

The Industrial User and POTW Relationship: Working Collaboratively Towards Permitting A New Pharmaceutical Discharge

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Agenda

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Project Background

Treatability Testing

REGULATIONS

Biological Bench Testing

Permitting Pharmaceutical Discharge



Pharmaceutical manufacturer (The Client) was preparing to manufacture a new medication.





Existing Pretreatment System



Prodrug Hydrolytic Pathway



Overall Project Objectives

- Can the Client's existing pretreatment system be used for pretreatment of the prodrug prior to discharging wastewater to the POTW?
- Will the prodrug or degradation byproducts inhibit nitrification or impact the POTW's whole effluent toxicity?

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Project Process





Treatability Testing Objectives



- Will the Client's existing pretreatment system be capable of treating the new prodrug via hydrolysis?
- What will the concentrations of the prodrug and byproducts leaving the pretreatment system be?



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Treatability Testing Protocol





Sample at 10 time intervals: 15 minutes - 72 hours

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Analyze samples for Prodrug and Byproducts

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Treatability Testing Results





Treatability Testing Results

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- Prodrug degradation proceeds quickly at pH 10,
- Safety factor of 2 over projected Prodrug discharge rates.
- Prodrug and byproducts will continue to degrade in Tank 2 when the pH is reduced to approximately pH 8

Projected Effluent Concentrations from Pretreatment System							
Flow Condition	Prodrug (mg/L)	Byproduct A (mg/L)	Byproduct B (mg/L)	Byproduct C (mg/L)			
Peak Instantaneous Flow Rate	0.1	1.2	1.4	0.35			
Average Flow Rate	<0.0761	1.0	1.3	0.75			

Biological Bench Testing Objectives

- Will discharge of residual concentrations of the prodrug and its' byproducts inhibit nitrification at the POTW?
- Will discharge of residual concentrations of the prodrug and its' byproducts impact the POTW 's whole effluent toxicity?
- Does removal of the prodrug and its byproducts occur in the POTW?





Biological Testing Conditions





Control Reactors

Condition 1 Reactors

Condition 2 Reactors

Condition 3 Reactors



Biological Testing Conditions



 Prodrug and Byproduct B in varying quantities 750 mL of 1000 ppm Ammonia Standard 	Prodrug and Byproduct B Concentrations simulated in POTW WWTP Influent		
— 1 Gallon Influent Wastewater	Test Condition	Prodrug (ug/L)	Byproduct B (ug/L)
	1-Peak flow through manufacturer's pretreatment system	1.0	14.4
 — 3.5 Gallons Mixed Liquor from Activated Sludge Basin 	2- No pretreatment, Discharge of wastewater directly to sewer	42.6	0.0
 Aeration Equipment (Stone Diffusers) 	3-Concentrations 2.5x's the laboratory MDL	200	1,000

Biological Bench Testing Results





Impact on nitrification is evaluated by comparing the rate at which Ammonia-Nitrogen was converted to nitrate & nitrite in the control and test condition reactors. (Oxidized Nitrogen Generation Rate)

Biological Bench Testing Results



 Results indicate the Prodrug and Byproduct B at the concentrations tested do not inhibit nitrification.

Statistical Evaluation of Mean Oxidized Nitrogen Generation Rate							
Approximate Hour Range	Mean Oxidized Nitrogen Generation Rate (µg/h/mg biomass)						
	Control	Condition 1	Condition 2	Condition 3			
0 to 7.1 hours	0.96	0.94	0.91	0.95			
18.6 to 29.5 hours	0.87	0.89	0.86	0.96			

Calculations were normalized to mass of biomass.

• Condition 1 and Condition 2 were not statistically different than the control reactors.



Whole Effluent Toxicity



 Condition 1 and Condition 2 passed for both Ceriodaphnia dubia (water flea) and the Pimephales promelas (fathead minnow)

 The water flea WET test for Condition 3 failed based on reproduction





Percent Removal of Prodrug and Byproduct B



- Percent removal could not be determined
- Prodrug adsorbed to solids
- Matrix interferences





Conclusions and Permitting



The Client's existing pretreatment system successfully degrades the prodrug.



The Prodrug and Byproduct B do not inhibit nitrification at the POTW at the concentrations tested.



Treated effluent at the concentrations tested does not impact WET for conditions that represent actual potential discharge conditions.



A permit limit of 435 grams per day was issued based on 60% of the Maximum Allowable Headworks Loading.

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Lessons Learned



REGULATIONS

Manufacturer desired to discharge water that could be safely managed by the POTW and protect the environment. New discharge was a concern for the POTW. POTW did not want to negatively impact the WWTP performance or the environment.

With a team of consultant, industry and POTW working collaboratively, testing was performed, and a permit was issued in approximately 13 months.