

TABLE 1 TO SUBPART MM OF PART 63—GENERAL PROVISIONS APPLICABILITY TO SUBPART MM

Table with 4 columns: General Provisions reference, Summary of requirements, Applies to subpart MM, and Explanation. Rows include 63.7(a)(1) and 63.7(h) regarding performance testing requirements and waivers.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 439

Pharmaceutical Manufacturing Point Source Category

CFR Correction

In Title 40 of the Code of Federal Regulations, Parts 425 to 699, revised as of July 1, 2003, the duplicated text from pages 401 and 408 is removed and the following text is reinstated.

Text to be reinstated on page 401:

\* \* \* \* \*

Appendix A to Part 439—Tables

Authority: 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

Source: 48 FR 49821, Oct. 27, 1983, unless otherwise noted.

General

§ 439.0 Applicability.

(a) This part applies to process wastewater discharges resulting from the research and manufacture of pharmaceutical products, which are generally, but not exclusively, reported under SIC 2833, SIC 2834 and SIC 2836 (1987 Standard Industrial Classification Manual).

(b) Although not reported under SIC 2833, SIC 2834 and SIC 2836, discharges from the manufacture of other pharmaceutical products to which this part applies include (but are not limited to):

- (1) Products manufactured by one or more of the four types of manufacturing processes described in subcategories A, B, C or D of this part, and considered

by the Food and Drug Administration to be pharmaceutical active ingredients;

(2) Multiple end-use products (e.g., components of formulations, chemical intermediates, or final products) derived from pharmaceutical manufacturing operations and intended for use primarily in pharmaceutical applications;

(3) Pharmaceutical products and intermediates not subject to other categorical limitations and standards, provided the manufacturing processes generate process wastewaters that are similar to those derived from the manufacture of pharmaceutical products elsewhere (an example of such a product is citric acid);

(4) Cosmetic preparations that are reported under SIC 2844 and contain pharmaceutical active ingredients, or active ingredients that are intended for the treatment of a skin condition. (These preparations do not include products such as lipsticks or perfumes that serve to enhance appearance, or provide a pleasing odor, but do not enhance skin care. Also excluded are deodorants, manicare preparations, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.)

(c) The provisions of this part do not apply to wastewater discharges resulting from the manufacture of the following products, or as a result of providing one or more of the following services:

- (1) Surgical and medical instruments and apparatus reported under SIC 3841;
(2) Orthopedic, prosthetic, and surgical appliances and supplies reported under SIC 3842;
(3) Dental equipment and supplies reported under SIC 3843;
(4) Medical laboratory services reported under SIC 8071;
(5) Dental laboratory services reported under SIC 8072;
(6) Outpatient care facility services reported under SIC 8081;

(7) Health and allied services reported under SIC 8091, and not classified elsewhere;

(8) Diagnostic devices other than those reported under SIC 3841;

(9) Animal feed products that include pharmaceutical active ingredients such as vitamins and antibiotics, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(10) Food and beverage products fortified with vitamins or other pharmaceutical active ingredients, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(11) Pharmaceutical products and intermediates subject to the provisions of 40 CFR part 414, provided their manufacture results in less than 50 percent of the total flow of process wastewater that is regulated by 40 CFR part 414 at the facility.

[63 FR 50424, Sept. 21, 1998]

§ 439.1 General definitions.

As used in this part:

(a) The general definitions, abbreviations and methods of analysis in 40 CFR part 401 shall apply.

\* \* \* \* \*

Text to be reinstated on page 408:

\* \* \* \* \*

standards specified in §§ 439.23 and 439.24.

[68 FR 12273, Mar. 13, 2003]

§ 439.26 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 standards by September 21, 2001:

**PRETREATMENT STANDARDS (PSES)**

Regulated parameter	Maximum daily <sup>1</sup>	Maximum monthly average <sup>1</sup>
Acetone .....	20.7	8.2
n-Amyl acetate .....	20.7	8.2
Ethyl acetate .....	20.7	8.2
Isopropyl acetate .....	20.7	8.2
Methylene chloride ...	3.0	0.7

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

[68 FR 12273, Mar. 13, 2003]

**§ 439.27 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
5 Methylene chloride .....	3.0	0.7

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

[63 FR 50431, Sept. 21, 1998; 64 FR 48104, Sept. 2, 1999]

**Subpart C—Chemical Synthesis Products**

**§ 439.30 Applicability.**

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by chemical synthesis.

[63 FR 50431, Sept. 21, 1998]

**§ 439.31 Special definitions.**

For the purpose of this subpart:  
 (a) *Chemical synthesis* means using one or a series of chemical reactions in the manufacturing process of a specified product.  
 (b) *Product* means any pharmaceutical product manufactured by chemical synthesis.

[68 FR 12273, Mar. 13, 2003]

**§ 439.32 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 limitation for BOD<sub>5</sub> is the same as specified in § 439.12(a).
- (b) The limitation for TSS is the same as specified in § 439.12(b).
- (c) The limitations for COD are the same as specified in § 439.12(c) and (d).
- (d) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

[63 FR 50431, Sept. 21, 1998, as amended at 68 FR 12273, Mar. 13, 2003]

**§ 439.33 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 § 439.32.

[63 FR 50432, Sept. 21, 1998]

**§ 439.34 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:

- (a) The limitations are the same as specified in § 439.14(a).
  - (b) The limitations for COD are the same as specified in § 439.12(c) and (d).
- \* \* \* \* \*

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**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Parts 54, 61, and 69**

[CC Docket Nos. 00-256 and 96-45; FCC 04-31]

**Multi-Association Group (MAG) Plan for Regulation of Interstate Services of Non-Price Cap Incumbent Local Exchange Carriers and Interexchange Carriers; Federal-State Joint Board on Universal Service**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** By this document, the Commission takes additional steps to provide rate-of-return carriers greater flexibility to respond to changing

marketplace conditions. In particular, the Commission modifies the “all-or-nothing” rule to permit rate-of-return carriers to bring recently acquired price cap lines back to rate-of-return regulation without requiring a waiver of the all-or-nothing rule. In this way, the Commission reduces the administrative costs and uncertainties of such acquisitions for rate-of-return carriers. The Commission also grants rate-of-return carriers the authority immediately to provide geographically deaveraged transport and special access rates, subject to certain limitations. With this additional pricing flexibility, rate-of-return carriers will be able to set more economically efficient rates and respond to competitive entry. Finally, the Commission merges Long Term Support with Interstate Common Line Support. This will make the Commission’s universal service mechanisms simpler and more transparent, while ensuring that rate-of-return carriers maintain existing levels of universal service support.

**DATES:** Effective June 7, 2004; except for § 61.38(b)(4), §§ 61.41(c), (d), and (e), and § 69.123(a)(1), (a)(2), (c), and (d), which contain information collection requirements that have not been approved by OMB. The Federal Communications Commission will publish a document in the **Federal Register** announcing the effective date.

**ADDRESSES:** All filings must be sent to the Commission’s Secretary, Marlene H. Dortch, Office of the Secretary, Federal Communications Commission, Room TW-A325, 445 Twelfth Street, SW., Washington, DC 20554. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein must be submitted to Judith Boley Herman, Federal Communications Commission, Room 1-C804, 445 Twelfth Street, SW., Washington, DC 20554, or via the Internet to *Judith.B.Herman@fcc.gov*, and to Kim A. Johnson, OMB Desk Officer, Room 10236 NEOB, 725 17th Street, NW., Washington, DC 20503, or via the Internet to *Kim\_A.Johnson@omb.eop.gov*.

**FOR FURTHER INFORMATION CONTACT:** Douglas Slotten, Wireline Competition Bureau, Pricing Policy Division, 202-418-1572, or Ted Burmeister, Wireline Competition Bureau, Telecommunications Access Policy Division, 202-418-7389.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission’s Report and Order (Order) in CC Docket Nos. 00-256 and 96-45, adopted on February 12, 2004, and released on February 26,