

RULE 67.15. PHARMACEUTICAL AND COSMETIC MANUFACTURING OPERATIONS (Effective 10/18/88: Rev. Adopted & Effective 5/15/96)

(a) **APPLICABILITY**

Except as otherwise provided in Section (b), this rule is applicable to any person who:

- (1) Manufactures pharmaceutical or cosmetic products;
- (2) Formulates ointments or cosmetics into configurations intended for sale and/or use;
- (3) Produces and/or separates medicinal chemicals such as antibiotics and vitamins from micro-organisms;
- (4) Manufactures botanical and/or biological products by the extraction of organic chemicals from vegetative materials or animal tissues; or
- (5) Formulates pharmaceutical products into various dosage forms such as tablets, capsules or injectable solutions that can be taken by a patient immediately and in an accurate amount.

(b) **EXEMPTIONS**

The provisions of this rule shall not apply to:

- (1) Any stationary source, as defined in Rule 20.1, which emits less than 15.0 pounds (6.8 kg) of volatile organic compounds (VOC) on each day at design production rate, provided the operator of such equipment maintains daily records necessary to establish maximum emission levels. These records shall be maintained for a minimum of three years and be made available to the District immediately upon request. For purposes of this exemption all process emissions, including those from equipment cleanup, shall be summed to determine maximum emission rate.
- (2) Any manufacturing processes subject to the requirements of Rule 67.10, including storage tanks for such processes.

(c) **DEFINITIONS** (Rev. Effective 5/15/96)

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

- (1) **"Cosmetic Manufacturing Plant"** means any plant producing or blending chemicals for use in cosmetic products and/or manufacturing cosmetic products by chemical processes.
- (2) **"Cosmetic Products"** means any material for external use for the beautification of the complexion and/or skin.

(3) **"Exempt Compounds"** means the same as defined in Rule 2.
(Rev. Effective 5/15/96)

(4) **"Fugitive Liquid Leak"** means a visible leak of liquid, containing VOC, at a rate in excess of three drops per minute.

(5) **"Fugitive Vapor Leak"** means any VOC vapor leak which results in a concentration of 500 ppmv or more measured as propane at a distance of 1/2 inch (1.3 cm) from the vapor path, other than non-repeatable, momentary readings.

(6) **"Pharmaceutical Manufacturing Plant"** means any plant producing or blending chemicals for use in pharmaceutical products and/or manufacturing pharmaceutical products by chemical processes.

(7) **"Pharmaceutical Products"** means any substances resulting from preparing, preserving or compounding of medicinal drugs, vitamins or other materials used to enhance personal health.

(8) **"Process Tanks"** means containers used for mixing, blending, folding, crystallizing or cleaning operations in the manufacture of pharmaceuticals and/or cosmetics.

(9) **"Volatile Organic Compounds (VOC)"** means any volatile compound or combination of volatile compounds of carbon, excluding methane, carbon monoxide, carbon dioxide, carbonic acid, ammonium carbonate, metallic carbides, metallic carbonates, and exempt compounds which may be emitted to the atmosphere during the manufacturing, mixing and/or subsequent drying of pharmaceutical and/or cosmetic products subject to this rule. (Rev. Effective 5/15/96)

(d) **STANDARDS**

A person shall not produce, manufacture, mix, blend, formulate, dry or encapsulate any pharmaceutical or cosmetic product subject to this rule unless the requirements of (d)(1) through (d)(8) are met:

(1) Reactors, distillation columns, crystallizers or centrifuges emitting more than 15.0 pounds (6.8 kg) of VOC on any day shall not be used unless all vent points for such devices are equipped with surface condensers which have an outlet exhaust gas temperature no greater than the maximum shown in the following table:

<u>Absolute Vapor Pressure of VOC at 20° C</u>	<u>Maximum Condenser Outlet Gas Temperature</u>
0.5 psia to 1.0 psia	25° C (77° F)
1.0 psia to 1.5 psia	10 (50° F)
1.5 psia to 2.9 psia	0 (32° F)
2.9 psia to 5.8 psia	15 (5° F)
over 5.8 psia	-25 (-13° F)

When blends of more than one VOC are used, the absolute vapor pressure of the most volatile component (i.e., that with the highest absolute vapor pressure) shall be used to determine the required maximum condenser outlet gas temperature.

Alternative control devices may be used with the approval of the Air Pollution Control Officer provided their combined VOC collection and abatement efficiency is at least 90 percent by weight.

(2) Centrifuges, rotary vacuum filters, or any other filters or devices having an exposed liquid surface where the liquid contains VOC having a total absolute vapor pressure of 0.5 psia or more at 20° C shall not be used unless a VOC collection and abatement system which reduces VOC emissions by a minimum of 90 percent by weight, and is approved by the Air Pollution Control Officer, is used.

(3) Process tanks for material containing VOC having a total absolute vapor pressure of 0.5 psia or more at 20° C shall not be used unless the tank is covered or otherwise sealed at all times except while loading, unloading or during maintenance of such tanks.

(4) Air dryers or other production equipment that, in combination, emit 33 pounds (15 kg) on any day or more of VOC shall not be used unless the emissions from such equipment are reduced by at least 90 percent by weight.

(5) VOC having a total absolute vapor pressure greater than 1.5 psia at 20° C shall not be transferred into a stationary storage tank with a capacity greater than 2000 gallons, unless such tank is equipped with all the following controls:

(i) A permanent submerged fill pipe which discharges at not more than six inches from the bottom of the tank; and,

(ii) A vapor return line which transfers at least 90 percent by weight of displaced VOC vapor from the stationary storage tank being filled back to the mobile or stationary supply tank; and,

(iii) A pressure-vacuum relief valve with relief settings of not less than ± 0.03 psig; or

(iv) An alternative VOC emission control system approved by the Air Pollution Control Officer which achieves at least 90 percent by weight combined collection and abatement efficiency of VOC emissions during liquid transfer.

(6) Fugitive liquid leaks in equipment storing, mixing, blending or transferring VOC shall be promptly repaired. This repair shall be completed the first time the equipment is off-line for a period of time long enough to complete the repair, but in no case longer than 72 hours after such leak was first detected and recorded. This record shall specify the time, date and location of each observed leak. An unrecorded leak shall be considered a violation of this rule.

(7) Fugitive vapor leaks from equipment storing, mixing, blending, reacting or transferring materials containing VOC shall be immediately recorded and promptly repaired. This repair shall be completed the first time the equipment is off-line for a period of time long enough to complete the repair, but in no case longer than 72 hours after such leak was first detected and recorded. This record shall specify the time, date and location of each observed leak. An unrecorded leak shall be considered a violation of this rule. For purposes of this subsection, the emission of VOC vapor from process tanks which are uncovered because of loading, unloading or maintenance shall not be considered a fugitive vapor leak. The emission of VOC vapor from process locations which, when in compliance with the provisions of this rule, have such emissions during normal operation and from controlled vents shall not be considered a fugitive vapor leak.

(8) An operation and maintenance program shall be submitted to the Air Pollution Control Officer for approval for VOC collection and control equipment required by Subsections (d)(1), (d)(2), (d)(4) and (d)(5). Each submittal shall be made within sixty days of installation of such equipment. Each program shall be implemented on approval of the Air Pollution Control Officer.

Each operation and maintenance program submitted for approval shall:

- (i) Seek to maintain the emission control efficiency required to comply with this rule,
- (ii) Identify all key system operating parameters. Key system operating parameters are those the Air Pollution Control Officer determines are necessary to maintain the required emission control efficiency, and
- (iii) Include proposed daily inspection schedules, anticipated ongoing maintenance steps and proposed daily recordkeeping practices regarding the key system operating parameters.

Daily records to demonstrate compliance with this subsection shall be kept for three years and be provided upon request to the Air Pollution Control Officer.

(e) VOC TEST METHODS

Total absolute vapor pressure of VOC containing compounds pursuant to Subsections (d)(2), (d)(3) and (d)(5) of this rule shall be calculated using the District's "Procedure for Estimating the Vapor Pressure of a Solvent Mixture" as it exists on December 18, 1990. If the vapor pressure of the liquid mixture exceeds the limits specified in Subsections (d)(2), (d)(3) and (d)(5), as applicable, the vapor pressure shall be determined in accordance with ASTM Test Method D 2879-83, Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope.

Measurements of VOC content pursuant to Subsections (d)(1) thru (d)(5) of this rule shall be conducted and reported in accordance with EPA Test Method 25 (40 CFR 60, Appendix A), as it exists on December 18, 1990. Measurements of collection efficiency subject to Subsections (d)(2), (d)(4) and (d)(5) of this rule shall be conducted in accordance with the EPA Guidelines for Capture Efficiency Determination.

The VOC content of fluids subject to Subsection (d)(6) of this rule shall be determined in accordance with ASTM Standard Recommended Practices for General Gas Chromatography Procedures E 260-73, General Techniques of Infrared Quantitative Analysis E 168-67, and General Techniques of Ultraviolet Quantitative Analysis.