

**RULE 1103. PHARMACEUTICALS AND COSMETICS
MANUFACTURING OPERATIONS**

(a) Applicability

The purpose of this rule is to reduce VOC emissions from; and the provisions of this rule shall apply to:

- (1) The manufacture of pharmaceutical and cosmetic products by chemical processes.
- (2) The production and separation of medicinal chemicals such as antibiotics and vitamins from microorganisms.
- (3) The manufacture of botanical and biological products by the extraction of organic chemicals from vegetable materials or animal tissues.
- (4) The formulation of pharmaceuticals into various dosage forms such as tablets, capsules, injectable solutions or ointments, that can be taken by the patient immediately and in an accurate amount; and the formulation of cosmetics into configurations intended for consumer use.

(b) Definitions

For the purpose of this rule, the following definitions shall apply:

- (1) CAPTURE EFFICIENCY, in percent, is the ratio of the weight of the VOC in the effluent stream entering the control device to the weight of VOC emitted from pharmaceutical or cosmetic manufacturing operations, both measured simultaneously, and shall be calculated by the following equation:

$$\text{Capture Efficiency} = [W_c/W_e] \times 100$$

Where: W_c = weight of VOC entering control device

W_e = weight of VOC emitted from the process

- (2) CONTROL DEVICE EFFICIENCY, in percent, is the ratio of the weight of the VOC removed by the control device from the effluent stream entering the control device to the weight of VOC in the effluent stream entering the control device, both measured simultaneously, and shall be calculated by the following equation:

$$\text{Control Device Efficiency} = [(W_c - W_a) / W_c] \times 100$$

Where: W_c = Weight of VOC entering control device

W_a = Weight of VOC discharged from the control device

- (3) COSMETICS MANUFACTURING PLANT is any plant producing or blending chemicals for use in cosmetic products and/or manufacturing cosmetic products by chemical processes.
- (4) EXEMPT COMPOUNDS See Rule 102 - Definition of Terms
- (5) IN-PROCESS TANKS are containers used for mixing, blending, heating, reacting, holding, crystallizing, evaporating, or cleaning operations in the manufacture of pharmaceuticals or cosmetics.
- (6) KEY SYSTEM OPERATING PARAMETER is an emission control system operating parameter, such as temperature, flow rate or pressure, that ensures operation of the abatement equipment within manufacturer specifications and compliance with the standards in Paragraphs (d)(1), (d)(2), and (d)(3).
- (7) LIQUID LEAK is the dripping of liquid volatile organic compounds at the rate of more than three drops per minute.
- (8) PHARMACEUTICAL MANUFACTURING PLANT is any plant producing or blending chemicals for use in pharmaceutical products and/or manufacturing pharmaceutical products by chemical processes with the Standard Industrial Classification of 2833, 2834, 2835, and 2836.
- (9) PRODUCTION EQUIPMENT is any equipment using or emitting VOC that is used in the manufacture of cosmetics or pharmaceuticals and is not exempt from permits pursuant to Rule 219 and does not include reactors, distillation columns, crystallizers and centrifuges which are subject to Subdivision (c) of this rule.
- (10) TOTAL VOC VAPOR PRESSURE is the sum of the vapor pressures of each of the compounds defined as VOCs.

VOC Composite Total Pressure is calculated as follows:

$$TP_c = \sum_{i=1}^n \frac{(W_i)(VP_i)/MW_i}{\frac{W_w}{MW_w} + \frac{W_e}{MW_e} + \sum_{i=1}^n \frac{W_i}{MW_i}}$$

Where:

W_c = Weight of VOC entering control device

W_i = Weight of the "i"th VOC compound, in grams (g)

W_w = Weight of water, in grams (g)

W_e = Weight of exempt compound, in grams (g)

MW_i = Molecular weight of the "i"th VOC compound, in $\frac{G}{\text{g-mole}}$

MW_w = Molecular weight of water, $\frac{G}{\text{g-mole}}$
in

MW_e = Molecular weight of exempt compound, $\frac{g}{\text{g-mole}}$
in

TP_c = VOC composite partial pressure at 20°C, in mm Hg

VP_i = Vapor pressure of the "i"th VOC compound at 20°C, in mm Hg

- (11) VOLATILE ORGANIC COMPOUND (VOC) is any chemical compound containing the element carbon, excluding methane, carbon monoxide, carbon dioxide, carbonic acid, metallic carbides and carbonates, ammonium carbonate, and exempt compounds.

(c) Equipment Requirements

- (1) An owner/operator shall not use reactors, distillation columns, crystallizers, or centrifuges emitting more than 15 pounds per day of VOC for each permit unit unless the vents are equipped with surface condensers or equivalent control devices as specified under Subparagraph (c)(1)(B).

- (A) An operator shall not use surface condensers for the control of organic gases unless the condenser outlet gas temperature is controlled as shown in the following table:

<u>Total Vapor Pressure of VOC at 20°C</u>	<u>Maximum Condenser Outlet Gas Temperature</u>
0.5 psi to 1.0 psi	25°C
> 1.0 psi to 1.5 psi	10
> 1.5 psi to 2.9 psi	0
> 2.9 psi to 5.8 psi	- 15
over 5.8 psi	- 25

- (B) An equivalent control devices may be used if it can achieve the equivalent percent of VOC condensed as determined by the method outlined in Subsection 4.1.1 (Condenser Performance) of Section 4.0 “Performance of Control Systems” in the EPA Document No. EPA-450/2-78-029 “Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products” December 1978. A condensed version of this method is shown below.

The percent of VOC condensed shall be calculated with the following equation:

$$PC = \frac{MFS_1 - \left(\frac{1 - MFS_1 \times MFS_2}{1 - MFS_2} \right)}{MFS_1} \times 100$$

Where PC = percent of VOC condensed
MFS₁ = mole fraction VOC into condenser
MFS₂ = mole fraction VOC out of condenser

Mole fraction of VOC in the condenser inlet and outlet shall be determined by chemical analysis or by dew point method as described in EPA document "Control of Volatile Organic Emissions from Manufacture of Synthesized

Pharmaceutical Products," Report No. EPA-450/2-78-029, Section 4.0 "Performance of Control Systems," pages 4-2 through 4-6.

- (2) An operator shall not use centrifuges, rotary vacuum filters, or any other filters, or devices having an exposed liquid surface where the liquid contains VOC having a total VOC vapor pressure of 0.5 psi or more at 20°C, unless such devices incorporate a hood or enclosure with a delivery system or ductwork to collect VOC emissions, exhausting to a control device which meets the applicable requirements in either Paragraphs (d)(1) or (d)(2) of this rule.
- (3) An operator shall not use in-process tanks for material containing VOC unless an apparatus or cover which prevents VOC evaporation is provided for the tank. The cover shall be closed or in place on the tank at all times except while loading or unloading the tank.

(d) **Operating Requirements**

An operator shall conform to the following operational requirements:

- (1) If the basic permit unit for production equipment including air dryers emits 330 pounds per day or more of volatile organic compounds, the emissions of such organic materials into the atmosphere shall be reduced by at least 90 percent by weight.
- (2) If the basic permit unit for production equipment including air dryers emits less than 330 pounds per day of volatile organic compounds, the emissions of such organic materials into the atmosphere shall be reduced to less than 33 pounds per day.
- (3) An operator shall not transfer VOC having a total VOC vapor pressure greater than 4.1 psi at 20°C, from any truck or rail car into any storage tank of a 2,000 gallon capacity or greater, unless VOC emissions during transfer are reduced by 90 percent by weight.
- (4) An operator shall install pressure/vacuum vents set at +0.03 psig on all storage tanks that store VOC with a total VOC vapor pressure greater than 1.5 psia at 20°C.
- (5) An operator shall repair all liquid leaks within 24 hours after the detection of the leak.

(e) **Recordkeeping Requirements**

Any person subject to Subdivisions (c) and (d) of this rule shall:

- (1) Maintain a current list of organic compounds in use including the vapor pressure of each compound at 20°C.
 - (2) Record on a daily basis the types and amounts of organic compounds in use.
 - (3) Record on a daily basis approved emission control system key system operating parameters as defined in Paragraph (b)(6).
 - (4) Records shall be retained at the facility for at least two years and be made available to the AQMD upon request.
 - (5) Facilities subject to Title V shall retain records at the facility for at least five years and make those records available to the AQMD upon request.
- (f) Test Methods
- (1) The calculation of emission reduction required in Paragraphs (d)(1) and (d)(2) shall be determined based on both the capture efficiency and control device efficiency as specified by the following:
 - (A) Capture efficiency shall be determined by the procedures presented in the USEPA technical guidance document, "Guidelines for Determining Capture Efficiency, January 9, 1995." Notwithstanding the test methods specified by the Guidelines any other method approved by the EPA, CARB, and AQMD Executive Officer may be substituted.
 - (B) Control device efficiency is based on the weight of VOC removed compared to the weight of VOC entering the device. The weight of VOC, measured and calculated as carbon, shall be determined by the USEPA Test Methods 25, 25A, or AQMD Method 25.1 (Determination of Total Gaseous Non-Methane Organic Emissions as Carbon) as applicable. EPA Test Method 18, or CARB Method 422 shall be used to determine emissions of exempt compounds.
 - (2) The determination of the vapor pressure of a VOC compound shall be determined by using values in scientifically recognized published reference works or by testing using method ASTM Method D2879 when such reference works are not available.
- (g) Exemptions
- The provisions of this rule shall not apply to the following:

- (1) Facilities that emit, at the design production rating, 15 pounds per day or less of volatile organic compounds; and,
- (2) Sterilizers regulated by Rule 1405 - Control of Ethylene and Chlorofluorocarbon Emissions from Sterilizers or Fumigation Processes.