Pretreatment Permit

Issued to

Permittee: Tower Laboratories, Ltd.
P.O. Box 306
Centerbrook, CT 06409

Location Address: 7 Heritage Park Road

Permit ID: SP0002414

Permit Expires: January 17, 2018

Section 1: General Provisions

(A) This permit is reissued in accordance with section 22a-430 of Chapter 446k, Connecticut General Statutes ("CGS"), and Regulations of Connecticut State Agencies ("RCSA") adopted thereunder, as amended, and a modified Memorandum of Agreement (MOA) dated June 3, 1981, by the Administrator of the United States Environmental Protection Agency which authorizes the State of Connecticut to administer a Pretreatment Program pursuant to 40 CFR Part 403.

(B) Tower Laboratories, Ltd., ("Permittee"), shall comply with all conditions of this permit including the following sections of the RCSA, which have been adopted pursuant to section 22a-430 of the CGS and are hereby incorporated into this permit. Your attention is especially drawn to the notification requirements of subsection (i)(2), (i)(3), (j)(1), (j)(6), (j)(8), (j)(9)(C), (j)(11)(C), (D), (E), (F), (k)(3) and (4) and (l)(2) of section 22a-430-3.

Section 22a-430-3 General Conditions

(a) Definitions
(b) General
(c) Inspection and Entry
(d) Effect of a Permit
(e) Duty to Comply
(f) Proper Operation and Maintenance
(g) Sludge Disposal
(h) Duty to Mitigate
(i) Facility Modifications; Notification
(j) Monitoring, Records and Reporting Requirements
(k) Bypass
(l) Conditions Applicable to POTWs
(m) Effluent Limitation Violations (Upsets)
(n) Enforcement
(o) Resource Conservation
(p) Spill Prevention and Control
(q) Instrumentation, Alarms, Flow Recorders
(r) Equalization

Section 22a-430-4 Procedures and Criteria

(a) Duty to Apply
(b) Duty to Reapply
(c) Application Requirements  
(d) Preliminary Review  
(e) Tentative Determination  
(f) Draft Permits, Fact Sheets  
(g) Public Notice, Notice of Hearing  
(h) Public Comments  
(i) Final Determination  
(j) Public Hearings  
(k) Submission of Plans and Specifications. Approval.  
(l) Establishing Effluent Limitations and Conditions  
(m) Case by Case Determinations  
(n) Permit issuance or renewal  
(o) Permit Transfer  
(p) Permit revocation, denial, or modification  
(q) Variances  
(r) Secondary Treatment Requirements  
(s) Treatment Requirements for Metals and Cyanide  
(t) Discharges to POTWs - Prohibitions  

(C) Violations of any of the terms, conditions, or limitations contained in this permit may subject the Permittee to enforcement action, including but not limited to, seeking penalties, injunctions and/or forfeitures pursuant to applicable sections of the CGS and RCSA. Specifically, civil penalties of up to twenty-five thousand dollars may be assessed per violation per day.

(D) Any false statement in any information submitted pursuant to this permit may be punishable as a criminal offense under section 22a-438 or 22a-131a of the CGS or in accordance with section 22a-6, under section 53a-157b of the CGS.

(E) The authorization to discharge under this permit may not be transferred without prior written approval of the Commissioner of Energy and Environmental Protection (“the Commissioner”). To request such approval, the Permittee and proposed transferee shall register such proposed transfer with the Commissioner at least 30 days prior to the transferee becoming legally responsible for creating or maintaining any discharge, which is the subject of the permit transfer. Failure by the transferee to obtain the Commissioner’s approval prior to commencing such discharge(s) may subject the transferee to enforcement action for discharging without a permit pursuant to applicable sections of the CGS and RCSA.

(F) Nothing in this permit shall relieve the Permittee of other obligations under applicable federal, state and local law.

(G) An annual fee shall be paid for each year this permit is in effect as set forth in section 22a-430-7 of the Regulations of Connecticut State Agencies.

(H) This permitted discharge is consistent with the applicable goals and policies of the Connecticut Coastal Management Act (section 22a-92 of the Connecticut General Statutes).

SECTION 2: DEFINITIONS

(A) The definitions of the terms used in this permit shall be the same as the definitions contained in section 22a-423 of the CGS and section 22a-430-3(a) and 22a-430-6 of the RCSA.

(B) In addition to the above the following definitions shall apply to this permit:

"----" in the limits column on the monitoring table means a limit is not specified but a value must be reported on the DMR.

"Average Monthly Limit" means the maximum allowable "Average Monthly Concentration" as defined in section 22a-430-3(a) of the RCSA when expressed as a concentration (e.g. mg/l); otherwise, it means "Average Monthly Discharge Limitation" as defined in section 22a-430-3(a) of the RCSA.

"Batch" means the total volume of wastewater collected in approximately three (3) 1,200-gallon
tanks.

"Daily Concentration" means the concentration of a substance as measured in a daily composite sample, or the arithmetic average of all grab sample results defining a grab sample average.

"Daily Quantity" means the quantity of waste generated during an operating day.

"Grab Sample Average (GSA)" means the arithmetic average of all grab sample analyses. Grab samples shall be collected just prior to discharge from the storage tanks (minimum of two grab samples per day).

"Instantaneous Limit" means the highest allowable concentration of a substance as measured by a grab sample, or the highest allowable measurement of a parameter as obtained through instantaneous monitoring.

"Maximum Daily Limit" means the maximum allowable "Daily Concentration" (defined above) when expressed as a concentration (e.g. mg/l); otherwise, it means the maximum allowable "Daily Quantity" as defined above unless it is expressed as a flow quantity. If expressed as a flow quantity it means "Maximum Daily Flow" as defined in section 22a-430-3(a) of the RCSA.

"mg/l" means milligrams per liter.

"NA" as a Monitoring Table abbreviation means "not applicable".

"NR" as a Monitoring Table abbreviation means "not required".

"Quarterly", in the context of sampling frequency, means sampling is required in the months of March, June, September and December.

"Range During Sampling" or "RDS", as a sample type, means the maximum and minimum of all values recorded as a result of analyzing each grab sample of; 1) a Composite Sample, or 2) a Grab Sample Average. For those permittees with continuous monitoring and recording pH meters, Range During Sampling shall mean the maximum and minimum readings recorded with the continuous monitoring device during the Composite or Grab Sample Average sample collection.

"Semi-Annually" in the context of a sampling frequency, means the sample must be collected in the months of June and December.

SECTION 3: COMMISSIONER'S DECISION

(A) The Commissioner has made a final determination and found that the continuance of the existing system to treat the discharge will protect the waters of the state from pollution. The Commissioner's decision is based on Application No. 201200500 for permit reissuance received on February 6, 2012 and the administrative record established in the processing of that application.

(B) (1) From the issuance of this permit through and including [LAST DAY OF MONTH, MONTH OF PERMIT REISSUANCE], the Commissioner hereby authorizes the Permittee to discharge in accordance with the terms and conditions of Permit No. SP0002414, issued by the Commissioner to the Permittee on August 2, 2007, the previous application submitted by the Permittee on March 24, 2005, and all modifications and approvals issued by the Commissioner or the Commissioner’s authorized agent for the discharge and/or activities authorized by, or associated with, Permit No. SP0002414, issued by the Commissioner to the Permittee on August 2, 2007.

(2) From [FIRST DAY OF MONTH, MONTH FOLLOWING PERMIT ISSUANCE] until this permit expires or is modified or revoked, the Commissioner hereby authorizes the Permittee to discharge in accordance with the terms and conditions of Permit No. SP0002414, issued by the Commissioner to the Permittee on [DATE OF PERMIT ISSUANCE], Application No. 201200500 received by the Department on February 6, 2012, and all modifications and approvals issued by the Commissioner or the Commissioner’s authorized agent for the discharge and/or activities authorized by, or associated with, Permit No. SP0002414, issued by the Commissioner to the Permittee on [DATE OF PERMIT ISSUANCE].
(C) The Commissioner reserves the right to make appropriate revisions to the permit in order to establish any appropriate effluent limitations, schedules of compliance, or other provisions that may be authorized under the Federal Clean Water Act or the Connecticut General Statutes or regulations adopted thereunder, as amended. The permit as modified or renewed under this paragraph may also contain any other requirements of the Federal Clean Water Act or Connecticut General Statutes or regulations adopted thereunder which are then applicable.

SECTION 4: EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

(A) The discharge shall not exceed and shall otherwise conform to specific terms and conditions listed below. The discharge is restricted by, and shall be monitored in accordance with, the table below.
Table A

**Wastewater Description:** Pretreated wastewaters from air compressor condensate, process equipment and floor cleaning, and sanitation wastewaters

**Monitoring Location Description:** During pumping from the storage tank to the tanker truck for hauling

**Discharge is to:** The Metropolitan District Commission Hartford Water Pollution Control Facility via truck.

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>UNITS</th>
<th>FLOW/TIME BASED MONITORING</th>
<th>INSTANTANEOUS MONITORING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>FLOW/TIME BASED MONITORING</strong></td>
<td><strong>INSTANTANEOUS MONITORING</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Average Monthly Limit</td>
<td>Maximum Daily Limit</td>
</tr>
<tr>
<td>Acetone</td>
<td>mg/l</td>
<td>8.2</td>
<td>8.2</td>
</tr>
<tr>
<td>Boron, Total</td>
<td>mg/l</td>
<td>NA</td>
<td>---</td>
</tr>
<tr>
<td>Ethyl acetate *</td>
<td>mg/l</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>Flow, Total (Day of Sampling)</td>
<td>gpd</td>
<td>NA</td>
<td>4,999</td>
</tr>
<tr>
<td>Flow, Maximum During 24 hr Period¹</td>
<td>gpd</td>
<td>NA</td>
<td>4,999</td>
</tr>
<tr>
<td>Isopropyl acetate *</td>
<td>mg/l</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>Methylene chloride *</td>
<td>mg/l</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>Lead, Total</td>
<td>mg/l</td>
<td>NA</td>
<td>---</td>
</tr>
<tr>
<td>n-Amyl acetate *</td>
<td>mg/l</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>Oil Petroleum, Total Recoverable</td>
<td>mg/l</td>
<td>NA</td>
<td>100.0</td>
</tr>
<tr>
<td>pH (Day of Sampling)</td>
<td>S.U.</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Table A Footnotes and Remarks:

**Footnotes:**
³ For this parameter, the Permittee shall maintain at the facility a record of the quantity (in gallons) of each shipment of wastewater from the facility for each day a shipment occurs and shall report the Maximum Daily Flow for each sampling month.

² The first entry in this column is the ‘Sample Frequency’. If this entry is not followed by a ‘Reporting Frequency’ and the ‘Sample Frequency’ is more frequent than monthly then the ‘Reporting Frequency’ is monthly. If the ‘Sample frequency’ is specified as monthly, or less frequent, then the ‘Reporting Frequency’ is the same as the ‘Sample Frequency’.

³ Composite” shall consist of grab samples collected from three storage tanks and combined into one sample.

**Remarks:**
* See Section 4(D) of this permit.
(B) All samples shall be comprised of only those wastewaters described in this schedule; therefore, samples shall be taken prior to combination with wastewaters of any other type and after all approved treatment units, if applicable. All samples taken shall be representative of the discharge during standard operating conditions.

(C) In cases where limits and sample type are specified but sampling is not required, the limits specified shall apply to all samples, which may be collected and analyzed by, the Department of Energy and Environmental Protection personnel, the Permittee, or other parties.

(D) Although n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride are regulated chemicals included in the federal wastewater discharge category associated with this facility (40 CFR 439), the Permittee is authorized to forego sampling for these parameters in accordance with section 40 CFR 403.12(e)(2) of the federal regulations. Consistent with this section of the regulations, the Permittee shall include a statement on each Discharge Monitoring Report (DMR), on a form provided (Attachment A), certifying there has been no increase in the levels of n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride due to the activities at the facility since filing of the last DMR. Additionally, in the event that any of these chemical parameters are found to be present or are expected to be present based on changes that occur in the Permittee’s operations, the Permittee shall notify the Department and must immediately comply with the permit requirements provided in the table above.

SECTION 5: SAMPLE COLLECTION, HANDLING AND ANALYTICAL TECHNIQUES AND REPORTING REQUIREMENTS

(A) Chemical analyses to determine compliance with effluent limits and conditions established in this permit shall be performed using the methods approved by the Environmental Protection Agency pursuant to 40 CFR 136 unless an alternative method has been approved in writing in accordance with 40 CFR 136.4 or as provided in section 22a-430-3(j)(7) of the RCSA. Chemicals which do not have methods of analysis defined in 40 CFR 136 shall be analyzed in accordance with methods specified in this permit.

(B) All metals analyses identified in this permit shall refer to analyses for Total Recoverable Metal as defined in 40 CFR 136 unless otherwise specified.

(C) The results of chemical analysis required above shall be entered on the Discharge Monitoring Report (DMR), provided by this office, and reported to the Bureau of Materials Management and Compliance Assurance at the following address. Except for continuous monitoring, any monitoring required more frequently than monthly shall be reported on an attachment to the DMR, and any additional monitoring conducted in accordance with 40 CFR 136 or other methods approved by the Commissioner shall also be included on the DMR, or as an attachment, if necessary. The report shall also include a detailed explanation of any violations of the limitations specified. The DMR shall be received at this address by the last day of the month following the month in which samples are taken.

Bureau of Materials Management and Compliance Assurance
Water Permitting and Enforcement Division (Attn: DMR Processing)
Connecticut Department of Energy and Environmental Protection
79 Elm Street
Hartford, CT 06106-5127

(D) If this permit requires monitoring of a discharge on a calendar basis (e.g. Monthly, quarterly, etc.) but a discharge has not occurred within the frequency of sampling specified in the permit, the Permittee must submit the DMR as scheduled, indicating “NO DISCHARGE.” For those permittees whose required monitoring is discharge dependent (e.g. per batch), the minimum reporting frequency is monthly. Therefore, if there is no discharge during a calendar month for a batch discharge, a DMR must be submitted indicating such by the end of the following month.

(E) NetDMR Reporting Requirements

1. Prior to one-hundred and eighty (180) days after the issuance of this permit, the Permittee may either submit monitoring data and other reports to the Department in hard copy form or electronically using NetDMR, a web-based tool that allows Permittees to electronically submit discharge monitoring reports (DMRs) and other required reports through a secure internet connection. Unless otherwise approved in writing by the Commissioner, no later than one-hundred and eighty (180) days after the issuance of this permit the
Permittee shall begin reporting electronically using NetDMR. Specific requirements regarding subscription to NetDMR and submittal of data and reports in hard copy form and for submittal using NetDMR are described below:

a. Submittal of NetDMR Subscriber Agreement

On or before fifteen (15) days after the issuance of this permit, the Permittee and/or the person authorized to sign the Permittee’s discharge monitoring reports (“Signatory Authority”) as described in RCSA Section 22a-430-3(b)(2) shall contact the Department at deep.netdmr@ct.gov and initiate the NetDMR subscription process for electronic submission of Discharge Monitoring Report (DMR) information. Information on NetDMR is available on the Department’s website at www.ct.gov/deep/netdmr. On or before ninety (90) days after issuance of this permit the Permittee shall submit a signed and notarized copy of the Connecticut DEEP NetDMR Subscriber Agreement to the Department.

b. Submittal of Reports Using NetDMR

Unless otherwise approved by the Commissioner, on or before one-hundred and eighty (180) days after issuance of this permit, the Permittee and/or the Signatory Authority shall electronically submit DMRs and reports required under this permit to the Department using NetDMR in satisfaction of the DMR submission requirement of Section 5(C) of this permit.

DMRs shall be submitted electronically to the Department no later than the 30th day of the month following the completed reporting period. All reports required under the permit, including any monitoring conducted more frequently than monthly or any additional monitoring conducted in accordance with 40 CFR 136, shall be submitted to the Department as an electronic attachment to the DMR in NetDMR. Once a Permittee begins submitting reports using NetDMR, it will no longer be required to submit hard copies of DMRs or other reports to the Department. The Permittee shall also electronically file any written report of non-compliance described in Section 6 of this permit as an attachment in NetDMR. NetDMR is accessed from: http://www.epa.gov/netdmr.

c. Submittal of NetDMR Opt-Out Requests

If the Permittee is able to demonstrate a reasonable basis, such as technical or administrative infeasibility, that precludes the use of NetDMR for electronically submitting DMRs and reports, the Commissioner may approve the submission of DMRs and other required reports in hard copy form (“opt-out request”). Opt-out requests must be submitted in writing to the Department for written approval on or before fifteen (15) days prior to the date a Permittee would be required under this permit to begin filing DMRs and other reports using NetDMR. This demonstration shall be valid for twelve (12) months from the date of the Department’s approval and shall thereupon expire. At such time, DMRs and reports shall be submitted electronically to the Department using NetDMR unless the Permittee submits a renewed opt-out request and such request is approved by the Department.

All opt-out requests and requests for the NetDMR subscriber form should be sent to the following address or by email at deep.netdmr@ct.gov:

Attn: NetDMR Coordinator

Connecticut Department of Energy and Environmental Protection
79 Elm Street
Hartford, CT 06106-5127

(F) Copies of all DMRs shall be submitted concurrently to the local Water Pollution Control Authority ("WPCA") involved in the treatment and collection of the permitted discharge.

SECTION 6: RECORDING AND REPORTING OF VIOLATIONS, ADDITIONAL TESTING REQUIREMENTS

(A) If any sample analysis indicates that an effluent limitation specified in Section 4 of this permit has been exceeded, a second sample of the effluent shall be collected and analyzed for the parameter(s) in question and the results reported to the Bureau of Materials Management and Compliance Assurance (Attn: DMR Processing)
within 30 days of the exceedance.

(B) The Permittee shall immediately notify the Bureau of Materials Management and Compliance Assurance and the local WPCA of all discharges that could cause problems to the Publicly Owned Treatment Works ("POTW"), including but not limited to slug loadings of pollutants which may cause a violation of the POTW’s NPDES permit, or which may inhibit or disrupt the POTW, its treatment processes or operations, or its sludge processes, use or disposal.

(C) In addition to the notification requirements specified in Section 1B of this permit, if any sampling and analysis of the discharge performed by the Permittee indicates a violation of limits specified in Section 4 of this permit, the Permittee shall notify the Bureau of Materials Management and Compliance Assurance within 24 hours of becoming aware of the violation.

SECTION 7: COMPLIANCE CONDITIONS

In accordance with 40 CFR §403.8(f)(2)(viii), the Commissioner may provide public notification, in a newspaper of general circulation in the area of the respective POTW, of permittees that at any time in the previous twelve months were in significant noncompliance with the provisions of this permit. For the purposes of this provision, a permittee that is a Significant Industrial User is in significant noncompliance if its violation(s) meet(s) one or more of the following criteria:

- **Chronic violations:** Those in which sixty-six (66%) percent or more of all measurements taken for the same pollutant parameter during a six-month period exceed (by any magnitude) the Average Monthly, Maximum Daily, or Maximum Instantaneous Limit(s).

- **Technical Review Criteria violations:** Those in which thirty-three (33%) or more of all of the measurements taken for the same pollutant parameter during a six-month period equal or exceed the Average Monthly, Maximum Daily, or Maximum Instantaneous Limit(s) multiplied by 1.4 for BOD, TSS, fats, oil, and grease, or 1.2 for all other pollutants except pH.

- **Monitoring Reports:** Failure to provide, within 45 days after the due date, required reports such as DMRs.

- **Compliance Schedule:** Failure to meet within 90 days after the schedule date, a compliance schedule milestone contained in or linked to a respective permit for starting construction, completing construction, or attaining final compliance.

- **Noncompliance Reporting:** Failure to accurately report noncompliance in accordance with provisions identified in Section 6 of this permit.

- **Discretionary:** Any other violation of an effluent limit that the Department determines has caused, alone or in combination with other discharges, a violation of the POTW’s NPDES permit, inhibition or disruption of the POTW, its treatment processes or operations, or its sludge processes, use or disposal.

- **Imminent Endangerment:** Any discharge of a pollutant that has caused imminent endangerment to human health, welfare or to the environment, or has resulted in the Department’s exercise of its emergency authority under 40 CFR §403.8(f)(1)(vi)(B) to halt or prevent such a discharge.

- **BMPs:** Any other violation or group of violations, which may include a violation of Best Management Practices, which the Department determines will adversely affect the operation or implementation of the pretreatment program.

This permit is hereby issued on January 18, 2013

/s/KIM E. HUDAK, P.E.
Kim E. Hudak, P.E.
Assistant Director
Water Permitting and Enforcement Division
Bureau of Materials Management and Compliance Assurance

KEH/EW
The Metropolitan District Commission Hartford WPCF
Certification: Waiver of Monitoring

Attachment A

“Based on my inquiry of the person or persons directly responsible for managing compliance with the Pretreatment Standard for New Sources 40 CFR 439.47 Pharmaceutical Manufacturing Category, I certify that, to the best of my knowledge and belief, there has been no increase in the level of n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride in the wastewaters due to the activities at the facility since filing of the last Discharge Monitoring Report.”

Authorized Official: ___________________________   Title: __________________________
Signature:____________________________________   Date:__________________________
DATA TRACKING AND TECHNICAL FACT SHEET

Permittee: Tower Laboratories, Ltd.

PERMIT, ADDRESS, AND FACILITY DATA

PERMIT #: SP0002414 APPLICATION #: 201200500

<table>
<thead>
<tr>
<th>Mailing Address:</th>
<th>Location Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street: P.O. BOX 306</td>
<td>Street: 7 Heritage Park Road</td>
</tr>
<tr>
<td>City: Centerbrook</td>
<td>City: Clinton</td>
</tr>
<tr>
<td>ST: CT</td>
<td>ST: CT</td>
</tr>
<tr>
<td>Zip: 06409</td>
<td>Zip: 06413</td>
</tr>
</tbody>
</table>

Contact Name: Jeff Brewer DMR Contact: Same

Phone No.: (860) 767-4883 Phone No.: 

Contact E-mail: jeffb@towerlabs.com DMR Contact E-mail: 

PERMIT INFORMATION

DURATION 5 YEAR X 10 YEAR _ 30 YEAR __

TYPE New _ Reissuance X Modification_

CATEGORIZATION POINT (X) NON-POINT (_) GIS #

NPDES (_) PRETREAT (X) GROUND WATER(UIC) (_) GROUND WATER (OTHER) (_)

NPDES MAJOR(MA) ___

NPDES SIGNIFICANT MINOR or PRETREAT SIU (SI) ___

NPDES or PRETREATMENT MINOR (MI) X

PRETREAT SIGNIFICANT INDUS USER(SIU) X

PRETREAT CATEGORICAL (CIU) X

POLLUTION PREVENTION MANDATE ___ ENVIRONMENTAL EQUITY ISSUE ___

SIC CODE: 2834 Pharmaceutical Preparations

COMPLIANCE ISSUES

COMPLIANCE SCHEDULE YES _ NO X

POLLUTION PREVENTION _ TREATMENT REQUIREMENT _ WATER CONSERVATION _

WATER QUALITY REQUIREMENT _ REMEDIATION _ OTHER

IS THE PERMITTEE SUBJECT TO A PENDING ENFORCEMENT ACTION? NO X YES _

OWNERSHIP CODE

Private X Federal _ State _ Municipal (town only) _ Other public

DEEP STAFF ENGINEER: Enna Wilson

PERMIT No. SP0002414 Page 1
PERMIT FEES

<table>
<thead>
<tr>
<th>Discharge Code</th>
<th>DSN Number</th>
<th>Annual Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>501047Y</td>
<td>201-1</td>
<td>$4,337.50</td>
</tr>
</tbody>
</table>

FOR SEWER DISCHARGES

Discharge to the Metropolitan District Commission Hartford Water Pollution Control Facility via truck. The facility ID. of the POTW is 064-001.

NATURE OF BUSINESS GENERATING DISCHARGE

Tower Laboratories, Ltd. is primarily engaged in the manufacturing of effervescent products for health, nutritional, cleansing and therapeutic needs. Manufacturing products include denture cleansers, laxatives, potassium supplements, sports, nutritional drinks, and aromatherapy tablets.

PROCESS AND TREATMENT DESCRIPTION (by DSN)

DSN 201-1: Consists of a maximum daily flow of 4,999 gallons per day of pretreated wastewaters from air compressor condensate, process equipment and floor cleaning, and sanitation wastewaters associated with the production of effervescent products for health, nutritional, cleansing, and therapeutic needs. These wastewaters are treated through an oil water separator.

EFFLUENT VIOLATIONS

A review of Tower Laboratories, Ltd. ’s DMRs over the last five (5) years revealed compliance with the effluent limitations of the existing permit.

RESOURCES USED TO DRAFT PERMIT

\[ X \] Federal Effluent Limitation Guideline \ 40 CFR 439.47, Subpart D, (PSNS)
\[ \] Pharmaceutical Manufacturing Point Source
\[ \] Performance Standards
\[ X \] Federal Development Document \ Pharmaceutical Manufacturing Point Source
\[ \] Name of category
\[ \] Treatability Manual
\[ X \] Department File Information
\[ \] Connecticut Water Quality Standards
\[ \] Anti-degradation Policy
\[ X \] Coastal Management Consistency Review Form (See Other Comments)
\[ X \] Other – Explain (See General Comments)

BASIS FOR LIMITATIONS, STANDARDS, OR CONDITIONS

\[ X \] Pretreatment Standards for New Sources (PSNS)
Case-by-Case Determination and Best Professional Judgment

DSN 201: total boron and lead, acetone (MDL, MIL), n-amyl acetate, ethyl acetate, isopropyl acetate, methylene chloride, pH, and total recoverable oil petroleum.

AML- Average Monthly limit, MDL-Maximum Daily Limit, MIL-Maximum Instantaneous Limit

GENERAL COMMENTS

The selection of parameters of concern was determined using best professional judgment on a case-by-case basis.

Basis for Effluent Limitations and Monitoring Requirements

During the technical review of Tower Laboratories, Ltd.’s application, DEEP staff used effluent characterization information in the application to determine that limits are needed for pH, acetone, n-amyl acetate, ethyl acetate, isopropyl acetate, methylene chloride, and total recoverable oil petroleum to protect the Metropolitan District Commission Hartford WPCF from pass-through or interference.

DEEP staff is recommending pH limits of (5.0 - 9.0) S.U., which are considered to be protective of sanitary sewer systems.

Wastewater discharges from the production of pharmaceutical preparations are regulated under 40 CFR 439, Pharmaceutical Manufacturing Category. Tower Laboratories, Ltd. initiated this discharge after May 2, 1995, the promulgation date of the Pretreatment Standards for New Sources (PSNS). Therefore, this facility is a new source, subject to the PSNS in 40 CFR 439, Subpart D. Section 439.47 (PSNS) identifies the following parameters for regulation: acetone, n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride. DEEP staff is proposing effluent limitations for these parameters that are more stringent than required under section 439.47 (PSNS) using the criteria of best professional judgment pursuant to Section 22a-430-4(m) of the RCSA based on a determination that these pollutants are not used or expected to be present in the effluent.

EPA’s General Pretreatment Streamlining Regulations for Existing and New Sources of Pollution, Section 403.8(f)(2)(v) and 403.12(e), authorize the Control Authority (CT DEEP) to waive permit monitoring requirements for pollutants that are not present and/or used anywhere in the Permittee’s facility, but are included in the respective federal category. Tower Laboratories, Ltd. has analyzed representative untreated samples of its process wastewater for acetone, n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride using the most sensitive EPA approved method. Only acetone was found in detectable levels in the samples. As a result, DEEP staff is recommending that Tower Laboratories, Ltd. be authorized to forego monitoring for n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride. Consistent with section 403.12(e)(2) of the regulations, the Permittee shall include a statement, as an attachment, on each Discharge Monitoring Report (DMR), certifying there has been no increase in the levels of n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride due to the activities at the facility since filing of the last DMR. Additionally, in the event that any of these chemical parameters are found to be present or are expected to be present based on changes that occur in the Permittee’s operations, the Permittee shall immediately notify the Department and begin monitoring for these parameters as required in the Table A. Acetone was found to be present in the untreated samples. Therefore, acetone was not included in the waiver of monitoring.

A special new condition is included in Section 4 of this permit that reads, “Although n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride are regulated chemicals included in the federal wastewater discharge category associated with this facility (40 CFR 439), the Permittee is authorized to forego sampling for these parameters in accordance with section 40 CFR 403.12(e)(2) of the federal regulations. Consistent with this section of the regulations, the Permittee shall include a statement on each Discharge Monitoring Report (DMR), on a form provided (Attachment A), certifying there has been no increase in the levels of n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride due to the activities at the facility since filing of the last DMR. Additionally, in the event that any of these chemical parameters are found to be present or are expected to be
present based on changes that occur in the Permittee’s operations, the Permittee shall notify the Department and must immediately comply with the permit requirements provided in the table above.”

The effluent limitations proposed for total recoverable oil petroleum are based on a report entitled “Treatability of Oil and Grease Discharged to Publicly Owned Treatment Works”, USEPA, Effluent Guidelines Division, EPA/440/1-75-066 (April 1975).

During the technical review of Tower Laboratories, Ltd’s renewal application and supporting analytical results, total boron and lead were listed as being at a concentration of at least 9.5 mg/l and 0.4 mg/l, respectively. Boron has been identified to be present in the raw materials for the denture cleaner formulation. In regards to total lead effluent level, DEEP staff requested the Applicant to conduct an investigation into the potential source of lead in the wastewater. On October 23, 2012, the Department received a letter detailing the results of the investigation into the potential source of lead in the wastewater. The result of the investigation determined that lead is found in Tower Laboratories wastewater from the concrete floors washing. This investigation also identified that the raw materials used in the cement manufacturing process contain lead concentration impurities. The Applicant also provided information about EPA research study on Cement Kiln Dust Waste (CKD) that supports this finding (available at http://www.epa.gov/osw/nonhaz/industrial/special/ckd/rtc/chap-5.pdf). The DEEP staff is recommending that monitoring requirements for total boron and lead be incorporated in this permit renewal.

Since this application does not include any new exterior construction at the facility, the applicant was not required to submit a CAM consistency form. This facility is considered to be consistent with the CAM Act.