

SECTION 4

INDUSTRY SUBCATEGORIZATION

4.1 Introduction

The purpose of subcategorization is to group together facilities of similar characteristics so that effluent limitations guidelines and standards representative of each group can be developed. This provides each subcategory with a uniform set of effluent limitations guidelines which take into account technological achievability and economic impacts unique to that subcategory.

For this final rulemaking, EPA considered the following factors in the subcategorization of the pharmaceutical manufacturing industry:

- Manufacturing processes;
- Wastewater characteristics and treatability;
- Product types;
- Raw materials;
- Plant size;
- Plant age;
- Plant location;
- Nonwater quality environmental impacts; and
- Treatment costs and energy requirements.

After evaluating the above factors, the Agency determined that subcategorization of the pharmaceutical manufacturing industry is necessary. The results of these evaluations are presented in the following sections:

- 4.2 discusses the regulatory background of subcategorization in the pharmaceutical manufacturing industry;
- 4.3 presents the final subcategorization basis; and
- 4.4 presents conclusions.

4.2 Background

The original subcategorization scheme for the pharmaceutical manufacturing industry was published in the November 17, 1976 Federal Register.⁽¹⁾ This subcategorization scheme was based on the operations listed below:

- Subcategory A - Fermentation Operations
- Subcategory B - Biological and Natural Extraction Operations
- Subcategory C - Chemical Synthesis Operations
- Subcategory D - Mixing, Compounding, or Formulating Operations
- Subcategory E - Pharmaceutical Research Operations.

Subsequently, EPA published proposed effluent limitations guidelines and standards for the pharmaceutical manufacturing industry in November 1982. As discussed in the preamble to the 1982 regulation, EPA proposed to combine Subcategories A through D above into a single subcategory.⁽²⁾ Along with comments on the November 1982 proposal, EPA received additional influent and effluent conventional and nonconventional pollutant data. EPA statistically analyzed both new and existing influent and effluent conventional and nonconventional pollutant data for all direct dischargers to determine if the proposed change to create a single subcategory was appropriate. A detailed discussion of the data sources and the statistical comparisons used is presented in IV of the 1983 Final Development Document ⁽³⁾, and is summarized below.

The statistical comparisons of conventional pollutants and the nonconventional pollutant COD indicated that the subcategorization scheme should separate fermentation and chemical synthesis operations (Subcategory A and C) from extraction and mixing, compounding, or formulating operations (Subcategory B and D). The analyses showed that the influent and effluent conventional pollutant and COD concentrations, as well as discharge flows, of facilities with Subcategory A and C operations are similar and that these same characteristics are similar between facilities with Subcategory B and D operations. These characteristics are different, however, between the Subcategory A and C facility group and the Subcategory B and D facility group. These differences indicated that different effluent discharge levels of conventional pollutants and COD would be expected when facilities in both groups used the same control

technology. However, because the existing separate subcategories accommodated these differences and because permitting authorities and the regulated industry were familiar with that scheme, EPA decided to maintain the existing subcategorization scheme at that time.

In the May 2, 1995 proposal, EPA proposed to continue to maintain the existing subcategorization scheme. As part of this proposal, EPA also indicated that Subcategory E (research) was limited to bench-scale research operations and was not intended to cover pilot-plant development operations. The majority of commenters on the May 2, 1995 proposal supported the continuation of the existing subcategorization scheme. Several industry commenters, however, opposed limitations on the types of wastewaters included in the Subcategory E group and argued that pilot-plant operations have been and should continue to be included under the Subcategory E definition.

After considering the comments received concerning the regulation of wastewaters from pilot-scale operations, EPA has decided not to change the existing description of the research subcategory in the applicability section. EPA concluded that it did not have sufficient information concerning Subcategory E generated wastewaters to change the existing description. If pilot-scale manufacturing operations occur at stand-alone research facilities or during research operations at manufacturing facilities, then BAT and BCT limits for these wastewaters can be determined by permit writers on a best professional judgment (BPJ) basis. Similarly, such wastewater generated at indirect discharging facilities may be addressed by the regulations found at 40 CFR 403.5 and by local limits on a case-by-case basis.

EPA has reviewed the additional characterization data collected since the 1983 final rulemaking to determine if the previous subcategorization scheme is still appropriate. The results of that review are described in 4.3.

4.3 Final Subcategorization Basis

For this rulemaking, EPA is finalizing the following four subcategories:

1. Subcategory A - Fermentation Operations;
2. Subcategory B - Biological and Natural Extraction Operations;
3. Subcategory C - Chemical Synthesis Operations; and
4. Subcategory D - Mixing, Compounding, or Formulating Operations.

Where the subcategory operation definitions are as follows:

- Fermentation. A chemical change induced by a living organism or enzyme, specifically, bacteria, or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi. Process operations that utilize fermentation to manufacture pharmaceutically active ingredients define Subcategory A.
- Biological and Natural Extraction. The chemical and physical extraction of pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi. The process operations involving biological and natural extraction define Subcategory B.
- Chemical Synthesis. The process(es) of using a chemical reaction or a series of chemical reactions to manufacture pharmaceutically active ingredients. The chemical synthesis process operations define Subcategory C.
- Mixing, Compounding, or Formulating. Processes through which pharmaceutically active ingredients are put in dosage forms. Processes involving mixing, compounding, or formulating define Subcategory D.

This subcategorization scheme is consistent with the conclusions drawn during the subcategorization analysis for the 1983 final rulemaking and with characterization data collected since 1983 and industry profile information gathered with the Detailed Questionnaire.

The following paragraphs discuss EPA's consideration of the nine factors listed in the beginning of this in determining appropriate subcategories for the pharmaceutical manufacturing industry.

The primary bases for subcategorization of facilities in this industry were found to be manufacturing processes and wastewater characteristics.

4.3.1 Manufacturing Processes

There are four basic manufacturing operations used in the pharmaceutical manufacturing industry: 1) fermentation, 2) biological or natural extraction, 3) chemical synthesis, and 4) mixing, compounding, and formulating. The following paragraphs present a brief overview of each of the manufacturing operations and the sources and characteristics of wastewater from each. A detailed discussion of these manufacturing operations is provided in 3.4.

Fermentation is the usual method for producing antibiotics and steroids. The process involves three basic steps: inoculum and seed preparation, fermentation, and product recovery. Most of the wastewater is generated from the fermentation and product recovery steps. Fermentation is typically a large-scale batch process. Product recovery is accomplished by solvent extraction, direct precipitation, ion exchange, and/or adsorption. Based on responses to the Detailed Questionnaire, the solvents most often used in fermentation operations are acetone, methanol, isopropanol, ethanol, and amyl alcohol. Priority pollutants used in fermentation operations include methylene chloride, toluene, and phenol. Copper and zinc are priority pollutant metals known to be utilized where precipitation is used for product recovery. Due to the food materials contained in spent fermentation broth, fermentation wastewaters are very amenable to biological treatment. Data from responses to the Detailed Questionnaire show that wastewater from fermentation plants is generally characterized by high BOD₅, COD, and TSS concentrations, large flows, and a pH range of approximately 4.0 to 8.0.

In biological and/or natural extraction manufacturing operations, pharmaceutical products are extracted from such natural sources as plant material, animal glands, and parasitic fungi through a series of volume reduction and chemical extraction steps. These operations are usually conducted on a much smaller scale than fermentation or chemical synthesis operations. The principal sources of wastewater from biological and natural extraction operations are spent raw materials (plant or animal tissue residue), floor and equipment washes, and spent solvents. Solvents used in

purification and extraction steps include the priority pollutants methylene chloride, toluene, chloroform, and 1,2 dichloroethane as well as the nonconventional pollutants ethanol, methanol, n-amyl acetate, isopropanol, and acetone. The priority pollutant phenol is used as a disinfecting chemical in this process. Ammonium salts are used for pH control during the extraction process. Data from responses to the Detailed Questionnaire show that wastewater from extraction operations is generally characterized by relatively low BOD₅, COD, and TSS concentrations, low flows, and pH values ranging from approximately 6.0 to 8.0.

Chemical synthesis is the process by which most drug compounds are manufactured. Chemical synthesis is generally a batch process using a conventional batch reaction vessel and involves techniques such as alkylations, carboxylation, esterifications, halogenations, and sulfonations. During chemical synthesis, wastewater is generally produced with each chemical modification that requires filling and emptying of the batch reactors. Primary sources of wastewater from chemical synthesis operations are process wastes (spent solvents, filtrates, and concentrates), floor and equipment washes, pump seal water, wet scrubber wastewater, and spills. A wide variety of priority pollutant and nonconventional chemicals are used as reaction and purification solvents during chemical synthesis. Priority pollutants used during chemical synthesis include several chlorinated alkanes and chlorinated aromatic compounds. The major nonconventional pollutants reported in the Detailed Questionnaire were methanol, acetone, isopropanol, ethyl acetate, ethanol, and the six-member ring compounds xylene, pyridine, and toluene. Wastewater from chemical synthesis operations is generally characterized by relatively high BOD₅, COD, and TSS concentrations, large flows, and a wide pH range.

Mixing, compounding, and formulating plants receive bulk pharmaceutical active ingredients as raw materials and subsequently manufacture final dosage forms for consumer use (tablets, liquids, capsules, ointments, etc.). Mixing, compounding, and formulating operations typically involve few production steps which generate wastewater. The primary wastewater sources from these operations are floor and equipment wash water, wet scrubbers, and spills. Wastewater from mixing, compounding, and formulating operations normally has low BOD₅, COD, and TSS concentrations, relatively small flows, and pH values ranging from 6.0 to 8.0.

Pilot-plant operations conducted at pharmaceutical manufacturing facilities can include biological studies, chemical research, and product development activities. Wastewaters from pilot-plant operations conducted in conjunction with and related to existing pharmaceutical manufacturing operations is covered by this final rule because these pilot plant operations would most likely generate wastewater with characteristics similar to the commercial manufacturing operations.

Each type of manufacturing operation in the pharmaceutical manufacturing industry is distinct. Fermentation and chemical synthesis manufacturing operations are typically large-scale batch processes characterized by large flows and relatively high BOD₅, COD, and TSS concentrations. Biological extraction and mixing, compounding, and formulating operations are characterized by low wastewater flows and relatively low BOD₅, COD, and TSS concentrations.

Because of these distinct manufacturing operations and the related wastewater characteristics, the Agency considered manufacturing processes as a basis for subcategorization of this industry.

4.3.2 Wastewater Characteristics and Treatability

As discussed in 4.3.1, each type of manufacturing process in the pharmaceutical manufacturing industry is distinct, and wastewaters are generated by differing unit operations and exhibit somewhat different characteristics. This summarizes discharge flow and wastewater characterization data submitted by the pharmaceutical manufacturing industry in the Detailed Questionnaire.

Tables 4-1 through 4-4 present flow, raw wastewater, and treated effluent characterization data from responses to the Detailed Questionnaire. The tables are arranged by subcategory (A, B, C, and D) and distinguish direct versus indirect dischargers. Because many facilities have operations from more than one subcategory, some data are presented for subcategory groups in the tables. Facilities with any manufacturing operations from Subcategories A or C, even those with manufacturing operations from Subcategory B and/or D, were included with the A, C, and A + C only facilities because most of the flow and pollutant load at these facilities comes from

Subcategory A or C manufacturing operations. Additional discussion of wastewater characterization data is presented in 5.0.

Table 4-1 presents discharge flow rate and BOD₅, COD, and TSS concentration averages and ranges in untreated wastewater. The table shows similar BOD₅, COD, and TSS average concentrations between facilities with Subcategory A and C operations and between facilities with Subcategory B and D operations. The table also shows that facilities with manufacturing operations from Subcategories A and/or C exhibit higher relative flows and BOD₅, COD, and TSS concentrations than those facilities with manufacturing operations from Subcategories B and/or D.

Tables 4-2 and 4-3 present low, high, and average priority and nonconventional organic pollutant concentration summary data for untreated wastewater. Organic pollutant data presented are the sums of individual pollutants reported as being present in the Detailed Questionnaire. These data do not indicate significant differences in pollutant concentrations for organics between Subcategory A and/or C wastewaters and Subcategory B and/or D wastewaters.

Table 4-4 presents low, high, and average pollutant concentration data for BOD₅, COD, and TSS in treated effluent from direct dischargers. These data do not represent the performance of any specific treatment technology, but are indicative of current overall treatment performance within the industry. These data indicate that BOD₅, COD, and TSS are generally treated to lower levels at the Subcategory B and/or D facilities. 8 discusses in detail the performance of specific wastewater treatment technologies in the pharmaceutical manufacturing industry. The data presented in 8 for advanced biological treatment systems, an important treatment technology commonly used in the pharmaceutical manufacturing industry, also indicate that Subcategory B and/or D facilities treat BOD₅, COD, and TSS to lower levels than can be achieved at the facilities with Subcategory A and/or C manufacturing operations.

The treatment performance data presented in 8 do not demonstrate any differentiation in treatment performance for priority and nonconventional organic pollutants among facilities with operations in different subcategories.

In summary, the distinctly different manufacturing operations identified in 4.2 result in distinctly different influent flow and pollutant concentrations between facilities with manufacturing operations from Subcategories A and/or C and facilities with manufacturing operations from Subcategories B and/or D. Facilities with manufacturing operations from Subcategories B and/or D are able to achieve lower treated effluent concentrations of BOD₅, COD, and TSS than facilities with operations from Subcategories A and/or C, using the same treatment technology.

4.3.3 Product Types

Manufacturing processes under the SIC code system in the pharmaceutical manufacturing industry are divided into the following:

- SIC 2833 Medicinal Chemicals and Botanical Products;
- SIC 2834 Pharmaceutical Preparations; and
- SIC 2836 Biological Products.

Medicinal chemicals and botanical products include three major product areas: fermentation products, chemical synthesis products, and natural extraction products. Fermentation products are primarily antibiotics and steroids. Chemical synthesis products include intermediates used to produce other chemical compounds as well as hundreds of bulk chemical products. Natural extraction products include such items as gland derivatives, animal bile salts and derivatives, and herb and tissue derivatives. Pharmaceutical preparations (formulation products) are formulated from bulk active ingredients prior to being marketed to the public. Biological products include materials extracted from biological materials such as vaccines, serums and various plasma derivatives.(4)

Because product types are a function of the manufacturing process used, the Agency concludes that the nature of the product manufactured is incorporated into the basis for subcategorization.

4.3.4 Raw Materials

The pharmaceutical manufacturing industry draws upon worldwide sources for the myriad of raw materials it needs to produce medicinal chemicals. Fermentation operations require many new raw materials falling into general chemical classifications such as carbohydrates, carbonates, steep liquors, nitrogen and phosphorus compounds, anti-foam agents and various acids and bases. These chemicals are used as carbon and nutrient sources (1), as foam control additives, and for pH adjustment in fermentation processes. Various solvents, acids, and bases are also required for extraction and purification processes. Hundreds of raw materials are required for the many batch chemical synthesis processes used by the industry. These include organic and inorganic compounds and are used in gas, liquid, and solid forms.(4)

Plant and animal tissues are also used by the pharmaceutical manufacturing industry to produce various biological and natural extraction products. The raw materials used in formulation operations are the products from other manufacturing operations. These include bulk chemicals from fermentation and chemical synthesis operations and such items as biles, blood fractions, salts, and various derivatives from biological and natural extraction operations.(4)

Because such a vast number and wide variety of raw materials are used within the industry, it is not practical to base subcategories directly on the raw materials used. In addition, the nature of raw materials used by the pharmaceutical manufacturing industry are related to the manufacturing process, and therefore, are indirectly accounted for in the final basis for subcategorization.

4.3.5 Plant Size

The Agency has determined that plant size in terms of production has no significant or consistent impact on the effectiveness of treatment technologies or wastewater characteristics and therefore did not consider plant size as a basis for subcategorization.

4.3.6 Plant Age

The age of a pharmaceutical manufacturing plant is an indefinite parameter primarily due to continual upgrading and modernization most facilities have undertaken in order to remain competitive. The cornerstone age (the age of the original facility) was evaluated relative to raw waste load and treated effluent load without any apparent relationship. The Agency therefore did not consider plant age as a basis for subcategorization.

4.3.7 Plant Location

The locations of pharmaceutical manufacturing facilities are typically based on a number of factors, including:

- Sources of raw materials;
- Proximity to markets for products;
- Availability of an adequate water supply;
- Cheap energy sources;
- Proximity to proper modes of transportation;
- Reasonably priced labor markets; and
- Tax considerations.

The majority of pharmaceutical manufacturing plants are located in New Jersey, New York, Pennsylvania, and Puerto Rico. Based on a review of available data, plant location does not affect the characteristics or treatability of process wastewater streams. The Agency therefore did not consider geographic location as a basis for subcategorization.

4.3.8 Nonwater Quality Environmental Impacts

Nonwater quality environmental impacts characteristics for the pharmaceutical manufacturing industry include:

- Sludge production;
- Waste solvent generation;

- Air pollution derived from wastewater generation and treatment; and
- Steam and electrical energy consumption due to wastewater treatment.

These factors all relate to the characteristics of the wastewater treated. Because wastewater characteristics are specifically accounted for in the final subcategorization approach, the Agency considers all non-water quality environmental impacts to be adequately addressed by the final subcategorization approach.

4.3.9 Treatment Costs and Energy Requirements

The same treatment unit operation, such as steam stripping to remove volatile organic pollutants, could be utilized to treat wastewater from a variety of sources. However, the cost of treatment and the energy required will vary depending on flow rates and wastewater characteristics. Because wastewater characteristics are specifically accounted for in the final subcategorization approach, treatment costs are adequately addressed. Therefore, while treatment costs, as discussed in 10, were considered by the Agency in selecting the technology bases for this final regulation, the Agency concludes that subcategorization based on treatment costs is not appropriate.

4.4 Conclusions

Based on EPA's review of industry data, as described earlier in this section, the Agency concludes that it is appropriate to maintain the four existing subcategories based on the different types of manufacturing operations used by the pharmaceutical manufacturing industry. The four subcategories for the pharmaceutical manufacturing industry covered by this final regulation are:

- Subcategory A - Fermentation Operations;
- Subcategory B - Biological and Natural Extraction Operations;
- Subcategory C - Chemical Synthesis Operations; and
- Subcategory D - Mixing, Compounding, or Formulating Operations.

Due to the similarities identified above between the characteristics and treatability of wastewater from fermentation and chemical synthesis operations, the Agency is establishing equivalent effluent limitations guidelines for Subcategories A and C. The Agency is also establishing equivalent effluent limitations guidelines for Subcategories B and D due to the similarity in characteristics and treatability of wastewater from biological extraction and mixing, compounding, and formulating operations.

At facilities that conduct fermentation and/or chemical synthesis operations, as well as biological extraction and/or mixing, compounding, or formulating operations, the vast majority of the wastewater discharge flow and pollutant load originates from the fermentation and chemical synthesis operations. Most facilities with fermentation and/or chemical synthesis operations conduct such operations at integrated facilities where other pharmaceutical manufacturing operations are also conducted, with discharges to a common wastewater treatment system. The Agency's treatment performance data reflect the integrated nature of such facilities.

For the purpose of analyzing and presenting data in subsequent sections of this development document, pharmaceutical manufacturing facilities are considered either Subcategory A and C facilities, or Subcategory B and D facilities. Due to the predominance of wastewater discharge flow and pollutant load from Subcategory A and C operations when these operations are conducted along with other pharmaceutical manufacturing operations at the same facility, and because of the integrated nature of such facilities, facilities with any Subcategory A or C operations are considered Subcategory A and C facilities. Subcategory B and D facilities are those facilities that have Subcategory B and/or D operations only.

Table 4-1

Summary of Discharge Flow Rate, Conventional Pollutants and COD Concentrations in Untreated Wastewater

Type of Discharge	1983 Subcategory	Pollutant	Untreated Wastewater Concentrations (mg/L)			Flow (1,000 gal/day)		
			Low	High	Ave.	Low	High	Ave.
Direct	A only	BOD ₅	3,360	5,600	4,480	493	1,250	872
		COD	9,100	10,900	10,000	493	1,250	872
		TSS	264	2,490	1,380	493	1,250	872
	C only	BOD ₅	0	812	218	<1	344	142
		COD	0	1,890	718	<1	344	142
		TSS	0	131	55	<1	344	142
	A and C only	BOD ₅	22	2,620	975	202	73,300	21,000
		COD	216	5,280	2,410	202	73,300	21,000
		TSS	39	849	332	202	73,300	21,000
	A and/or C + Other(a)	BOD ₅	11	9,700	2,230	51	2,000	1,010
		COD	123	16,500	4,050	51	2,000	1,010
		TSS	40	383	185	51	2,000	1,010
Indirect	A only	BOD ₅	NA	NA	2,700	47	786	424
		COD	NA	NA	NA	47	786	424
		TSS	NA	NA	757	47	786	424
	C only	BOD ₅	1,250	5,430	3,470	<1	1,620	169
		COD	1,200	22,200	7,980	<1	1,620	169
		TSS	19	1,000	265	<1	1,620	169
	A and C only	BOD ₅	0	1,770	885	16	2,540	1,280
		COD	0	4,390	2,190	16	2,540	1,280
		TSS	0	888	444	16	2,540	1,280
	A and/or C + Other(a)	BOD ₅	95	11,500	2,540	<1	7,310	494
		COD	152	19,700	4,750	<1	7,310	494
		TSS	14	6,070	820	<1	7,310	494

Table 4-1 (Continued)

Type of Discharge	1983 Subcategory	Pollutant	Untreated Wastewater Concentrations (mg/L)			Flow (1,000 gal/day)		
			Low	High	Ave.	Low	High	Ave.
Direct	B only	BOD ₅	-	-	-	-	-	-
		COD	-	-	-	-	-	-
		TSS	-	-	-	-	-	-
	D only	BOD ₅	0	328	117	2	692	110
		COD	0	1,140	271	2	692	110
		TSS	2	306	63	2	692	110
	BD only	BOD ₅	NA	NA	53	NA	NA	63
		COD	NA	NA	27	NA	NA	63
		TSS	NA	NA	16	NA	NA	63
Indirect	B only	BOD ₅	1,850	2,350	2,100	2	165	28
		COD	59	3,110	1,240	2	165	28
		TSS	81	552	250	2	165	28
	D only	BOD ₅	0	4,650	601	<1	42,600	680
		COD	0	6,610	907	<1	42,600	680
		TSS	0	2,060	283	<1	42,600	680
	BD only	BOD ₅	150	2,940	799	1	1,050	186
		COD	184	2,600	1,060	1	1,050	186
		TSS	24	743	265	1	1,050	186

(a) Facilities with combinations of manufacturing operations from other than Subcategories A, B, C, D, AC, and BD are included as other.

NA = Not available.

Table 4-2

Summary of Priority Pollutant Concentrations in Untreated Wastewater

Type of Discharge	Current Subcategory	Cyanide or Priority	# of Facilities Contributing Data	Untreated Wastewater Conc. (mg/L)		
				Low	High	Ave.
Direct	A only	C P	0 0			
	C only	C P	1 4	- 0.4	- 404	4,850 196
	A and C only	C P	1 4	- 20	- 657	1,730 306
	Other(a)	C P	1 6	- 0.3	- 11,900	38 2,860
Indirect	A only	C P	0 0			
	C only	C P	1 17	- 0.2	- 4,850	5 589
	A and C only	C P	0 1	-	-	619
	Other(a)	C P	2 32	229 0	850 79,900	539 3,630
Direct	B only	P	0			
	D only	P	3	0.2	30	10
	B and D only	P	0			
Indirect	B only	P	1	-	-	691
	D only	P	23	0.00	31,400	1,450
	B and D only	P	2	14.65	350	182

(a)"Other subcategory" denotes facilities which manufacture products in the following subcategories or subcategory combinations: ABD, ACD, AD, CD, ABCD, AB, BC, ABC, and BCD.

P - Priority organic pollutants.

C - Cyanide.

B/D facilities did not report any cyanide in their loads or waste streams.

Table 4-3

Summary of Nonconventional Pollutant Concentrations in Untreated Wastewater

Type of Discharge	1983 Subcategory	Ammonia or Other Nonconventionals	# of Facilities Contributing Data	Untreated Wastewater Concentrations (mg/L)		
				Low	High	Ave.
Direct	A only	N	0			
		A	0			
	C only	N	5	16	15,600	3,270
		A	1	-	-	228
A and C only	N	4	282	7,450	3,030	
	A	1	-	-	21	
A and/or C + Other(a)	N	8	114	39,500	9,930	
	A	5	0.05	842	332	
Indirect	A only	N	2	54	107	81
		A	1	-	-	0.05
	C only	N	21	0	54,100	7,530
		A	12	10	948	354
A and C only	N	2	6,860	20,800	13,900	
	A	0				
A and/or C + Other(a)	N	52	0	385,400	12,900	
	A	27	0	217,700	8,890	
Direct	B only	N	0			
		A	0			
	D only	N	7	0	14,200	3,130
A		1	-	-	0.7	
B and D only	N	1	-	-	6	
	A	0				
Indirect	B only	N	7	0	2,010	694
		A	1	-	-	16
	D only	N	54	0	492,400	12,900
A		4	0.5	348	99	
B and D only	N	9	45	49,700	9,200	
	A	0	-			

(a)Facilities with combinations of manufacturing operations from other than Subcategories A, B, C, D, AC, and BD are included as other.

N - Nonconventional.

A - Ammonia.

Table 4-4

Summary of Conventional Pollutants and COD Treated Effluent Concentrations

Type of Discharge	1983 Subcategory	Pollutant	Effluent Concentrations (mg/L)		
			Low	High	Ave.
Direct	A only	BOD ₅	66	189	128
		COD	1,400	1,700	1,550
		TSS	97	264	180
	C only	BOD ₅	0	15	8
		COD	0	923	268
		TSS	0	53	33
	A and C only	BOD ₅	8	211	90
		COD	216	834	530
		TSS	9	232	122
	A and/or C + Other(a)	BOD ₅	8	68	35
		COD	123	679	277
		TSS	12	143	71
Direct	B only	BOD ₅	-	-	-
		COD	-	-	-
		TSS	-	-	-
	D only	BOD ₅	0	145	17
		COD	0	1,140	123
		TSS	2	34	11
	B and D only	BOD ₅	NA	NA	4
		COD	NA	NA	27
		TSS	NA	NA	16

(a)Facilities with combinations of manufacturing operations from other than Subcategories A, B, C, D, AC, and BD are included as other.

NA = Not available.

REFERENCES

1. U.S. EPA. Pharmaceutical Manufacturing Point Source Category; Interim Final Rulemaking, 41 Federal Register 50676 (November 17, 1976).
2. U.S. EPA. Pharmaceutical Manufacturing Point Source Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards; Proposed Regulation, 47 Federal Register 53584 (November 26, 1982).
3. U.S. EPA, Office of Water. Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category. EPA 440/1-83/084, U.S. Environmental Protection Agency, Washington, D.C., September 1983.
4. U.S. EPA, Office of Water. Development Document for Interim Final Effluent Limitations and Proposed New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category. EPA 440/1-75/060, U.S. Environmental Protection Agency, Washington, D.C., December 1976.