceutical manufacturing of products into areas or labs within its building. As mentioned in the previous section, the raw materials, chemicals, and API are stored in the Raw Materials warehouse and are issued to the different pharmaceutical product areas when requested. The current pharmaceutical products manufactured at the facility includes the following:

- Eligard

- Fen-Solvi
- EPSS – Eligard with improved packaging.
- Polymer Manufacturing Suites
- Polymer R&D
- Note: The facility no longer manufactures dermatological products in the Derms East and West areas. The Derms East area is currently vacant, and the Derms West area is under construction for the EPSS product line.

Pharmaceutical Manufacturing –

The raw materials and APIs that are issued from the Raw Materials warehouse are received in the centralized mixing or bulking lab. The bulking process occurs in one centralized area or lab within the facility. The mixing/compounding/formulating operations for each pharmaceutical product (Eligard, EPSS and Fen-Solvi) are the same, but the volumes change depending on the pharmaceutical product manufactured. The volumes for each pharmaceutical product will be identified in the narrative of the bulking operations.

The raw materials and APIs are mixed and compounded in carboys (Eligard – 10L, EPSS – 20L) using a magnetic stir plate. The mixed product is sent through an oven and then pumped through a series of filters to a media bag. The filters used during this process are single use and are collected as non-hazardous waste for disposal. The media bag is used in the filling machine designed to create dosage forms in syringe vials. The filling machine has a 5-station manifold and silicone tubing to fill syringes. The silicone tubing is single use and is disposed after every product filling run. The stainless-steel fill nozzles are rinsed in a lab sink, sterilized and reused. The facility manufactures 100 syringes per tub. The typical production runs for each pharmaceutical product are identified below:

- Eligard – 120 tubs
- EPSS – 60 to 210 tubs
- Fen-Solvi – 60 tubs

The dosage form products are freeze-dried (lyophilization) to stabilize the product in either final dosage form (EPSS) or ready for combining with the polymer syringe component.

Polymer Manufacturing –

The polymer is manufactured in two suites. The raw materials issued from the warehouse are received and mixed in an 8L helicone mixing vessel, the facility currently manufactures about two to three batches per week. The mixture is heated to dry and are extruded out of the containers into milling machines. The helicone vessel is cleaned with solvents to dissolve the residual polymer. The bottom of the container is opened to aid in cleaning. The waste solvent is collected and hauled off-site as hazardous waste.

The milled polymer powder is contained and sealed in a Syringe A bulking area/lab. According to facility representatives, the facility manufactures about 5 batches of polymer per week.

Polymer Development –

The polymer research and development are conducted in the Polymer Lab, located east of the Derms East area in the facility. The polymers developed and tested in this lab are produced in 10L batches. Acetone is

used for cleaning and dissolving polymer in this lab. The waste acetone is collected and shipped off-site as hazardous waste.

Specialty Injectables –

The APIs used in specialty injectables is in powder form and are mixed in a 20L vessel, transferred to a 20L tank and are milled in a 200µ machine. The milled product is contained in a carrier container and are transferred to a 30L tank and then moved to the filling room for dosage form in vials. These products do not undergo lyophilization. The vessels used in this manufacturing operation are washed in the washrooms.

Purified Water –

The facility uses supply water that has undergone reverse osmosis (RO) for use in its manufacturing operations. Approximately 1 gallon of reject water or brine is generated for every 3 gallons of RO-treated water. The RO brine generated from the process is discharged directly to the City sewer. The RO water is first contained in a 5,400-gallon tank for facility use, with the exception of the Eligard manufacturing process. The water undergoes an additional treatment process and contained in a separate 5,400-gallon tank for use in the Specialty Injectables and Eligard manufacturing processes.

Boiler Room –

The facility boilers are blown down daily, based on conductivity and are annually evacuated for maintenance/inspection. The boilers wastewaters are discharged directly to the City sewer.

Ancillary Wastestreams –

According to the facility representatives, a certain volume (about 250 to 450 gallons per day) of steam condensate is discharged to the Eligard and South lift stations and to the wastewater treatment system. In addition, the facility performs cleaning of the production areas/labs and this wastewater is discharged to the wastewater treatment system.

Describe any substantial changes in manufacturing processes (or planned changes):

The facility is currently performing construction to increase its manufacturing EPSS production in the old Derms West area. The old Derms East area is currently vacant, but the facility may add new manufacturing processes in this space. The Derms pharmaceutical products areas were discontinued since 2019 and as a result, the wastewater generated decreased significantly. In addition, the generation of waste acetone is tightly controlled. As a result of acetone exceedances in the past two years, the facility has tightly controlled the use of acetone in the Polymer Development lab. The facility collects this wastewater and hauls off-site as hazardous waste.

Did these changes result in substantial change in wastewater?	☒yes	☐no
Were these substantial changes reported, as required in 40 CFR 403.12(j)?	☒yes	☐no

Wastewater Treatment/Managment

Describe the wastewater treatment system or wastewater management:

Wastewater Collection and lift stations –

The south lift station (photo log # 271) collects regulated process wastewater from the Specialty Injectables, EPSS and old Derms East labs. The north lift station (photo log # 270) collects regulated process wastewater from the H2 area within the Derms East lab. The facility does not allow the north lift station to pump to wastewater treatment but instead, the north lift station pumps to a 12,000-gallon collection tank. The valves on the pipes leading to wastewater treatment are locked. The 12,000-gallon collection tank has alarms that are triggered at about 3,500 and 6,000 gallons. The wastewater within this tank is hauled off-site and is tested for pH and flashpoint to ensure they are within the characteristic pH hazardous waste levels and a flashpoint below 140º C.

The regulated process wastewaters generated in the pharmaceutical products bulking lab are collected in the 75-gallon Eligard lift station (photo log # 269) located on the west side of the Raw Materials warehouse.

Wastewater Treatment –

The wastewater pumped from the Eligard and South lift stations are collected in the 2,800-gallon equalization tank (photo log # 262). The facility has a larger backup overflow, in case this is needed. The contents in the 2,800-gallon equalization tank are pumped to the 2 waste treatment skids at about 37% capacity (photo log # 263). The 2 wastewater treatment skids are identical in functionality for pH neutralization and capacity.

The wastewater enters Stage 1 (450-gallon capacity) of the pH neutralization skid and is treated for pH and defoaming agent is added if needed. The pH treatment acid/base and defoaming agent is adequately contained in spill containment equipment (photo log #268). The treatment pH meter is set for 5.0 to 10.3. If Stage 1 wastewater is outside this range, the appropriate volume of either H_2SO_4 acid or caustic soda is added to adjust the pH within the set criteria. The wastewater is moved across a weir to Stage 2 within the system and is monitored for a pH range of 7.0 to 9.0. If the pH of the Stage 2 wastewater is outside this range, then the wastewater is rerouted back to Stage 1 for additional treatment (photo log #264). If the Stage 2 wastewater is within range, then the contents are discharged through the discharge pipe from the treatment skid (photo log # 265). The discharge pipes from the two treatment skids combine into one common discharge pipe. This is defined as outfall 001 and the facility continuously monitors for pH and flow. A monitoring point valve is also located on this discharge pipe (photo log # 267).

Are all treatment units functioning?	☒yes ☐no
Bypasses or emergency overflows from the treatment system?	☐yes ☒no

Applicable Regulated Operation(s) Pharmaceutical - 40 CFR 439	
Does the Facility fall in the SIC Codes 2833, 2834 or 2836?	yes
Are products considered to be pharmaceutically active ingredients	yes
Multiple end use products such as components of formulation, chemical intermediates or final products derived from pharm manufacturing operations and to be used for use primarily in pharmaceutical applications	yes
Which pharmaceutical manufacturing operations are performed? **Subpart A – Fermentation** **Subpart B – Extraction** **Subpart C – Chemical Synthesis** **Subpart D – Mixing/Compounding and Formulation** **Subpart E - Research**	Based on information gathered during the facility inspection, the facility does not perform fermentation or extraction unit operations. The facility performs mixing, compounding, and formulating to manufacture its products in dosage form. The wastewater generated from these unit operations are subject to Subpart D which contains the following definitions in 40 C.F.R. § 439.41(a) and (b): (a) ***Mixing, compounding, and formulating operations*** means processes that put pharmaceutical products in dosage forms. (b) ***Product*** means any pharmaceutical product manufactured by blending, mixing, compounding, and formulating pharmaceutical ingredients. The term includes pharmaceutical preparations for both human and veterinary use such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions.
Do all process wastes flow through a monitoring point before being diluted? **If no, can an internal monitoring point be established (423.17(b))**	Yes, all regulated process wastes flow to either the Eligard or South Lift Stations, and then to the waste treatment system. The facility also discharges an estimated 250 to 450 gallons of steam condensate to the waste treatment. The steam condensate is considered unregulated.
Do the monitoring location and self-monitoring sampling days appear to produce results that are representative of the discharge? **(403.12(g)(3))**	yes
Is the monitoring location free from dilution? **(403.6(d) and 403.12(g)(c))**	No, the facility discharges steam condensate, an unregulated wastestream.

Sampling and Reporting	Notes
Where DMRs submitted on time in June and December of the previous calendar year? **(403.12(e))**	yes
Where all parameters monitored? **(403.12(e) and 467.16 and 465.35)**	yes
Where all parameters reported correctly?	yes
Does the DMR include measured or estimated average and maximum daily flows? **(403.12(e))**	yes
Are appropriate sample types collected? • **Grab - pH, cyanide, total phenols, oil and grease, sulfide, and volatile organic compounds (some may be lab or field composited)** • **All other pollutants - 24-hour composite samples through flow-proportional composite sampling techniques, unless time-proportional composite sampling or grab sampling is authorized by the EPA** **(403.12(g)(3))**	yes
Do sample collection and analysis meet requirements in 40 CFR 136 (hold time, preservation, container type, method)? **(403.12(g)(5))**	yes
Where DMRs signed and certified by required personnel? **(403.12(l))**	yes
Is the IU sampling at the required frequency (min 2/year)? **(403.12(e))**	yes
If the IU is sampling more frequently than required, are the results included in the report? **(403.12(g)(6))**	Acetone sampled monthly
Do sampling records contain: • **The date, exact place, method, and time of sampling and the names of the person or persons taking the samples;** • **The dates analyses were performed;** • **Who performed the analyses;** • **The analytical techniques/methods use; and** • **The results of such analyses.** • **Record keeping requirements** **(403.12(o)(1))**	yes

Sampling and Reporting	Notes
Are records kept for at least 3 years? **(403.12(o)(2))**	yes
If IU sampling indicates a violation, was the EPA notified within 24 hours of the IU becoming aware of the violation? **(403.12(g)(2))**	NA
If IU sampling indicates a violation, did the IU repeat the sampling and analysis and submit the results of the repeat analysis to the EPA within 30 days after becoming aware of the violation? **(403.12(g)(2))**	NA
Was POTW notified immediately of all discharges that could cause problems to the POTW, including any slug loadings, as defined by §403.5(b)? **If no, were there such instances where the POTW should have been notified?** **(403.12(f))**	**NA**
Is the facility required to have a slug discharge control plan? If yes, it must contain to following: • **Description of discharge practices, including non-routine batch Discharges;** • **Description of stored chemicals;** • **Procedures for immediately notifying the POTW of Slug Discharges, including any Discharge that would violate a prohibition under §403.5(b) with procedures for follow-up written notification within five days; and** • **If necessary, procedures to prevent adverse impact from accidental spills, including inspection and maintenance of storage areas, handling and transfer of materials, loading and unloading operations, control of plant site run-off, worker training, building of containment structures or equipment, measures for containing toxic organic pollutants (including solvents), and/or measures and equipment for emergency response.** **(403.8(f)(2)(vi))**	**Describe any Deficiencies:** Based on the facility inspection, the slug discharge control plan adequately addresses the conditions at the facility.
Did the IU promptly notify the EPA and the POTW in advance of any substantial change in the volume or character of pollutants in their discharge? **(403.12(j))**	NA
Did the IU submit notification of hazardous waste discharge? If no, should they have? **(403.12(j) and (p))**	NA
Did the IU submit notification of bypass? If no, should they have? **(403.17)**	NA
Did the IU submit a complete baseline monitoring report (180 days before discharge) and a 90-day compliance report? **(403.12(b) and (d))**	NA

Significant Noncompliance Evaluation (403.8(f)(2)(viii))	Notes
If effluent violations have occurred, is the IU in significant non-compliance (SNC) for chronic or technical review criteria?	NA
Has the IU caused or contributed to pass through or interference? If yes, evaluate for SNC.	NA
Has any discharge from the IU resulted in imminent endangerment to human health, welfare or to the environment? If yes, evaluate for SNC.	NA
Has the IU failed to meet a compliance milestone contained in an Order within 90 days? If yes, evaluate for SNC.	NA
Has the IU failed to provide, within 45 days after the due date, required reports such as baseline monitoring reports, 90-day compliance reports, periodic self-monitoring reports, and reports on compliance with compliance schedules? If yes, evaluate for SNC.	NA
Has the IU failed to accurately report noncompliance? If yes, evaluate for SNC.	NA

Records Reviewed

- 2022 and 2023 Waste Disposal Tracking spreadsheets (hazardous and non-hazardous wastes)
- 2021 Slug Discharge Control Plan
- SOP 01029 – Acetone Spill SOP
- SOP 00669 – Chemical Spill Response
- Sample Data Sheets – 07/2022 to 03/2023

Miscellaneous Information

As discussed during the facility inspection, the EPA will issue a Notice of Discharge Requirements to replace the control mechanism issued by the Colorado Department of Public Health and Environment. The CDPHE has not been delegated the Pretreatment Program and the EPA is the Approval Authority and is collaborating with the town of Windsor to issue control mechanisms for categorical industrial users in the Town. The EPA will provide Tolmar a permit application to complete and submit to the EPA by May 30, 2023.

Report Review and Signature		
Drafter Name	Address/Phone Number	Date
Al Garcia	**U.S. EPA Region 8** **1595 Wynkoop Street** **8WP-CWW** **Denver, Colorado 80202** **303-312-6382**	04/20/2023
Reviewer Name	Address/Phone Number	Date
Stephanie Passarelli	**U.S. EPA Region 8** **1595 Wynkoop Street** **8ENF-W-NP** **Denver, Colorado 80202** **303-312-6803**	04/24/2023
Supervisor Signature/Name	Address/Phone Number	Date
MICHAEL BOEGLIN Digitally signed by MICHAEL BOEGLIN Date: 2023.05.04 11:21:54 -06'00' **Mike Boeglin**	**U.S. EPA Region 8** **1595 Wynkoop Street** **8WP-CWW** **Denver, Colorado 80202** **303-312-6133**	05/04/2023

Summary of Findings

Tolmar, Inc.

NPDES ID# COPF-000106

Pretreatment Inspection Findings	Follow up Action Items
1. The Pretreatment Regulations at 40 C.F.R. § 403.6(d) states the following: "Except where expressly authorized to do so by an applicable Pretreatment Standard or Requirement, no Industrial User shall ever increase the use of process water, or in any other way attempt to dilute a Discharge as a partial or complete substitute for adequate treatment to achieve compliance with a Pretreatment Standard or Requirement." The Pharmaceutical PSNS standards at 40 C.F.R. § 439.47 do not authorize dilution. Tolmar, Inc. currently discharges approximately 250 to 450 gallons of steam condensate to the waste treatment system. Steam condensate is determined to be an unregulated wastestream to the Pharmaceutical PSNS at 40 C.F.R. § 439.47.	**Pretreatment Requirement** 40 C.F.R. § 403.6(d) 40 C.F.R. § 439.47 **Corrective Actions** The facility needs to provide accurate volume measurements of the steam condensate discharged to the waste treatment system in the permit application to EPA. EPA recommends Tolmar evaluate the feasibility of rerouting the steam condensate to avoid discharging it to the waste treatment system to eliminate or minimize the dilution of regulated wastestreams.

Attachment 1 – Photo Log	
Photo #	Description
(RIMG0258.jpg)	QC lab dishwasher (Room 806) – *photo unrecoverable from memory card*
(RIMG0259.jpg)	QC lab two-compartment sink (Room 806) – *photo unrecoverable from memory card*
(RIMG0260.jpg)	QC Lab-lab waste satellite collection room (Room 807) - *photo unrecoverable from memory card*
(RIMG0261.jpg)	Water purification System-Filters and brine tank - *photo unrecoverable from memory card*
Photolog #1 (RIMG0262.jpg)	Wastewater treatment system – 2,800-gallon equalization tank
Photolog #2 (RIMG0263.jpg)	Wastewater treatment system – overview of 2,800-gallon equalization tank and pH neutralization skids
Photolog #3 (RIMG0264.jpg)	pH neutralization skid –recirculation loop between stage 1 and stage 2
Photolog #4 (RIMG0265.jpg)	pH neutralization skid –discharge pipe from stage 2
Photolog #5 (RIMG0266.jpg)	pH neutralization skid –discharge pipe from stage 2(duplicate)
Photolog #6 (RIMG0267.jpg)	pH neutralization skid –combined discharge pipe from both pH neutralizations skids and monitoring point, pH meter and flow meter
Photolog #7 (RIMG0268.jpg)	pH neutralization skids –caustic/acid and defoamer treatment chemicals
Photolog #8 (RIMG0269.jpg)	Eligard lift station (75 gallons)
Photolog #9 (RIMG0270.jpg)	North lift station
Photolog #10 (RIMG0271.jpg)	South lift station

DMR DATA REVIEW FORM – Pharmaceuticals, Subpart D (439.47) PSNS

Facility Name: Tolmar Inc.
Inspector(s): DMR Date: -07/18/22 @ 0730
NPDES ID Number: Inspection Date:

Parameter	Daily Maximum (avg limit) – mg/L	Monthly Average – mg/L	Reported Value (mg/L)	Actual Value	Limits Exceeded?	Required Monitoring Frequency (403.12(e))	Actual Monitoring Frequency	Required Holding Time, Preservation, Container, and Method Met? (Part 136 Tables IA-G and II)	Required Sample Type Met? (403.12(g)(3))
Acetone	20.7	8.2	0.025			1 / 6 months			
n-Amyl acetate	20.7	8.2	<0.01			1 / 6 months			
Ethyl acetate	20.7	8.2	<0.02			1 / 6 months			
Isopropyl acetate	20.7	8.2	<0.02			1 / 6 months			
Methylene chloride	3.0	0.7	<0.005			1 / 6 months			
pH	limit ≥5.0 (403.5(b)(2))[1, 2]	n/a							

1. 403.12(e) does not require CIUs to monitor for pH, but the CIU is required to comply with the Specific Prohibition requiring discharges with pH ≥5.0 if it is at the outfall to the POTW.
2. Note: pH≤2 or ≥12.5 is hazardous waste and *may be* subject to hazardous waste reporting (403.12(p))

Acetone sampling date	**Result (mg/L)**
08/09/22	1.6
09/19/22	0.0011

DMR DATA REVIEW FORM – Pharmaceuticals, Subpart D (439.47) PSNS

Facility Name: Tolmar
Inspector(s): DMR Date:10/11/22
NPDES ID Number: Inspection Date:

Parameter	Daily Maximum (avg limit) – mg/L	Monthly Average – mg/L	Reported Value (mg/L)	Actual Value	Limits Exceeded?	Required Monitoring Frequency (403.12(e))	Actual Monitoring Frequency	Required Holding Time, Preservation, Container, and Method Met? (Part 136 Tables IA-G and II)	Required Sample Type Met? (403.12(g)(3))
Acetone	20.7	8.2	0.33			1 / 6 months			
n-Amyl acetate	20.7	8.2	<2.001			1 / 6 months			
Ethyl acetate	20.7	8.2	<0.002			1 / 6 months			
Isopropyl acetate	20.7	8.2	<0.0037			1 / 6 months			
Methylene chloride	3.0	0.7	<0.000			1 / 6 months			
pH	limit ≥5.0 (403.5(b)(2)[1, 2]	n/a							

1. 403.12(e) does not require CIUs to monitor for pH, but the CIU is required to comply with the Specific Prohibition requiring discharges with pH ≥5.0 if it is at the outfall to the POTW.
2. Note: pH≤2 or ≥12.5 is hazardous waste and *may be* subject to hazardous waste reporting (403.12(p))

Acetone sampling date	**Result (mg/L)**
11/14/22	<0.10
12/07/22	1.1

DMR DATA REVIEW FORM – Pharmaceuticals, Subpart D (439.47) PSNS

Facility Name: Tolmar
Inspector(s): DMR Date: 01/09/23
NPDES ID Number: Inspection Date:

Parameter	Daily Maximum (avg limit) – mg/L	Monthly Average – mg/L	Reported Value)mg/L)	Actual Value	Limits Exceeded?	Required Monitoring Frequency (403.12(e))	Actual Monitoring Frequency	Required Holding Time, Preservation, Container, and Method Met? (Part 136 Tables IA-G and II)	Required Sample Type Met? (403.12(g)(3))
Acetone	20.7	8.2	0.75			1 / 6 months			
n-Amyl acetate	20.7	8.2	<0.001			1 / 6 months			
Ethyl acetate	20.7	8.2	<0.002			1 / 6 months			
Isopropyl acetate	20.7	8.2	<0.0087			1 / 6 months			
Methylene chloride	3.0	0.7	0.0002			1 / 6 months			
pH	limit ≥5.0 (403.5(b)(2)[1, 2]	n/a							

1. 403.12(e) does not require CIUs to monitor for pH, but the CIU is required to comply with the Specific Prohibition requiring discharges with pH ≥5.0 if it is at the outfall to the POTW.
2. Note: pH≤2 or ≥12.5 is hazardous waste and *may be* subject to hazardous waste reporting (403.12(p))

Acetone sampling date	**Result (mg/L)**
02/07/23	1.70
03/01/23	<0.0055