SANITATION DISTRICTS OF LOS ANGELES COUNTY

INDUSTRIAL WASTE SECTION
1955 Workman Mill Road, Whittier, CA 90601-1400
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BASELINE MONITORING REPORT (BMR)

Pharmaceutical Manufacturing Category (40 CFR 439)
Subcategories A, B, C and D
Point Source Category Regulations

(Please print or type)

I. Company Information

Name: _____ Tel: ( ) _____
Situs Address: _____
_____ Zip: _____
Mailing Address: _____
_____ Zip: _____
Sanitation Districts' Industrial Wastewater Discharge Permit Number[1] _____
Sanitation Districts' Industrial Wastewater Discharge Permit Flow Rate _____ gal/day
Federal Standard Industrial Classification Numbers (SIC) characterizing this facility _____
Company's Industrial Waste Contact Person _____
Title: _____
Person In Charge of Local Operations: _____
Title: _____
Owner of Company (parent company or corporate entity if appropriate): _____
Address of Owner: _____

II. Environmental Control Permits – List environmental control permits held by or for your facility.

_____
_____
_____

III. Category Determination

A. Describe operations that are performed at your **facility**[2] from raw material to finished product (add additional sheets as needed).

_____
_____
_____
_____

[1] One Baseline Monitoring Report (BMR) must be completed for **every** industrial wastewater discharge point to the sewer from your facility.
[2] If your facility has more than one sewer connection, indicate in the description area which operations discharge to which permit number.

B. Carefully review the "General Applicability" stated in the attached Summary of Final Federal Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category. Are any of the products manufactured and/or researched at your facility covered by the Pharmaceutical Manufacturing Category (40 CFR Part 439)?

☐ Yes ☐ No

If the answer is *No*, your facility is exempt from the Pharmaceutical Manufacturing Category regulations. Your claim will be verified through inspections of your facility by Districts' personnel. Please skip to Section IX of this form, complete the certification statement, and return this form to the Districts.

If the answer is *Yes*, please continue.

C. If your facility only discharges wastewater resulting from pharmaceutical research (i.e., only subjects to Pharmaceutical Manufacturing Category, Subpart E – Research Subcategory which has no categorical pretreatment standards), please skip to Section IX of this form, complete the certification statement, and return this form to the Districts. **Otherwise, please continue**.

D. Complete the following table for each product or chemical which is manufactured at your facility and is covered by the Pharmaceutical Manufacturing Category (use additional sheets as needed).

Name of Product	Manufactured by Processes or Activities				Average Daily Production Rate
	Subcategory A	Subcategory B	Subcategory C	Subcategory D	
	Fermentation Products	Extraction Products	Chemical Synthesis	Mixing/ Compounding and Formulation	

E. Date the pharmaceutical manufacturing operation(s) started: _____,

IV. <u>Information on Regulated Pollutants Used or Generated</u> – (You may skip this section and proceed to Section V if your company will perform self-monitoring for all regulated pollutants).

Permit limits and compliance monitoring are required for each regulated pollutant generated or used at your facility. However, permit limits and compliance monitoring are not required for regulated pollutants that are neither used nor generated at your facility. Please complete the following table(s) based on a review of all raw materials in use, and an assessment of the process chemistry, products and by-

products resulting from each of the manufacturing process. A list of raw materials and products shall be attached to this BMR.

A. Please complete the following table if your facility is covered under *Subpart A – Fermentation Products Subcategory* and/or *Subpart C – Chemical Synthesis Products Category*.

Regulated Pollutant	Is used or Generated	Is Neither Used nor Generated
Cyanide (T)		
Ammonia (as N)		
Acetone		
4-Methyl-2-Pentanone		
Isobutyraldehyde		
N-Amyl Acetate		
N-Butyl Acetate		
Ethyl Acetate		
Isopropyl Acetate		
Methyl Formate		
Isoproply Ether		
Tetrahydrofuran		
Benzene		
Toluene		
Xylenes		
N-Hexane		
N-Heptane		
Methylene Chloride		
Chloroform		
1,2-Dichloroethane		
Chlorobenzene		
O-Dichlorobenzene		
Diethyl Amine		
Triethyl Amine		

B. Please complete the following table if your facility is covered under *Subpart B – Extraction Products Subcategory* and/or *Subpart D – Mixing/Compounding and Formulation Subcategory*.

Regulated Pollutant	Is used or Generated	Is Neither Used nor Generated
Acetone		
N-Amyl Acetate		
Ethyl Acetate		
Isopropyl Acetate		
Methylene Chloride		

C. If your facility neither uses nor generates **any** of the regulated pollutants, please proceed to Section IX of this form. **Otherwise, please continue**.

V. **Flow Measurement Information** – Please complete the following tables (use additional sheets as needed). Also, attach a schematic process flow diagram showing wastestreams, flow rates, treatment units and sampling locations.

Description of EPA Regulated Wastewater Flows[3]	Average Daily Flow (gal/day)	Maximum Daily Flow (gal/day)	Flow Description[4]		Does Wastestream Receive Pretreatment? Yes or No Describe
			E/M	I/C	

[3] Separately include all wastestreams discharging to this connection/outfall which are covered by EPA categorical regulation(s). (A, B, C, and/or D) they are covered.

[4] Please indicate by letter in this column whether wastewater flow value is (E) Estimated or (M) Measured, and (I) Intermittent or (C) Continuous.

Description of EPA Unregulated Wastewater Flows[5]	Average Daily Flow (gal/day)	Maximum Daily Flow (gal/day)	Flow Description[3]		Does Wastestream Receive Pretreatment? Yes or No Describe
			E/M	I/C	

Description of EPA Unregulated Wastewater Flows[6]	Average Daily Flow (gal/day)	Maximum Daily Flow (gal/day)	Flow Description[3]		Does Wastestream Receive Pretreatment? Yes or No Describe
			E/M	I/C	

VI. Measurement of Pollutants

Wastewater discharged from your facility must be sampled and analyzed for all pollutants discharged at your facility, including all of the constituents listed in Table I, II, III and/or IV of the attached "Summary of Final Federal Pretreatment Standards" which are used or generated at your facility. The wastewater must be sampled and analyzed in accordance with 40 CFR 403.12(b)(d)(iii-viii), and Table V of the enclosed "Summary of Final Federal Pretreatment Standards." The copies of the wastewater analysis results must be included with this BMR when it is submitted to the Districts. The results must indicate the analytical test method used for each parameter. All analyses must be performed by a state-certified or Districts' approved laboratory.

A minimum of four (4) grab samples must be used for pH, cyanide, total phenols, oil and grease, sulfide, and volatile organics. The four grab samples should be taken at equally spaced intervals over a 24-hour period, or over the period in which your facility typically discharges wastewater if it is less than 24 hours. For all other pollutants including ammonia (as nitrogen), 24-hour composite samples must be obtained through flow-proportional composite sampling techniques where feasible. All samples must be

[5] Includes wastewater flows to this connection/outfall from operations not covered by EPA industrial categorical regulations and not considered dilution flows.

[6] Dilution flows include non-contact cooling water and boiler blowdown, D. I. Backwash and R. O. reject water from incoming water supply treatment, and wastestreams listed in Appendix D to 40 CFR 403 and sanitary wastes. Sanitary wastes should not be listed here unless they discharge through the legal sampling point.

taken during periods typical of normal work cycles. Historical sampling data from your facility may be used in lieu of taking new samples, if the samples are still representative of the discharge from your facility. For new sources only, estimates of pollutant values are allowed. However, within 90 days of commencement of discharge, the new source discharger must submit a 90-day compliance report to the Districts on an additional BMR form.

The volume of flow discharge during the period in which the samples are taken must also be determined. If your facility does not have a flowmeter on its effluent, the volume may be estimated using meter readings on influent water with losses calculated, or any other appropriate method.

Please complete the following table describing the sampling and analytical results accompanying this BMR.

Sample Type	Sampling Date & Time	Sampling Location	Name & Address of Company Obtaining Sample	Name & Address of Laboratory Performing Analysis
Composite				
Grab #1				
Grab #2				
Grab #3				
Grab #4				

Total volume of wastewater discharged during the period in which samples were taken: _____.

I certify that the sampling and analysis provided with this BMR is representative of normal work cycles and expected pollutant discharges to the Districts.

Date: _____
Sign Name: _____
Print Name: _____
Title: _____

VII. Determination of Limitations and Compliance

Complete the following tables to determine concentration limits for your facility and compliance with the limitations. Note that concentration limitations must be adjusted to take into account any dilution flows (see Section V).

In order to be in compliance with the regulations, you must meet both daily maximum and monthly average discharge limitations. Compliance with monthly average discharge limitations is determined by averaging concentrations in all samples taken during a calendar month. If only one sample is taken during a month, the sample must meet all monthly average discharge limitations. In completing the following tables, use the highest sample from all of your samples to determine compliance with daily maximum limitations, and average all sample results taken within a monthly period to determine compliance with monthly average discharge limitations.

In filling out the tables, determine the daily maximum and monthly average pretreatment standards for your facility by using the appropriate values for your subcategory(ies) from the tables in the "Summary of Final Federal Pretreatment Standards – Pharmaceutical Manufacturing Category." If a particular pollutant is not regulated under your subcategory(ies), or is neither used nor generated at your facility, simply put "None" in the box for that pretreatment standard.

Compliance Determination for Daily Maximum Pretreatment Standards					
Pollutant	Daily Maximum Pretreatment Standard (mg/l)	Dilution Factor [7]	Modified Daily Maximum Pretreatment Standard [8]	Daily Sample Result (mg/l) [9]	In Compliance? [10] (Yes or No)
Cyanide [11, 12]	33.5				
Ammonia [12]	84.1				
Acetone	20.7				
4-Methyl-2-Pentanone (MIBK) [12]	20.7				
Isobutyraldehyde [12]	20.7				
N-Amyl Acetate	20.7				
N-Butyl Acetate [12]	20.7				
Ethyl Acetate	20.7				
Isoproply Acetate	20.7				
Methyl Formate [12]	20.7				
Isopropyl Ether [12]	20.7				
Tetrahydrofuran [12]	9.2				
Benzene [12]	3.0				

[7] The dilution factor is determined as $(F_T-F_D)/F_T$ where F_T is the total daily flowrate from your facility and F_D is the average daily flowrate of dilution flows (see Section V). If there are no dilution flows at your facility, the dilution factor is 1.

[8] The daily maximum pretreatment standard times the dilution factor.

[9] The highest value on any single day. If you have multiple grab samples for one day, average the sample results to obtain the daily value

[10] Compare the (modified) daily maximum pretreatment standard for each pollutant to the sample result for the pollutant.

[11] When monitoring for Cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide pretreatment standards must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(E)(2) and (4).

[12] Regulated under subcategories A and C only.

Compliance Determination for Daily Maximum Pretreatment Standards					
Pollutant	Daily Maximum Pretreatment Standard (mg/l)	Dilution Factor [7]	Modified Daily Maximum Pretreatment Standard [8]	Daily Sample Result (mg/l) [9]	In Compliance? [10] (Yes or No)
Toluene [12]	0.3				
Xylenes [12]	3.0				
N-Hexane [12]	3.0				
N-Heptane [12]	3.0				
Methylene Chloride	3.0				
Chloroform [12]	0.1				
1,2-Dichloroethane [12]	20.7				
Chlorobenzene [12]	3.0				
O-Dichlorobenzene [12]	20.7				
Diethyl Amine [12]	255.0				
Triethy l Amine [12]	255.0				

Compliance Determination for Monthly Average Pretreatment Standards					
Pollutant	Monthly Average Pretreatment Standard (mg/l)	Dilution Factor [7]	Modified Monthly Average Pretreatment Standard [13]	Monthly Sample Result (mg/l) [14]	In Compliance? [15] (Yes or No)
Cyanide [11, 12]	9.4				
Ammonia [12]	29.4				
Acetone	8.2				
4-Methyl-2-Pentanone (MIBK) [12]	8.2				

[13] The monthly average pretreatment standard times the dilution factor.
[14] Average all samples results taken within a calendar month to obtain the monthly average value. If you have sample results from more than one month, enter the highest monthly average.
[15] Compare the (modified) monthly average pretreatment standard for each pollutant to the sample result for the pollutant.

Compliance Determination for Monthly Average Pretreatment Standards					
Pollutant	Monthly Average Pretreatment Standard (mg/l)	Dilution Factor [7]	Modified Monthly Average Pretreatment Standard [13]	Monthly Sample Result (mg/l) [14]	In Compliance? [15] (Yes or No)
Isobutyraldehyde [12]	8.2				
N-Amyl Acetate	8.2				
N-Butyl Acetate [12]	8.2				
Ethyl Acetate	8.2				
Isoproply Acetate	8.2				
Methyl Formate [12]	8.2				
Isopropyl Ether [12]	8.2				
Tetrahydrofuran [12]	3.4				
Benzene [12]	0.7				
Toluene [12]	0.2				
Xylenes [12]	0.7				
N-Hexane [12]	0.7				
N-Heptane [12]	0.7				
Methylene Chloride	0.7				
Chloroform [12]	0.03				
1,2-Dichloroethane [12]	8.2				
Chlorobenzene [12]	0.7				
O-Dichlorobenzene [12]	8.2				
Diethyl Amine [12]	100.0				
Triethyl Amine [12]	100.0				

VIII. Statement of Compliance

An authorized official of the company as defined in 40 CFR 403.12(l) must review the following statements of compliance, which must be certified to by a qualified professional.

I hereby certify that the EPA categorical pretreatment standards which apply to this facility are being met on a consistent basis as evidenced by the attached data. ☐ *Yes* ☐ *No*

I hereby certify that dilution is not being used in lieu of treatment to meet the EPA categorical pretreatment standards. ☐ *Yes* ☐ *No*

If the answer to either of the above statements is *No*, then additional pretreatment, flow reduction or operations and maintenance measures to bring the company into compliance with the EPA categorical regulations must be proposed below. Anticipated completion dates must be provided.

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

A detailed compliance schedule for the above changes must be attached. This schedule shall contain increments of progress in the form of dates for the commencement and completion of major events leading to the construction and operation of additional pretreatment required for the facility to meet the EPA categorical pretreatment standards (e.g. hiring an engineer, completing preliminary plans, completing final plans, executing contract for major components, commencing construction, completing construction, etc.). A commitment to design, install or alter pretreatment or process systems to effect future compliance does not relieve your company of the requirement to immediately comply with discharge limits by whatever means necessary (cessation, impounding, hauling, etc.) until a more permanent solution is implemented.

Date: _____
Reviewed by: (company official's signature) _____
Print Name: _____
Job Title: _____

Qualified professional certification:

Date: _____
Certified by: (qualified professional's signature) _____
Print Name: _____
Qualifications as an Environmental Professional: _____
_____
_____
Company Name: _____
Company Address: _____

IX. Certification

The following statement as set forth in 40 CFR 403.6(a)(2)(ii) must be signed by an authorized company official as defined in 40 CFR 403.12(l).

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Date: _____

Signature of authorized company official: _____

Print name of official: _____

Title of authorized company official: _____

"Authorized company official" means:

1. For a partnership: a general partner.
2. For a sole proprietorship: the proprietor.
3. For a corporation: a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation; or the manager of one or more manufacturing, production, or operation facilities, provided, the manager is authorized to make management decisions which govern the operation of the regulated facility including having the explicit or implicit duty of making major capital investment recommendations, and initiate and direct other comprehensive measures to assure long term environmental compliance with environmental laws and regulations; can ensure that the necessary systems are established or actions taken to gather complete and accurate information for control mechanism requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

4. A duly authorized official of one of the individuals described above may substitute if:
   a. The authorization is made in writing by one of the individuals described above;
   b. The authorization specifies either an individual or a position having responsibility for the overall operation of the permittee's facility, such as the position of plant manager, operator of a well, or well field superintendent, or a position of equivalent responsibility, or having overall responsibility for environmental matters for the company; and
   c. The written authorization is submitted to the Districts.