Environmental Protection Agency

§ 439.41 Special definitions.

For the purpose of this subpart:
(a) Mixing, compounding, and formulating operations means processes that put pharmaceutical products in dosage forms.
(b) Product means any pharmaceutical product manufactured by blending, mixing, compounding, and formulating pharmaceutical ingredients. The term includes pharmaceutical preparations for both human and veterinary use such as ampules,

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide pretreatment standards in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e) (2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.
(d) Compliance with the standard in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility’s manufacturing processes neither use nor generate cyanide.


Subpart D—Mixing/Compounding and Formulation

§ 439.40 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by mixing, compounding and formulating operations.

[63 FR 50435, Sept. 21, 1998]

§ 439.41 Special definitions.

For the purpose of this subpart:
(a) Mixing, compounding, and formulating operations means processes that put pharmaceutical products in dosage forms.
(b) Product means any pharmaceutical product manufactured by blending, mixing, compounding, and formulating pharmaceutical ingredients. The term includes pharmaceutical preparations for both human and veterinary use such as ampules,

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide pretreatment standards in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e) (2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.
(d) Compliance with the standard in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility’s manufacturing processes neither use nor generate cyanide.

§ 439.42 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 $\text{BOD}_5$ is the same as specified in §439.12(a). No facility shall be required to attain a monthly average limitation for $\text{BOD}_5$ that is less than the equivalent of 45 mg/L.

(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 §439.22(c) and (d).


§ 439.43 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 $\text{BOD}_5$, TSS and pH are the same as the corresponding limitations in §439.42.

[63 FR 50436, Sept. 21, 1998]

§ 439.44 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: The limitations for COD are the same as specified in §439.22(c) and (d).

[68 FR 12274, Mar. 13, 2003]

§ 439.45 New source performance standards (NSPS).

(a) Any new source subject to this subpart must achieve the same standards as specified in §439.25(a).

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §439.43 and §439.44.

[68 FR 12274, Mar. 13, 2003]

§ 439.46 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)**

<table>
<thead>
<tr>
<th>Regulated parameter</th>
<th>Maximum daily $^1$</th>
<th>Maximum monthly average $^1$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>20.7</td>
<td>8.2</td>
</tr>
<tr>
<td>n-Amyl acetate</td>
<td>20.7</td>
<td>8.2</td>
</tr>
<tr>
<td>Ethyl acetate</td>
<td>20.7</td>
<td>8.2</td>
</tr>
<tr>
<td>Isopropyl acetate</td>
<td>20.7</td>
<td>8.2</td>
</tr>
<tr>
<td>Methylene chloride</td>
<td>3.0</td>
<td>0.7</td>
</tr>
</tbody>
</table>

$^1$ mg/L (ppm).

[68 FR 12274, Mar. 13, 2003]

§ 439.47 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:

<table>
<thead>
<tr>
<th>Regulated parameter</th>
<th>Pretreatment standards $^1$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum daily discharge</td>
<td>Average monthly discharge must not exceed</td>
</tr>
<tr>
<td>Acetone</td>
<td>20.7</td>
</tr>
<tr>
<td>n-Amyl acetate</td>
<td>20.7</td>
</tr>
<tr>
<td>Ethyl acetate</td>
<td>20.7</td>
</tr>
<tr>
<td>Isopropyl acetate</td>
<td>20.7</td>
</tr>
<tr>
<td>Methylene chloride</td>
<td>3.0</td>
</tr>
</tbody>
</table>

$^1$ mg/L (ppm).

[63 FR 50436, Sept. 21, 1998; 64 FR 48104, Sept. 2, 1999]