

79 Elm Street • Hartford, CT 06106-5127

www.ct.gov/deep

Affirmative Action/Equal Opportunity Employer

PRETREATMENT PERMIT
issued to

Location Address:

Faria Limited LLC
d/b/a Sheffield Pharmaceuticals
170 Broad Street
New London, CT, 06320

170 Broad Street
New London, CT 06320

Permit ID: SP0002442

Permit Expires: September 12, 2015

SECTION 1: GENERAL PROVISIONS

- (A) This permit is issued 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) **Faria Limited LLC, d/b/a Sheffield Pharmaceuticals**, ("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 subsections (i)(2), (i)(3), (j)(1), (j)(6), (j)(8), (j)(9)(C), (j)(11)(C), (D), (E), and (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 RCSA.
- (H) This permitted discharge is consistent with the applicable goals and policies of the Connecticut Coastal Management Act (section 22a-92 of the CGS).

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 sections 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.

"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 Composite" means (1) a composite sample taken over a full operating day consisting of grab samples collected at equal intervals of no more than sixty (60) minutes and combined proportionally to flow, or (2) a composite sample continuously collected over a full operating day proportionally to flow. Upon submission of documentation by the applicant satisfactory to the commissioner that a discharge is of consistent effluent quality, the commissioner may allow equal sampling intervals of up to four (4) hours for a daily composite sample.

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

"Grab Sample Average" or "GSA" means the arithmetic average of all grab sample analyses. Grab samples shall be collected at least once every four hours over a full operating day for as long as a discharge exists on that day (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 a sampling frequency, means sampling is required in the months of March, June, September, and December. In the event that the discharge does not occur in any of these sampling months, the Permittee shall sample during the next discharge event.

"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-annual" in the context of a sampling frequency, means the sample must be collected in each six-month period and reported in the months of June and December.

"Twice per Month" when used as a sample frequency shall mean two samples per calendar month collected no less than twelve (12) days apart.

SECTION 3: COMMISSIONER'S FINAL DETERMINATION

- (A) The Commissioner has made a final determination and found that the system installed for the treatment of the discharge, will protect the waters of the state from pollution. The Commissioner's final determination is based on Application No. 201104540 for permit received on May 27, 2011 and the administrative record established in the processing of that application.
- (B) From September 13, 2013 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. SP0002442 issued by the Commissioner to the Permittee on September 13 2013, Application No. 201104540 received by the Department on May 27, 2011, 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. SP0002442, issued by the Commissioner to the Permittee on September 13, 2013.
- (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

Monitoring Location: 1

Discharge Serial Number: 201-1

Wastewater Description: Pretreated wastewaters from cleaning operations associated with the formulation and packaging of gels, toothpastes, creams, ointments, denture adhesives, and iodine ointments, vacuum pump condensate, and the cleaning of laboratory glassware and equipment.

Monitoring Location Description: At the sample valve after the final centrifugal pump (C1)

Discharge is to: The City of New London Water Pollution Control Facility

PARAMETER		UNITS	FLOW/TIME BASED MONITORING					INSTANTANEOUS MONITORING		
			Average Monthly Limit	Maximum Daily Limit	Sample/Reporting Frequency ²	Sample Type or Measurement to be reported	Instantaneous limit or required range	Sample/ Reporting Frequency ²	Sample Type or measurement to be reported	
	Acetone	mg/l	1.0	2.0	Quarterly	GSA	3.0	NR	Grab	
	Copper, Total	mg/l	---	---	Twice Per Month	Daily Composite	NA	NR	Grab	
	Ethyl acetate	mg/l	0.25	0.5	Semi-Annual	GSA	0.5	NR	Grab	
	Flow (Day of Sampling)	gpd	NA	16,000	Twice Per Month	Total Flow	NA	NR	NA	
	Flow, Maximum During 24 hr Period ¹	gpd	NA	16,000	Daily	Total Flow	NA	NR	NA	
	Fluoride, Total	mg/l	20.0	30.0	Monthly	Daily Composite	30.0	NR	Grab	
	Isopropyl acetate	mg/l	0.25	0.5	Semi-Annual	GSA	0.5	NR	Grab	
	Methylene chloride	mg/l	0.25	0.5	Semi-Annual	GSA	0.5	NR	Grab	
	n-Amyl acetate	mg/l	0.25	0.5	Semi-Annual	GSA	0.5	NR	Grab	
	Oil Petroleum, Total Recoverable	mg/l	100.0	150.0	Monthly	GSA	150.0	NR	Grab	
	pH (Day of Sample)	S.U.	NA	NA	Twice Per Month	NA	6.0-10.0	NR	RDS	
	pH, Maximum	S.U.	NA	NA	NR	NA	10.0	Continuous	Continuous	
	pH, Minimum	S.U.	NA	NA	NR	NA	6.0	Continuous	Continuous	
	Phosphorus, Total As P	mg/l	NA	---	Monthly	Daily Composite	NA	NR	Grab	
	Surfactants (MBAS)	mg/l	NA	---	Quarterly	Daily Composite	NA	NR	Grab	
	Titanium, Total	mg/l	NA	---	Quarterly	Daily Composite	NA	NR	Grab	
	Total Suspended Solids	mg/l	NA	---	Monthly	Daily Composite	NA	NR	Grab	
	Zinc, Total	mg/l	---	---	Twice Per Month	Daily Composite	NA	NR	Grab	

Table A Footnotes:

¹ For this parameter, the Permittee shall maintain at the facility a record of the Total Daily Flow for each day of discharge and shall report the Maximum Daily Flow for each 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 frequently, then the 'Reporting Frequency' is the same as the 'Sample Frequency'.

- (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 chemicals regulated under the Federal categorical pretreatment standard applicable to this facility (40 CFR 439, Subpart D), 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 of this permit), 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 monitoring requirements provided in the table above.
- (E) The Permittee shall collect all wastewater generated from the cleaning of tanks used in the manufacturing of formulations containing zinc oxide and non-conforming materials as described in Appendix I of the Operation and Maintenance Plan and dispose of these materials through a licensed hauler in a manner acceptable to the Commissioner.

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 DMR, provided by this office, and reported to the Bureau of Materials Management and Compliance Assurance at the following address below. 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) 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 SCHEDULE

- (A) On or before one hundred and fifty (**150**) days after the date of issuance of this permit, the Permittee shall submit for the Commissioner's review and written approval a scope of study for an investigation to reduce the flow of DSN 201-1 or eliminate the discharge. The scope of study shall include a substantive plan and schedule, for the Commissioner's review and written approval, for conducting the investigation, reporting to the Commissioner on the results of such investigation, including an evaluation of which alternatives are prudent and feasible, and implementation of the preferred alternative.
- (B) On or before three hundred and sixty-five (**365**) days after the date of issuance of this permit, the Permittee shall submit for the Commissioner's review and written approval a comprehensive and thorough report that describes and evaluates alternative actions which may be taken by the Permittee to accomplish reduction of the discharge flow or elimination of the discharge. Such report shall:
- (a) evaluate alternative actions to accomplish reduction of the discharge flow or elimination of the discharge including, but not limited to, pollutant source reduction, process changes/innovations, chemical substitutions, recycle and zero-discharge systems, water conservation measures, and other internal and/or end-of-pipe treatment technologies;
 - (b) state in detail the most expeditious schedule for performing each alternative;
 - (c) list all permits and approvals required for each alternative, including but not limited to any permits required under sections 22a-32, 22a-42a, 22a-342, 22a-361, 22a-368, 22a-430, or 22a-430b of the CGS;
 - (d) propose a preferred alternative or combination of alternatives with supporting justification; and
 - (e) propose a detailed program and schedule to perform all actions required in conjunction with the preferred alternative including but not limited to a schedule for submission of engineering plans

and specifications for any internal and/or end of pipe treatment facilities, start and completion of any construction activities related to any treatment facilities, and applying for and obtaining all permits and approvals required for such actions.

- (C) The Permittee shall perform the approved actions in accordance with the approved schedule. Within fifteen (15) days after completing such actions, the Permittee shall certify to the Commissioner in writing that the actions have been completed as approved.
- (D) The Permittee shall use best efforts to submit to the Commissioner all documents required by this section of the permit in a complete and approvable form. If the Commissioner notifies the Permittee that any document or other action is deficient, and does not approve it with conditions or modifications, it is deemed disapproved, and the Permittee shall correct the deficiencies and resubmit it within the time specified by the Commissioner or, if no time is specified by the Commissioner, within thirty (30) days of the Commissioner's notice of deficiencies. In approving any document or other action under this Compliance Schedule, the Commissioner may approve the document or other action as submitted or performed or with such conditions or modifications as the Commissioner deems necessary to carry out the purposes of this section of the permit. Nothing in this paragraph shall excuse noncompliance or delay.
- (E) Dates. The date of submission to the Commissioner of any document required by this section of the permit shall be the date such document is received by the Commissioner. The date of any notice by the Commissioner under this permit, including but not limited to notice of approval or disapproval of any document or other action, shall be the date such notice is personally delivered or the date three (3) days after it is mailed by the Commissioner, whichever is earlier. Except as otherwise specified in this permit, the word "day" as used in this section of the permit means calendar day. Any document or action which is required by this section of the permit to be submitted, or performed, by a date which falls on, Saturday, Sunday, or a Connecticut or federal holiday, shall be submitted or performed on or before the next day which is not a Saturday, Sunday, or Connecticut or federal holiday.
- (F) Notification of noncompliance. In the event that the Permittee becomes aware that it did not or may not comply, or did not or may not comply on time, with any requirement of this section of the permit or of any document required hereunder, the Permittee shall immediately notify the Commissioner and shall take all reasonable steps to ensure that any noncompliance or delay is avoided or, if unavoidable, minimized to the greatest extent possible. In so notifying the Commissioner, the Permittee shall state in writing the reasons for the noncompliance or delay and propose, for the review and written approval of the Commissioner, dates by which compliance will be achieved, and the Permittee shall comply with any dates, which may be approved in writing by the Commissioner. Notification by the Permittee shall not excuse noncompliance or delay, and the Commissioner's approval of any compliance dates proposed shall not excuse noncompliance or delay unless specifically so stated by the Commissioner in writing.
- (G) Notice to Commissioner of changes. Within fifteen (15) days of the date the Permittee becomes aware of a change in any information submitted to the Commissioner under this section of the permit, or that any such information was inaccurate or misleading or that any relevant information was omitted, the permittee shall submit the correct or omitted information to the Commissioner.
- (H) Submission of documents. Any document, other than a discharge monitoring report, required to be submitted to the Commissioner under this section of the permit shall, unless otherwise specified in writing by the Commissioner, be directed to:

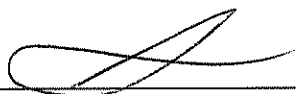
Ewa Wozniak, Sanitary Engineer
Water Permitting and Enforcement Division
Bureau of Materials Management and Compliance Assurance
Department of Energy and Environmental Protection
79 Elm Street
Hartford, CT 06106-5127

SECTION 8: 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 its 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, and oil and grease, or 1.2 for all other pollutants except pH.
- **Monitoring Reports:** Failure to provide, within forty-five (45) days after the due date, required reports such as DMRs.
- **Compliance Schedule:** Failure to meet within ninety (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 9/13/13 and shall expire two (2) years from such date.


Macky McCleary
Deputy Commissioner
Department of Energy and Environmental Protection

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 Existing Sources 40 CFR 439.46 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: Faria Limited LLC, d/b/a Sheffield Pharmaceuticals

PERMIT, ADDRESS, AND FACILITY DATA

PERMIT#: SP0002442

APPLICATION #: 201104540

<u>Mailing Address:</u>					<u>Location Address:</u>						
Street:	170 Broad Street				Street:	170 Broad Street					
City:	New London	ST:	CT	Zip:	06320	City:	New London	ST:	CT	Zip:	06320
Contact Name:	Jeffrey Davis				DMR Contact	Jeffrey Davis					
Phone No.:	(860) 442-4451				Phone No.:	(860) 442-4451					
Contact E-mail:	jeff.davis@sheffield-pharmaceuticals.com				DMR Contact E-mail:	jeff.davis@sheffield-pharmaceuticals.com					

PERMIT INFORMATION

DURATION 2 YEAR X 10 YEAR 30 YEAR
TYPE New X Reissuance Modification
CATEGORIZATION POINT (X) NON-POINT () GIS #
 NPDES () PRETREAT (X) GROUND WATER(UIC) () GROUND WATER (OTHER) ()
 NPDES MAJOR(MA)
 NPDES SIGNIFICANT or PRETREAT SIU (SI) X
 NPDES or PRETREATMENT (MI)
 PRETREAT SIGNIFICANT INDUS USER(SIU) X
 PRETREAT CATEGORICAL (CIU) X

POLLUTION PREVENTION MANDATE ENVIRONMENTAL EQUITY ISSUE

SIC CODE: 2833 Medicinal Chemicals and Botanical Products

COMPLIANCE SCHEDULE YES X NO

POLLUTION PREVENTION TREATMENT REQUIREMENT WATER CONSERVATION X

WATER QUALITY REQUIREMENT REMEDIATION OTHER

OWNERSHIP CODE

Private X Federal State Municipal (town only) Other public

IS THE PERMITTEE SUBJECT TO A PENDING ENFORCEMENT ACTION? NO YES X (See Other Comments)

DEEP STAFF ENGINEER: Ewa Wozniak

<i>Discharge Code</i>	<i>DSN Number</i>	<i>Annual Fee</i>
501047Y	201-1	\$4,337.50

Discharge to the City of New London Water Pollution Control Facility via its collection system. The facility ID. of the POTW is 095-001.

Faria Limited LLC, d/b/a Sheffield Pharmaceuticals conducts formulation and packaging of gels, toothpastes, creams, ointments, denture adhesives, and iodine ointments.

DSN 201-1: The process wastewater is generated from the cleaning of mixing tanks and associated equipment used to formulate toiletries, toothpaste, over-the-counter creams and ointments, cosmetic creams and ointments, vacuum pump condensate and the cleaning of laboratory glassware and equipment. The treatment system consists of solids settling, oil water separation, and pH adjustment.

X Federal Effluent Limitation Guideline 40 CFR 439 Subpart D
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
The Applicant filed the appropriate CMCR form and demonstrated consistency with
applicable statutory goals and policies.

X Other – Explain (See General Comments)

X Case-by-Case Determination and Best Professional Judgment

DSN 201-1: pH, copper, phosphorus, fluoride, titanium, and zinc, total recoverable oil petroleum, acetone, n-amyl acetate, ethyl acetate, isopropyl acetate, methylene chloride, and surfactants (MBAS).

GENERAL COMMENTS

The selection of parameters of concern was determined using best professional judgment on a case-by-case basis. Also, permit requirements are consistent with other permits issued to facilities with pharmaceutical operations by the Department.

Basis for Effluent Limitations and Monitoring Requirements

During the technical review of Faria Limited LLC's application, DEEP staff used effluent characterization information in the application to determine that limits are needed for **pH, total recoverable oil petroleum, acetone, n-amyl acetate, ethyl acetate, isopropyl acetate, methylene chloride and fluoride** to protect the City of New London WPCF from pass-through or interference.

DEEP staff is recommending **pH** limits of (6.0 - 10.0) S.U., which are considered to be protective of sanitary sewer systems.

The effluent limitations proposed for **total recoverable oil petroleum**, which has been identified as oil and grease (hydrocarbon fraction) previously, 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).

Section 22a-430-4(s) of the Regulations of Connecticut State Agencies (RCSA) was used as a guideline in establishing limitations for **fluoride**. Based on a review of the discharge monitoring data and treatment to be provided, Faria Limited LLC will be able to meet these proposed effluent limitations.

Wastewater discharges from the production of pharmaceutical manufacturing are regulated under 40 CFR 439, Pharmaceutical Manufacturing Category. Faria Limited LLC initiated this unauthorized discharge prior to May 2, 1995. Although the facility is subject to the Pretreatment Standards in 40 CFR 439, DEEP staff is proposing effluent limitations for the following parameters that are more stringent than required under 40 CFR 439 using the criteria of best professional judgment pursuant to section 22a-430-4(m) of the RCSA and 40 CFR 125.3(d), based on a determination that these pollutants are not used at the facility or expected to be present in the effluent: **acetone, n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride**.

DEEP staff is recommending monitoring requirements for total titanium, copper and zinc, total recoverable oil petroleum, total phosphorus (as P), and surfactants (MBAS) due to the potential for these parameters to be present in the effluent. Faria Limited LLC, on rare occasions, manufactures formulations containing zinc oxide. The Permittee will be required to collect all wastewater generated from the cleaning of tanks used in manufacturing those formulations and dispose of these materials through a licensed hauler in a manner acceptable to the Commissioner.

EPA's General Pretreatment Streamlining Regulations for Existing and New Sources of Pollution, 40 CFR 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. Faria Limited LLC has analyzed representative untreated samples of its process wastewater for **n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride** using the most sensitive EPA approved methods. None of these four parameters were found in detectable levels in the samples. As a result, DEEP staff is recommending that Faria Limited LLC be authorized to forego monitoring of the four pollutants. Consistent with 40 CFR 403.12(e)(2), 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 the filing of the last DMR. Additionally, in the event that any of these chemical parameters is found to be present or is 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 the parameter(s) as required in Table A of the permit. Acetone was found to be present in the untreated samples. Therefore, acetone was not included in the waiver of monitoring.

OTHER COMMENTS

A field Notice of Violation (FNOVWRIN11301) was issued to the Faria Limited LLC on April 20, 2011 to address wastewater discharges that the Applicant had initiated or was maintaining into the City of New London POTW, without having obtained a discharge permit. The Water Permitting and Enforcement Division is pursuing a formal enforcement action for these violations. This proposed permit contains a compliance schedule, which requires Faria Limited LLC to investigate and implement actions to reduce the flow of or eliminate the discharge, and shall expire two (2) years from the date of issuance.

A special condition is included in Section 4 of this permit that reads "The Permittee shall collect all wastewater generated from the cleaning of tanks used in the manufacturing of formulations containing zinc oxide and non-conforming materials as described in Appendix I of the Operation and Maintenance Plan and dispose of these materials through a licensed hauler in a manner acceptable to the Commissioner."

The Faria Limited LLC submitted, on May 27, 2011, for the Commissioner's review and approval wastewater discharge permit applications for all unpermitted pharmaceutical related wastewater discharges into the City of New London POTW. Faria Limited LLC registered a minor discharge of non-contact cooling water to the sanitary sewer (100 gpd) under the Minor Non-contact Cooling Water General Permit (GCW000256). Also, the company registered its stormwater discharges under the Stormwater Associated with Industrial Activities General Permit (GSI002328). The Permittee is also subject to the terms and conditions of the General Permit for the Discharge of Minor Boiler Blowdown (no registration required).

Prior to public notice, the Department shared the proposed draft permit with the company in an e-mail, dated July 3, 2013. The company commented on the proposed draft permit in an e-mail, dated July 11, 2013. In the e-mail, the company requested to have the acetone limits increased. The company indicated that four (4) out of a total of thirteen (13) acetone analyses that were done within the last two years had acetone concentrations higher than what was proposed in the draft permit. The Department reviewed the company's acetone results and changed the average monthly, maximum daily and maximum instantaneous limits for acetone from 0.25 mg/l, 0.50 mg/l, and 0.50 mg/l to 1.0 mg/l, 2.0 mg/l, and 3.0 mg/l, respectively. These new proposed acetone limits are substantially more stringent than the acetone limits proposed in 40 CFR 439. In addition, the Department also changed the monitoring frequency from semi-annually to quarterly. The revised draft permit was shared with the company in an e-mail, dated August 5, 2013. Jeff Davis, the Production Manager at Sheffield Pharmaceuticals, e-mailed the Department back on August 5, 2013, acknowledging the changes in the proposed draft permit.

The revised draft permit was also shared with Peter Vetter, Project Manager at Veolia Water, New London WPCA in an e-mail, dated August 1, 2013. Mr. Vetter e-mailed the Department on August 2, 2013, stating that he reviewed the proposed draft permit and had no comments to offer. In addition, the proposed draft permit was also shared with the Municipal Group of the Bureau of Water Protection & Land Reuse, Planning & Standards Division. The Municipal Group also did not have any comments to the proposed draft permit.

The proposed draft permit was published in the New London Day on August 9, 2013. The Department did not receive any comments on the proposed draft permit modification.