ENHANCED CONTENT - TABLE OF CONTENTS

Title 40

PART 439 - PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

Authority: 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

Source: 48 FR 49821, Oct. 27, 1983, unless otherwise noted.

General

§ 439.0 Applicability.

(a) This part applies to process wastewater discharges resulting from the research and manufacture of pharmaceutical products, which are generally, but not exclusively, reported under SIC 2833, SIC 2834 and SIC 2836 (1987 Standard Industrial Classification Manual).

(b) Although not reported under SIC 2833, SIC 2834 and SIC 2836, discharges from the manufacture of other pharmaceutical products to which this part applies include (but are not limited to):

(1) Products manufactured by one or more of the four types of manufacturing processes described in subcategories A, B, C or D of this part, and considered by the Food and Drug Administration to be pharmaceutical active ingredients;

(2) Multiple end-use products (e.g., components of formulations, chemical intermediates, or final products) derived from pharmaceutical manufacturing operations and intended for use primarily in pharmaceutical applications;

(3) Pharmaceutical products and intermediates not subject to other categorical limitations and standards, provided the manufacturing processes generate process wastewaters that are similar to those derived from the manufacture of pharmaceutical products elsewhere (an example of such a product is citric acid);

(4) Cosmetic preparations that are reported under SIC 2844 and contain pharmaceutical active ingredients, or active ingredients that are intended for the treatment of a skin condition. (These preparations do not include products such as lipsticks or perfumes that serve to enhance appearance, or provide a pleasing odor, but do not enhance skin care. Also excluded are deodorants, manicure preparations, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.)

(c) The provisions of this part do not apply to wastewater discharges resulting from the manufacture of the following products, or as a result of providing one or more of the following services:

(1) Surgical and medical instruments and apparatus reported under SIC 3841;

(2) Orthopedic, prosthetic, and surgical appliances and supplies reported under SIC 3842;

(3) Dental equipment and supplies reported under SIC 3843;

(4) Medical laboratory services reported under SIC 8071;

(5) Dental laboratory services reported under SIC 8072;

(6) Outpatient care facility services reported under SIC 8081;

(7) Health and allied services reported under SIC 8091, and not classified elsewhere;

(8) Diagnostic devices other than those reported under SIC 3841;

(9) Animal feed products that include pharmaceutical active ingredients such as vitamins and antibiotics, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(10) Food and beverage products fortified with vitamins or other pharmaceutical active ingredients, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(11) Pharmaceutical products and intermediates subject to the provisions of 40 CFR part 414, provided their manufacture results in less than 50 percent of the total flow of process wastewater that is regulated by 40 CFR part 414 at the facility.

[63 FR 50424, Sept. 21, 1998]

§ 439.1 General definitions.

As used in this part:

(a) The general definitions, abbreviations and methods of analysis in 40 CFR part 401 shall apply.

(b) ***Bench-scale operation*** means the laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

(c) ***Cyanide (T)*** means the parameter total cyanide.

(d) ***In-plant monitoring point*** means a location within a plant, where an individual process effluent can be exclusively monitored before it is diluted or mixed with other process wastewaters en route to the end-of-pipe.

(e) ***Maximum daily*** means the highest allowable discharge of wastewater pollutants during a calendar day or any 24 hour period that reasonably represents a calendar day for purposes of sampling.

(f) ***Maximum monthly average*** means the highest allowable average of daily discharges of wastewater pollutants over a calendar month, and is calculated as the sum of all daily values measured during a calendar month divided by the number of daily values measured during that month.

(g) ***mg/L*** means milligrams per liter or parts per million (ppm)

(h) ***Minimum level*** means the level at which an analytical system gives recognizable signals and an acceptable calibration point.

(i) ***Nitrification capability*** means the capability of a POTW treatment system to oxidize ammonia or ammonium salts initially to nitrites (via *Nitrosomonas* bacteria) and subsequently to nitrates (via *Nitrobacter* bacteria). Criteria for determining the nitrification capability of a POTW treatment system are: bioassays confirming the presence of nitrifying bacteria; and analyses of the nitrogen balance demonstrating a reduction in the concentration of ammonia or ammonium salts and an increase in the concentrations of nitrites and nitrates.

(j) ***Non-detect (ND)*** means a concentration value below the minimum level that can be reliably measured by the analytical method.

(k) ***Pilot-scale operation*** means processing equipment being operated at an intermediate stage between laboratory-scale and full-scale operation for the purpose of developing a new product or manufacturing process.

(l) ***POTW*** means publicly owned treatment works (40 CFR 403.3).

(m) ***Process wastewater,*** as defined at 40 CFR 122.2 and for the purposes of this part, does not include the following:

(1) Trimethyl silanol, any active anti-microbial materials, process wastewater from imperfect fermentation batches, and process area spills. Discharges containing such materials are not subject to the limitations and standards of this part.

(2) Non-contact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other non-process water generated on site. Discharges of such waters and wastewaters are not subject to the limitations and standards of this part.

(n) ***Non-conventional pollutants*** means parameters that are neither conventional pollutants (40 CFR 401.16), nor "toxic" pollutants (40 CFR 401.15).

(o) ***Surrogate pollutant*** means a regulated parameter that, for the purpose of compliance monitoring, is allowed to serve as a surrogate for a group of specific regulated parameters. Plants would be allowed to monitor for a surrogate pollutant(s), when the other parameters for which it stands are receiving the same degree of treatment as the surrogate pollutant(s) and all of the parameters discharged are in the same treatability class(es) as their respective surrogate pollutant(s). Treatability classes have been identified in appendix A of this part for both steam stripping and biological treatment technologies, which are the respective technology bases for PSES/PSNS and BAT/NSPS limitations controlling the discharge of regulated organic parameters.

(p) ***Xylenes*** means a combination of the three isomers: o-xylene, m-xylene, and p-xylene.

[63 FR 50425, Sept. 21, 1998; 64 FR 48104, Sept. 2, 1999, as amended at 68 FR 12270, Mar. 13, 2003]

§ 439.2 General monitoring requirements.

(a) Permit compliance monitoring is required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility, except where the regulated pollutant is monitored as a surrogate parameter. Permit limits and compliance monitoring are not required for regulated pollutants that are neither used nor generated at the facility. Except for cyanide, for which an alternate monitoring requirement is established in subparts A and C of this part, a determination that regulated pollutants are neither used nor generated should be 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 processes. This determination along with a recommendation of any surrogate must be submitted with permit applications for approval by the permitting authority, reconfirmed by an annual chemical analysis of wastewater from each monitoring location, and measurement of a non-detect value for each regulated pollutant or its surrogate. Permits must specify that such determinations will be maintained in the facility's permit records with their discharge monitoring reports and will be available to regulatory authorities upon request.

(b) Unless noted otherwise, self-monitoring will be conducted at the point where the final effluent is discharged.

[68 FR 12271, Mar. 13, 2003]

§ 439.3 General pretreatment standards.

Any source subject to this part that introduces process wastewater pollutants into a publicly owned treatment works (POTW) must comply with 40 CFR part 403.

[63 FR 50425, Sept. 21, 1998]

§ 439.4 General limitation or standard for pH.

The pH must remain within the range 6.0 to 9.0 in any discharge subject to BPT, BCT or NSPS limitations or standards in this part.

[68 FR 12271, Mar. 13, 2003]

Subpart A - Fermentation Products

§ 439.10 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by fermentation.

[63 FR 50426, Sept. 21, 1998]

§ 439.11 Special definitions.

For the purpose of this subpart:

(a) ***Fermentation*** means process operations that utilize 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 to produce a specified product.

(b) ***Product*** means pharmaceutical products derived from fermentation processes.

[68 FR 12271, Mar. 13, 2003]

§ 439.12 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The maximum monthly average limitation for BOD_5, expressed as mass loading (lbs., kg) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD_5 load of the raw process wastewater (*i.e.*, the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. These residual amounts may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from waste streams; incineration of concentrated solvent wastestreams (including tar still bottoms); and concentration of broth for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The maximum monthly average limitation for TSS, expressed as mass loading (lbs., kg) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, the limitations for COD are as follows:

Effluent Limitations (BPT)

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
COD	1675	856

[1]mg/L (ppm).

(d) If the maximum monthly average COD concentration in paragraph (c) of this section is higher than a concentration value reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the monthly average limitation for COD corresponding to the lower concentration value must be applied.

(e) The effluent limitations for cyanide are as follows:

Effluent Limitations (BPT)

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
Cyanide (T)	33.5	9.4

[1]mg/L (ppm).

(f) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide effluent limitations in paragraph (e) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(g) Compliance with the limitation in paragraph (e) or (f) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

[63 FR 50426, Sept. 21, 1998, as amended at 68 FR 12271, Mar. 13, 2003]

§ 439.13 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in § 439.12.

[63 FR 50426, Sept. 21, 1998]

§ 439.14 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT:

Effluent Limitations (BAT)

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
Ammonia (as N)	84.1	29.4
Acetone	0.5	0.2
4-methyl-2-pentanone	0.5	0.2
Isobutyraldehyde	1.2	0.5
n-Amyl acetate	1.3	0.5
n-Butyl acetate	1.3	0.5
Ethyl acetate	1.3	0.5
Isopropyl acetate	1.3	0.5
Methyl formate	1.3	0.5
Amyl alcohol	10.0	4.1

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
Ethanol	10.0	4.1
Isopropanol	3.9	1.6
Methanol	10.0	4.1
Methyl Cellosolve	100.0	40.6
Dimethyl sulfoxide	91.5	37.5
Triethyl amine	250.0	102.0
Phenol	0.05	0.02
Benzene	0.05	0.02
Toluene	0.06	0.02
Xylenes	0.03	0.01
n-Hexane	0.03	0.02
n-Heptane	0.05	0.02
Methylene chloride	0.9	0.3
Chloroform	0.02	0.13
1,2-dichloroethane	0.4	0.1
Chlorobenzene	0.15	0.06
o-Dichlorobenzene	0.15	0.06
Tetrahydrofuran	8.4	2.6
Isopropyl ether	8.4	2.6
Diethyl amine	250.0	102.0
Acetonitrile	25.0	10.2

[1] mg/L (ppm).

(b) The limitations for COD are the same as specified in § 439.12(c) and (d).

(c) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

[68 FR 12271, Mar. 13, 2003]

§ 439.15 New source performance standards (NSPS).

(a) Any new source subject to this subpart must achieve the following standards:

Performance Standards (NSPS)

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
BOD_5	267	111
TSS	472	166
COD	1675	856
Ammonia (as N)	84.1	29.4
Acetone	0.5	0.2
4-methyl-2-pentanone	0.5	0.2
Isobutyraldehyde	1.2	0.5
n-Amyl acetate	1.3	0.5
n-Butyl acetate	1.3	0.5
Ethyl acetate	1.3	0.5
Isopropyl acetate	1.3	0.5
Methyl formate	1.3	0.5
Amyl alcohol	10.0	4.1
Ethanol	10.0	4.1
Isopropanol	3.9	1.6
Methanol	10.0	4.1
Methyl Cellosolve	100.0	40.6
Dimethyl sulfoxide	91.5	37.5
Triethyl amine	250.0	102.0
Phenol	0.05	0.02
Benzene	0.05	0.02
Toluene	0.06	0.02
Xylenes	0.03	0.01
n-Hexane	0.03	0.02
n-Heptane	0.05	0.02
Methylene chloride	0.9	0.3
Chloroform	0.02	0.13
1,2-dichloroethane	0.4	0.1
Chlorobenzene	0.15	0.06

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
o-Dichlorobenzene	0.15	0.06
Tetrahydrofuran	8.4	2.6
Isopropyl ether	8.4	2.6
Diethyl amine	250.0	102.0
Acetonitrile	25.0	10.2

[1] mg/L (ppm)

(b) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

(c) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §§ 439.13 and 439.14.

[68 FR 12272, Mar. 13, 2003]

§ 439.16 Pretreatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must continue achieving the standards for cyanide specified in paragraph (c) of this section and must achieve the following standards by September 21, 2001:

Pretreatment Standards (PSES)

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
Ammonia (as N)[2]	84.1	29.4
Acetone	20.7	8.2
4-methyl-2-pentanone	20.7	8.2
Isobutyraldehyde	20.7	8.2
n-Amyl acetate	20.7	8.2
n-Butyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
Isopropyl acetate	20.7	8.2
Methyl formate	20.7	8.2
Isopropyl ether	20.7	8.2
Tetrahydrofuran	9.2	3.4
Benzene	3.0	0.7

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
Toluene	0.3	0.2
Xylenes	3.0	0.7
n-Heptane	3.0	0.7
n-Hexane	3.0	0.7
Methylene chloride	3.0	0.7
Chloroform	0.1	0.03
1,2-dichloroethane	20.7	8.2
Chlorobenzene	3.0	0.7
o-Dichlorobenzene	20.7	8.2
Diethyl amine	255.0	100.0
Triethyl amine	255.0	100.0

[1] mg/L (ppm)

[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(b) Sources that discharge to a POTW with nitrification capability (defined at § 439.1(i)) are not required to achieve the pretreatment standard for ammonia (as N).

(c) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

[68 FR 12272, Mar. 13, 2003]

§ 439.17 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the same standards as specified in § 439.16.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(i)) are not required to achieve the pretreatment standard for ammonia (as N).

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide standards in § 439.17(b) must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e)(2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on

internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the standards in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

[63 FR 50429, Sept. 21, 1998; 64 FR 10393, Mar. 4, 1999; 64 FR 48104, Sept. 2, 1999, as amended at 68 FR 34832, June 11, 2003]

Subpart B - Extraction Products

§ 439.20 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by extraction.

[63 FR 50430, Sept. 21, 1998]

§ 439.21 Special definitions.

For the purpose of this subpart:

(a) ***Extraction*** means process operations that derive pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi by chemical and physical extraction.

(b) ***Product*** means any substance manufactured by an extraction process, including blood fractions, vaccines, serums, animal bile derivatives, endocrine products and medicinal products such as alkaloids that are isolated from botanical drugs and herbs.

[68 FR 12272, Mar. 13, 2003]

§ 439.22 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The limitation for BOD_5 is the same as specified in § 439.12(a). No facility shall be required to attain a monthly average limitation for BOD_5 that is less than the equivalent of 45 mg/L.

(1) The long-term average daily BOD_5 load of the raw process wastewater (*i.e.*, the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from wastestreams; incineration of concentrated solvent wastestreams (including tar still bottoms); and broth concentration for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) Except for the provisions in paragraph (d) of this section, the limitations for COD are as follows:

Effluent Limitations (BPT)

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
COD	228	86

[1] mg/L (ppm)

(d) If the maximum monthly average COD concentration in paragraph (c) of this section is higher than a concentration value reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then a monthly average limitation for COD corresponding to the lower concentration value must be applied.

[63 FR 50430, Sept. 21, 1998, as amended at 68 FR 12273, Mar. 13, 2003]

§ 439.23 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in § 439.22.

[63 FR 50430, Sept. 21, 1998]

§ 439.24 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT: Limitations for COD are the same as the corresponding limitations in § 439.22(c) and (d).

[63 FR 50431, Sept. 21, 1998]

§ 439.25 New source performance standards (NSPS).

(a) Any new source subject to this subpart must achieve the following standards:

Performance Standards (NSPS)

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
BOD_5	35	18
TSS	58	31
COD	228	86

[1] mg/L (ppm)

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §§ 439.23 and 439.24.

[68 FR 12273, Mar. 13, 2003]

§ 439.26 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must achieve the following standards by September 21, 2001:

Pretreatment Standards (PSES)

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
Acetone	20.7	8.2
n-Amyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
Isopropyl acetate	20.7	8.2
Methylene chloride	3.0	0.7

[1] mg/L (ppm).

[68 FR 12273, Mar. 13, 2003]

§ 439.27 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the following pretreatment standards:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Acetone	20.7	8.2
2 n-Amyl acetate	20.7	8.2
3 Ethyl acetate	20.7	8.2
4 Isopropyl acetate	20.7	8.2
5 Methylene chloride	3.0	0.7

[1] Mg/L (ppm).

[63 FR 50431, Sept. 21, 1998; 64 FR 48104, Sept. 2, 1999]

Subpart C - Chemical Synthesis Products

§ 439.30 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by chemical synthesis.

[63 FR 50431, Sept. 21, 1998]

§ 439.31 Special definitions.

For the purpose of this subpart:

(a) ***Chemical synthesis*** means using one or a series of chemical reactions in the manufacturing process of a specified product.

(b) ***Product*** means any pharmaceutical product manufactured by chemical synthesis.

[68 FR 12273, Mar. 13, 2003]

§ 439.32 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The limitation for BOD_5 is the same as specified in § 439.12(a).

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) The limitations for COD are the same as specified in § 439.12(c) and (d).

(d) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

[63 FR 50431, Sept. 21, 1998, as amended at 68 FR 12273, Mar. 13, 2003]

§ 439.33 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD5, TSS and pH are the same as the corresponding limitations in § 439.32.

[63 FR 50432, Sept. 21, 1998]

§ 439.34 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT:

(a) The limitations are the same as specified in § 439.14(a).

(b) The limitations for COD are the same as specified in § 439.12(c) and (d).

(c) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

[67 FR 12273, Mar. 13, 2003]

§ 439.35 New source performance standards (NSPS).

(a) Any new source subject to this subpart must achieve the same standards as specified in § 439.15(a).

(b) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

(c) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.33 and § 439.34.

[68 FR 12273, Mar. 13, 2003]

§ 439.36 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must continue achieving the standards for cyanide specified in paragraph (b) of this section and must achieve the standards specified in § 439.16(a) by September 21, 2001.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.1(i)) are not required to achieve the standards for ammonia (as N).

(b) The standards for cyanide are the same as specified in § 439.12(e), (f) and (g).

[68 FR 12274, Mar. 13, 2003]

§ 439.37 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the same standards as specified in § 439.36.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(i)) are not required to achieve the pretreatment standard for ammonia (as N).

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Effluent limitation[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide pretreatment standards in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e) (2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the standard in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

[63 FR 50434, Sept. 21, 1998; 64 FR 10393, Mar. 4, 1999; 64 FR 48104, Sept. 2, 1999, as amended at 68 FR 34832, June 11, 2003]

Subpart D - Mixing/Compounding and Formulation

§ 439.40 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by mixing, compounding and formulating operations.

[63 FR 50435, Sept. 21, 1998]

§ 439.41 Special definitions.

For the purpose of this subpart:

(a) ***Mixing, compounding, and formulating operations*** means processes that put pharmaceutical products in dosage forms.

(b) ***Product*** means any pharmaceutical product manufactured by blending, mixing, compounding, and formulating pharmaceutical ingredients. The term includes pharmaceutical preparations for both human and veterinary use such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions.

[68 FR 12274, Mar. 13, 2003]

§ 439.42 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The limitation for BOD_5 is the same as specified in § 439.12(a). No facility shall be required to attain a monthly average limitation for BOD_5 that is less than the equivalent of 45 mg/L.

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) The limitations for COD are the same as specified in § 439.22(c) and

(d) .

[63 FR 50435, Sept. 21, 1998, as amended at 68 FR 12274, Mar. 13, 2003]

§ 439.43 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in § 439.42.

[63 FR 50436, Sept. 21, 1998]

§ 439.44 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT: The limitations for COD are the same as specified in § 439.22(c) and (d).

[68 FR 12274, Mar. 13, 2003]

§ 439.45 New source performance standards (NSPS).

(a) Any new source subject to this subpart must achieve the same standards as specified in § 439.25(a).

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.43 and § 439.44.

[68 FR 12274, Mar. 13, 2003]

§ 439.46 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must achieve the following standards by September 21, 2001:

Pretreatment Standards (PSES)

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
Acetone	20.7	8.2

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
n-Amyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
Isopropyl acetate	20.7	8.2
Methylene chloride	3.0	0.7

[1] mg/L (ppm).

[68 FR 12274, Mar. 13, 2003]

§ 439.47 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the following pretreatment standards:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Acetone	20.7	8.2
2 n-Amyl acetate	20.7	8.2
3 Ethyl acetate	20.7	8.2
4 Isopropyl acetate	20.7	8.2
5 Methylene chloride	3.0	0.7

[1] Mg/L (ppm).

[63 FR 50436, Sept. 21, 1998; 64 FR 48104, Sept. 2, 1999]

Subpart E - Research

§ 439.50 Applicability.

This subpart applies to discharges of process wastewater resulting from pharmaceutical research.

[63 FR 50436, Sept. 21, 1998]

§ 439.51 Special definitions.

For the purpose of this subpart, *product* means products or services resulting from research and product development activities.

[68 FR 12274, Mar. 13, 2003]

§ 439.52 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The limitation for BOD_5 is the same as specified in § 439.12(a). No facility shall be required to attain a monthly average limitation for BOD_5 that is less than the equivalent of 45 mg/L.

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) The maximum monthly average limitation for COD, expressed as mass loading (lbs, kg) per day, must reflect not less than 74 percent reduction in the long-term average daily COD load of the raw (untreated) process wastewater, multiplied by a variability factor of 2.2. No facility shall be required to attain a limitation for COD that is less than the equivalent of 220 mg/L.

(d) The long-term average daily BOD_5 or COD mass loading of the raw process wastewater (*i.e.,* the base number to which the percent reduction is applied) is defined as the average daily BOD_5 or COD load during any calendar month, over 12 consecutive months within the most recent 36 months.

(1) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 or COD load in the influent to the wastewater treatment system must exclude any portion of the load associated with solvents, except for residual amounts of solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 or COD loading.

(2) The practices of recovery, and/or separate disposal or reuse include: recovery of solvents from wastestreams; and incineration of concentrated solvent wastestreams (including tar still bottoms). This regulation does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 or COD may be achieved by any of several, or a combination, of these practices.

(e) The pH must be within the range 6.0 to 9.0.

[63 FR 50436, Sept. 21, 1998, as amended at 68 FR 12274, Mar. 13, 2003]

Appendix A to Part 439 - Tables

Table 1 - Surrogate Parameters for Direct Dischargers

[Utilizing biological treatment technology]

Regulated parameters	Treatability class
Amyl alcohol	Alcohols.
Ethanol[1]	
Isopropanol[1]	
Methanol[1]	
Phenol	
Isobutyraldehyde[1]	Aldehydes.
n-Heptane[1]	Alkanes.
n-Hexane[1]	
Diethylamine[1]	Amines.
Triethylamine	
Benzene	Aromatics.
Toluene[1]	

Regulated parameters	Treatability class
Xylenes[1]	
Chlorobenzene	
o-Dichlorobenzene	
Chloroform[1]	Chlorinated Alkanes.
Methylene chloride[1]	
1,2-Dichloroethane[1]	
Ethyl acetate[1]	Esters.
Isopropyl acetate	
n-Amyl acetate	
n-Butyl acetate	
Methyl formate	
Tetrahydrofuran[1]	Ethers.
Isopropyl ether	
Acetone[1]	Ketones.
4-Methyl-2-pentanone (MIBK)	
Ammonia (aqueous)	Miscellaneous.[2]
Acetonitrile	
Methyl Cellosolve	
Dimethyl Sulfoxide	

[1] These parameters may be used as a surrogate to represent other parameters in the same treatability class.

[2] Surrogates have not been identified for the “Miscellaneous” treatability class.

Table 2 - Surrogate Parameters for Indirect Dischargers (Utilizing Steam Stripping Treatment Technology)

Regulated parameters	Treatability class
Benzene	
Toluene[1]	
Xylenes	
n-Heptane	High strippability.
Chloroform[1]	

Regulated parameters	Treatability class
Methylene chloride[1]	
Chlorobenzene	
Ammonia (aqueous)	
Diethyl amine	
Triethyl amine	
Acetone[1]	
4-methyl-2-pentanone	
n-Amyl acetate	
n-Butyl acetate	
Ethyl acetate	Medium strippability.
Isopropyl acetate	
Methyl formate	
Isopropyl ether	
Tetrahydrofuran[1]	
1,2-dichloroethane	
o-Dichlorobenzene	

[1] These parameters may be used as a surrogate to represent other parameters in the same treatability class.

[63 FR 50437, Sept. 21, 1998; 64 FR 10393, Mar. 4, 1999, as amended at 68 FR 12275, Mar. 13, 2003]