Chapter NR 237

PHARMACEUTICAL MANUFACTURING

NR 237.01 Purpose. The purpose of this chapter is to establish effluent limitations, performance standards, and pretreatment standards for discharges of process wastes from the pharmaceuticals manufacturing point source category.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.02 Applicability. This chapter applies to any facility which manufactures pharmaceuticals by fermentation, extraction, chemical synthesis, or mixing, compounding, and formulation or conducts pharmaceutical research and which discharges or may discharge process wastewater pollutants to waters of the state or introduces or may introduce process wastewater pollutants into a publicly owned treatment works.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.03 General definitions. In addition to the definitions set forth in ss. NR 205.03, 205.04, and 211.03, the following definitions are applicable to the terms used in this chapter:

(1) "Cyanide destruction unit" means a treatment system specifically designed to remove cyanide.

(2) "Existing source" means any point source, except for a new source as defined in sub. (7), from which pollutants are or may be discharged either into waters of the state or into a publicly owned treatment works.

(3) "Extraction operation" means an operation which produces either biological or natural extraction products, such as blood fractions, vaccines, serums, animal bile derivatives, endocrine products, or medicinal products, such as alkaloids, isolated from botanical drugs and herbs.

(4) "Long term daily average raw waste load" means the average daily mass of a pollutant discharged to the wastewater treatment system over the 12 consecutive month period with the greatest production within the most recent 36 months.

(5) "Maximum 30–day average" means the maximum average of daily values for 30 consecutive days.

(6) "Mixing, compounding, and formulation operation" means an operation which blends, mixes, compounds, or formulates pharmaceutical ingredients into preparations, such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions, for either human or veterinary use.

(7) "New source" means any point source for which construction commenced after November 26, 1982, and from which pollutants are or may be discharged directly to the waters of the state or to a publicly owned treatment works.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.04 Monitoring requirement. Unless otherwise noted, self–monitoring shall be conducted at the final effluent discharge point.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.05 Cyanide. (1) CERTIFICATE. Permittees not using or generating cyanide must certify to the control authority that cyanide is neither used nor generated.

(2) DIRECT DISCHARGERS. The following requirements are applicable to any facility which is a direct discharger and which uses or generates cyanide:

(a) If all waste streams containing cyanide are diverted to a cyanide destruction unit and if the effluent from the cyanide destruction unit is discharged to a biological treatment system, self monitoring shall be conducted after cyanide treatment and before dilution with other streams, except as provided in par. (b).

(b) Self monitoring may be conducted at the final effluent discharge point if 3 adjustments are made:

1. The daily maximum cyanide limitation is multiplied by 0.18;

2. The 30–day maximum cyanide limitation is multiplied by 0.35; and

3. The daily and 30–day maximum cyanide limitations are further adjusted according to the ratio of the flow of the waste streams containing cyanide to the total process wastewater discharge flow.

(c) If all waste streams containing cyanide are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self monitoring shall be conducted at the final effluent discharge point as provided in par. (b).

(3) DISCHARGES TO A PUBLICLY OWNED TREATMENT WORKS. The following requirements are applicable to any facility which discharges to a POTW and which uses or generates cyanide:

(a) If all waste streams containing cyanide are diverted to a cyanide destruction unit, self monitoring shall be conducted after cyanide treatment and before dilution with other streams, except as provided in par. (b).

(b) Self monitoring may be conducted at the final effluent discharge point if the daily and 30–day maximum cyanide standards are adjusted according to the ratio of the flow of the waste streams containing cyanide to the total process wastewater discharge flow.

(c) If all waste streams containing cyanide are not treated, self monitoring shall be conducted at the final effluent discharge point as provided in par. (b).

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.06 Dilution. Dilution to meet the standards set forth in this chapter may not be practiced.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.07 Compliance dates. (1) Any existing source subject to this chapter which discharges to waters of the state shall achieve:

(a) The effluent limitations representing BPT by July 1, 1977; and

(b) The effluent limitations representing BAT by July 1, 1984.

(2) Any new source subject to this chapter which discharges to waters of the state shall achieve NSPS at the commencement of discharge.

(3) Any existing source subject to this chapter which introduces process wastewater pollutants into a POTW shall achieve PSES by October 27, 1986.

(4) Any new source subject to this chapter which introduces process wastewater pollutants into a POTW shall achieve PSNS at the commencement of discharge.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.08 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available. (1) EXISTING SOURCE. Except as provided in 40 CFR 125.30 to 125.32, any existing source subject to this chapter shall achieve the effluent limitations set forth in subs. (2), (3) and (4) representing the degree of effluent reduction attainable by the application of BPT.

(2) BIOLOGICAL OXYGEN DEMAND AND CHEMICAL OXYGEN DEMAND. (a) Except as provided in par. (c), the limitation for the daily average mass of BOD_5 and COD for any calendar month shall be calculated by multiplying the long term daily average raw waste load by a variability factor and the difference between 1 and the required fractional reduction as given in the following table:

Table 1

Pharmaceutical Manufacturing

BPT Effluent Limitations		
Pollutant or pollutant property	**Variability factor**	**Required fractional reduction**
BOD_5	3.0	0.9
COD	2.2	0.74

(b) The limitations for BOD_5 and COD shall be expressed in mass per unit time.

(c) Extraction operations and mixing, compounding, and formulation operations are not required to reduce the maximum 30–day average BOD_5 concentration to less than 45 mg/l or reduce the maximum 30–day average COD concentration to less than 220 mg/l.

(d) 1. For fermentation operations, calculation of raw waste loads of BOD_5 and COD shall exclude any waste load associated with separable mycelia and solvents in those waste loads, except that residual amounts of solvents remaining after solvent recovery, separate disposal, or reuse may be included in the raw waste load. Removal, disposal, and reuse includes physical separation and removal of separable mycelia, recovery of solvents from waste streams, incineration of concentrated solvent waste streams, incineration of tar still bottoms, and broth concentration for disposal other than to the treatment system.

2. For extraction, chemical synthesis, and mixing, compounding, and formulation operations, calculation of raw waste loads of BOD_5 and COD shall exclude any waste load associated with solvents in those waste loads, except that residual amounts of solvents remaining after solvent recovery, separate disposal, or reuse may be included in the raw waste load. Removal, disposal, and reuse includes recovery of solvents from waste streams and incineration of concentrated solvent waste streams and incineration of tar still bottoms.

(3) TOTAL SUSPENDED SOLIDS. The TSS BPT effluent limitation shall be calculated by multiplying the BOD_5 limitation, as calculated in sub. (2), by 1.7.

(4) CYANIDE AND pH. The following limitations for cyanide and pH apply:

Table 2

Pharmaceutical Manufacturing

BPT Effluent Limitations		
	milligrams per liter	
Pollutant or pollutant property	**Maximum for any 1 day**	**Average of daily values for 30 consecutive days**
Cyanide (1)	33.5	9.4
pH	(2)	(2)

(1) This applies only to those plants using or generating cyanide and to discharges not resulting from research.
(2) Within the range of 6.0 to 9.0.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.09 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable. (1) Except as provided in 40 CFR 125.30 to 125.32 and sub. (2), any existing source subject to this chapter which uses or generates cyanide shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of BAT:

Table 3

Pharmaceutical Manufacturing

BAT Effluent Limitations		
	milligrams per liter	
Pollutant or pollutant property	**Maximum for any 1 day**	**Average of daily values for 30 consecutive days**
Cyanide	33.5	9.4

(2) This section does not apply to discharges resulting from pharmaceutical research at facilities which do not manufacture pharmaceuticals.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.10 New source performance standards. (1) Except as provided in sub. (2), any new source subject to this chapter shall achieve the following standards:

Table 4

Pharmaceutical Manufacturing

NSPS		
	milligrams per liter	
Pollutant or pollutant property	**Maximum for any 1 day**	**Average of daily values for 30 consecutive days**
Cyanide	33.5	9.4
pH	(1)	(1)

(1) Within the range of 6.0 to 9.0 at all times

(2) This section does not apply to discharges resulting from pharmaceutical research at facilities which do not manufacture pharmaceuticals.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.11 Pretreatment standards for existing sources. (1) Except as provided in ss. NR 211.13 and 211.14 and sub. (2), any existing source subject to this chapter which introduces pollutants into a POTW and which uses or generates

cyanide shall comply with ch. NR 211 and achieve the following PSES:

Table 5
Pharmaceutical Manufacturing

PSES		
	milligrams per liter	
Pollutant or pollutant property	**Maximum for any 1 day**	**Average of daily values for 30 consecutive days**
Cyanide	33.5	9.4

(2) This section does not apply to discharges resulting from pharmaceutical research at facilities which do not manufacture pharmaceuticals.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.12 Pretreatment standards for new sources. (1) Except as provided in s. NR 211.13 and sub. (2), any existing source subject to this chapter which introduces pollutants into a POTW and which uses or generates cyanide shall achieve the standards set forth in s. NR 237.11.

(2) This section does not apply to discharges resulting from pharmaceutical research at facilities which do not manufacture pharmaceuticals.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

NR 237.13 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology. (1) Except as provided in 40 CFR 125.30 to 125.32 and sub. (2), any existing source subject to this chapter shall achieve the effluent limitations set forth in s. NR 237.09 for BOD_5, TSS, and pH.

(2) This section does not apply to discharges resulting from pharmaceutical research at facilities which do not manufacture pharmaceuticals.

History: Cr. Register, May, 1990, No. 413, eff. 6–1–90.

Note: The Wisconsin administrative code corresponds to the code of federal regulations as cross referenced in the following table:

State Code	Code of Federal Regulations
s. NR 205.030	40 CFR 401.11
s. NR 205.04	40 CFR 401.11
ch. NR 211	40 CFR Part 403
s. NR 211.03	40 CFR 403.3
s. NR 211.13	40 CFR 403.7
s. NR 211.14	40 CFR 403.13
s. NR 211.15	40 CFR 403.12
ch. NR 237	40 CFR Part 439