

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

National Database Information	
Inspection Type	CEI
NPDES ID Number	COPF00106
Inspection ID	202505_COPF00106
Inspection Date	5/29/2025
Entry Time	9:53AM
Exit Time	1:00 PM

General	
Inspector Name	[REDACTED]
Telephone	[REDACTED]
Inspector Type	EPA Region 8
Inspector Name	[REDACTED]
Telephone	[REDACTED]
Inspector Type	EPA Region 8

Facility Location Information	
Business Name	Tolmar
Facility Location	1201 Cornerstone Drive, Windsor, CO 80550
Mailing Address	701 Center Avenue, Fort Collins, CO 80526
Type of Business/Operations	Pharmaceutical Manufacturing
Average Production Rate	Approximately 2 batches/week
Number of Employees	150
Days of Operation	24 hours/day, 365 days/year except holidays and planned shutdowns
Type/Number of Shifts	Manufacturing: 2 12-hour shifts. QA/QC lab personnel work 8-hour shifts; the inspector did not determine whether the labs also operate 24 hours/day.

Name	Title
[REDACTED]	EHS Specialist
[REDACTED]	EHS Manager/Associate Director – Maintenance and Facilities
[REDACTED]	EHS Specialist

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

General Inspection and Facility Information

Inspection Description

The U.S. Environmental Protection Agency (EPA) inspectors [REDACTED] and [REDACTED] conducted a facility inspection at Tolmar (the facility) on May 29, 2025. [REDACTED] contacted [REDACTED] on May 13, 2025, to notify him of the inspection and discuss timing and logistics. [REDACTED] also invited [REDACTED] at the Town of Windsor to participate in the inspection; however, no Town of Windsor staff were available to participate on the scheduled inspection date. The inspection was conducted to evaluate the facility's compliance with its Notification of Discharge Requirements under the Pharmaceutical Manufacturing Point Source Category and the General Pretreatment Regulations ("permit," CO-PF00106), issued by the EPA.

The facility inspection consisted of an opening interview, facility walk-through tour, and a closing conference. The inspectors documented their observations using digital photos and written notes in bound, hard copy checklists. All digital photos taken during the inspection are included in the attached photo log. The inspectors reviewed all periodic compliance reports (PCRs) submitted by the facility under its current permit and the facility's current slug discharge control plan provided by the facility electronically prior to the facility inspection.

The inspectors entered the facility at 9:53 AM and introduced themselves and displayed their credentials to all attendees before the opening interview. The inspectors interviewed [REDACTED], [REDACTED] ("facility representatives") about the facility and the associated unit operations/processes, including raw materials/chemicals and management or treatment of discharged and non-discharged wastestreams. The facility representatives demonstrated the Building Management System, which provides on-demand, web-based access to real-time data on the depth of wastewater at each lift station, the volume of wastewater in the equalization tank, the pH reading from each probe in the wastewater skids, and the effluent flow. The facility representatives described how the data from the pH and flow meters are recorded, analyzed, and reported. During the facility walk-through the inspectors observed the unit operations; the chemical and waste storage, transfer, and handling areas; wastewater generation, management, treatment processes; 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, the inspectors provided compliance assistance regarding the applicable pretreatment regulations and permit requirements. The inspectors signed out of the facility at 1:00 PM.

On the day of the inspection, [REDACTED] provided photographs (photos 26 and 27) demonstrating that waste chemicals had been removed from the wastewater treatment area. On June 9, 2025, [REDACTED] responded to follow-up questions and requests for information via email. The response included a copy of the facility's current Chemical Spill Response SOP, the approved Slug Discharge Control Plan, hazardous waste hauling manifests dated 5/6/2025 and 5/9/2025 (two manifests on each date), and the timing for commencement of Paliperidone production (November 2023).

Chemicals/Raw Materials Overview

*Based on opening interview, facility walk-through, and facility plans; list is not comprehensive.

Chemical/Raw Material	Volume/Mass	Storage Location	Process Use
Flammables: isopropyl alcohol (IPA), acetonitrile, acetone, ethanol, methanol, N-methyl-2-pyrrolidone (NMP), toluene	IPA and NMP: multiple 55-gal drums Acetonitrile: multiple 5-gal drums Acetone and methanol: multiple 2.1-ft ³ shipping boxes Others: not documented	Flammable materials shed in the Raw Materials Warehouse	Pharmaceutical manufacturing
Cleaners/disinfectants: sporicide, hydrogen peroxide	Not documented	Oxidizer storage shed in Raw Materials Warehouse	Pharmaceutical manufacturing
Sulfuric Acid	Two 55-gallon drums	Wastewater treatment skids in spill containment	Wastewater treatment – pH neutralization
Caustic Soda	Three 55-gallon drums	Two in wastewater treatment skids in spill containment; one in adjacent staging area on secondary containment pallet	Wastewater treatment – pH neutralization
Defoamer	Two approximately 2-gal jugs. Three 5-gal buckets (partially filled)	Two in wastewater treatment skids in spill containment; three next to wastewater treatment skids without secondary containment. See Finding 1 in the Summary of Findings at the end of this report.	Wastewater treatment
Propylene glycol	One approximately 200-gallon tank	Next to chiller near wastewater treatment skids, not in secondary containment	Chiller
Solid chemicals	Various sizes	Raw Materials Warehouse	Pharmaceutical manufacturing
Active pharmaceutical ingredients	Various sizes/small quantities	Raw Materials Warehouse	Pharmaceutical manufacturing
Solvents	Various sizes	Raw Materials Warehouse and Labs	Pharmaceutical manufacturing
Floor Drains in Storage Areas?			☒ yes ☐ no

Description of Chemical Handling/Transfer to Process Operations:

Raw materials, active pharmaceutical ingredients (API), and chemicals are received at the shipping docks on the south side of the facility and stored in the adjacent Raw Materials warehouse (also referred to as the “receiving warehouse” by the facility representatives). Solid/powder and liquid raw materials are stored in their shipping packaging on or below racks in the warehouse. Wastewater treatment chemicals are moved to the wastewater treatment area for use. Other raw materials, API, and chemicals are moved to various manufacturing areas or labs when needed.

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

☒yes ☐no

Describe Spill or Slug Discharge Potential:

The facility has identified and taken measures to minimize the potential for spills or slug discharges to the sanitary sewer.

The inspectors observed liquids stored in the Raw Materials Warehouse; these included but were not limited to polyethylene glycol, decon spore (biocide), and soybean casein digest broth (TSB). Floor drains in the Raw Materials warehouse connect directly to the Town of Windsor collection system and were equipped with barricades to exclude spilled materials (photos 2 and 3). Similarly, a floor drain in the pilot plant chemical storage area has been covered to prevent discharges to the collection system (photo 19).

Chemicals in use and staged for use in the wastewater treatment area, including caustic soda, sulfuric acid, and defoaming agent, were stored in secondary containment (photos 12 – 15 and 17). Three partially full buckets of defoaming agent were stored without secondary containment (photo 13) approximately 50 feet from the nearest floor drain. The facility representative stated that these were old chemicals that were to be removed to a waste storage area.

All chemical storage areas included spill kits and the facility’s Chemical Spill Response Plan (SOP-00669) includes detailed notification and cleanup procedures for chemical spills.

An approximately 200-gallon tank of propylene glycol was stored near the chiller without secondary containment. The tank was stored next to a floor drain that connects directly to the Town of Windsor collection system (photo 18). See Finding 2 in the Summary of Findings at the end of this report.

Process/Operations

Describe the facility industrial process.

Note: This description is limited to the processes observed and discussed during the inspection. See the Tolmar Fact Sheet for the facility's Discharge Requirements for a complete description of the industrial process at the facility.

The facility manufactures the injectable drugs Eligard and Paliperidone, as well as polymers that are packaged separately for use in administering the pharmaceutical products. Eligard is manufactured in different formulations (Eligard, EPSS, and Fen-Solvi) and packaging for different end uses; the mixing, compounding, and formulation operations are the same for the Eligard products, but the volumes change depending on the product manufactured.

The raw materials and APIs that are issued from the Raw Materials warehouse are received in the mixing or bulking lab for the relevant product (Eligard or Paliperidone). The materials are mixed in small batches (approximately 5 gallons) then packaged into syringes and labeled in the packaging area. The syringes are sent through a lyophilizer that freeze-dries the pharmaceutical product. The mixing and filling equipment are cleaned and sterilized with hot water, CIP 100 (alkaline cleaning agent), and CIP 200 (acid cleaner and disinfectant). Wastewater from the floor drains and lab sinks in the Eligard area flows to the Eligard Lift Station (photo 7). Wastewater from the floor drains and lab sinks in the Paliperidone area flows to the South Lift Station (photo 25). The floor drains in the manufacturing areas also receive steam condensate from the boiler system.

The facility manufactures two types of polymer. One type is manufactured in the polymer manufacturing suite (Polymer West/Syringe A). The raw materials issued from the warehouse for polymer manufacturing are received and mixed in small batches. The mixture is heated to dry and then extruded into milling machines to create polymer powder. NMP, a non-flammable solvent, is used to dissolve the polymer powder for packaging. The polymer is packaged into syringes. Some of the polymer syringes are connected with syringes containing pharmaceutical products. The polymer mixing and filling equipment is cleaned with hot water, CIP 100, and CIP 200. Wastewater from the floor drains and lab sinks in the polymer manufacturing areas flows to the South Lift Station.

Another type of polymer is manufactured in the lab adjacent to the storage area. The manufacturing process is as described above, but acetone is also used to clean the equipment. Wastewater from this process flows to the North Lift Station and is collected in the adjacent 12,000-gallon tank (photo 23) to be hauled off-site as hazardous waste. Stormwater that collects within the secondary containment area for this tank is pumped to the facility's stormwater retention pond after staff have confirmed that there are no leaks in the tank that would have contaminated the stormwater.

The facility maintains a Research and Development lab that is used to develop and pilot test new products and procedures. The materials used, and waste generated, in the Research and Development lab and pilot plant are similar to those in the manufacturing areas. Wastewater from this area is collected and hauled offsite as hazardous waste. The facility maintains a chemical storage area for chemicals used in the pilot plant. A floor drain in the pilot plant chemical storage area that connects directly to the Town of Windsor collection system was blocked to prevent discharges of spilled chemicals (photo 19).

Describe any substantial changes in manufacturing processes (or planned changes): According to the facility representatives, there has been no substantial change in the manufacturing processes. The facility began commercial production of Paliperidone in November 2023, which is after the facility's permit application was submitted (June 2023) but before the permit was issued (February 2024). The Fact Sheet for the current permit does not address the Paliperidone production process; however, the facility representatives described the manufacturing process and products used as substantially similar to that used for the Eligard process that is described in the Fact Sheet, with the exception of the API. The facility representatives stated that the wastewater produced from the two processes is substantially similar. See Finding 3 in the Summary of Findings at the end of this report.

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

The federal pretreatment regulations and the facility's permit require notification of any substantial change in the volume or character of pollutants in the facility's discharge. The previous permit issued by the Colorado Department of Public Health and Environment (CDPHE), which was in effect at the time the Paliperidone production began, included the same requirement as the current permit, to notify the control authority in advance of any substantial change in the volume or character of pollutants in its discharge, including any listed or characteristic hazardous wastes. As stated above, according to the facility representatives, production of Paliperidone produces wastewater that is substantially similar to that produced from Eligard manufacturing. See Finding 3 in the Summary of Findings at the end of this report.

Wastewater Treatment/Management

Describe the wastewater treatment system or wastewater management:

The facility disposes of various wastewater streams through treatment prior to discharge, direct discharge to the Town of Windsor publicly owned treatment works (POTW), and offsite disposal. These three wastewater management methods are described in this section.

Wastewaters Treated Prior to Discharge

As described above, wastewater from the following sources is treated in the Wastewater Treatment area.

- Eligard area: Wastewater is generated from cleaning the mixing and filling equipment. The primary component of the wastewater is hot water, followed by CIP 100 (acid) and CIP 200 (base) cleaning chemicals, and trace amounts of residual API. Two drains direct wastewater to the 80-gallon Eligard Lift Station (photo 7).
- Paliperidone area: Wastewater is generated from cleaning the mixing and filling equipment. The primary component of the wastewater is hot water, followed by CIP cleaning chemicals, and trace amounts of residual API. Drains direct wastewater to the South Lift Station.
- Polymer West/Syringe A area: Drains in the polymer manufacturing suite direct wastewater consisting of wash water with trace amounts of polymer and NMP to the South Lift Station.
- Steam condensate: Drains throughout the manufacturing areas collect steam condensate. The facility representatives estimated that approximately 210 gallons/day of condensate flows into the collection system for the wastewater treatment system.

Wastewater from the South Lift Station and Eligard Lift Station is pumped to the 2,800-gallon equalization tank in the wastewater treatment area (photo 8). The facility maintains a process management system for the wastewater treatment process that is programmed to begin treatment when the equalization tank is 37% filled. The facility also maintains a backup tank to provide additional wastewater storage that would allow the Eligard process to continue in the event that the wastewater treatment system is not operational (photo 9). The facility representatives stated that the

backup tank has only been used twice, during system testing. The backup tank, if used for a treatment system outage, would be pumped and the wastewater hauled offsite for disposal.

Wastewater is pumped from the equalization tank to two treatment skids (photos 10 – 14). The pumps operate on a lead-lag system that is programmed to optimize treatment efficiency, pumping to one or both treatment skids based on wastewater pH and several system operational parameters. Each skid is identical. The wastewater is pumped to a 450-gallon treatment tank that is divided into two sides. The wastewater first enters “Side A” where a rough pH adjustment is performed. The wastewater then flows to “Side B” where the pH is tested. If the pH meets the effluent limitations in the permit, the wastewater is discharged. If not, the wastewater recirculates back to Side A. The pH is tested again using an in-line monitor in the effluent discharge line (photo 16).

Wastewaters Discharged without Treatment

Brine from the facility’s reverse osmosis system, boiler blowdown, cooling water from the lyophilizer, and wastewater from the building’s air handling system are discharged directly to the collection system without treatment. Cooling water from the lyophilizer flows to an underground tank to cool before being discharged directly to the Town of Windsor collection system.

Wastewaters Collected and Hauled Off-Site

The wash sinks and floor drains in the polymer lab direct wastewater containing acetone to the North Lift Station. As stated above, this wastewater is collected and hauled offsite as hazardous waste. Waste solvents, oily waste, and other hazardous wastes are collected in the labs and manufacturing areas and stored in the hazardous waste storage shed (photo 21) or a satellite hazardous waste storage cage for hazardous waste removal (photo 24). The hazardous waste storage shed includes a self-contained sump that would capture any spills in the shed. The satellite storage cage included spill kits and there were no drains in the vicinity. All containers were marked with accumulation dates and all but two of the containers in the hazardous waste shed were within 90 days of the accumulation date. One container of oily waste in the hazardous waste storage shed had an accumulation date of 6/13/2023. The facility representative stated that the facility had switched to a new hazardous waste hauler and the new hauler was not satisfied with the waste profile for the container. The facility was working with the hauler to provide a profile for the waste. Another container of waste ink in the hazardous waste storage shed had an accumulation date of 6/12/2023. The facility representative stated that the hauler required a photograph of the material in the container, but the facility representative did not want to open it because it contains a strong solvent. See Finding 4 in the Summary of Findings at the end of this report.

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

Yes

Applicable Regulated Operation(s)
Pharmaceutical - 40 CFR 439

from pharm manufacturing operations and to be used for use primarily in pharmaceutical applications	
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	The facility performs Mixing/Compounding and Formulation (Subpart C) and Research and Development lab (Subpart E). Subpart E does not contain pretreatment requirements.
Do all process wastes flow through a monitoring point before being diluted? If no, can an internal monitoring point be established (423.17(b))	No. Process waste and condensate commingle when they first enter drains in the processing areas. EPA used the combined wastestream formula to calculate effluent limitations. During the inspection, the facility representative stated that approximately 210 gallons/day of condensate enters the wastestream.
Do the monitoring location and self-monitoring sampling days appear to produce results that are representative of the discharge? (403.12(g)(3))	The monitoring location is in the effluent pipe after treatment and just before the outfall (photos 12, 15, and 16). The monitoring location appears to produce representative samples. The inspectors did not discuss the sampling days with the facility representatives. The facility discharges approximately 20 days per month during sanitization and batching processes.
Is the monitoring location free from dilution? (403.6(d) and 403.12(g)(c))	Yes. The monitoring location includes non-regulated wastestreams which were taken into account through use of the combined wastestream formula to calculate the permit limits. No other dilution sources were identified.

Sampling and Reporting

	Notes
Were DMRs submitted on time in June and December of the previous calendar year? (403.12(e))	Yes
Were all parameters monitored? (403.12(e) and 467.16 and 465.35)	Yes
Were all parameters reported correctly?	Yes. The permit includes inconsistent reporting requirements for flow monitoring. The facility was reporting monthly average and daily maximum flows, as requested suggested in Table 1 of the permit. In April 2025, EPA notified the facility that the flow should be reported as the measured total monthly flow and a calculated daily average. Beginning with the first calendar quarter of 2025, the facility revised its flow reporting as requested.

Sampling and Reporting	
	Notes
Does the DMR include measured or estimated average and maximum daily flows? (403.12(e))	The DMR includes total monthly and daily average flows, as required by the facility's permit.
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. Flow and pH are monitored continuously. The facility reports the minimum and maximum pH based on a spreadsheet that records pH readings in 5-minute increments. The facility collects grab samples for all other parameters, which is the appropriate sample type for the volatile organic compounds (VOCs) that are limited in the permit. The facility representatives stated that samples are collected into a glass jar then transferred to the sample containers.
Do sample collection and analysis meet requirements in 40 CFR 136 (hold time, preservation, container type, method)? (403.12(g)(5))	Yes. Based on review of the facility's periodic compliance reports and supporting documentation, the sample collection and analysis meet the permit requirements. Facility staff transport samples to an analytical lab located in Fort Collins, CO.
Were DMRs signed and certified by required personnel? (403.12(l))	Yes
Is the IU sampling at the required frequency? (403.12(e))	Yes. The facility monitors flow and pH continuously and samples its discharge quarterly for regulated VOCs, as required by the permit.
If the IU is sampling more frequently than required, are the results included in the report? (403.12(g)(6))	In April 2025, one sample exceeded the monthly average limit for acetone (5.5 mg/L). Facility staff collected a second sample which was below 5.5 mg/L. The facility representatives stated that the average of the two samples will be reported on the DMR.
If end-of pipe sampling for cyanide is impractical because of dilution, is the IU sampling at in-plant monitoring points? Is the IU complying with cyanide limitations by certifying that the facility's manufacturing processes neither use nor generate cyanide? (439.12(f) and (g) and 439.37(c) and (d))	N/A. The permit does not include limits for cyanide.
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 periodic compliance reports include the date and time of sampling, the signature of the sampler, the date of analysis, the analytical methods, and the analytical results. The reports did not include the location the sample was taken or the sample collection method. In April 2025, [REDACTED] contacted [REDACTED] to notify him of the requirement for sampling records to include the sample location and sample collection method. [REDACTED] indicated that this information would be included in future reports. The facility

Sampling and Reporting	
	Notes
- The analytical techniques/methods use; and - The results of such analyses. - Record keeping requirements (403.12(o)(1))	has a single sampling location (outfall 001) and collects only grab samples.
Are records kept for at least 3 years? (403.12(o)(2))	The inspectors reviewed sampling records for the current permit period (i.e., dating back to February 2024). The inspectors reviewed the facility's monthly calibration records for the 5 pH probes in the wastewater treatment system on site; those records were maintained for at least 3 years.
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))	N/A. The IU sampling did not indicate any violations.
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))	N/A
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))	The facility reported a slug discharge during the previous permit period. According to facility representatives, there have been no spills or slug discharges since that incident.
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	Describe any Deficiencies: Based on the facility inspection, the slug discharge control plan adequately addresses the conditions at the facility. The slug discharge control plan does not include a description of stored chemicals, but the facility's Chemical Spill Response Plan lists the types of chemicals stored at the facility, along with clean-up procedures and personal protective equipment for each. EPA reviewed version 11.0 of the Chemical Spill Response Plan, dated January 28, 2021.

Sampling and Reporting	
	Notes
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))	
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))	According to the facility representatives, there has been no substantial change in the volume or character of pollutants since the current permit was issued. See Finding 3 in the Summary of Findings at the end of this report.
Did the IU submit notification of hazardous waste discharge? If no, should they have? (403.12(j) and (p))	N/A. According to the facility representatives, the facility has not discharged any substance which, if otherwise disposed of, would be a hazardous waste.
Did the IU submit notification of bypass? If no, should they have? (403.17)	The facility submitted notification of a bypass that occurred during the previous permit period. According to the facility representatives, there have been no other bypasses since that time.
Did the IU submit a complete baseline monitoring report (180 days before discharge) and a 90-day compliance report? (403.12(b) and (d))	Yes. The facility has submitted information to satisfy the requirements to submit a baseline monitoring report and 90-day compliance report.

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?	N/A
Has the IU caused or contributed to pass through or interference? If yes, evaluate for SNC.	The facility has not exceeded its limits. The EPA communicated with Town of Windsor staff prior to the inspection, who did not indicate any issues associated with discharges from Tolmar.
Has any discharge from the IU resulted in imminent endangerment to human health, welfare or to the environment? If yes, evaluate for SNC.	No
Has the IU failed to meet a compliance milestone contained in an Order within 90 days? If yes, evaluate for SNC.	N/A

Significant Noncompliance Evaluation
(403.8(f)(2)(viii))

Notes

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.

No

Has the IU failed to accurately report noncompliance?
If yes, evaluate for SNC.

No

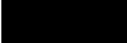
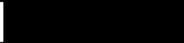
Records Reviewed

- Periodic compliance reports for the 2nd quarter of FY2024 through the 2nd quarter of FY2025
- pH meter calibration records
- SOP-00669 – Chemical Spill Response, Version 11.0, 28 Jan 2021
- SOP-00719 – Slug Discharge Control Plan for 1201 Cornerstone Facility, Version 3.0
- Hazardous waste hauling manifests dated 5/6/2025 and 5/9/2025

Miscellaneous Information

Tolmar began hauling wastewater from the North Lift Station to address a series of acetone exceedances in 2019 and 2020. According to facility representatives, the facility subsequently identified and eliminated the source of the excess acetone in wastewater draining to the North Lift Station. The facility representatives stated that an employee had been dumping waste acetone into a drain. During the inspection, the facility representatives asked whether they could begin treating and discharging wastewater from the North Lift Station. The facility representatives also described testing that was underway at the facility to use a gas chromatograph mass spectrometer to detect acetone in the wastestream at the wastewater skids (photo 14). According to the facility representatives, the facility is testing the instrument for use in monitoring the effluent stream before discharge to ensure the acetone limits are not exceeded.

As discussed during the facility inspection, introducing a new wastestream to the discharge will necessitate recalculation of the facility's discharge limits. To request a modification of the permit to include the wastewater from the North Lift Station, the permittee is advised to submit a revised permit application that includes the relevant information for all wastestreams that Tolmar proposes to discharge to the Town of Windsor POTW. See Finding 5 in the Summary of Findings at the end of this report.

Report Review and Signature		
Drafter Name	Address/Phone Number	Date
	U.S. EPA Region 8 1595 Wynkoop Street ECA-W-N Denver, Colorado 80202	6/9/2025
		
Reviewer Name	Address/Phone Number	Date
	U.S. EPA Region 8 1595 Wynkoop Street ECA-W-N Denver, Colorado 80202	6/9/2025
		
Reviewer Name	Address/Phone Number	Date
	U.S. EPA Region 8 1595 Wynkoop Street 8WP-CWW Denver, Colorado 80202	6/9/2025
		
Supervisor Signature/Name	Address/Phone Number	Date
	U.S. EPA Region 8 1595 Wynkoop Street ECA-W-N Denver, Colorado 80202	6/12/2025
		

Summary of Findings

Tolmar

NPDES ID# CO-PF00106

June 9, 2025

Pretreatment Inspection Findings	Follow up Action Items
1. Waste chemicals (defoamer) were stored near the wastewater treatment skid without secondary containment. (photo 13) The pretreatment regulations in Title 40 of the Code of Federal Regulations (40 CFR), section 403.5(a) state, "A User may not introduce into a POTW any pollutant(s) which cause Pass Through or Interference." On May 29, 2025, [REDACTED] provided photos (photos 26 and 27) demonstrating that the defoamer containers had been removed from the wastewater treatment area and moved to a containment shed.	<u>Pretreatment Requirement</u> 40 CFR 403.5(a) <u>Corrective Actions</u> No further action is required.
2. Propylene glycol was stored without secondary containment near a floor drain (photo 18). The pretreatment regulations at 40 CFR 403.8(f)(1)(iii)(B)(6) require that control mechanisms issued to significant industrial users must contain "Requirements to control Slug Discharges, if determined by the POTW to be necessary." The pretreatment regulations at 40 CFR 403.8(f)(2)(vi)(D) require that a slug discharge control plan, where required, must include "procedures to prevent adverse impact from accidental spills..."	<u>Pretreatment Requirement</u> 40 CFR 403.8(f)(1)(iii)(B)(6) 40 CFR 403.8(f)(2)(vi)(D) <u>Corrective Actions</u> Contact the Town of Windsor wastewater treatment facility to determine whether secondary containment is necessary based on an evaluation of the potential for a slug discharge of propylene glycol from Tolmar to cause interference or passthrough at the POTW. If propylene glycol has the potential to negatively impact the POTW, ensure that propylene glycol at Tolmar is stored and handled to prevent slug discharges, in accordance with procedures described in the facility's slug discharge control plan. In your response to the EPA, describe the actions that will be taken, if any, to prevent potential propylene glycol spills from negatively impacting the POTW.

Pretreatment Inspection Findings	Follow up Action Items
3. The facility did not notify the Control Authority and POTW of the addition of Paliperidone production and associated waste discharges. The pretreatment regulations at 40 CFR 403.12(j) state, “All Industrial Users shall promptly notify the Control Authority (and the POTW if the POTW is not the Control Authority) in advance of any substantial change in the volume or character of pollutants in their Discharge, including the listed or characteristic hazardous wastes for which the Industrial User has submitted initial notification under paragraph (p) of this section.”	<u>Pretreatment Requirement</u> 40 CFR 403.12(j) <u>Corrective Actions</u> Review the permit application submitted to the EPA in June 2023 to determine whether it accurately and completely represents the current product manufacturing processes and waste discharges at the facility. In your response to the EPA, either 1) confirm that the June 2023 permit application is representative of the current manufacturing activities and discharges from the facility, or 2) provide notification of a change in the volume or character of pollutants in the discharge.
4. Two containers of hazardous waste in the hazardous waste storage shed had accumulation dates nearly two years old (photo 21).	<u>Recommendation</u> Work with the hazardous waste hauler to ensure the hazardous wastes are removed from the site and properly disposed as soon as possible. Contact the Colorado Department of Public Health and Environment’s Hazardous Materials and Waste Management Division (HMWMD) for compliance assistance on meeting the requirements of the Resource Conservation and Recovery Act (RCRA). The HMWMD’s contact information for technical assistance is 303-692-3320 or comments.hmwmd@state.co.us.
5. The facility has eliminated the source of excess acetone in the waste stream from the polymer lab and would like to discharge wastewater from the North Lift Station to the wastewater treatment skids and Outfall 001. The pretreatment regulations at 40 CFR 403.6(e) provide that, “[w]here process effluent is mixed prior to treatment with wastewaters other than those generated by the regulated process, fixed alternative discharge limits may be derived by the Control Authority or by the Industrial User with the written concurrence of the Control Authority...Modification is authorized whenever there is a material or significant change in the values used in the calculation to fix alternative limits for the regulated pollutant. An Industrial User must immediately report any such material or significant change to the Control Authority. Where appropriate new alternative categorical limits shall be calculated within 30 days.”	<u>Pretreatment Requirements</u> 40 CFR 403.6(e) <u>Corrective Actions</u> Prior to introducing a new regulated wastestream to the discharge, the facility must submit a revised permit application that accurately characterizes the wastes proposed to be discharged to the POTW.