Resolution 18-102

RESOLUTION AUTHORIZING EXECUTION OF AN
INDUSTRIAL SEWER CONNECTION PERMIT MODIFICATION TO:
**Enteris Biopharma**
Block 69 / Lot 73.05
Town of Boonton

**WHEREAS**, the Rockaway Valley Regional Sewerage Authority (hereinafter "the Authority") is authorized by the Sewerage Authorities Law [N.J.S.A. 40:14A-7(11)] to make and enforce rules and regulations for the management and regulation of its business and affairs and/or the use, maintenance, and operation of the sewerage system and any other of its properties and to amend the same; and

**WHEREAS**, the Authority is a Delegated Local Agency of the New Jersey Department of Environmental Protection and administers an industrial pretreatment program within the service area of the Authority; and

**WHEREAS**, in accordance with the regulations governing industrial pretreatment programs established at N.J.S.A. 7:14A-1 et. seq., the Authority is required to issue permits and renew permits to industrial discharges within the RVRSA that discharge process wastewater to the Authority's facility; and

**WHEREAS**, in compliance with the regulations contained at N.J.A.C. 7:14A-15.10, public notice of the issuance of a draft Industrial Sewer Connection Permit to Enteris Biopharma was published in the Daily Record on August 18, 2018, and a thirty (30) day public comment period commenced from the date of publication until September 17, 2018, wherein no comments were received.

**NOW THEREFORE, BE IT RESOLVED,** by the Rockaway Valley Regional Sewerage Authority as follows:

1. The Executive Director, Joann Mondsini, is hereby authorized to execute an Industrial Sewer Connection Permit modification in accordance with the terms and conditions of a form of Industrial Sewer Connection Permit (ISCP), SIC Code 2834 dated November 1, 2018 marked Schedule "A" attached hereto and a part hereof, a copy of which is also,

on file at the offices of RVRSA, to Enteris Biopharma, subject to compliance with any permit condition(s) which must be satisfied prior to issuance of this permit modification, if any; and also subject to compliance with all remaining engineering requirements, if any.

2. This approval is subject to the payment of the appropriate RVRSA pretreatment annual permit fee.

3. This ISCP is subjected to a flow limitation not to exceed 11,000 gallons per day, monthly average.

I hereby certify that this Resolution was adopted at a meeting of the Rockaway Valley Regional Authority held on October 11, 2018.

On motion of Glenn Corbett

Second by Michael Guadagno

And a Roll Call Vote as Follows:

Yeas: (7) Andes, Cegelka, Corbett, Guadagno, Isselin, Rossi, Schorno

Nays: (0) None

Abstain: (0) None

Absent: (3) Lowell, Recchia, Vincitore

Michael Guadagno

Michael Guadagno
Board Secretary

# FACT SHEET
## Enteris Biopharma

This fact sheet sets forth the principal facts and the significant factual, legal, and policy considerations examined during preparation of the draft permit.

| | |
|---|---|
| **PERMIT ACTION**: | Modification of the Industrial Sewer Connection Permit (ISCP)<br>Effective Date: xx/xx/2018 Expiration Date: 08/31/2019 |
| **PERMITEE NAME AND ADDRESS**: | Enteris Biopharma<br>83 Fulton Street<br>Boonton, NJ 07005<br>Phone No.: (973) 331-9650 |
| **FACILITY NAME AND ADDRESS:** | Enteris Biopharma<br>83 Fulton Street<br>Boonton, NJ 07005 |
| **FACILITY CONTACT INFORMATION:** | Mr. Andrejs (Andy) Rasums<br>Director, Quality Assurance<br>Phone No.: (973) 453-3517<br>Fax No.: (973) 588-5966<br>Email: arasums@enterisbiopharma.com |
| **RECEIVING LOCAL AGENCY:** | Rockaway Valley Regional Sewerage Authority |
| **RECEIVING COLLECTION SYSTEM:** | Local collection system owned and operated by the Town of Boonton |

**DESCRIPTION OF FACILITY OPERATIONS:**

Enteris Biopharma develops, tests, and manufactures pharmaceutical products and finished pharmaceutical dosage forms. This facility's SIC code is 2834. This facility is subjected to 40 CFR § 439 – Pharmaceutical Manufacturing Point Source Category, Subpart E – Research. Enteris Biopharma is discharging approximately **11,000 GPD** (monthly average) of combined waste stream generated from its research facility, laboratory and offices. The process wastewater is pretreated prior to discharge. The pretreatment consists of neutralization tanks for pH correction.

**DESCRIPTION OF DISCHARGE LOCATION (see attached Figure 1):**

**Name:** 001
**Latitude:** 40° 54' 51.43" N
**Longitude:** 74° 23' 37.98" W
**Description:** Manhole located in the parking lot of the facility.

**SUMMARY OF PERMIT CONDITIONS (see attached Table 1):**

The following pollutants are regulated: 5-day Biochemical Oxygen Demand ($BOD_5$), 5-day Carbonaceous Biochemical Oxygen Demand ($CBOD_5$), Total Suspended Solids (TSS), Total Dissolved Solids (TDS), pH, Oil & Grease (HEM), Total Petroleum Hydrocarbon (TPHC), Total phosphorus, Ammonia-Nitrogen ($NH_3$-N), Arsenic, Cadmium, Chromium, Copper, Lead, Mercury, Molybdenum, Nickel, Selenium, Zinc, Cyanide, Phenols, organics, and flow.

The basis for the limitations established is summarized in the local limits evaluation report titled RVRSA Local Limit Study, dated November 2014, last revised December 2016, including the April 14, 2017 Addendum; approved by the NJDEP on April 24, 2017, and approved by the RVRSA board on August 10, 2017 and on December 14, 2017.

Below is a summary of key aspects of this modified permit.

1. *Flow:* By a letter dated April 27, 2018, Enteris Biopharma requested a flow reduction of 6,000 gallons. The monthly average flow limitation has been reduced from the previous permit from 17,000 gpd to 11,000 gpd.

2. *Parameters of Concern:* None

3. *Other parameters:* The following parameters limitations have been updated or have been added as per the local limits study dated, November 2014, last revised December 2016, including April 14, 2017 Addendum; approved by the NJDEP on April 24, 2017, and approved by the RVRSA board on August 10, 2017 and on December 14, 2017. **Limitation updated:** $CBOD_5$, $BOD_5$, Total Suspended Solids (TSS), Ammonia-Nitrogen ($NH_3$-N), Oil & Grease (HEM), arsenic, cadmium, chromium, copper, lead, mercury, nickel, zinc and cyanide. **Parameters added:** TPHC, molybdenum, and selenium. **Parameters removed:** Silver

4. As per a letter received by RVRSA on April 27, 2018, from Enteris Biopharma, Enteris Biopharma has informed RVRSA that their production has changed and they have permanently discontinued all fermentation operations and they are now engaged only in pharmaceutical research and development. Therefore, the CFR subcategory has changed from Subpart A (Fermentation Product) to Subpart E (Research) and they are no longer subject to regulations under Subpart CFR 439.16. RVRSA is requiring Enteris Biopharma to continue analyzing the following organic parameters (monitor only) for process control purposes: Acetone, 4-methyl-2-penatanone (MIBK), Isobutyraldehyde, n-Amyl acetate, n-Butyl acetate, Ethyl acetate, Isopropyl acetate, Methyl formate, Isopropyl Ether, Tetrahydrofuran, Benzene, Toluene, Xylenes, n-Hexane, n-Heptane, Methylene chloride, Chloroform, 1,2-Dichloroethane, Chlorobenzene, o-Dichlorobenzene, Diethyl amine, Triethyl amine, Acetonitrile, Ethanol.

**VARIANCES OR ALTERNATIVES TO PERMIT CONDITIONS:**

None

**REGULATIONS APPLICABLE TO THIS PERMIT ACTION:**

This permit is issued in accordance with N.J.S.A 58:10A-6f, N.J.A.C. 7:14A-19.8, and 40CFR Part 403.8. Requirements for the contents of this Fact Sheet are in accordance with N.J.A.C. 7:14A-15.8.

This facility is subjected to 40 CFR § 439: Pharmaceutical Manufacturing Point Source Category; Subpart E: Research

**INDUSTRIAL PRETREATMENT PROGRAM CONTACT PERSON:**

Additional information concerning this permit may be obtained from Natalie Pisarcik, RVRSA IPP Coordinator, at 973-263-1555, ext. 213.

## TABLE – 1 : DISCHARGE LIMITATIONS

# ENTERIS BIOPHARMA

### Sample Location: Sampling Manhole (Combined)

| Parameter | Daily Max. Limit | Mo. Avg. Limit | Sample Frequency | Sample-Type |
|---|---|---|---|---|
| Flow | Report | 11,000 GPD (3) | Continuous | Metered |
| $CBOD_5$ | 500 mg/L (1) (2) | | Quarterly | Composite |
| $BOD_5$ | Report | | Quarterly | Composite |
| TSS | 500 mg/L (1) (2) | | Quarterly | Composite |
| TDS | Report | | Quarterly | Composite |
| pH | 5.5 - 9.5 S.U. (1) (4) | | Quarterly | Grab |
| $NH_3$-N | 80 mg/L (1) (2) | | Quarterly | Composite |
| O & G (HEM) | 350 mg/L (1) | | Quarterly | Grab |
| TPHC | 150 mg/l (1) | 100 mg/L (1) | Quarterly | Grab |
| Phosphorus (T) | Report | | Quarterly | Composite |
| Cyanide | 0.5 mg/L (1) | | Semi-Annually | Grab |
| Arsenic | 0.2 mg/L (1) | | Annually | Composite |
| Cadmium | 0.4 mg/L (1) | | Annually | Composite |
| Chromium | 1.3 mg/L (1) | | Annually | Composite |
| Copper | 1.7 mg/L (1) | | Annually | Composite |
| Lead | 1.0 mg/L (1) | | Annually | Composite |
| Mercury | 0.06 mg/L (1) | | Annually | Composite |
| Molybdenum | 0.3 mg/L (1) | | Annually | Composite |
| Nickel | 0.8 mg/L (1) | | Annually | Composite |
| Selenium | 0.2 mg/L (1) | | Annually | Composite |
| Zinc | 2.1 mg/L (1) | | Annually | Composite |
| Phenols | Report | | Annually | Grab |
| Organics | Report (5) | | Annually | Grab |

Notes:

(1) Discharge limits are based upon the RVRSA local limits.

(2) $CBOD_5$ and/or TSS concentration exceeding 250 mg/l and $NH_3$-N concentration exceeding 40 mg/L are subject to the Surcharge for Wastewaters of Excessive Strength as per Section 8B of this ISCP. Permittee may not discharge over the $CBOD_5$ limit of 500 mg/L, the TSS limit of 500 mg/L, or the $NH_3$-N limit of 80 mg/L unless a variance has been issued by the RVRSA providing therefore. Discharge above the above stated limitations will be considered a permit violation and subject to applicable enforcement actions.

(3) Flow limitation is a total of combined process and sanitary flows. Monthly average flow of not more than 11,000 gallons per day (GPD).

(4) The pH sample shall be analyzed by a NJDEP certified lab, within 15 minutes of collection of the sample.

(5) Organics: Acetone, 4-methyl-2-penatanone (MIBK), Isobutyraldehyde, n-Amyl acetate, n-Butyl acetate, Ethyl acetate, Isopropyl acetate, Methyl formate, Isopropyl Ether, Tetrahydrofuran, Benzene, Toluene, Xylenes, n-Hexane, n-Heptane, Methylene chloride, Chloroform, 1,2-Dichloroethane, Chlorobenzene, o-Dichlorobenzene, Diethyl amine, Triethyl amine, Acetonitrile, Ethanol.

Additional Notes:

The Self-Monitory Report (SMR) is due and shall be received by the RVRSA office on or before the 21st day of the month following the sampling month, or next business day (if date shall fall on a weekend and/or holiday). If no pollutant sample is collected or analyzed during a month, then the monthly report shall include at least flow data.

Parameters shall be tested according to the monitoring frequency and submitted in a monthly SMR along with copies of analytical results and chain of custody. All SMR's submitted must comply with and contain the signatory requirement as required under 40 CFR § 403.6 (a)(2)(ii) and must be signed by a responsible corporate officer as required under 40 CFR § 430.12(l).

Composite samples shall be collected over a twenty-four (24) hour period (programmed to sample every 15 minutes, unless otherwise stated). Each composite sample shall be a representative composite of the regulated discharge (e.g. 24-hour composite sample for 24-hour operation/discharge).

This facility is subject to 40 CFR § 439 "Pharmaceutical Manufacturing Point Source Category, Subpart E: Research"

The "Quarterly" sampling shall occur during the following months:
- 2018: January, April, July, October
- 2019: February, May, August, November
- 2020: March, June, September, December
- 2021: January, April, July, October

The "Semi-Annually" sample period shall correspond to the January – June and July – December months.

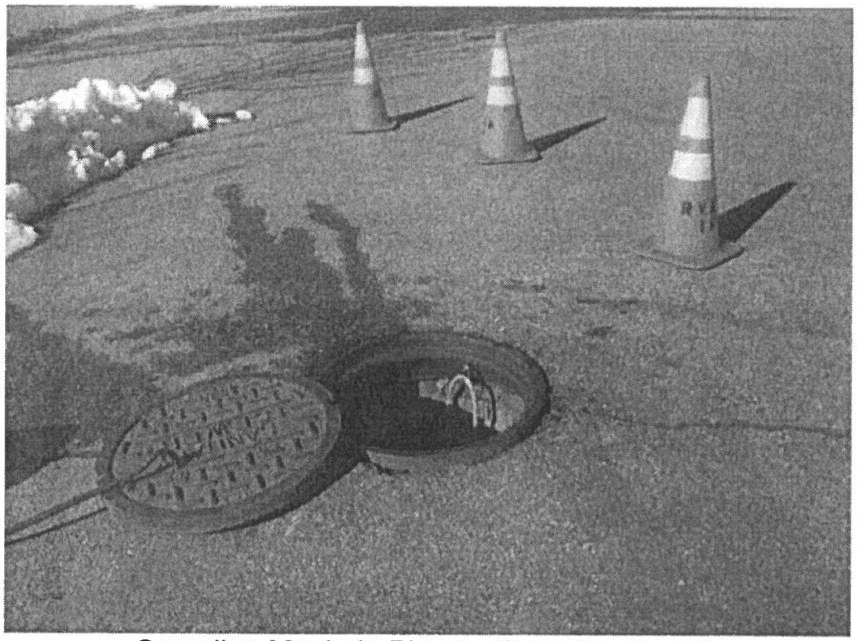
The “Annually” sample period shall correspond to the January – December calendar year.

Copies of manifests for process wastewater trucked offsite for disposal shall be made available for review by our offices.

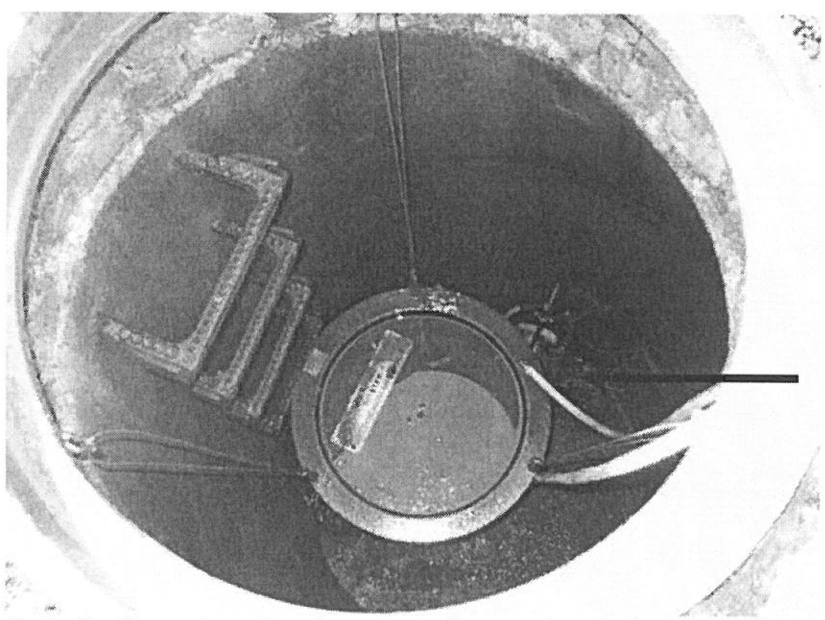
## FIGURE 1: Photos of Sampling Location

# ENTERIS BIOPHARAMA

SAMPLE MANHOLE (**Discharge location: 001**)
Manhole located in the parking lot of the facility.



Sampling Manhole Picture (Sampling Event)



**Arrow** is indicating where to place sampling probe during sampling events.