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,