

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]

#### Subpart D—Mixing/Compounding and Formulation Subcategory

##### § 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 Specialized definitions.

For the purpose of this subpart:

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

(b) The term *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.

[63 FR 50435, Sept. 21, 1998]

##### § 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 average monthly effluent limitation for BOD<sub>5</sub>, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD<sub>5</sub> load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD<sub>5</sub> 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<sub>5</sub> 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<sub>5</sub> 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<sub>5</sub> 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<sub>5</sub> may be achieved by any of several, or a combination, of these practices.

(b) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD<sub>5</sub> limitation determined in paragraph (a) of this section.

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

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Regulated parameter	Effluent limitations <sup>1</sup>	
	Maximum daily discharge	Average monthly discharge must not exceed
COD .....	228	86
pH .....	( <sup>2</sup> )	( <sup>2</sup> )

<sup>1</sup> Mg/L (ppm).  
<sup>2</sup> Within the range 6.0 to 9.0.

(d) If the average monthly COD concentrations in paragraph (c) of this section are higher than concentration values 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 average monthly effluent limitations for COD corresponding to the lower concentration values must be applied.

[63 FR 50435, Sept. 21, 1998]

**§ 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<sub>5</sub>, 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. Limitations for COD are the same as the corresponding limitations in § 439.42 (c) and (d).

[63 FR 50436, Sept. 21, 1998]

**§ 439.45 Standards of performance for new (point) sources (NSPS).**

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

Regulated parameter	Performance standards <sup>1</sup>	
	Maximum daily discharge	Average monthly discharge must not exceed
BOD <sub>5</sub> .....	35	18
TSS .....	58	31
COD .....	228	86
pH .....	( <sup>2</sup> )	( <sup>2</sup> )

<sup>1</sup> Mg/L (ppm).  
<sup>2</sup> Within the range 6.0 to 9.0.

(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 in the earlier version of this section 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.

[63 FR 50436, Sept. 21, 1998]

**§ 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 pretreatment standards by September 21, 2001:

Regulated parameter	Pretreatment standards <sup>1</sup>	
	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

<sup>1</sup> Mg/L (ppm).

[63 FR 50436, Sept. 21, 1998]

**§ 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 <sup>1</sup>	
	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