

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.

(k) The term *non-conventional pollutants* means parameters that are neither conventional pollutants (40 CFR 401.16), nor “toxic” pollutants (40 CFR 401.15).

(l) The term *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 to 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.

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

(n) The abbreviation Mg/L means milligrams per liter or parts per million (ppm).

[63 FR 50425, Sept. 21, 1998; 64 FR 48104, Sept. 2, 1999]

§ 439.2 Monitoring requirements.

Unless otherwise noted, self-monitoring will be conducted at the final effluent discharge point.

§ 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 Monitoring requirements.

Permit limits and compliance monitoring are 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 recommendation of any surrogate must be submitted with permit applications for approval by the permitting authority, and reconfirmed by an annual chemical analysis of wastewater from each monitoring location, and the measurement of a non-detect value for each regulated pollutant or its surrogate. Permits shall 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.

[63 FR 50425, Sept. 21, 1998]

Subpart A—Fermentation Products Subcategory

§ 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 Specialized definitions.

For the purpose of this subpart:

(a) The term *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.

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(b) The term *product* means pharmaceutical products derived from fermentation processes.

[63 FR 50426, Sept. 21, 1998]

§ 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 average monthly effluent limitation for BOD₅, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD₅ load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD₅ load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD₅ 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 BOD₅ 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 BOD₅ 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 BOD₅ 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 BOD₅ limitation determined in paragraph (a) of this section.

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

Regulated parameter	Effluent limitation ¹	
	Maximum daily discharge	Average monthly discharge must not exceed
COD	1675	856
pH	(²)	(²)

¹ Mg/L (ppm).
² 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.

(e) The effluent limitations 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).

(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.