

Environmental Protection Agency

§ 439.22

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]

Subpart B—Extraction Products Subcategory

§ 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 Specialized definitions.

For the purpose of this subpart:

(a) The term *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) The term *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.

[63 FR 50430, Sept. 21, 1998]

§ 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 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. Residual amounts of these substances 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 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 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, effluent limitations for COD and pH are as follows:

Regulated parameter	Effluent limitations ¹	
	Maximum daily discharge	Average monthly discharge must not exceed
COD	228	86
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