PRE-TREATMENT COMPLIANCE SAMPLING INSPECTION REPORT

RIJ Pharmaceutical Corp.
40 Commercial Avenue
Middletown, NY 10941

NYU200026

November 17, 2005

Participating Personnel: U.S. Environmental Protection Agency
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RIJ Pharmaceutical Corp.
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Approved for the Director By: Ray Bram, for
John S. Kushwara, Chief
Monitoring and Assessment Branch

PRE-TREATMENT COMPLIANCE SAMPLING INSPECTION REPORT

A. Objective

On November 17, 2005, the US Environmental Protection Agency (USEPA) conducted a pre-treatment compliance sampling inspection (CSI) at RIJ Pharmaceutical Corp. (the facility) located in Middletown, NY. The inspection was performed in order to determine if the wastewaters discharged from the facility were in compliance with the Code of Federal Regulations (CFR):

- for the Pharmaceutical Manufacturing Point Source Category, Subpart D - Mixing/Compounding and Formulation Subcategory - 40 CFR § 439.47 and
- for the General Pretreatment Regulations for Existing and New Sources of Pollution - 40 CFR § 403.

This facility is also regulated by the Town of Wallkill, NY. The wastewaters discharged to the Town of Wallkill municipal sewer system and to the Town of Wallkill (TW) WWTP are subject to the Town of Wallkill Wastewater Discharge Permit No. 3-05 that expires on December 31, 2006.

B. Facility Description, History, Operations, and Flow Characteristics

The facility is located at 40 Commercial Avenue in Middletown, Orange County, NY. The facility operates one, daily 8-hour shift from 7:30 a.m. about 5:30 a.m., five days per week (Mondays through Fridays, periodically on Saturdays), and about 50 weeks per year. The company employs about 15 people on a daily basis at the facility.

The facility began discharging in 1985, and is involved primarily in the manufacture of the following types of pharmaceutical products: antacid, laxative & anti-diarrheal, cold & allergy, analgesic, anti-fungal, selected prescription, and other.

The facility's customer base includes wholesalers and distributors such as AmeriSource, Bergen, Kinray, major pharmaceuticals, Rugby, Weis, Happy Harry's, and others. Their present capacity is over seven million units annually with additional expansion to 30 million units annually. Attachment 1 (Products manufactured at the facility) provides a detailed product listing of the facility's outputs that may vary on a daily basis.

The manufacturing and related capabilities include:

- Product/Process Development

- Quality Assurance & Quality Control

- Blending - to ensure the highest degree of purity and formulation accuracy, as well as production speed, the facility offers state-of-the-art equipment, stringent in-process quality monitoring. High quality raw materials are selected to be incorporated into the products. Inventory management is conducted in strict conformance with internal quality control.

- Packaging & Labeling - features automated filling, safety sealing, and labeling capabilities.

- Regulatory & Compliance - internal regulatory compliance staff interfaces with Federal, state, and local authorities in an effort to meet all current regulations. Internal audits are performed to assure that all regulations set forth are met or exceeded. This effort supports current good manufacturing procedures and all applicable regulatory validations.

Manufacturing processes include dispensing, blending or granulation (aqueous), and packaging. The manufacturing process involves the blending of product constituents in large mixing tanks called compounding tanks (about 500 gallons capacity). The combined product is then pumped to a final holding tank called storing/filling tanks (1000 gallons). From the storing/filling tank, the pharmaceutical product is bottled in the analogous containers.

Only one type of pharmaceutical product is typically produced each workday. During the day of the CSI, the facility was manufacturing an antacid known as Ri-Gel II Suspension (a generic pharmaceutical similar to Mylanta II).

The types of cleaning processes can be characterized as:

- Partial cleaning: Washing and rinsing is done in cases where another batch of the same product will be manufactured. A major cleaning below is needed if more than 10 batches of the same product have been manufactured.

- Major cleaning: Complete cleaning of process equipment by washing, rinsing, and air-drying is done in cases where another batch of the same product will be manufactured.

The generic cleaning process for a tank is as follows:

- Pre-rinse with warm DI water that generates about 3-4 gallons of wastewater

- First rinse: cleaned with soap and warm DI water that generates about 50 gallons of wastewater

- Second rinse: cleaned with soap and DI water that generates about 50 gallons of wastewater

C. Water and Wastewater

The water intake of the facility is from the Town of Wallkill Water Department. The municipal water used by the facility may have further treatment for use in the various applications and processes involved in pharmaceutical product development. For example, the de-ionized (DI) water system provides DI water as needed for pharmaceutical manufacturing processes and laboratory usage.

The majority of the manufacturing wastewater from this site is generated in the washroom areas of the facility where each have floor discharge drains. These were the only floor drains that were observed in the facility. Process vessel parts are cleaned in these rooms with the runoff flowing to the floor discharge drain. Mop buckets that are used to clean floors throughout the facility are also dumped down the floor drain that discharges to the sewer line sampled at discharge point 001.

Wastewater is generated primarily from washing equipment and glassware that may have coatings and other residue. The cleaning of hoppers (that hold pharmaceutical products) and blending and/or other related equipment is the primary source of wastewater generation that was observed. Tanks are cleaned with water and soap, and then thoroughly rinsed. The wastewater generated is transferred into 55-gallon drums in order to quantify and estimate wastewater flow. After the wastewater flow is quantified, the wastewater is poured into the floor drains that lead to the sanitary sewer.

The filling of bottles involves some spillage which is cleaned up and this wastewater goes into tanks collecting wastewater. The wastewater can be categorized under the following activities: manufacturing (equipment & facility washdown, process), laboratory usage, and domestic uses. Approximately 100-200 gallons per day of industrial wastewater are discharged to the municipal sewerage system as a batch discharge. Presently, the wastewater from the building is conveyed in a single hydraulic system that combines both sanitary and industrial flows.

Manufactured products that fail to meet pharmaceutical specifications are hauled to a landfill by A-1 Environmental Regulators. According to the facility representative, manufactured product that fails to meet specifications rarely occurs. Wastes are collected as nonhazardous wastes.

D. Wastewater Treatment

The wastewater from the facility has no wastewater pre-treatment prior to discharge into the Town of Wallkill municipal sewer system and then to the Town of Wallkill (TW) WWTP.

E. Sampling

The facility had two batch discharges of rinse water during the CSI. With each discharge, samples were collected from two sampling locations: 1) pharmaceutical rinse water after the tank has been rinsed, and 2) the manhole in the parking lot at the front of the facility which consisted of a mixture of mainly rinse wastewater and a small quantity of sanitary wastewater. This manhole was installed several years ago to facilitate sampling. The first batch discharge began at 11:50 a.m. while the second batch discharge was at 6:26 p.m.

Grab samples were taken from the pharmaceutical rinse water before the rinse water was poured into the floor drain for volatile organic compounds (VOA) specifically, acetone (2-propanone), n-amyl acetate, ethyl acetate, isopropyl acetate, methylene chloride, benzidine, bis(2-ethyhexyl)phthalate (BEHP), and toluene. VOA samples were stored on wet ice and were laboratory composited. Grab samples were also taken for oil and grease.

Grab-composited samples were taken from the pharmaceutical rinse water discharged in the manhole for the analysis of metals, specifically aluminum (Al), antimony (Sb), arsenic (As), cadmium (Cd), chromium (Cr), copper (Cu), iron (Fe), lead (Pb), manganese (Mn), mercury (Hg), molybdenum (Mo), nickel (Ni), selenium (Se), silver (Ag), and zinc (Zn).

Grab-composited samples were also taken from the pharmaceutical rinse water discharged in the manhole for the analysis of carbonaceous biochemical oxygen demand - 5 day ($CBOD_5$), chemical oxygen demand (COD), total suspended solids (TSS), fluoride, total phenolics, total phosphorus, sulfide, total kjeldahl nitrogen (TKN), and total cyanide (CN).

In addition, total residual chlorine (TRC) was taken from the pharmaceutical rinse water. TRC was taken to determine which procedure to use in collecting the samples for your survey. The TRC analysis of the wastewater was zero. Temperature and pH readings were taken at the manhole. The temperature reading was 22.8 ° C. and the pH was 8.41. At the completion of the sampling, split samples were provided to the facility.

F. Findings and Conclusions

The complete results of the sampling survey are compared to the applicable Federal categorical pretreatment standards and the Town of Wallkill standards in Table 1. Results indicate non-compliance with the Town of Wallkill standards for the following eight parameters.

Parameter	Daily Maximum Concentration 40 CFR: § 439.46 § 403 (mg/L)	Daily Maximum Concentration TW (mg/L)	Sampling Results (mg/L)	Percent Exceedance of Sampling Result from Discharge Limits %
Carbonaceous Biochemical Oxygen Demand - 5 day, ($CBOD_5$)	N/A	300	550	83
Chemical Oxygen Demand, (COD)	N/A	600	860	43
Total Suspended Solids, (TSS)	N/A	300	6600	2100
Phenolics, Total	N/A	0.5	1.6	220
Aluminum (Al), Total	N/A	25	850	3300
Copper (Cu), Total	N/A	0.5	1.2	140
Iron (Fe), Total	N/A	3	37	1133
Zinc (Zn), Total	N/A	0.5	2.5	400

G. Recommendations

Based on the November 17, 2005 pre-treatment compliance sampling inspection (CSI) at RIJ Pharmaceutical Corporation, the facility has been found to have deficiencies in compliance with the requirements and limitations of the applicable Town of Wallkill industrial wastewater discharge standards. The facility is not in compliance with the daily maximum limits for $CBOD_5$, COD, TSS, total phenolics, total Al, total Cu, total Fe, and total Zn as indicated by sampling and analytical results.

Actions appropriate to ensure compliance are recommended. The facility has been sent a Notice of Non-Compliance (copy attached). This notice identifies the deficiencies found, and requests that they be corrected and that the USEPA be informed of the specific corrective measures chosen to ensure continued compliance with their effluent limitations.

Table 1				
RIJ Pharmaceutical Corp. 40 Commercial Avenue, Middletown, NY 10941 Pre-treatment Compliance Sampling Inspection - November 17, 2005 Comparison of the effluent limitations for 40 CFR § 439.47 and the TW limits with the Sampling Results				
Parameter	**Daily Maximum Concentration 40 CFR: § 439.46 § 403 (mg/L)**	**Daily Maximum Concentration TW (mg/L)**	**Sampling Results (mg/L)**	**Percent Exceedance of Sampling Result from Discharge Limits %**
Carbonaceous Biochemical Oxygen Demand - 5 day, ($CBOD_5$)	**N/A**	**300**	**550**	**83**
Chemical Oxygen Demand, (COD)	**N/A**	**600**	**860**	**43**
Chlorine, Total Residual, (TRC)	**N/A**	**N/A**	0	0
Solids, Total (TS)	**N/A**	**2000**	NS	0
Total Suspended Solids, (TSS)	**N/A**	**300**	**6600**	**2100**
Fluoride	**N/A**	**5**	0.10U L DS	0
Oil & Grease	**N/A**	**50**	40 L	0
Phenolics, Total	**N/A**	**0.5**	**1.6**	**220**
Phosphorus (P), Total	**N/A**	**10**	4	0
Sulfide	**N/A**	**2**	0.050U L	0

Total Kjeldahl Nitrogen, (TKN)	**N/A**	**30**	2.5	0
Aluminum (Al), Total	**N/A**	**25**	**850**	**3300**
Antimony (Sb), Total	**N/A**	**10**	0.1U	0
Arsenic (As), Total	**N/A**	**0.05**	0.02U J	0
Cadmium (Cd), Total	**N/A**	**0.05**	0.01U	0
Chromium (Cr), Total	**N/A**	**0.5**	0.05	0
Copper (Cu), Total	**N/A**	**0.5**	**1.2**	**140**
Cyanide (CN), Total	**N/A**	**0.5**	0.012	0
Iron (Fe), Total	**N/A**	**3**	**37**	**1133**
Lead (Pb), Total	**N/A**	**1**	0.24U	0
Manganese (Mn), Total	**N/A**	**3**	0.2	0
Mercury (Hg), Total	**N/A**	**0.05**	0.0011 L	0
Molybdenum (Mo), Total	**N/A**	**0.5**	0.02U	0
Nickel (Ni), Total	**N/A**	**1.5**	0.1U	0
Selenium (Se), Total	**N/A**	**0.1**	0.075U	0
Silver (Ag), Total	**N/A**	**0.1**	0.006U J	0
Zinc (Zn), Total	**N/A**	**0.5**	**2.5**	**400**
Temperature (° Celsius)	**40**	**65.6**	22.8	0
pH (standard units)	**5.0 (minimum)**	**6.0 to 9.0**	8.41	0
Benzidine	**N/A**	**0.082**	DM	0
Bis(2-ethyhexyl)phthalate (BEHP)	**N/A**	**1.5**	DM	0
Toluene	**N/A**	**6.5**	DM	0
Acetone (2-Propanone)	**20.7**	**20.7**	0.25U	0
n-Amyl Acetate	**20.7**	**20.7**	0.25U	0
Ethyl Acetate	**20.7**	**20.7**	0.25U	0

Isopropyl Acetate	**20.7**	**20.7**	0.25U	0
Methylene Chloride	**3**	**3**	0.25U	0

Codes:

DM = Due to matrix-related interferences, sample was diluted. As a result of the significant dilution, the reporting limit for VOA was raised to 250 µg/L. The standard reporting limit is 5.0 µg/L.

DS = Due to safety precautions, the distillation step for the NPDES sample was not performed.

J = The identification of the analyte is acceptable and the reported value is an estimate.

L = The identification of the analyte is acceptable and the reported value may be biased low. The actual value is expected to be greater than the reported value.

N/A = Not Applicable

NS = Parameter was not sampled

U = The analyte was not detected at or above the reporting limit.

Case Narrative:
RIJ Pharmaceutical #05110053

The National Environmental Laboratory Accreditation Conference (NELAC) is a voluntary environmental laboratory accreditation association of State and Federal agencies. NELAC established and promoted a national accreditation program that provides a uniform set of standards for the generation of environmental data that are of known and defensible quality. The EPA Region 2 Laboratory is NELAC accredited. The Laboratory tests that are accredited have met all the requirements established under the NELAC Standards.

Comment(s):

The pH of Sample AG08606 (Field ID: Grab-Composite) was pH>2. Multiple aliquots of nitric acid were added to the sample until a consistent measurement of pH<2 was observed.

Fluoride Analysis: Due to safety precautions, the distillation step required for NPDES samples was not performed. Heating a non-homogeneous acid-water mixture may result in burning or possibly a violent explosion. The primary objective for performing a distillation is to remove interferences. In place of the distillation, each NPDES sample submitted for Fluoride analysis is performed by analyzing a sample aliquot along with a matrix spike and matrix spike duplicate. The Laboratory's acceptance criterion for matrix spike recovery is 80 to 120%. A sample with a matrix spike recovery of less than 80% for the analyte in question would be considered to have a detectable interference present. The percent recovery of the matrix spike and matrix spike duplicate was within our acceptance criterion.

Mercury Analysis: Sample AG08606 (Field ID: Grab-Composite) was analyzed for Mercury past the 28 day holding time established for the analysis for Mercury in soil samples. This occurred due to instrument difficulties that were not resolved within the holding time. The Mercury result was qualified with a "L."

Reporting Limit(s):

The Laboratory was able to achieve the standard reporting limits for each analyte requested except for the following analyte(s):

VOAs: Laboratory Sample AG08609 (Field ID: Grab-Rinse 1&2): The sample was diluted due to matrix-related interferences. As a result of the significant dilution, the Laboratory's reporting limit for the VOAs was raised to 250 ug/L. The standard reporting limit is 5.0 ug/L.

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Method(s):

- Biological Oxygen Demand, EPA Method 405.1 (SOP C-21 (5 Days, 20°C Method)
- Chemical Oxygen Demand, EPA Method 410.4 (SOP C-53; Colorimetric)
- Cyanide, Total Analysis, EPA Method 335.3 (SOP C-28; Colorimetric Method)
- Fluoride Analysis, EPA Method 340.2 (SOP C-93; Electrode Method)
- Metals Analysis, EPA Method 200.7 (SOP C-109; ICP/AES Method)
- Mercury Analysis, EPA Method 245.1 (SOP C-110; CVAAS Method)
- Oil & Grease Analysis, EPA Method 1664 Rev. A (SOP C-95; Gravimetric Method)
- Phosphorus, Total (as P) Analysis, EPA Method 365.1 (SOP C-68; Colorimetric Method)
- Phenolics, Total Analysis, EPA Method 420.4 (SOP C-29; Colorimetric Method)
- Residue, Non-Filterable (TSS), EPA Method 160.2 (SOP C-33; Gravimetric Method)
- Sulfide Analysis, EPA Method 376.2 (SOP C-115; Colorimetric)
- Total Kjeldhal Nitrogen (as N) Analysis, EPA Method 351.2 (SOP C-40; Colorimetric Method)
- Volatiles Analysis, EPA Method 624 (SOP C-89; Purge & Trap GC/MS Method)

Approval: J. R. [illegible] Date: 2-3-06

U.S. Environmental Protection Agency
Region 2 Laboratory
2890 Woodbridge Avenue
Edison, NJ 08837

Data Report: RIJ Pharmaceutical Corp

Project Number: 05110053

Program: B304

Project Leader: L. BOURODIMOS

Remark Codes	Explanation
U	THE ANALYTE WAS NOT DETECTED AT OR ABOVE THE REPORTING LIMIT.
J	THE IDENTIFICATION OF THE ANALYTE IS ACCEPTABLE; THE REPORTED VALUE IS AN ESTIMATE.
UJ	THE ANALYTE WAS NOT DETECTED AT OR ABOVE THE REPORTING LIMIT. THE REPORTING LIMIT IS AN ESTIMATE.
N	THERE IS PRESUMPTIVE EVIDENCE THAT THE ANALYTE IS PRESENT; THE ANALYTE IS REPORTED AS A TENTATIVE IDENTIFICATION.
NJ	THERE IS PRESUMPTIVE EVIDENCE THAT THE ANALYTE IS PRESENT; THE ANALYTE IS REPORTED AS A TENTATIVE IDENTIFICATION. THE REPORTED VALUE IS AN ESTIMATE.
R	THE PRESENCE OR ABSENCE OF THE ANALYTE CANNOT BE DETERMINED FROM THE DATA DUE TO SEVERE QUALITY CONTROL PROBLEMS. THE DATA ARE REJECTED AND CONSIDERED UNUSABLE.
K	THE IDENTIFICATION OF THE ANALYTE IS ACCEPTABLE; THE REPORTED VALUE MAY BE BIASED HIGH. THE ACTUAL VALUE IS EXPECTED TO BE LESS THAN THE REPORTED VALUE.
L	THE IDENTIFICATION OF THE ANALYTE IS ACCEPTABLE; THE REPORTED VALUE MAY BE BIASED LOW. THE ACTUAL VALUE IS EXPECTED TO BE GREATER THAN THE REPORTED VALUE.
NV	NOT VALIDATED
INC	RESULT NOT ENTERED

U.S. EPA Region 2 Laboratory
Data Report

Survey Name: RIJ Pharmaceutical Corp

Project Number: 05110053

*Sorted By Sample ID

AG08608 Field/Station ID: Trip Blank Date Received: 11/18/2005
Matrix: Aqueous

Sample Description:

Analysis Type: VOA PHARMA GCMS AQUEOUS

CAS Number	Analyte Name	Result	Remark Codes	Units
67-64-1	ACETONE	---	5.0U	ug/L
628-3-7	AMYL ACETATE	---	5.0U	ug/L
141-78-6	ETHYL ACETATE	---	5.0U	ug/L
75-09-2	METHYLENE CHLORIDE	---	5.0U	ug/L
108-21-4	ISOPROPYL ACETATE	---	5.0U	ug/L
	TOLUENE	---	5.0U	ug/L

AG08609 Field/Station ID: Grab - Rinse 1 & 2 Date Received: 11/18/2005
Matrix: Aqueous(chlor.)

Sample Description:

Analysis Type: VOA PHARMA GCMS AQUEOUS

CAS Number	Analyte Name	Result	Remark Codes	Units
67-64-1	ACETONE	---	250U	ug/L
628-3-7	AMYL ACETATE	---	250U	ug/L
141-78-6	ETHYL ACETATE	---	250U	ug/L
75-09-2	METHYLENE CHLORIDE	---	250U	ug/L
108-21-4	ISOPROPYL ACETATE	---	250U	ug/L
	TOLUENE	---	250U	ug/L

Project Approval: J. R. [illegible] **Date:** 2-3-06

Refer to Page 1 for an explanation of Remark Codes

US EPA REGION 2 LABORATORY

CHAIN OF CUSTODY/ FIELD DATA FORM

Page 1 of 1 pages

SURVEY NAME & LOCALITY: NJ Pharmaceuticals

PROJECT LEADER: Richard Cohoots

PROGRAM: SF ☐ :

SITE ID _____ OPERABLE UNIT _____

PROGRAM RESULTS CODE _____

Decision	RCRA ☐	RCRA ENF ☐	NPDES ☐	SDWA ☐	AM ☐	CAA ☐	TSCA ☐	OD ☐	CRIMINAL ENF ☐	CIVIL ENF ☐
Unit Code Y206	D210	D307	B304	C215	B224	A305	L306	B253		

Permit #: _____

LAB ID/ FIELD ID	# OF CONTERS	MATRIX	SPECIAL REQUIREMENTS?	DESCRIPTION & INSTRUCTIONS INCLUDING LOCATION, ESTIMATED CONCENTRATIONS, SPECIAL REPORTING LIMITS, SPECIAL TEST REQUIREMENTS & ALIQUOTING	Preservative (circle)	Collection Time (24hr clock) Begin	End	Collection Date mm/dd/yy
VOABLANK	3	B	☐	2-4 month vials / VOA	123456789		1040	04/30/01
COLOR	3	B	☐	3-40 mL vials / VOA	123456789		1025	04/30/01
			☐		123456789			
			☐		123456789			
			☐		123456789			
			☐		123456789			
			☐		123456789			
			☐		123456789			
			☐		123456789			
			☐		123456789			
			☐		123456789			

COMMENTS: VOA compounds are: acetone
n-amylacetate
ethylacetate
iso propylacetate
methylene chloride

Preservative

1=ice
2=H2SO4 pH<2
3=HNO3 pH<2
4=HCl pH<2
5=Na2S2O3
6=NaOH pH>9
7=Ascorbic Acid
8 = FAS
9=ZnAc

		Time	Date
Person Assuming Responsibility for Sample(s): Richard Cohoots		1300	04/30/01
Relinquished By: Richard Cohoots	Received By: [illegible]	[illegible]	[illegible]
Relinquished By:	Received By:		
Relinquished By:	Received By:		

Matrix:

A=aqueous
B=aqueous (chlorinated)
C=soil
D=sediment
E=sludge
F=multiphasic
G=solvent
H=biota
I=oil
J=other

Survey Complete? Y ☐ N ☐

Attachment 1: Products Manufactured at the facility

RIJ PHARMACEUTICAL CORPORATION

40 COMMERICAL AVENUE • MIDDLETOWN, NY. 10941

Tel. (845) 692-5799 Fax. (845) 692-3023

A Message from Dr. Brij Gupta, President

"Our 52,000 square foot facility in Middletown, New York comprises a state of the art research laboratory and modern production lines. RIJ Pharmaceuticals' quality control system, which continually relies on the human element, is combined with our in-house warehousing and fully enclosed shipping and receiving center, to provide an integrated approach to customer satisfaction ... thereby offering you unprecedented levels of service and security at an exceptional value.

We hope that we may satisfy your expectations for your next generic pharmaceutical requirement. From our existing line of liquid and powder preparations to special product requests, we have ***just the right formula for your success."***

SAMPLE PRODUCTS LISTING

The following list of drug and pharmaceutical products are currently being manufactured at our laboratory and production facilities. We are continually adding new products to this list. If you are looking for a specific product that is not included, please call us for a product update or information about custom formulations.

ANTACID PRODUCTS

NDC NO.	PRODUCT	COMPARES TO	SIZES*
53807-502-05	Ri-Mox Suspension	Maalox®	5 oz.
53807-502-12	Ri-Mox Suspension	Maalox®	12 oz.
53807-502-28	Ri-Mox Suspension	Maalox ®	Gallon
53807-172-01	Ri-Mox Suspension Cherry	Maalox ®	12 oz.
53807-151-12	Ri-Mox Plus Suspension	Maalox ® Plus	12 oz.
53807-174-12	Ri-Mox Plus Extra Suspension	Maalox ® Plus E.S.	12 oz
53807-507-12	Ri-Mox Plus Extra Suspension(NEW)	Maalox ®Plus E.S.	12 oz
53807-237-12	Ri-Gel Supreme	Mylanta ® Supreme	12 oz.
53807-126-05	Ri-Gel Suspension	Mylanta ®	5 oz.
53807-126-12	Ri-Gel Suspension	Mylanta ®	12 oz.
53807-126-28	Ri-Gel Suspension	Mylanta ®	Gallon
53807-170-01	Ri-Gel Suspension Cherry	Mylanta ®	12 oz.
53807-158-05	Ri-Gel II Suspension	Mylanta II ®	5 oz.
53807-158-12	Ri-Gel II Suspension	Mylanta II ®	12 oz.
53807-158-28	Ri-Gel II Suspension	Mylanta II ®	Gallon
53807-134-12	Ri-Mag Suspension	Riopan ®	12 oz.
53807-135-12	Ri-Mag Plus Suspension	Riopan Plus ®	12 oz.
53807-137-12	Riginic Suspension	Gaviscon ®	12oz.
53807-132-02	Aluminum Hydroxide Gel Modified	Alternagal ®	5 oz.
53807-132-01	Aluminum Hydroxide Gel Modified	Alternagal®	16 oz.
53807-130-01	Aluminum Hydroxide Gel USP	Amphojel®	12 oz.
53807-130-16	Aluminum Hydroxide Gel USP	Amphojel®	16 oz.
53807-162-01	Simethicone Drops	Mylicon®	1 oz.

* Other sizes available upon request. Please inquire.

" Just the right formula for your success."

LAXATIVE AND ANTIDIARRHEAL PRODUCTS

NDC. NO.	PRODUCT	COMPARES TO	SIZES *
53807-125-12	Milk of Magnesia	Phillips ® Milk of Magnesia	12 oz
53807-125-16	Milk of Magnesia	Phillips ® Milk of Magnesia	16 oz.
53807-125-28	Milk of Magnesia	Phillips ® Milk of Magnesia	Gallon
53807-401-12	Milk of Magnesia, Mint	Phillips ® Milk of Magnesia, Mint	12 oz.
53807-401-16	Milk of Magnesia, Mint	Phillips ® Milk of Magnesia, Mint	16 oz.
53807-152-08	Bismuth Liquid	Pepto® Bismol	8 oz.
53807-152-16	Bismuth Liquid	Pepto® Bismol	16 oz.
53807-152-04	Bismuth Liquid	Pepto® Bismol	Gallon
53807-192-08	Bismuth Liquid Maximum Strength	Pepto® Bismol Maximum Strength	8 oz.
53807-503-08	Kao-Bis Suspension	Kao® Pectate I	8 oz.
53807-503-12	Kao-Bis Suspension	Kao® Pectate	12 oz.
53807-503-16	Kao-Bis Suspension	Kao® Pectate	16 oz.
53807-503-28	Kao-Bis Suspension	Kao® Pectate	Gallon
53807-193-08	Dioctyl Syrup	Colace Syrup®	8 oz.
53807-193-16	Dioctyl Syrup	Colace Syrup®	16 oz.
53807-216-16	Dioctyl- Liquid	Colace Liquid®	16 oz.
53807-197-13	Ri-Mucil Regular	Metamucil® Regular	13 oz.
53807-197-02	Ri-Mucil Regular	Metamucil® Regular	21 oz.
53807-200-13	Ri-mucil Orange	Metamucil® Orange	13 oz.
53807-200-02	Ri-mucil Orange	Metamucil® Orange	21 oz.
53807-209-10	Ri-mucil Sugar Free	Metamucil® Sugar Free	10 oz.
53807-209-01	Ri-mucil Sugar Free	Metamucil® Sugar Free	13 oz.
53807-212-01	Ri-mucil Orange Sugar Free	Metamucil® Orange Sugar Free	13 oz.

COLD AND ALLERGY PRODUCTS

53807-408-04	Ri-Tussin Syrup	Robitussin	4 oz.
53807-408-08	Ri-Tussin Syrup	Robitussin ®	8 oz.
53807-408-16	Ri-Tussin Syrup	Robitussin ®	16 oz.
53807-408-28	Ri-Tussin Syrup	Robitussin ®	Gallon.
53807-409-04	Ri-Tussin DM	Robitussin DM ®	4 oz.
53807-409-08	Ri-Tussin DM	Robitussin DM ®	8 oz.
53807-409-16	Ri-Tussin DM	Robitussin DM ®	16 oz.
53807-409-28	Ri-Tussin DM	Robitussin DM ®	Gallon.
53807-217-04	Ri-Tussin DM, A/F, S/F	Robitussin DM, A/F, S/F ®	4 OZ.
53807-217-08	Ri-Tussin DM, A/F, S/F	Robitussin DM, A/F, S/F ®	8 OZ.
53807-219-04	Ri-Tussin S/F	Robitussin S/F ®	4 OZ.
53807-228-04	Ri-Tussin CF	Robitussin CF ®	4 OZ.
53807-228-08	Ri-Tussin CF	Robitussin CF ®	8 OZ.
53807-204-04	Diphenhydramine Oral Liquid	Benadryl ®	4 oz.
53807-204-08	Diphenhydramine Oral Liquid	Benadryl ®	8 oz.
53807-204-16	Diphenhydramine Oral Liquid	Benadryl ®	16 oz.
53807-204-28	Diphenhydraqmine Oral Liquid	Benadryl®	Gallon
53807-154-04	Diphenhydramine Cough Syrup	Benylin ® Cough syrup	4 oz
53807-154-08	Diphenhydramine Cough Syrup	Benylin ® Cough syrup	8 oz
53807-154-16	Diphenhydramine cough syrup	Benylin ® Cough syrup	16 oz
53807-154-28	Diphenhydramine Cough Syrup	Benylin ® Cough Syrup	Gallon
53807-227-04	Bromapp Oral Liquid DM	Dimetapp DM ® Elixir	4 oz.
53807-227-08	Bromapp Oral Liquid DM	Dimetapp DM ® Elixir	8 oz.
53807-226-04	Bromapp Oral Liquid	Dimetapp ® Elixir	4 oz.
53807-226-08	Bromapp Oral Liquid	Dimetapp ® Elixir	8 oz.
53807-226-16	Bromapp Oral Liquid	Dimetapp ® Elixir	16 oz
53807-226-28	Bromapp Oral Liquid	Dimetapp ® Elixir	Gallon

RIJ PHARMACEUTICALCORPORATION • 40COMMERICALAVENUE • MIDDLETOWN, NY.10941
Tel. (845) 692-5799 • Fax (845) 692-3023

COLD AND ALLERGY PRODUCTS (continued)

NDC. NO.	PRODUCT	COMPARES TO	SIZES *
53807-176-01	Bromotane Oral Liquid	Dimetane Elixir	4 oz.
53807-155-04	Ritifed Syrup	Actifed	4 oz
53807-155-08	Ritifed Syrup	Actifed	8 oz.
53807-155-16	Ritifed Syrup	Actifed	16 oz.
53807-155-28	Ritifed Syrup	Actifed	Gallon
53807-422-04	Pseudoephedrine HCL Syrup	Sudafed Liquid	4 oz.
53807-422-08	Pseudoephedrine HCL Syrup	Sudafed Liquid	8 oz.
53807-422-16	Pseudoephedrine HCL Syrup	Sudafed Liquid	16 oz.
53807-422-28	Pseudoephedrine HCL Syrup	Sudafed Liquid	Gallon
53807-142-01	Pseudoephedrine Cough Syrup	Sudafed Cough Syrup	4 oz.
53807-142-28	Pseudoephedrine Cough Syrup	Sudafed Cough Syrup	Gallon
53807-202-06	Nite Time	Nyquil	6 oz.
53807-202-10	Nite Time	Nyquil	10 oz.
53807-203-06	Nite Time Cherry	Nyquil Cherry	6 oz.
53807-203-10	Nite Time Cherry	Nyquil Cherry	10 oz.
53807-230-04	T. Medic Cold & Allergy	Triaminic Cold & Allergy	4 oz.
53807-232-04	T. Medic Cough & Sore Throat	Triaminic Cough & Sore Throat	4 oz.
53807-233-04	T. Medic Cold & Nite Time Cough	Triaminic Cold & Nite Time Cough	4 oz.
53807-234-04	T. Medic Cold & Cough	Triaminic Cold & Cough	4 oz.
53807-235-04	T. Medic Cough	Triaminic Cough	4 oz.
53807-236-04	T. Medic Allergy Congeston	Triaminic Allergy Congeston	4 oz.
53807-238-04	T. Medic Chest Congeston	Triaminic Chest Congeston	4 oz.
53807-182-06	Nedicon DX Drops	Naldecon DX Drops	30 ml.
53807-183-01	Nedicon DX Syrup	Naldecon DX Syrup	4 oz.
53807-199-01	Ri-Histine Cold Formula	Novahistine	4 oz.

ANALGESIC PRODUCTS

NDC. NO	PRODUCTS	COMPARES TO	SIZES
53807-129-04	Non- Aspirin Elixir	Tylenol for Children	4 oz.
53807-129-08	Non- Aspirin Elixir	Tylenol for Children	8 oz.
53807-129-16	Non- Aspirin Elixir	Tylenol for Children	16 oz
53807-129-28	Non- Aspirin Elixir	Tylenol for Children	Gallon
53807-196-01	Non- Aspirin Elixir Grape	Tylenol for Children Grape	4 oz.
53807-131-01	Non- Aspirin Elixir Ex. Strength	Tylenol for Extra Strrengh	8 oz.
53807-143-01	Non- Aspirin Childrens' Drops	Tylenol for Children Drops	0.5 oz.
53807-220-05	Non-Aspirin Childrens' Drops Suspension Grape	Tylenol for Children Drops Suspension Grape	0.5 oz.

ANTIFUNGAL PRODUCTS

53807-123-45	Tolnaftate Powder 1%	Tinactin Powder	45 gms.
53807-123-02	Tolnaftate Powder 1%	Tinactin Powder	90 gms.

* Other sizes available upon request. Please inquire.

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ADDITIONAL PRODUCTS

NDC. NO.	PRODUCT	COMPARES TO	SIZES *
53807-136-08	Povidon-iodine 10%	Betadine® Solution	8 oz
53807-136-02	Povidon-iodine 10%	Betadine® Solution	16 oz
53807-136-03	Povidon-Iodine 10%	Betadine® Solution	Gallon
53807-159-01	Povidon-Iodine Doughe	Betadine® Douche	8 oz
53807-133-15	Cabamoxide Ear Drops	Debrox® Drops	0 5 oz
53807-133-02	Carbamoxide Ear Drops	Debrox® Drops	1 oz
53807-156-01	Cank Oxide	Glyoxide® Drops	0.5 oz
53870-156-02	Cank Oxide	Glyoxide® Drops	1 oz
53807-177-16	Ferous sulfate Elixir	Feosol® Elixir	16 oz
53807-177-28	Ferrous Sulfate Elixir	Feosol® Elixir	Gallon
53807-175-01	Ipecac Syrup	Ipecac syrup	1 oz
53807-185-01	Ri-Trol	Emetrol®	4 oz

PRESCRIPTION PRODUCTS

53807-157-01	Ri-Tex Liquid	Entex® Liquid	16 oz
53807-188-01	Sodium Fluoride Drops	Sodium Fluoride Liquid Drops	30 ml

* Other sizes available upon request. Please inquire.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
2890 WOODBRIDGE AVENUE
EDISON, NEW JERSEY 08837-3679

MAY 01 2006

Dr. Brij M. Gupta, President
RIJ Pharmaceutical Corp.
40 Commercial Avenue
Middletown, NY 10941

RE: Pre-treatment Compliance Sampling Inspection of the RIJ Pharmaceutical Corp. facility, located in Middletown, New York on November 17, 2005

Dear Dr. Gupta:

The United States Environmental Protection Agency (USEPA) pre-treatment Compliance Sampling Inspection of the RIJ Pharmaceutical facility, revealed discharge limitation exceedences at your facility as set forth in the accompanying Notice of Non-Compliance. If you have any questions about this inspection, please telephone Lambro Bourodimos, PhD, PE of my staff at (732) 321-6704. Thank you for your cooperation in this matter.

Sincerely,

Ray Basu, for

John S. Kushwara, Chief
Monitoring and Assessment Branch

Enclosure
cc: Edward A. Smith
Town of Wallkill Water and Sewer Department
52 Golf Links Road
Middletown, NY 10940

NOTICE OF NON-COMPLIANCE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM (NPDES) (Read instructions on back of last part before completing)	**PERMITTEE (Facility) NAME AND ADDRESS** RIJ Pharmaceutical Corp. 40 Commercial Avenue Middletown, NY 10941
PERMITTEE REPRESENTATIVE (Receiving the Notice)/TITLE Dr. Brij M. Gupta, President	**NPDES PERMIT NO.** **Categorical IU Pretreatment**

During the compliance inspection carried out on **November 17, 2005**, the non-compliance issue (s) noted below were found. Additional areas of non-compliance may be brought to your attention following a complete review of the Inspection Report and other information on file with the REGULATORY AUTHORITY administering your pre-treatment PERMIT.

NOTICE OF NON-COMPLIANCE

NON-COMPLIANCE ISSUE(S) (Describe)

The facility has been found to have deficiencies in compliance with the requirements and limitations of the applicable Federal categorical pretreatment standards and the Town of Wallkill industrial wastewater discharge standards. The facility is not in compliance with the daily maximum limits for $CBOD_5$, COD, TSS, total phenolics, total Al, total Cu, total Fe, and total Zn as indicated by sampling and analytical results. See the Findings and Conclusion section of the pre-treatment CSI report for this facility for details.

MONITORING LOCATION (Describe)

FLOW MEASUREMENT (Describe)

SAMPLE COLLECTION/HOLDING TIME (Describe)

SAMPLE PRESERVATION (Describe)

TEST PROCEDURES, SECTION 304(H), 40 CFR 136 (Describe)

RECORD KEEPING (Describe)

ADDITIONAL COMMENTS

REQUESTED ACTION-Your attention to the correction of the non-compliance issue (s) noted above is requested. Receipt of a description of the corrective actions taken will be considered in the determination of the need for further Administrative or Legal Action. Your response is to be **(Inspector line out inappropriate response method)**: (1) ~~*included with your next NPDES Discharge Monitoring Report (DMR)*~~; *or (2) submitted as directed by the inspector*. Questions regarding possible follow-up action can be answered by the REGULATORY AUTHORITY to which your DMRs are submitted and which administers your NPDES permit.

INSPECTOR'S SIGNATURE	**INSPECTOR'S ADDRESS/TELEPHONE NO.**	**REGULATORY AUTHORITY/ADDRESS**	**DATE**
Lampros E. Bourodimos **INSPECTORS PRINTED NAME** Lampros E. Bourodimos, PhD, PE	US EPA - Region 2 2890 Woodbridge Ave. Edison, NJ 08837 (732) 321-6704	US EPA - Region 2 2890 Woodbridge Ave., Bldg 209 Bay B Edison, New Jersey 08837	04/13/2006

United States Environmental Protection Agency
Washington, D.C. 20460

Water Compliance Inspection Report

Section A: National Data System Coding (i.e., PCS)

Transaction Code	NPDES	yr/mo/day	Inspection Type	Inspector	Fac Type
1 N 2 5	3 NY0200026 11	12 051117 17	18 2	19 R	20 2

Remarks
21 66

Inspection Work Days	Facility Self-Monitoring Evaluation Rating	BI	QA	Reserved
67 16 69	70	71 N	72 N	73 74 75 80

Section B: Facility Data

Name and Location of Facility Inspected *(For industrial users discharging to POTW, also include POTW name and NPDES permit number)*	Entry Time/Date	Permit Effective Date
RIJ Pharmaceutical Corp. 40 Commercial Ave. Middletown, NY 10941	7:25 am 17 Nov 2005	1 Jan 2006
	Exit Time/Date	**Permit Expiration Date**
	7:35 pm 17 Nov 2005	31 Dec 2006

Name(s) of On-Site Representative(s)/Title(s)/Phone and Fax Number(s)
Dr. Brij M. Gupta, President
(845) 692-5799

Other Facility Data *(e.g., SIC NAICS, and other descriptive information)*

Name, Address of Responsible Official/Title/Phone and Fax Number
Same as above

Contacted ☑ Yes ☐ No

Section C: Areas Evaluated During Inspection *(Check only those areas evaluated)*

✓ Permit	☐ Self-Monitoring Program	✓ Pretreatment	☐ MS4
✓ Records/Reports	☐ Compliance Schedules	☐ Pollution Prevention	☐ Multimedia
✓ Facility Site Review	☐ Laboratory	☐ Storm Water	
✓ Effluent/Receiving Waters	☐ Operations & Maintenance	☐ Combined Sewer Overflow	
☐ Flow Measurement	☐ Sludge Handling/Disposal	☐ Sanitary Sewer Overflow	

Section D: Summary of Findings/Comments
(Attach additional sheets of narrative and checklists, including Single Event Violation codes, as necessary)

SEV Codes	SEV Description
A C R 1 2	Numeric Effluent Violation

Name(s) and Signature(s) of Inspector(s)	Agency/Office/Phone and Fax Numbers	Date
Lampros E. Bourodimos	USEPA/2DESA/MAB/MOS	17 Nov 2005
Lampros E. Bourodimos		

Signature of Management Q A Reviewer	Agency/Office/Phone and Fax Numbers	Date

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Sections F thru L: Complete on all inspections, as appropriate. N/A = Not Applicable

PERMIT NO. NY0200026

SECTION F - Facility and Permit Background

ADDRESS OF PERMITTEE IF DIFFERENT FROM FACILITY *(Including City, County and ZIP code)*	DATE OF LAST PREVIOUS INVESTIGATION BY EPA/STATE
	FINDINGS

SECTION G - Records and Reports

RECORDS AND REPORTS MAINTAINED AS REQUIRED BY PERMIT. ☑ YES ☐ NO ☐ N/A *(Further explanation attached _____)*

DETAILS:

(a) ADEQUATE RECORDS MAINTAINED OF:			
(i) SAMPLING DATE, TIME, EXACT LOCATION	☑ YES	☐ NO	☐ N/A
(ii) ANALYSES DATES, TIMES	☑ YES	☐ NO	☐ N/A
(iii) INDIVIDUAL PERFORMING ANALYSIS	☑ YES	☐ NO	☐ N/A
(iv) ANALYTICAL METHODS/TECHNIQUES USED	☑ YES	☐ NO	☐ N/A
(v) ANALYTICAL RESULTS *(e.g., consistent with self-monitoring report data)*	☑ YES	☐ NO	☐ N/A
(b) MONITORING RECORDS *(e.g.,flow, pH, D.O., etc.)* MAINTAINED FOR A MINIMUM OF THREE YEARS INCLUDING ALL ORIGINAL STRIP CHART RECORDINGS *(e.g. continuous monitoring instrumentation, calibration and maintenance records).*	☐ YES	☐ NO	☑ N/A
(c) LAB EQUIPMENT CALIBRATION AND MAINTENANCE RECORDS KEPT.	☐ YES	☐ NO	☑ N/A
(d) FACILITY OPERATING RECORDS KEPT INCLUDING OPERATING LOGS FOR EACH TREATMENT UNIT.	☐ YES	☐ NO	☑ N/A
(e) QUALITY ASSURANCE RECORDS KEPT.	☑ YES	☐ NO	☐ N/A
(f) RECORDS MAINTAINED OF MAJOR CONTRIBUTING INDUSTRIES *(and their compliance status)* USING PUBLICLY OWNED TREATMENT WORKS.	☐ YES	☐ NO	☑ N/A

SECTION H - Permit Verification

SECTION OBSERVATIONS VERIFY THE PERMIT. ☑ YES ☐ NO ☐ N/A *(Further explanation attached _____)*

DETAILS:

(a) CORRECT NAME AND MAILING ADDRESS OF PERMITTEE.	☑ YES	☐ NO	☐ N/A
(b) FACILITY IS AS DESCRIBED IN PERMIT.	☑ YES	☐ NO	☐ N/A
(c) PRINCIPAL PRODUCT(S) AND PRODUCTION RATES CONFORM WITH THOSE SET FORTH IN PERMIT APPLICATION.	☐ YES	☐ NO	☑ N/A
(d) TREATMENT PROCESSES ARE AS DESCRIBED IN PERMIT APPLICATION.	☐ YES	☐ NO	☑ N/A
(e) NOTIFICATION GIVEN TO EPA/STATE OF NEW, DIFFERENT OR INCREASED DISCHARGES.	☐ YES	☐ NO	☑ N/A
(f) ACCURATE RECORDS OF RAW WATER VOLUME MAINTAINED.	☐ YES	☐ NO	☑ N/A
(g) NUMBER AND LOCATION OF DISCHARGE POINTS ARE AS DESCRIBED IN PERMIT.	☐ YES	☐ NO	☑ N/A
(h) CORRECT NAME AND LOCATION OF RECEIVING WATERS.	☑ YES	☐ NO	☐ N/A
(i) ALL DISCHARGES ARE PERMITTED.	☑ YES	☐ NO	☐ N/A

SECTION I - Operation and Maintenance

TREATMENT FACILITY PROPERLY OPERATED AND MAINTAINED. ☐ YES ☐ NO ☑ N/A *(Further explanation attached _____)*

DETAILS:

(a) STANDBY POWER OR OTHER EQUIVALENT PROVISIONS PROVIDED.	☐ YES	☐ NO	☐ N/A
(b) ADEQUATE ALARM SYSTEM FOR POWER OR EQUIPMENT FAILURES AVAILABLE.	☐ YES	☐ NO	☐ N/A
(c) REPORTS ON ALTERNATE SOURCE OF POWER SENT TO EPA/STATE AS REQUIRED BY PERMIT.	☐ YES	☐ NO	☐ N/A
(d) SLUDGES AND SOLIDS ADEQUATELY DISPOSED.	☐ YES	☐ NO	☐ N/A
(e) ALL TREATMENT UNITS IN SERVICE.	☐ YES	☐ NO	☐ N/A
(f) CONSULTING ENGINEER RETAINED OR AVAILABLE FOR CONSULTATION ON OPERATION AND MAINTENANCE PROBLEMS.	☐ YES	☐ NO	☐ N/A
(g) QUALIFIED OPERATING STAFF PROVIDED.	☐ YES	☐ NO	☐ N/A
(h) ESTABLISHED PROCEDURES AVAILABLE FOR TRAINING NEW OPERATORS.	☐ YES	☐ NO	☐ N/A
(i) FILES MAINTAINED ON SPARE PARTS INVENTORY, MAJOR EQUIPMENT SPECIFICATIONS, AND PARTS AND EQUIPMENT SUPPLIERS.	☐ YES	☐ NO	☐ N/A
(j) INSTRUCTIONS FILES KEPT FOR OPERATION AND MAINTENANCE OF EACH ITEM OF MAJOR EQUIPMENT.	☐ YES	☐ NO	☐ N/A
(k) OPERATION AND MAINTENANCE MANUAL MAINTAINED.	☐ YES	☐ NO	☐ N/A
(l) SPCC PLAN AVAILABLE.	☐ YES	☐ NO	☐ N/A
(m) REGULATORY AGENCY NOTIFIED OF BY PASSING. *(Dates _____ _____)*	☐ YES	☐ NO	☐ N/A
(n) ANY BY-PASSING SINCE LAST INSPECTION.	☐ YES	☐ NO	☐ N/A
(o) ANY HYDRAULIC AND/OR ORGANIC OVERLOADS EXPERIENCED.	☐ YES	☐ NO	☐ N/A

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SECTION J - Compliance Schedules

PERMITTEE IS MEETING COMPLIANCE SCHEDULE. ☐ YES ☐ NO ☑ N/A *(Further explanation attached _____)*

CHECK APPROPRIATE PHASE(S):

- ☐ (a) THE PERMITTEE HAS OBTAINED THE NECESSARY APPROVALS FROM THE APPROPRIATE AUTHORITIES TO BEGIN CONSTRUCTION.
- ☐ (b) PROPER ARRANGEMENT HAS BEEN MADE FOR FINANCING *(mortgage commitments, grants, etc.)*,
- ☐ (c) CONTRACTS FOR ENGINEERING SERVICES HAVE BEEN EXECUTED.
- ☐ (d) DESIGN PLANS AND SPECIFICATIONS HAVE BEEN COMPLETED.
- ☐ (e) CONSTRUCTION HAS COMMENCED.
- ☐ (f) CONSTRUCTION AND/OR EQUIPMENT ACQUISITION IS ON SCHEDULE.
- ☐ (g) CONSTRUCTION HAS BEEN COMPLETED.
- ☐ (h) START-UP HAS COMMENCED.
- ☐ (i) THE PERMITTEE HAS REQUESTED AN EXTENSION OF TIME.

SECTION K - Self-Monitoring Program

	YES	NO	N/A
Part 1 — Flow measurement *(Further explanation attached _____)*			
PERMITTEE FLOW MEASUREMENT MEETS THE REQUIREMENTS AND INTENT OF THE PERMIT. DETAILS:	☐	☐	☑
(a) PRIMARY MEASURING DEVICE PROPERLY INSTALLED.	☐	☐	☐
TYPE OF DEVICE: ☐ WEIR ☐ PARSHALL FLUME ☐ MAGMETER ☐ VENTURI METER ☐ OTHER *(Specify _____)*			
(b) CALIBRATION FREQUENCY ADEQUATE. *(Date of last calibration _____)*	☐	☐	☐
(c) PRIMARY FLOW MEASURING DEVICE PROPERLY OPERATED AND MAINTAINED.	☐	☐	☐
(d) SECONDARY INSTRUMENTS *(totalizers, recorders, etc.)* PROPERLY OPERATED AND MAINTAINED.	☐	☐	☐
(e) FLOW MEASUREMENT EQUIPMENT ADEQUATE TO HANDLE EXPECTED RANGES OF FLOW RATES.	☐	☐	☐
Part 2 — Sampling *(Further explanation attached _____)*			
PERMITTEE SAMPLING MEETS THE REQUIREMENTS AND INTENT OF THE PERMIT. DETAILS:	☑	☐	☐
(a) LOCATIONS ADEQUATE FOR REPRESENTATIVE SAMPLES.	☑	☐	☐
(b) PARAMETERS AND SAMPLING FREQUENCY AGREE WITH PERMIT.	☑	☐	☐
(c) PERMITTEE IS USING METHOD OF SAMPLE COLLECTION REQUIRED BY PERMIT. IF NO, ☐ GRAB ☐ MANUAL COMPOSITE ☐ AUTOMATIC COMPOSITE FREQUENCY _____	☐	☐	☐
(d) SAMPLE COLLECTION PROCEDURES ARE ADEQUATE.	☑	☐	☐
(i) SAMPLES REFRIGERATED DURING COMPOSITING	☐	☐	☑
(ii) PROPER PRESERVATION TECHNIQUES USED	☑	☐	☐
(iii) FLOW PROPORTIONED SAMPLES OBTAINED WHERE REQUIRED BY PERMIT	☐	☐	☑
(iv) SAMPLE HOLDING TIMES PRIOR TO ANALYSES IN CONFORMANCE WITH 40 CFR 136.3	☑	☐	☐
(e) MONITORING AND ANALYSES BEING PERFORMED MORE FREQUENTLY THAN REQUIRED BY PERMIT.	☐	☑	☐
(f) IF (e) IS YES, RESULTS ARE REPORTED IN PERMITTEE'S SELF-MONITORING REPORT.	☐	☐	☐
Part 3 — Laboratory *(Further explanation attached _____)*			
PERMITTEE LABORATORY PROCEDURES MEET THE REQUIREMENTS AND INTENT OF THE PERMIT. DETAILS:	☑	☐	☐
(a) EPA APPROVED ANALYTICAL TESTING PROCEDURES USED. *(40 CFR 136.3)*	☑	☐	☐
(b) IF ALTERNATE ANALYTICAL PROCEDURES ARE USED, PROPER APPROVAL HAS BEEN OBTAINED.	☐	☐	☐
(c) PARAMETERS OTHER THAN THOSE REQUIRED BY THE PERMIT ARE ANALYZED.	☐	☑	☐
(d) SATISFACTORY CALIBRATION AND MAINTENANCE OF INSTRUMENTS AND EQUIPMENT.	☑	☐	☐
(e) QUALITY CONTROL PROCEDURES USED.	☑	☐	☐
(f) DUPLICATE SAMPLES ARE ANALYZED. 5 % OF TIME.	☑	☐	☐
(g) SPIKED SAMPLES ARE USED. 5 % OF TIME.	☑	☐	☐
(h) COMMERCIAL LABORATORY USED.	☑	☐	☐
(i) COMMERCIAL LABORATORY STATE CERTIFIED.	☑	☐	☐

LAB NAME	STL (Severn Trent Laboratories)	Lancaster Laboratories
LAB ADDRESS	315 Fullerton Avenue	2425 New Holland Pike
	Newburgh NY 12550	Lancaster, PA 17605

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SECTION L - Effluent/Receiving Water Observations *(Further explanation attached _____)*

OUTFALL NO.	OIL SHEEN	GREASE	TURBIDITY	VISIBLE FOAM	VISIBLE FLOAT SOL	COLOR	OTHER
001	none	none	slight	slight	none	milky	—

(Sections M and N: Complete as appropriate for sampling inspections)

SECTION M - Sampling Inspection Procedures and Observations *(Further explanation attached _____)*

- ☑ GRAB SAMPLES OBTAINED
- ☐ COMPOSITE OBTAINED
- ☐ FLOW PROPORTIONED SAMPLE
- ☐ AUTOMATIC SAMPLER USED
- ☑ SAMPLE SPLIT WITH PERMITTEE
- ☐ CHAIN OF CUSTODY EMPLOYED
- ☐ SAMPLE OBTAINED FROM FACILITY SAMPLING DEVICE

COMPOSITING FREQUENCY _____ PRESERVATION _____

SAMPLE REFRIGERATED DURING COMPOSITING: ☐ YES ☐ NO

SAMPLE REPRESENTATIVE OF VOLUME AND NATURE OF DISCHARGE _____

SECTION N - Analytical Results *(Attach report if necessary)*

See pre-treatment Compliance Sampling Inspection report for this facility conducted on 17 Nov 2005

EPA Form 3560-3 (9-77)