

**RULE 2.35 PHARMACEUTICAL MANUFACTURING OPERATIONS**

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## 100 GENERAL

- 101 **PURPOSE:** The purpose of this Rule is to limit the emissions of volatile organic compounds (VOCs) from the manufacture of pharmaceutical and cosmetic products or devices.
- 102 **APPLICABILITY:** The provisions of this Rule shall apply to the following:
- 102.1 The manufacture of pharmaceutical and cosmetic products by chemical processes.
  - 102.2 The production and separation of medicinal chemicals such as antibiotics and vitamins from microorganisms.
  - 102.3 The manufacture of botanical and biological products by the extraction of organic chemicals from vegetative materials or animal tissues.
  - 102.4 The formulation of pharmaceuticals into various dosage forms such as tablets, capsules, injectable solutions, injectable solutions or ointments, or other means that can be taken by the patient immediately and in an accurate amount; and the formulation of cosmetics into configurations intended for consumer use.
- 110 **EXEMPTION - SMALL FACILITIES:** The requirements of Sections 301, 302, 303, 305, 306, 307, and 502 of this Rule shall not apply to facilities that emit, at the design production rating, less than 10 pounds per day of volatile organic compounds provided the requirements of Section 501 are met. Calculations shall not include emissions from surface preparation and cleanup solvent.
- 111 **EXEMPTION - ETHYLENE OXIDE STERILIZERS:** Ethylene oxide sterilizers which are subject to the provisions of Rule 9.4, ETHYLENE OXIDE STERILIZERS AND AERATORS, are exempt from the provisions of Section 303.

## 200 DEFINITIONS

- 201 **CONTROL DEVICE:** Equipment such as an incinerator or adsorber used to prevent air pollutants from reaching the ambient air.

- 202 **COSMETICS MANUFACTURING PLANT:** Any plant producing or blending chemicals for use in cosmetic products and/or manufacturing cosmetics products. Any facility or operation that has 2844 as their Standard Industrial Classification Code. Cosmetic manufacturing plants may include, but are not limited to, establishments primarily engaged in manufacturing perfumes (natural and synthetic), cosmetics, toilet preparations, shampoos and shaving products, and the blending and compounding of perfume bases.
- 203 **EMISSION CONTROL SYSTEM:** A control device and its associated collection system.
- 204 **IN-PROCESS TANK:** Containers used for mixing, blending, heating, reacting, holding, crystallizing, evaporating, or cleaning operations in the manufacture of pharmaceuticals or cosmetics.
- 205 **PHARMACEUTICAL MANUFACTURING PLANT:** Any plant producing or blending chemicals for use in pharmaceutical products and/or employing chemical processes in the manufacture of pharmaceutical products or medical devices. Any facility or operation that has 283 as the first three digits of their Standard Industrial Classification Code. Pharmaceutical manufacturing plants may include, but are not limited to, establishments primarily engaged in manufacturing, fabricating, or processing medicinal chemicals and pharmaceutical products for human or veterinary use.
- 206 **PHARMACEUTICAL PRODUCT:** A preparation or compound of medicinal drugs including, but not limited to, a prescription drug, analgesic, decongestant, antihistamine, cough suppressant, vitamin, mineral and herb, and is used by humans for consumption to enhance human health.
- 207 **SURFACE PREPARATION AND CLEANUP:** The removal of contaminants such as dust, soil, oil, grease, etc., prior to any step in a manufacturing process from parts, products, tools, machinery, equipment, and general work areas.
- 208 **VOLATILE ORGANIC COMPOUND (VOC):** As defined in Rule 1.1, General Provisions and Definitions.
- 209 **VOLATILE ORGANIC COMPOUND (VOC) CONTENT:** Weight of VOC per volume of material as calculated pursuant to the applicable Sections of 600.

300 STANDARDS

301 **REACTORS, DISTILLATION COLUMNS, CRYSTALLIZERS, AND CENTRIFUGES:** A person shall not emit more than 10 pounds per day of VOCs from any reactor, distillation column, crystallizer, or centrifuge unless such emissions are reduced by one of the following:

301.1 An emissions control system pursuant to the following:

- a. The VOC emission control system shall be approved in writing by the APCO,
- b. The VOC emission control system shall be operated with an overall capture and control efficiency of at least 85 percent by weight during periods of emission producing activity.

301.2 Surface condensers for the control of VOCs having the outlet gas temperature controlled as set forth in **Table 1**.

Table 1			
Vapor Pressure of Liquid Volatile Organic Compounds at 20° C (68° F)		Maximum Condenser Outlet Gas Temperature	
mm Hg	Psia	°C	°F
26 - 52	0.5 - 1.0	25	77
52 - 78	1.0 - 1.5	10	50
78 - 150	1.5 - 2.9	0	32
150 - 300	2.9 - 5.8	- 15	5
> 300	> 5.8	- 25	- 13

302 **SEPARATION OPERATIONS:** A person shall not emit more than 10 pounds per day of VOCs from any rotary vacuum filter or any other filter or separation device having an exposed liquid surface where the liquid contains VOCs with a combined vapor pressure of 26 mm Hg (0.5 psia) or more at 20° C (68° F) unless such emissions are reduced by an emissions control system with an overall control efficiency of 85% or more on a mass basis as determined per Section 607 of this Rule.

303 **STERILIZERS:** A person shall not operate any chemical sterilizer using gaseous VOCs unless emissions of VOCs from any such sterilizer exceeding 10 pounds per day are

reduced by an emissions control system with an overall capture and control efficiency of 85% or more on a mass basis as determined per Section 607 of this Rule.

- 304 **IN-PROCESS TANKS:** A person shall not use in-process tanks for material containing VOCs unless a cover is provided. These covers must remain closed unless production, sampling, maintenance, loading, or unloading operations require operator access.
- 305 **AIR DRYERS:** A person shall not emit more than 10 pounds per day of VOCs from any air dryer unless such emissions are reduced by at least by an emissions control system with an overall control efficiency of 85% or more on a mass basis as determined per Section 607 of this Rule.
- 306 **BULK LOADING:** A person shall not transfer organic liquids having a vapor pressure greater than 212 mm Hg (4.1 psia) at 20° C (68° F) from any rail car or tank truck into any storage tanks with a capacity greater than 2,000 gallons unless VOC emissions during transfer are reduced by a vapor recovery system with an overall capture and control efficiency of 90% or more on a mass basis as determined per Section 607 of this Rule.
- 307 **STORAGE TANKS:** All storage tanks that store organic liquids with a vapor pressure greater than 78 mm Hg (1.5 psia) at 20° C (68° F) shall be equipped with pressure/vacuum vents set at a minimum of  $\pm$  2 mm Hg ( $\pm$  0.03 psia).
- 308 **OPERATING REQUIREMENTS:** An operator shall repair all vapor and liquid leaks from which VOCS can be observed to be running or dripping. The repair shall be completed the first time the equipment is off-line for a period long enough to complete the repair, but not longer than 48 hours after detection of the vapor or liquid leak.
- 309 **STORAGE AND DISPOSAL - GENERAL:** All VOC-containing materials subject to this rule, whether in its form for intended use or as a waste or used product, shall be stored in non-absorbent, non-leaking containers which shall be kept closed at all times, except when filling or emptying, and disposed of in a manner to prevent evaporation of VOCs into the atmosphere at the facility.
- 310 **REQUIREMENTS FOR SURFACE PREPARATION AND CLEANUP MATERIALS:** All surface preparation and cleanup shall meet the following requirements:

- 310.1 Any solvent cleaning of application equipment, parts, products, tools, machinery, equipment, general work areas, and the storage and disposal of VOC-containing materials used in surface preparation and cleanup operations shall be carried out pursuant to Rule 2.31, Surface Preparation and Cleanup.
- 310.2 The disposal of waste solvent and solvent residue shall be by one of the following methods:
- a. A commercial waste solvent reclamation service licensed by the State of California; or
  - b. A facility that is federally or state licensed to treat, store, and dispose of such waste; or
  - c. Recycling in conformance with Section 25143.2 of the California Health and Safety Code.

#### **400 ADMINISTRATIVE REQUIREMENTS**

- 401 **OPERATION AND MAINTENANCE PLAN:** Any person using an emission control device pursuant to Section 305 of this Rule, as a means of complying with this rule, must submit with the application for Authority to Construct, pursuant to Rule 3.1, GENERAL PERMIT REQUIREMENTS, an O&M Plan for the emission control device to the APCO for approval. The O&M Plan shall specify operation and maintenance procedures which will demonstrate continuous operation of the control device during periods of emission producing operations. The O&M Plan shall also specify which records must be kept to document these operation and maintenance procedures. These records shall comply with the requirements of Section 503 of this Rule. Any person using an emission control device must fully comply with all O&M Plans submitted for approval, even if such O&M Plans have not yet been approved, unless notified in writing by the APCO.

#### **500 MONITORING AND RECORDS**

- 501 **SMALL-USER RECORDS:** Any person seeking to satisfy the conditions of Section 110 shall keep records on a daily basis which show the types and amounts of VOCs used.
- 502 **ORGANIC COMPOUND PROCESSING RECORDS:** Any person subject to the requirements of Sections 301, 302, 303, or 305 shall keep records for each source that does not require

air pollution abatement equipment. These records shall contain the following information:

502.1 A person shall maintain a current list of VOCs in use including the vapor pressure of each compound at 20° C (68° F).

502.2 A person shall keep records on a daily basis which show the types and amount of VOCs used.

503 **RECORD KEEPING - EMISSION CONTROL SYSTEMS:** If compliance with this rule is achieved through the use of a emission control system, in addition to any other applicable record requirements, the owner or operator shall maintain:

503.1 Daily records of key operating parameters such as temperatures, pressures, flowrates, and hours of operation of the control device to verify compliance of the capture and control device.

503.2 Maintenance work which interferes with the operation of the control device.

504 **SOLVENT WASTE/RESIDUE DISPOSAL RECORDS:** Any person subject to the requirements of Section 310.2 of this Rule shall maintain the following records concerning the disposal of solvent waste and solvent residue:

504.1 The date, type, and amount of solvent waste or residue removed; and

504.2 The identification of the licensed facility for each solvent waste or residue disposal.

505 **REPORTING:** All records required by this Rule shall be maintained on site for a period of two years and made available to the APCO upon request.

## 600 TEST METHODS AND CALCULATIONS

601 **GENERAL:** For the purposes of this Rule, the following test methods shall be used. Other test methods determined to be equivalent and approved in writing by the District and the EPA may also be used. VOC emissions or other parameters determined to exceed any limits established by this Rule through the use of any of the following test methods shall constitute a violation of this Rule.

- 602 **VOC CONTENT:** The VOC content of liquids and solvents subject to the provisions of this Rule, excluding exempt compounds, shall be determined by procedures contained in EPA Reference Test Method 24 (40 CFR 60, Appendix A).
- 603 **EXEMPT COMPOUNDS:** Measurement of exempt compounds shall be conducted and reported in accordance with ASTM Test Method D 4457-85.
- 604 **RECOVERY SYSTEM EFFICIENCY:** The control efficiency of vapor recovery systems shall be determined in accordance with CARB Method 202.
- 605 **CAPTURE EFFICIENCY:** The capture efficiency of a VOC emission control system's collection device shall be determined according to EPA's "Guidelines for Determining Capture Efficiency," January 9, 1995 and 40 CFR 51, Appendix M, Methods 204-204F, as applicable.
- 606 **CONTROL EFFICIENCY:** The control efficiency of a VOC emission control system's collection device shall be determined by using EPA Methods 2, 2A, or 2D for measuring flow rates and EPA Method 25, 25A, or 25B for measuring total gaseous organic concentrations at the inlet and outlet of the control device. EPA Method 18 or CARB Method 422 shall be used to determine the emissions of exempt compounds.
- 607 **OVERALL CAPTURE AND CONTROL EFFICIENCY:** For VOC emission control systems that consist of a single VOC emission control device, the overall capture and control efficiency shall be calculated by using the following equation:
- $$CE_{\text{overall}} = [CE_{\text{capture}} \times CE_{\text{control}}] / 100\%$$
- Where:
- |                       |   |   |
|-----------------------|---|---|
| CE <sub>overall</sub> | = | Overall Capture and Control Efficiency        |
| CE <sub>capture</sub> | = | Capture Efficiency of the device*             |
| CE <sub>control</sub> | = | Control Efficiency of the collection device** |
- \*As determined in Section 605  
 \*\*As determined in Section 606
- 608 **SOLVENT COMPOSITION:** The identity of components in liquids subject to the provisions of this Rule shall be determined by EPA Reference Test Method 18 (40 CFR 60, Appendix A), ASTM Method E168-67, ASTM Method E169-87, or ASTM Method E260-85, as applicable.

609 **VAPOR PRESSURE:** The vapor pressure of liquids subject to the provisions of this Rule shall be determined by ASTM D2879-86 or may be obtained from a public source such as: Boublik, T., V. Freid and E. Hala, *"The Vapor Pressure of Pure Substances"*, Elsevier Scientific Publishing Co., New York (1973), *Perry's Chemical Engineer's Handbook*, McGraw-Hill Book Company (1984), *CRC Handbook of Chemistry and Physics*, Chemical Rubber Publishing Company (1986-87), and *Lange's Handbook of Chemistry*, John A. Dean, editor, McGraw-Hill Book Company (1985).