

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Aniline*	8,690	3,220
2-Butanone (MEK)*	161,000	57,900
n-Butyl Acetate*	2,230	826
o-Dichlorobenzene*	2,230	826
1,2-Dichloroethane*	2,230	826
N,N-Dimethylaniline*	8,690	3,220
1,4-Dioxane*	8,690	3,220
Ethyl Acetate*	2,230	826
Furfural*	8,690	3,220
Isobutyraldehyde*	2,230	826
Isopropyl Acetate*	2,230	826
Isopropyl Ether*	2,230	826
Methyl Isobutyl Ketone (MIBK)*	2,230	826
2-Methylpyridine*	8,690	3,220
Petroleum Naphtha*	8,690	3,220
Pyridine*	1,000	1,000
Tetrahydrofuran*	9,210	3,360

§ 439.48 [Reserved]

Subpart E—Research Subcategory

20. Sections 439.50 through 439.52 are revised to read as follows:

§ 439.50 Applicability; description of the research subcategory; prohibition.

(a) The provisions of this subpart are applicable to discharges resulting from bench-scale pharmaceutical research operations and product development activities. This subpart does not apply to pilot- or full-scale operations that generate wastewaters using fermentation, extraction, chemical synthesis, or mixing, compounding and formulating. Such operations are covered under subparts A, B, C, and D, respectively.

(b) The discharge of non-process wastewaters and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharges of such non-process wastewater and excluded materials into publicly owned treatment works or waters of the United States, by a source subject to this subpart without an NPDES permit or individual control mechanism authorizing such discharge is prohibited.

§ 439.51 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR part 401 and § 439.1 shall apply to this subpart.

(b) The term “product” shall mean any product or service resulting from pharmaceutical research, which includes microbiological, biological, and chemical operations.

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

(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 degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) The allowable discharge for the pollutant parameters BOD₅ and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the waste treatment plant corresponding to the maximum production period for a given pharmaceutical plant as defined in paragraph (a)(4) of this section.

(2) The allowable effluent discharge limitation for the daily average mass of BOD₅ in any calendar month shall specifically not reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD₅ multiplied by a variability factor of 3.0. However, a plant shall not be required to attain a 30-day average BOD₅ effluent limitation of less than the equivalent of 45 mg/L.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically not reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2. However, a plant shall not be required to attain a 30-day average COD effluent

limitation of less than the equivalent of 220 mg/L.

(4) The long term daily average raw waste load for the pollutant parameters BOD₅ and COD is defined as the average daily mass of each pollutant influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(5) To assure equity in regulation of discharges from sources covered by this subpart of the point source category, calculation of raw waste loads of BOD₅ and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads, except the residual amounts of solvents remaining after the practice of solvent recovery and/or separate disposal or reuse. These practices of removal, disposal, or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This subpart does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining permit conditions. These limits may be achieved by any one of several programs and practices or a combination thereof.

(6) The allowable effluent discharge limitation for the daily average mass of TSS in any calendar month shall be 1.7 times the BOD₅ limitation determined in paragraph (a)(2) of this section.

(7) The pH shall be within the range of 6.0–9.0 standard units.