



Environmental Protection and Growth Management Department  
**POLLUTION PREVENTION DIVISION - AIR QUALITY PROGRAM**  
One North University Drive, Suite 203, Plantation, Florida 33324  
954-519-1260 • FAX 954-519-1495

## PERMITTEE

Actavis Laboratories FL, Inc.  
4955 Orange Drive  
Fort Lauderdale, Florida 33314

Authorized Representative:  
Mr. James Schwier, General Manager

Air Permit No. 0112791-018-AO  
Air Operation Permit

Fort Lauderdale Facility  
Broward County, Florida

## PROJECT

This is the final air operation permit which authorizes Actavis Laboratories FL, Inc. to operate a pharmaceutical research and development (R & D) and manufacturing facility. The Standard Industrial Classification No. is 2834 and the North American Standard Classification System No. is 355412. This project incorporates the conditions in air construction permit no. 0112197-017-AC issued on June 6, 2015 to install a Glatt 30 fluid bed processor for use in the R & D operations. The operation permit has the same conditions as the construction permit and therefore there are no additional requirements. The facility is located in Broward County at 4955 Orange Drive and 4011 S.W. 47<sup>th</sup> Avenue, Fort Lauderdale. The Latitude and Longitude are 26° 04' 18" North and 80° 12' 40" West, respectively. This final permit is organized into the five (5) Sections: Section 1 (General Information); Section 2 (Administrative Requirements); Section 3 (Facility Wide Conditions); Section 4 (Emissions Unit Specific Conditions); and Section 5 (Appendices). The acronyms and abbreviations are defined in Appendix A of Section 5 of this permit.

**Permitting Authority:** Applications for air operation permits are subject to review in accordance with the provisions of Chapter 403, Florida Statutes (F.S.) and Chapters 62-4 and 62-210 of the Florida Administrative Code (F.A.C.). The Permitting Authority responsible for making a permit determination for this project is the Pollution Prevention Division (PPD). The Permitting Authority's physical address is: One North University Drive, Suite 203, Plantation, Florida 33324. The Permitting Authority's telephone number is 954-519-1260.

**Petitions.** A person whose substantial interests are affected by the proposed decision may petition for an administrative hearing in accordance with Sections 120.569 and 120.57, F.S. The petition must contain the information set forth below and must be filed (received) in the Office of the Broward County Attorney at 115 S. Andrews Avenue, Room: 423, Fort Lauderdale, Florida 33301-1872 (Telephone: 954/357-7600, Fax: 954/357-7641). Petitions filed by the applicant or any of the parties listed below must be filed within 14 days of receipt of this notice. Petitions filed by any other person must be filed within 14 days of receipt of this proposed action. A petitioner must mail a copy of the petition to the applicant at the address indicated above, at the time of filing. The failure of any person to file a petition within the appropriate time period shall constitute a waiver of that person's right to request an administrative determination (hearing) under Sections 120.569 and 120.57, F.S., or to intervene in this proceeding and participate as a party to it. Any subsequent intervention will be only at the approval of the presiding officer upon the filing of a motion in compliance with Rule 28-106.205, F.A.C.

A petition that disputes the material facts on which the PPD's action is based must contain the following information: (a) The name and address of each agency affected and each agency's file or identification number, if known; (b) The name, address, and telephone number of the petitioner; the name, address and telephone number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding; and an explanation of how the petitioner's substantial interests will be affected by the agency

## FINAL AIR OPERATION PERMIT

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determination; (c) A statement of how and when each petitioner received notice of the agency action or proposed action; (d) A statement of all disputed issues of material fact. If there are none, the petition must so indicate; (e) A concise statement of the ultimate facts alleged, as well as the rules and statutes which entitle the petitioner to relief; (f) A statement of the specific rules or statutes the petitioner contends require reversal or modification of the agency's proposed action; and, (g) A statement of the relief sought by the petitioner, stating precisely the action petitioner wishes the agency to take with respect to the agency's proposed action.

A petition that does not dispute the material facts upon which the permitting authority's action is based shall state that no such facts are in dispute and otherwise shall contain the same information as set forth above, as required by Rule 28-106.301, F.A.C.

Because the administrative hearing process is designed to formulate final agency action, the filing of a petition means that the Department's final action may be different from the position taken by it in this notice. Persons whose substantial interests will be affected by any such final decision of the permitting authority on the application have the right to petition to become a party to the proceeding, in accordance with the requirements set forth above.

**Mediation:** Mediation is not available in this proceeding.

**Effective Date:** This permitting decision is final and effective on the date filed with the clerk of the Permitting Authority unless a petition is filed in accordance with the above paragraphs or unless a request for extension of time in which to file a petition is filed within the time specified for filing a petition pursuant to Rule 62-110.106, F.A.C., and the petition conforms to the content requirements of Rules 28-106.201 and 28-106.301, F.A.C. Upon timely filing of a petition or a request for extension of time, this action will not be effective until further order of the Permitting Authority.

**Judicial Review:** Any party to this permitting decision (order) has the right to seek judicial review of it under Section 120.68, F.S., by filing a notice of appeal under Rule 9.110 of the Florida Rules of Appellate Procedure with the clerk of the Office of the Broward County Attorney at 115 S. Andrews Avenue, Room: 423, Fort Lauderdale, Florida 33301-1872 (Telephone: 954/357-7600, Fax: 954/357-7641, and by filing a copy of the notice of appeal accompanied by the applicable filing fees with the appropriate PPD.

0112197-018-AO Effective Date: May 31, 2016

Renewal Application Due Date: March 31, 2016

Expiration Date: May 31, 2021

Executed in Plantation, Florida

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Robert C. Wong  
Environmental Program Supervisor  
POLLUTION PREVENTION DIVISION

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### CERTIFICATE OF SERVICE

The undersigned duly designated deputy agency clerk hereby certifies that this Air Permit package was sent by electronic mail, or a link to these documents made available electronically on a publicly accessible server, with received receipt requested before the close of business on the date indicated below to the following persons.

Ms. Diane Pupa, SFDEP, Air Section, [diane.pupa@dep.state.fl.us](mailto:diane.pupa@dep.state.fl.us)

Mr. James Schwier, Actavis Laboratories Fl. Inc., [james.s.schwier@actavis.com](mailto:james.s.schwier@actavis.com)

Mr. Keith Westin, Actavis Laboratories Fl. Inc., [keith.westin@actavis.com](mailto:keith.westin@actavis.com)

Clerk Stamp

**FILING AND ACKNOWLEDGMENT FILED**, on this date,  
pursuant to Section 120.52(7), Florida Statutes, with the  
designated agency clerk, receipt of which is hereby  
acknowledged.

\_\_\_\_\_  
Clerk

\_\_\_\_\_  
Date

## SECTION 2. ADMINISTRATIVE REQUIREMENTS

### FACILITY DESCRIPTION

Actavis operates a pharmaceutical research and development (R & D) facility at 4955 Orang Drive and a manufacturing facility at 4011 S.W. 47<sup>th</sup> Avenue in Fort Lauderdale, Florida. The facilities' operation consists of three emissions units, which includes the manufacturing operation using a catalytic oxidizer, fluidized bed processors and coating pans, storage tanks, drying ovens, cleaning, miscellaneous R & D activities, tablet machine presses, central vacuum systems, and miscellaneous equipment and work areas.

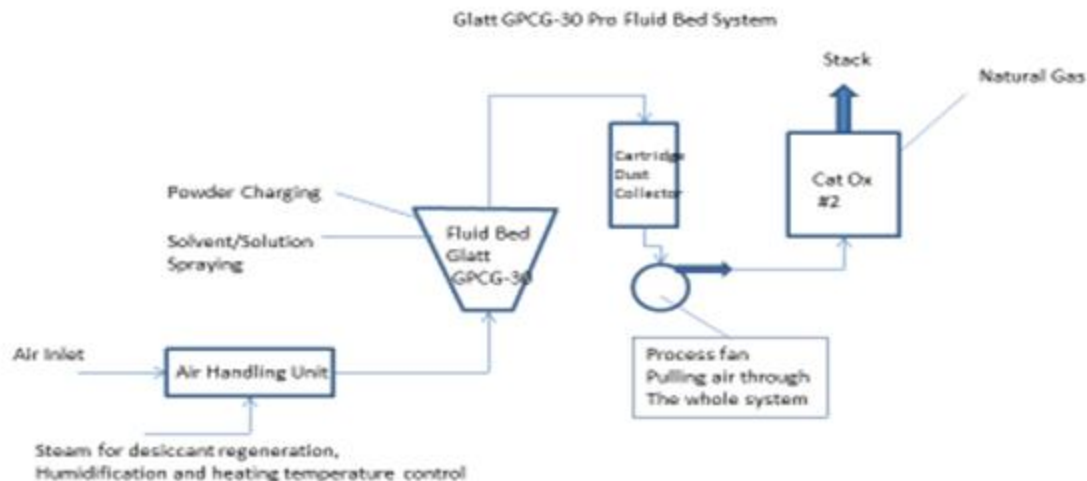
The new system, which was installed at the 4955 Orange Drive location, includes the Glatt 30 fluid bed dryer, desiccant wheel, air handling unit (AHU), dust collector and controls. The dryer uses organic solvents and is vented to a new dust collector for particulate matter control, followed by existing catalytic oxidizer #2 (ID-M461) for volatile organic compounds (VOC) control. The remaining oxidizers ID-M-149, M461, and M-827, previously referred as #3, #4, and #5, are now referred as #1, #2, and #3.

The charging process takes place by means of a closed pneumatic transfer system which moves the raw materials into the dryer bowl. The bowl size will vary from 59 to 151 liters, depending on the product being evaluated. The raw materials are mixed vigorously in the conditioned gas stream. The product is dried to the desired end moisture content by the existing supply and by 1,770 cfm of air flow through the system.

When solution is required, a portable weigh scale, solution tank and pump is positioned in the designated location within the R & D room. The tank weight is constantly monitored by the weight scale. The product is transferred from the solution tank by means of the portable pump to the dryer's spray system. The tank venting system features a nitrogen blanket maintained with a relief valve. The dryer is cleaned with isopropyl alcohol. Evaporative losses from cleaning are not controlled by the catalytic oxidizer. The washings are collected and disposed of offsite at a licensed facility.

The air handling system is a once-through system with the inlet air being drawn from outdoors and ducted into the AHU, where it is desiccated before being introduced to the fluid bed dryer. The fluidizing air is exhausted from the dryer through a high-static pressure fan, and routed to the new dust collector and then to the catalytic oxidizer which operates based upon the solvent or non-solvent load of the exhaust air. The processing room is maintained under negative pressure relative to the surrounding space. The maximum solution spray rate is 1,500 grams per minute; the average spray rate is 250 grams per minute. Approximately 146 batches are produced per year; batch times range 4 to 18 hours, averaging 12 hours. Solvent usage is about 59.8 gallons per batch.

The figure below is a simple process flow diagram:



## SECTION 2. ADMINISTRATIVE REQUIREMENTS

The facility consists of the following emissions units (EU).

EU ID	Description of Emissions Unit
005	<i>Manufacturing Operations using Catalytic Oxidizers</i> – Volatile Organic Compound (VOC) and Hazardous Air Pollutant (HAP) emissions from fluid bed processors and coating pans are directed to dust collectors and catalytic oxidizers controls prior to discharge to the atmosphere. A Glatt 30 Fluid bed dryer for use in the R & D operations which includes the fluid bed dryer, desiccant wheel, air handling unit (AHU)), dust collector, and controls. See Equipment List.
006	<i>Fugitive Sources of VOC and HAP Emissions</i> - storage tanks, drying ovens, cleaning, miscellaneous research and development (R&D) activities, etc. See Equipment List.
007	<i>Fugitive Sources of Particulate Matter (PM/PM10) Emissions</i> - Manufacturing and R&D fluid-beds, drying ovens, tablet machines/presses, central vacuum systems, and miscellaneous equipment and work areas. See – Equipment List.

Volatile organic compounds and HAP(s) emissions generated during the manufacturing of pharmaceutical products are collected in exhaust systems and directed to a vapor collection and processing system (VCPS). The VCPS includes all equipment such as ducts, valves, exhaust system, computer hardware, software, and catalytic oxidizers that manages the VOC and HAP emissions from the time of generation until the final discharge to the atmosphere.

### APPLICABLE REGULATIONS

A summary of applicable regulations is shown in the following table.

Summary of Federal Regulations	EU	Summary of State of Florida Statutes and Regulations	EU
N/A		Chapter 403, Florida Statutes, 62-4 F.A.C. - Permits, 62-210 F.A.C. - Stationary Sources. 62-4.070(3) F.A. C. – Reasonable Assurance	FAC WIDE 005, 006, 007
		62-296.320(2), F.A.C. - Objectionable Odor-Facility-wide. 62-296.320(1) (a), F.A.C. - VOC or Organic Solvent Emissions –Facility-wide. 62-296.320(4) (b), F.A.C. - General Visible Emissions Standards -20% opacity facility-wide, per Florida DEP Guidance, DARM-PER-33 62-296.320(1) (a) F.A.C. - VOC or Organic Solvent Emissions	FAC WIDE
<b>Summary of Broward County Regulations</b>		62-297.310 (7)(b)(3) F.A.C. - Recordkeeping and Monitoring	005, 006, 007
Chapter 27 Air Pollution Control, Article IV, Sec. 27-175(b) & (a). These regulations refer to: Concealment of emissions (b) & Maintenance (a) (Not federally enforceable)	FAC WIDE		

## SECTION 2. ADMINISTRATIVE REQUIREMENTS

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### FACILITY REGULATORY CLASSIFICATION

The facility is not a major source of hazardous air pollutants (HAP).

- The facility does not operate units subject to the acid rain provisions of the Clean Air Act (CAA).
- The facility is not a Title V major source of air pollution in accordance with Chapter 62-213, F.A.C.; by relying on control devices (i.e. catalytic oxidizers) to limit the VOC emissions to below 100 TPY. Any future permitting action that requires increasing the VOC limit to above 100 TPY would subject the source to an after-the-fact pre-construction review in accordance with Rule 62-212.400(2) (g), F.A.C.
- The facility is not a major stationary source in accordance with Rule 62-212.400, F.A.C. for the Prevention of Significant Deterioration (PSD) of Air Quality.
- The facility is a synthetic minor source of VOC and HAP in accordance with Chapter 62-213 (Title V), F.A.C.

*Permitting Note:* The 2.5 MMBTU/hr. Fulton Model VMP 60 natural gas-fired boiler, with a consumption rate of 2,392 cubic feet per hour; and heat content of 1,040 BTUC/cubic foot qualifies for permit exemption pursuant to Rule 62-210.300(3)(a)33, F.A.C. Also, there are no NSPS or NESHAPS regulations that apply to natural gas-fired boilers with heat input less than 10 MMBTU/hr. The addition of the Glatt 30 fluid bed processor dryer does not trigger additional requirements.

1. Permitting Authority: The permitting authority for this project is the Pollution Prevention Division (PPD). The PPD's physical and mailing is One North University Drive, Suite 203, Plantation, Florida 33324 and telephone number is 954-519-1260. All documents related to applications for permits to operate an emissions unit shall be submitted to the PPD.
2. Compliance Authority: All documents related to compliance activities such as reports, tests, and notifications shall be submitted to the PPD at: One North University Drive, Suite 203, Plantation, Florida 33324 and telephone number is 954-519-1260.
3. Appendices: The following Appendices are attached as a part of this permit: Appendix A (Citation Formats and Glossary of Common Terms); Appendix B (General Conditions); Appendix C (Common Conditions).
4. Applicable Regulations, Forms and Application Procedures: Unless otherwise specified in this permit, the construction and operation of the subject emissions units shall be in accordance with the capacities and specifications stated in the application. The facility is subject to all applicable provisions of: Chapter 403, F.S.; and Chapters 62-4, 62-204, 62-210, 62-212, 62-213, 62-296 and 62-297, F.A.C. Issuance of this permit does not relieve the permittee from compliance with any applicable federal, state, or local permitting or regulations.
5. New or Additional Conditions: For good cause shown and after notice and an administrative hearing, if requested, the Department may require the permittee to conform to new or additional conditions. The Department shall allow the permittee a reasonable time to conform to the new or additional conditions, and on application of the permittee, the Department may grant additional time. [Rule 62-4.080, F.A.C.]
6. Modifications: No new emissions unit shall be constructed and no existing emissions unit shall be modified without obtaining an air construction permit from the Department. Such permit shall be obtained prior to beginning construction or modification. [Rules 62-210.300(1) and 62-212.300(1) (a), F.A.C.]
7. Renewal. Prior to 60 days before the expiration date of this permit, the permittee shall apply for a renewal of the permit. A renewal application shall be timely and sufficient. If the application is submitted prior to 60 days before expiration of the permit, it will be considered timely and sufficient. If the renewal application is submitted at a later date, it will not be considered timely and sufficient unless it is submitted and made complete prior to the expiration of the operation permit. When the application for renewal is timely and

## SECTION 2. ADMINISTRATIVE REQUIREMENTS

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sufficient, the existing permit shall remain in effect until the renewal application has been finally acted upon by the Department. [Rule 62-4.090, F.A.C.]

8. Annual Operating Report (AOR): The information required by the Annual Operating Report for Air Pollutant Emitting Facility (DEP Form No. 62-210.900(5)) shall be submitted by April 1 of each year, for the previous calendar year, to the PPD. All synthetic non-Title V sources or all facilities with the potential to emit 10 tons/year or more of volatile organic compounds (VOC) or 25 tons/year or more of nitrogen oxides (NO<sub>x</sub>) and located in an ozone nonattainment area or ozone air quality maintenance area shall submit a completed DEP Form 62-210.900(5) unless the annual operating report is submitted using the DEP's electronic annual operating report software. Emissions shall be computed in accordance with the provisions of subsection 62-210.370(2), F.A.C. [Rule 62-210.370(3), F.A.C.]

*{Permitting Note: Resources to help you complete your AOR are available on the electronic AOR (EAOR) website at: <http://www.dep.state.fl.us/air/emission/eaor>. If you have questions or need assistance after reviewing the information posted on the EAOR website, please contact the Department by phone at (850) 717-9000 or email at [eaor@dep.state.fl.us](mailto:eaor@dep.state.fl.us).}*

### SECTION 3. FACILITY WIDE CONDITIONS

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1. **Not Federally Enforceable Objectionable Odor Prohibited**. No person shall cause, suffer, allow or permit the discharge of air pollutants, which cause or contribute to an objectionable odor. An “objectionable odor” means any odor present in the outdoor atmosphere which by itself or in combination with other odors, is or may be harmful or injurious to human health or welfare, which unreasonably interferes with the comfortable use and enjoyment of life or property, or which creates a nuisance.  
[Rule 62-296.320(2) and 62-210.200 (Definitions), F.A.C.]
2. **VOC or Organic Solvents Emissions**. The owner or operator shall allow no person to store, pump, handle, process, load, unload or use in any process or installation, volatile organic compounds or organic solvents without applying known and existing vapor emission control devices or systems deemed necessary and ordered by the PPD.  
  
The following requirements are deemed necessary by the PPD: use of a VCPS (defined below) to control VOCs.  
[Rule 62-296.320(1) (a), F.A.C., Rule 62-4.070(3), F.A.C., and Broward County Code, Sec. 27-175(f)]  
{ **VCPS Definition:** The vapor collection and processing system (VCPS) includes all equipment such as ducts, valves, exhaust system, computer hardware and software, and catalytic oxidizers that manages the VOC and HAP emissions from the time of generation until the final discharge to the atmosphere. }
3. **General Visible Emissions**. No person shall cause, let, permit, suffer or allow to be discharged into the atmosphere the emissions of air pollutants from any activity equal to or greater than 20% opacity. EPA Method 9 is the method of compliance pursuant to Chapter 62-297, F.A.C. This regulation does not impose a specific testing requirement.  
[Rule 62-296.320(4) (b), F.A.C.]
4. **Circumvention**. No person shall circumvent any air pollution device, or allow the emission of air pollutants without the applicable air pollution control device operating properly.  
[Rule 62-210.650, F.A.C.,]
5. **Not Federally Enforceable (1) Concealment**. No person shall build, erect, install, or use any article, machine, equipment or other contrivance, the use of which will conceal any emission which would otherwise constitute a violation of any provisions of Broward County Codes.  
  
**Not Federally Enforceable (2) Maintenance**. No person shall operate any air pollution control equipment or systems without proper and sufficient maintenance to assure compliance with Broward County Codes. In addition, the owner or operator shall implement the following Preventive Maintenance Inspection Program (PMIP) by:
  - (1) Conducting and documenting ongoing training for current and new employees on the verification of the operability of each VCPS;
  - (2) Inspecting each VCPS at least once a month and document results at least 5 days after each inspection;
  - (3) Obtaining a certified verification check from the manufacturer on operability for all VCPS at least once a year and after each modification or repair of a VCPS;
  - (4) Conducting VOC destruction efficiency testing on each catalytic oxidizer (see “*Testing*”, below)[Rule 62-4.070(3), F.A.C. and Broward County Code, Sec. 27-175(d)]  
(*Permitting Note:* PPD considers an oxidizer efficiency equal to or greater  
[Broward County Code, Sec. 27-175(b)])
6. **Unconfined Emissions of Particulate Matter**.
  1. No person shall cause, let, permit, suffer or allow the emissions of unconfined particulate matter from any activity, including vehicular movement; transportation of materials; construction, alteration, demolition or wrecking; or industrially related activities such as loading, unloading, storing or handling; without taking reasonable precautions to prevent such emissions.



### SECTION 3. FACILITY WIDE CONDITIONS

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2. Any permit issued to a facility with emissions of unconfined particulate matter shall specify the reasonable precautions to be taken by that facility to control the emissions of unconfined particulate matter.
3. Reasonable precautions include the following:
  - a. Paving and maintenance of roads, parking areas and yards.
  - b. Application of water or chemicals to control emissions from such activities as demolition of buildings, grading roads, construction, and land clearing.
  - c. Application of asphalt, water, oil, chemicals or other dust suppressants to unpaved roads, yards, open stock piles and similar activities.
  - d. Removal of particulate matter from roads and other paved areas under the control of the owner or operator of the facility to prevent reentrainment, and from buildings or work areas to prevent particulate from becoming airborne.
  - e. Landscaping or planting of vegetation.
  - f. Use of hoods, fans, filters, and similar equipment to contain, capture and/or vent particulate matter.
  - g. Confining abrasive blasting where possible.
  - h. Enclosure or covering of conveyor systems.
4. In determining what constitutes reasonable precautions for a particular facility, the PPD shall consider the cost of the control technique or work practice, the environmental impacts of the technique or practice, and the degree of reduction of emissions expected from a particular technique or practice.  
[Rule 62-297.320(4) (c), F.A.C.]
7. Special Compliance Tests. When PPD, after investigation, has good reason (such as complaints, increased visible emissions or questionable maintenance of control equipment) to believe that any applicable emission standard contained in a Department rule or in a permit issued pursuant to those rules is being violated, it shall require the owner or operator of the emissions unit to conduct compliance tests which identify the nature and quantity of pollutant emissions from the emissions unit, unless the Department obtains other information sufficient to demonstrate compliance. The owner or operator of the emissions unit shall provide a report on the results of said tests to the PPD in accordance with the provisions of subsection 62-297.310(10), F.A.C.  
[Rule 62-297.310(8) (c), F.A.C.]

This section of the permit addresses the following emission units.

EU No.	Emission Unit Description
005	<i>Manufacturing Operations using Catalytic Oxidizers</i> – Volatile Organic Compound (VOC) and Hazardous Air Pollutant (HAP) emissions from fluid bed processors and coating pans are directed to dust collectors and catalytic oxidizers controls prior to discharge to the atmosphere. A Glatt 30 Fluid bed dryer for use in the R & D operations which includes the fluid bed dryer, desiccant wheel, air handling unit (AHU), dust collector, and controls. See Equipment List.
006	<i>Fugitive Sources of VOC and HAP Emissions</i> - storage tanks, drying ovens, cleaning, miscellaneous research and development (R&D) activities, etc. See Equipment List.
007	<i>Fugitive Sources of Particulate Matter (PM/PM10) Emissions</i> - Manufacturing and R&D fluid-beds, drying ovens, tablet machines/presses, central vacuum systems, and miscellaneous equipment and work areas. See Equipment List.

Volatile organic compounds (VOC) and hazardous air pollutants HAP(s) emissions generated during the manufacturing of pharmaceutical products are collected in exhaust systems and directed to a vapor collection and processing system (VCPS). The VCPS includes all equipment such as ducts, valves, exhaust system, computer hardware, software, and catalytic oxidizers that manages the VOC and HAP emissions from generation until discharge to the atmosphere.

## EMISSIONS STANDARDS

1. Synthetic Minor Source of VOC and HAP Emissions. In order to maintain a synthetic minor classification under the PSD, Title V, and Title III permitting program, the owner or operator shall ensure that in any consecutive fifty-two (52) week period, the emissions from all sources, including fugitive emissions, within the combined facilities (i.e. 4011 & 4955) remain below the following threshold: 100 tons of VOC, 10 tons of any individual HAP, and 25 tons of total HAPs. Any future modification that requires increasing the VOC emissions limit to a level greater than 100 TPY would subject the facility to pre-construction review under the PSD permitting program.  
[Rule 62-4.070(3)&(5), F.A.C., Rule 62-210.200(194)(a)&(b), F.A.C., Rule 62-212.400, F.A.C. and Rule 62-212.500, F.A.C.]
2. Non-fugitive VOC Emissions from Sources using the VCPS (see note below).
  - (1) The efficiency of the catalytic oxidizers shall be 95 percent or higher.
  - (2) The amount of VOC solvents used in batch operations with exhaust emissions directed to the VCPS shall not exceed 1,800 tons during any rolling 52 week period.
  - (3) The collection efficiency of the VCPS shall be 100 percent (i.e. no leaks).  
[Rule 62-4.070(3) & (5), F.A.C.]

(*Permitting Note.* The 1,800 tons limit corresponds to 90 TPY non-fugitives emissions from the oxidizers (assuming 95 percent oxidizer efficiency). Exceedance of 90 TPY requires a permit revision to increase the frequency of record-keeping and facility-wide emissions calculations in order provide PPD with additional reasonable assurance of synthetic minor status)

## METHOD OF OPERATION

3. Modes of Operation. The modes of operation are Non-Solvent (aqueous) and Solvent (VOC). The VCPS shall be in the “Solvent” mode for batch processing so that VOC emissions generated during solvent spraying operations are directed to the oxidizer for processing (instead of directly to the atmosphere).  
[Rule 62-4.070(3) & (5), F.A.C.]

*(Permitting Note.* Mechanical or computer logic failure could cause the system to go into the oxidizer bypass mode (i.e. Non-Solvent mode) instead of Solvent mode during operations that generates VOC emissions.)

4. Operation during VCPS failure.

(1) *VCPS failure due to malfunction.* Excess emissions resulting from startup, shutdown or malfunction of any emissions unit shall be permitted providing:

- (a) The best operational practices plan (BOPP) to minimize emissions is adhered to; and
- (b) The duration of excess emissions shall be minimized but in no case exceed two hours in any 24 hour period unless specifically authorized by the PPD for longer duration.

(2) – (3) [Reserved]

(4) *VCPS failure not due to malfunction.* Excess emissions which are caused entirely or in part by poor maintenance, poor operation, or any other equipment or process failure which may reasonably be prevented during startup, shutdown, or malfunction shall be prohibited.

[Rules 62-210.700(1) and (4), F.A.C.]

*(Permitting Note.* Malfunction means any unavoidable mechanical and/or electrical failure of the VCPS or process equipment or of a process resulting in operation in an abnormal or unusual manner. Failures caused in part by poor maintenance or careless operations are not malfunctions. The owner or operator could use historical VCPS failure reports to demonstrate that the cause of failure was abnormal or unusual.)

*(Permitting Note.* See Best Operational Practices Plan (BOPP)

## TEST METHODS AND PROCEDURES

5. Annual Emissions Tests Required. The owner or operator shall conduct emissions testing annually on each VCPS to determine the collection system efficiency and the VOC destruction efficiency for each catalytic oxidizer from all facility operations. All repairs to the VCPS (including oxidizer functionality testing) shall be conducted prior to formal testing.  
[Rule 62-4.070(3) & (5) F.A.C., Rule 62-297.310(8) (a) 2., F.A.C. and Settlement Agreement - Cases No. 02-0023 and 02-0024]
6. Catalytic Oxidizer/VCPS tests shall be conducted in accordance with the appropriate USEPA Method(s) and Actavis’s Catalytic Oxidizer – Test Protocol submitted to the PPD (dated April 25, 2005). Tests shall be conducted under facility and equipment representative performance and maximum worst case operating conditions that will result in the lowest expected VOC destruction efficiency from each catalytic oxidizer  
[Rule 62-4.070(3) & (5) F.A.C., Rule 62-297.310(3), F.A.C. and Settlement Agreement - Cases No. 02-0023 and 02-0024]
7. EPA Test Method 25A shall be used to demonstrate the destruction efficiency of each catalytic oxidizer operating at both Actavis facilities indicated in this permit.  
[Rule 62-4.070(3) & (5) F.A.C., Rule 62-297.401(25), F.A.C. and Settlement Agreement - Cases No. 02-0023 and 02-0024]

## NOTIFICATION, RECORDKEEPING AND REPORTING REQUIREMENTS

8. Testing Notification. The owner or operator shall notify the PPD, at least 15 days prior to the date on which each VCPS/Catalytic Oxidizer(s) test is to begin, of the date, time, and place of each such test, and the test contact person who will be responsible for coordinating and having such test conducted for the owner or operator. The owner or operator shall also provide PPD with the test protocol at least 30 days prior to testing. [Rule 62-4.070(3) & (5) F.A.C. and Rule 62-297.310(7) (a) 9. F.A.C.]
9. Notification of VCPS Failure Due to Malfunction. In case of excess emissions resulting from malfunctions, the owner or operator shall immediately notify the PPD in accordance with Rule 62-4.130, F.A.C. which requires that the notification includes pertinent information as to the cause of the problem, and what steps are being taken to correct the problem and to prevent its recurrence. [Rule 62-210.700(6) F.A.C., Rule 62-4.130 F.A.C. and Rule 62-4.070(3) & (5) F.A.C.]  
(Permitting Note. Notification of VCPS and/or Catalytic Oxidizer failure not due to malfunction shall be in accordance with General Conditions No. 8 and 16.)
10. Emission Records. The owner or operator shall maintain records of: (1) weekly calculations of the VOC and HAP emissions (i.e. fugitives and non-fugitives) from all facility pharmaceutical manufacturing operations, and (2) calculations of the entire facility VOC and HAP emissions (in tons/year) for a rolling fifty-two (52) week period. The owner or operator shall use the VOC destruction efficiency obtained from the most recent VCPS performance testing to calculate non-fugitive emissions from the VCPS. [Rule 62-4.070(3) & (5), F.A.C.]
11. Emissions Recordkeeping. The owner or operator shall demonstrate compliance with permit Specific Condition No. 1 and 2 by maintaining records of the facility's JDE Enterprise Tracking System and Master Batch Records (or any other equivalent tracking and monitoring system), indicating the amount of raw material solvents dispensed and the %VOC and %HAP content of pharmaceutical manufacturing operations on a weekly basis for a 52-week rolling period. The owner or operation shall retain a copy of JDE Enterprise Tracking System records and Master Batch Records to demonstrate and compute emissions in accordance with Specific Conditions No. 12 and 13 for a period of (5) five years from the date on which such emissions information is submitted to the PPD for any regulatory purpose. [Rule 62-210.370(2) (h) F.A.C. and Rule 62-4.070(3) & (5), F.A.C.]
12. Emissions Computation.
  - (a) The owner or operator shall employ, on a pollutant-specific basis, the most accurate methodology to compute the emissions of a pollutant from an emissions unit. An owner or operator may use materials used in or at the emissions unit(s); and
  - (b) Assumes that the emissions unit(s) emits all of the pollutant that is contained in or created by any material used in or at the emissions unit if it cannot otherwise be accounted for in the process or in the capture and destruction of the pollutant by the unit's air pollution control equipment.

Where the vendor of a raw material which is used in or at the emissions unit(s) publishes a range of pollutant content from such material, the owner or operator shall use the highest value of the range to compute the emissions, unless the owner or operator demonstrates using site-specific data that another content within the range is more accurate. In the case of an emissions unit using coatings or solvents, the owner or operator shall document, through purchase receipts, records and sales receipts, the beginning and ending VOC and HAP inventories, the amount of VOC and HAP purchased during the computational period, and the amount of VOC and HAP disposed of in the liquid phase during such period. [Rule 62-210.370(2) (a) and (c), F.A.C. and Rule 62-4.070(3) & (5), F.A.C.]
13. Fugitive Emissions. In computing the emissions of a pollutant from a facility or emissions unit, the owner or operator shall account for the fugitive emissions of the pollutant, to the extent quantifiable, associated with such facility or emissions unit. [Rule 62-210.370(2) (g), F.A.C. and Rule 62-4.070(3) & (5), F.A.C.]

14. VCPS Records. The owner or operator shall maintain all records related to each VCPS including, but not limited to, operator training, periodic inspections, failures, maintenance and testing, in a form suitable for review by PPD for a period of 5 years. Records of verification check for operability shall be maintained for the life of the VCPS.  
[Rules 62-4.070(3) & (5), F.A.C.]
15. Emissions Reporting. The owner or operator shall retain a copy of all records used to compute emissions, including by not limited to, raw material solvent usage, JDE Enterprise Tracking System solvent and non-solvent dispensing/usage information, Master Batch Records, percent (%) VOC and percent (%)HAP quantities dispensed and emitted per manufacturing operations, and any other information relating to facility emissions and emissions calculations for a period of five (5) years. All records shall be made readily available to PPD personnel upon request.  
[Rule 62-210.370(2)(h), F.A.C., Rule 62-4.070(3) & (5), F.A.C.]
16. Test Reports. The owner or operator of an emissions unit for which a compliance test is required shall file a report with the PPD on the results of each such test. The required test report shall be filed to the PPD as soon as practical but no later than 45 days after the last sampling run of each test is completed. The test report shall provide sufficient detail on the emissions unit(s) tested and the test procedures used to allow the PPD to determine if the test was properly conducted and the test results properly computed. The report shall also contain results of supplementary system tests (e.g. the oxidizer's functionality reports to verify the operation modes (see "Modes of Operation" above)).

As a minimum, the test report shall provide the following information:

- a. The type, location, and designation of the emissions unit tested.
- b. The facility at which the emissions unit is located.
- c. The owner or operator of the emissions unit.
- d. The normal type and amount of fuels used and materials processed, and the types and amounts of fuels used and material processed during each test run.
- e. The means, raw data and computations used to determine the amount of fuels used and materials processed, if necessary to determine compliance with an applicable emission limiting standard.
- f. The type of air pollution control devices installed on the emissions unit, their general condition, their normal operating parameters and their operating parameters during each test run.
- g. A sketch of the duct within 8 stack diameters upstream and 2 stack diameters downstream of the sampling ports, including the distance to any upstream and downstream bends or other flow disturbances.
- h. The date, starting time and duration of each sampling run.
- i. The test procedures used, including any alternative procedures authorized pursuant to Rule 62-297.620, F.A.C. Where optional procedures are authorized in this chapter, indicate which option was used.
- j. The number of points sampled and configuration and location of the sampling plane.
- k. For each sampling point for each run, the dry gas meter reading, velocity head, pressure drop across the stack, temperatures, average meter temperatures and sample time per point.
- l. The type, manufacturer and configuration of the sampling equipment used.
- m. Data related to the required calibration of the test equipment.
- n. Data on the identification, processing and weights of all filters used.
- o. Data on the types and amounts of any chemical solutions used.
- p. Data on the amount of pollutant collected from each sampling probe, the filters, and the impingers, are reported separately for the compliance test.
- q. The names of individuals who furnished the process variable data, conducted the test, analyzed the samples and prepared the report.
- r. All measured and calculated data required to be determined by each applicable test procedure for each run.

- s. The detailed calculations for one run that relate the collected data to the calculated emission rate.
- t. The applicable emission standard, and the resulting maximum allowable emission rate for the emissions unit, plus the test result in the same form and unit of measure.
- u. A certification that, to the knowledge of the owner or his authorized agent, all data submitted are true and correct. When a compliance test is conducted for the PPD or its agent, the person who conducts the test shall provide the certification with respect to the test procedures used. The owner or his authorized agent shall certify that all data required and provided to the person conducting the test are true and correct to his knowledge.

[Rule 62-4.070(3) & (5), F.A.C., Rule 62-297-310(10), F.A.C. and Settlement Agreement - Cases No. 02-0023 and 02-0024]

17. **VCPS Failure Report.** The owner or operator shall submit an incident report on each VCPS failure within fifteen (15) days of the event. The report shall include pertinent information as to the cause of the failure, steps taken to correct the problem and to prevent a reoccurrence, and an estimate of the excess VOC emissions due to the VCPS failure along with the total facility wide VOC emissions for the previous 52 weeks.

[Rule 62-4.070(3) & (5), F.A.C.]

**Actavis Laboratories FL, Inc. – Florida  
Revised Equipment List\***

\*This list represents permanent, fixed pieces of equipment only.

Unit Number	Description	Equipment Location	Equipment Added in the past 5 yrs.
P-001/1	FLUID BED/GLATT	4955	
P-105	FLUID BED/GLATT	4955	
P-106	FLUID BED/GLATT	4955	
P-107	FLUID BED/GLATT	4955	
P-108	FLUID BED/GLATT	4955	
P-1232	FLUID BED/GLATT	4955	X
P-385	FLUID BED/GLATT	4955	
P-386	FLUID BED/GLATT	4955	
P-387	FLUID BED/GLATT	4955	
P-667	FLUID BED/GLATT	4955	X
P-668	FLUID BED/GLATT	4955	X
F-164	FLUID BED/GLATT	4955	
F-165	FLUID BED/GLATT	4955	
GPCG-30	FLUID BED/GLATT	4955	
RD-003	FLUID BED/GLATT	Not Specified	
M-149	OXIDIZER #1	4955	
M-461	OXIDIZER #2	4955	
M-827	OXIDIZER #3	4955	X
P-1114	GRANULATOR/GR AL	4955	
P-280	GRANULATOR/GR AL	4955	X
P-2955	GRANULATOR/GR AL	Not Specified	X
P-607	GRANULATOR/GR AL	4955	
F-191	PAN COATER	4955	
P-1320	PAN COATER	4955	X
P-188	PAN COATER	Not Specified	
P-388	PAN COATER	4955	
P-389	PAN COATER	4955	
P-390	PAN COATER	4955	
P-391	PAN COATER	4955	
P-592	PAN COATER	4955	
P-672	PAN COATER	4955	X
P-673	PAN COATER	4955	X

9-890	PAN COATER	4955	X
P-981	PAN COATER	4955	X
P-982	PAN COATER	4955	X
P-983	PAN COATER	4955	X
P-984	PAN COATER	4955	
P-985	PAN COATER	4955	
P-993	PAN COATER	4955	
RD-016	PAN COATER	4011	
P-003/2	ENCAPSULATOR	Not Specified	
P-068	ENCAPSULATOR	Not Specified	
P-1522	ENCAPSULATOR	Not Specified	X
P-212	ENCAPSULATOR	Not Specified	
P-240	ENCAPSULATOR	Not Specified	X
P-963	ENCAPSULATOR	Not Specified	
RD-098	ENCAPSULATOR	Not Specified	X
F-207	DRYING OVEN	4955	
F-208	DRYING OVEN	4955	
F-219	DRYING OVEN	4955	
F-220	DRYING OVEN	4955	
P-004/3	DRYING OVEN	Not Specified	
P-004/5	DRYING OVEN	Not Specified	
P-1117	DRYING OVEN	4955	X
P-1118	DRYING OVEN	4955	X
P-1119	DRYING OVEN	4955	X
P-1321	DRYING OVEN	Not Specified	X
P-1322	DRYING OVEN	Not Specified	X
P-1323	DRYING OVEN	Not Specified	X
P-202	DRYING OVEN	Not Specified	
P-203	DRYING OVEN	Not Specified	
P-204	DRYING OVEN	Not Specified	
P-205	DRYING OVEN	Not Specified	
RD-043	DRYING OVEN	Not Specified	X
F-295	TABLET PRESS	Not Specified	X
F-352	TABLET PRESS	Not Specified	X
P-053	TABLET PRESS	Not Specified	
P-1092	TABLET PRESS	Not Specified	
P-1129	TABLET PRESS	Not Specified	
P-1253	TABLET PRESS	Not Specified	X
P-222	TABLET PRESS	Not Specified	
P-828	TABLET PRESS	Not Specified	
P-846	TABLET PRESS	Not Specified	X



RD-001	TABLET PRESS	Not Specified	X
RD-012	TABLET PRESS	Not Specified	X
RD-100	TABLET PRESS	Not Specified	X
RD-102	TABLET PRESS	Not Specified	X
RD-119	TABLET PRESS	Not Specified	X
WP0007	TABLET PRESS	Not Specified	
P-221	TABLET PRESS	Not Specified	
P-002/1	BLENDER	Not Specified	X
P-122	BLENDER	Not Specified	X
P-123	BLENDER	Not Specified	X
P-156	BLENDER	Not Specified	
P-189	BLENDER	Not Specified	X
P-338	BLENDER	Not Specified	
P-986	BLENDER	Not Specified	X
P-987	BLENDER	Not Specified	X
M-3714	CENTRAL VACUUM SYSTEM	Not Specified	
M-542	CENTRAL VACUUM SYSTEM	Not Specified	X
M-543	CENTRAL VACUUM SYSTEM	Not Specified	X
P-1227	CENTRAL VACUUM SYSTEM	Not Specified	
M-170	GENERATOR	Not Specified	
M-171	GENERATOR	Not Specified	
M-172	GENERATOR	Not Specified	
M-211	GENERATOR	Not Specified	
M-3552	GENERATOR	Not Specified	
M-296	PROCESS BOILER	Not Specified	
M-297	PROCESS BOILER	Not Specified	
M-987	PROCESS BOILER	Not Specified	

**Equipment Permanently Removed**  
(Subsequent to issuance of Permit 0112197-013-AF)

Unit Number	Description
P-113	FLUID BED/GLATT
F-172	PAN COATER
P-226	TABLET PRESS
P-004/6	DRYING OVEN
P-055	BLENDER
M-107	CENTRAL VACUUM SYSTEM

## Best Operational Practices Plan

### PURPOSE:

The purpose of this Best Operational Practices Plan (BOPP) is to minimize emissions during a Vapor Collection & Processing System (VCPS) (oxidizer) malfunction or interruption.

### PROCEDURES:

1. At the time of the oxidizer failure due to a malfunction, dampers for exhaust process air will be redirected to allow the exhaust to discharge directly to atmosphere.
  - 1.1. An alarm will be displayed on the HMI
  - 1.2. An alarm will be displayed on the Building Maintenance System
  - 1.3. Production personnel will contact the maintenance department
  - 1.4. Watson will immediately begin to rectify the oxidizer failure.
2. < 2 Hour - If it appears that the maintenance will have the malfunction diagnosed and repaired in less than 2 hours of the failure:
  - 2.1. Maintenance fix problem
  - 2.2. Once fixed, redirect dampers for exhaust to back through the oxidizer
  - 2.3. Production will fill out attached form and submit to EHS Manager within 24 hours
3. > 2 Hour - If it appears that the malfunction cannot be rectified within 2 hours, the following will occur:
  - 3.1. The maintenance mechanic diagnosing the situation will notify his supervisor.
    - 3.1.1. If the supervisor is unavailable, the maintenance mechanic shall continue to call the chain of command until someone is notified.
  - 3.2. Supervisor or above will notify:  
Broward County PPD at 954-519-1220, Monday – Friday 8:00 am – 4:00 pm.  
If unable to contact someone at this number or non-compliance is first determined after normal business hours or on weekends and holidays, the following number must be used 954-519-1499.
    - 3.2.1. Notification shall also be made PPDHOTLINE@broward.org with a copy to the EHS Manager
    - 3.2.2. Information for notification must include:
      - 3.2.2.1. Name of facility
      - 3.2.2.2. Location of facility
      - 3.2.2.3. Air permit number 0112197-012-AO
      - 3.2.2.4. General condition – 15: Reporting of Non-compliance, which states: The Permittee shall report any periods of noncompliance to the PPD immediately.
      - 3.2.2.5. expected duration of non-compliance
  - 3.3. After the failure has been corrected and operation of the oxidizer has been restored, Actavis will redirect the exhaust stream back to the oxidizer.
  - 3.4. The attached form will be provided to the EHS Manager within 24 hours of the oxidizer failure/interruption
4. No new batch processing requiring solvent spraying shall be initiated if the oxidizer is not operational.
5. EHS manager will provide a written report to PPD within 14 days of malfunction/interruption as describing the event and corrective actions.

