**FLORIDA DEPARTMENT OF ENVIRONMENTAL PROTECTION**
Southwest District Office
13051 North Telecom Parkway
Temple Terrace, Florida 33637-0926

RICK SCOTT
GOVERNOR

HERSCHEL T. VINYARD JR.
SECRETARY

# FINAL PERMIT

**PERMITTEE**

West Pharmaceutical Services of Florida, Inc.
11600 53rd Street North
Clearwater, Florida 33760

Authorized Representative:
Mr. Andy Phillips, Director of Operations

Air Permit No. 1030150-017-AO
Permit Expires: xx/xx/xxxx
West Pharmaceutical Services - Clearwater
Minor Air Operation Permit
Operation Permit Renewal

This is the final permit to renew Air Operation Permit No. 1030150-017-AO for a medical vial closures manufacturing facility at the Clearwater location of West Pharmaceutical Services of Florida, Inc. (Standard Industrial Classification No. 3466) located in Pinellas County at 11600 53rd Street North in Clearwater, Florida. The UTM coordinates are Zone 17, 332.14 km East, and 3084.86 km North.

This final permit is organized by the following sections:

Section 1. General Information

Section 2. Administrative Requirements and Facility-wide Specific Conditions

Section 3. Emissions Unit Specific Conditions

Section 4. Appendices

Due to the technical nature of the project, the permit contains numerous acronyms and abbreviations, which are defined in Appendix A of Section 4 of this permit.

This air pollution permit is issued under the provisions of: Chapter 403 of the Florida Statutes (F.S.) and Chapters 62-4, 62-204, 62-210, 62-212, 62-296 and 62-297 of the Florida Administrative Code (F.A.C.). The permittee is authorized to conduct the proposed work in accordance with the conditions of this permit.

A person whose substantial interests are affected by the proposed permitting decision may petition for an administrative proceeding (hearing) under sections 120.569 and 120.57 of the Florida Statutes. The petition must contain the information set forth below and must be filed (received) in the Office of General Counsel of the Department at 3900 Commonwealth Boulevard, Mail Station #35, Tallahassee, Florida 32399-3000. Petitions filed by the permit applicant or any of the parties listed below must be filed within fourteen days of receipt of this notice of final permit. Petitions filed by any persons other than those entitled to written notice under section 120.60(3) of the Florida Statutes must be filed within fourteen days of publication of the public notice or within fourteen days of receipt of this notice of final permit, whichever occurs first. Under section 120.60(3), however, any person who asked the Department for notice of agency action may file a petition within fourteen days of receipt of that notice, regardless of the date of publication. A petitioner shall 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 of the Florida Administrative Code.

All petitions filed under these rules shall contain:

(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 determination;
(c) A statement of when and how the petitioner received notice of the agency decision;
(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, including the specific facts the petitioner contends warrant reversal or modification of the agency's proposed action;
(f) A statement of the specific rules or statutes the petitioner contends require reversal or modification of the agency's proposed action, including an explanation of how the alleged facts relate to the specific rules or statutes; 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 Department'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 of the Florida Administrative Code.

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 Department on the application have the right to petition to become a party to the proceeding, in accordance with the requirements set forth above.

Mediation is not available in this proceeding.

Any party to this order has the right to seek judicial review of it under section 120.68 of the Florida Statutes, by filing a notice of appeal under rule 9.110 of the Florida Rules of Appellate Procedure with the clerk of the Department of Environmental Protection in the Office of General Counsel, 3900 Commonwealth Boulevard, Mail Station #35, Tallahassee, Florida 32399-3000, and by filing a copy of the notice of appeal accompanied by the applicable filing fees with the appropriate district court of appeal. The notice must be filed within thirty days after this order is filed with the clerk of the Department.

Executed in Hillsborough County, Florida

_____ _____

Kelley M. Boatwright — Effective Date
District Air Program Administrator
Southwest District

## CERTIFICATE OF SERVICE

The undersigned duly designated deputy agency clerk hereby certifies that this Final Air Permit package (the Final Permit and the Appendices) 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 persons listed below.

Andy Phillips, West Pharmaceutical Services, Inc. (Andy.Phillips@WestPharma.com)

Gary Robbins, Pinellas County Air Quality Division (grobbins@pinellascounty.org)

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)

## FACILITY AND PROJECT DESCRIPTION

### Existing Facility

This facility is an existing medical vial manufacturing plant that uses miscellaneous volatile organic compounds/organic solvents (VOC/OS), hazardous air pollutants (HAPs), and lubricants. The maximum allowable VOC emissions and HAP-containing material usage limitations in the permit enable this facility to be considered as a synthetic non-Title V facility. Isopropyl alcohol (IPA), West Blend (99.75% IPA), and Lubex (95% aliphatic hydrocarbons) are used as lubricants in the cutting, drawing, and assembly of rubber and aluminum components. These components are assembled for use as closures for pharmaceutical containers. Current equipment utilized at the facility is as follows (Note: This equipment list is for information only and is not intended to be a limit of this permit):

10 Rubber and metal lining machines (use IPA)
16 Punch presses (12 use Lubex, 3 uses West Blend or Lubex, and 1 uses IPA)
1 Ink station (used to mix ink, BH Hardener and VD Thinner)
4 Automated pad printers (use ink, BH Hardener and VD Thinner)
1 5 gallon equipment parts cleaning tank (uses Dibasic Ester)
13 Flip-Off assembly machines
2 Packaging machines

The 5-gallon equipment parts cleaning tank is subject to the VOC reasonable available control technology (RACT) requirements of Rule 62-296.511, F.A.C.

IPA and West Blend fumes are collected and discharged outside through a series of ductwork. There are also fugitive emissions of IPA and West Blend.

Emissions from using Lubex in the punch presses are fugitive emissions. These emissions are not collected by the duct system and enter the outdoors via general building ventilation.

Emissions from the 5-gallon equipment parts cleaning tank are also fugitive emissions.

The facility has the following pieces of equipment that exhaust air into the atmosphere. The facility is not taking any emission reduction credit from any piece of equipment that may reduce potential emissions.

- A Press Blower with a design airflow rate of 1.020 cubic feet per minute (cfm) from a stack 27 feet high.
- An Assembly Blower with a design airflow rate of 1,020 cfm from a stack 26 feet high.
- A West Production Blower and inline Trion Air Boss T1001 Electronic Air Cleaner (or equivalent) with a design airflow rate of 688 cfm from a stack 26 feet high. The Production Blower pulls air through the Trion Air Boss T1001 Electronic Air Cleaner (or equivalent) received from hot air blowers that are used to dry parts coated with Lubex.
- Clean room exhaust system, consisting of an exhaust fan located on the roof with a design airflow rate of 2,000 cfm from a stack 35 feet high.

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

| Facility ID No. 1030150 | |
|---|---|
| **EU ID No.** | **Emissions Unit Description** |
| 002 | Medical Vial Closure Manufacturing Line |

**Exempt Emission Sources/Activities**

- Natural gas usage of approximately 500 cubic feet per month to dry the parts associated with the West Production Blower and inline Trion Air Boss T1001 Electronic Air Cleaner (or equivalent). [Rule 62-210.300(3)(b)1., F.A.C.]

**FACILITY REGULATORY CLASSIFICATION**

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

– The facility has no 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.

– The facility is not a major stationary source in accordance with Rule 62-212.400(PSD), F.A.C.

– This facility is a synthetic non-Title V source for volatile organic compounds (VOC) and hazardous air pollutants (HAP). The emission limitations, restriction on hours of operation, restriction on the type or amount of material combusted, stored or processed in this permit will ensure that the facility's VOC and HAP emissions will be below the threshold for a Title V source.

**PERMIT HISTORY/AFFECTED PERMITS**

This operation permit renewal modifies and replaces Air Operation Permit No. 1030150-015-AO.

## ADMINISTRATIVE REQUIREMENTS

**1.** Permitting Authority - The permitting authority for this project is the Florida Department of Environmental Protection (Department), Southwest District Office's Air Permitting Program. The mailing address and phone number is:

Florida Department of Environmental Protection
Southwest District Office
Air Permitting Program
13051 North Telecom Parkway
Temple Terrace, Florida 33637-0926
Telephone: 813-470-5700

All documents related to applications for permits shall be submitted to the above address.

**2.** Compliance Authority - All documents related to compliance activities such as reports, tests, and notifications shall be submitted to the Pinellas County Air Quality Division. The mailing address and phone number of the Local Air Program is:

Pinellas County Air Quality Division
509 East Avenue South, Suite 138
Clearwater, Florida 33756
Telephone: 727-464-4422

**3.** Appendices - The following Appendices are attached as part of this permit:

a. Appendix A. Citation Formats and Glossary of Common Terms;

b. Appendix B. General Conditions;

c. Appendix C. Common Conditions; and

d. Appendix D. Common Testing Requirements.

**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 - Unless otherwise exempt by rule, the permittee shall not initiate any construction, reconstruction, or modification at the facility and shall not install/modify any pollution control device at the facility without obtaining prior authorization from the Department. Modification is defined as: Any physical change or changes in the method of operations or addition to a facility that would result in an increase in the actual emissions of any air pollutant subject to air regulations, including any not previously emitted, from any emission unit or facility.

[Rules 62-210.200 - Definition of "Modification" and 62-210.300(1)(a), F.A.C.]

**7.** Annual Operating Report - On or before **April 1** of each year, the permittee shall submit a completed DEP Form 62-210.900(5), "Annual Operating Report for Air Pollutant Emitting Facility" (AOR) for the preceding calendar year. The report may be submitted electronically in accordance with the instructions received with the AOR package sent by the Department, or a hardcopy may be sent to the Compliance Authority.
[Rule 62-210.370(3), F.A.C.]

**8.** Operation Permit Renewal Application - A completed application for renewal of the operation permit shall be submitted to the Permitting Authority with a copy to the Pinellas County Air Quality Division no later than 60 days prior to the expiration date of this operation permit. To properly apply for an operation permit, the applicant shall submit the following:

a. the appropriate permit application form *(see current version of Rule 62-210.900, F.A.C. (Forms and Instructions), and/or FDEP Division of Air Resource Management website at: http://www.dep.state.fl.us/air/)*;

b. the appropriate operation permit application fee from Rule 62-4.050(4)(a), F.A.C.;

c. copies of the most recent month of records/logs specified in Specific Condition No. A.10.

[Rules 62-4.030, 62-4.050, 62-4.070(3), 62-4.090, 62-210.300(2), and 62-210.900, F.A.C.]

## FACILITY-WIDE SPECIFIC CONDITIONS

**9**. Objectionable Odor - The permittee shall not cause, suffer, allow, or permit the discharge of air pollutants from this plant which cause or contribute to an objectionable odor. Objectionable odor is defined as 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.
[Rules 62-296.320(2) and 62-210.200, Definitions - Objectionable Odor, F.A.C.; Pinellas County Code, Section 58-178]

## B. EU No. 002- Medical Vial Closure Manufacturing Line

This section of the permit addresses the following emissions unit (EU).

| EU ID No. | Emissions Unit Description |
|---|---|
| 002 | Medical Vial Closure Manufacturing Line – The medical vial closure manufacturing line uses miscellaneous volatile organic compounds/organic solvents (VOC/OS), hazardous air pollutants (HAPs), and lubricants. Isopropyl alcohol (IPA), West Blend (99.75%), and Lubex (95% aliphatic hydrocarbons) are used as lubricants in the cutting, drawing, and assemble of rubber and aluminum components. These components are assembled for use as closures for pharmaceutical containers.<br><br>VOC emissions from this facility shall not exceed 78.0 tons per any consecutive 12-month period.<br><br>The only hazardous air pollutants (HAPs) that are used at this facility are xylenes and toluene diisocyanate, which are only contained in the VD Thinner and BH Hardner used in the ink station and printing processes. The combined maximum usage of VD Thinner, BH hardener and other insignificant sources (ink, Tekusolv, and Dibasic Ester) shall not exceed five (5) tons per any consecutive 12-month period. |

### PERFORMANCE RESTRICTIONS

**A.1.** Operating Hours - The hours of operation at this facility are not limited (i.e., 8,760 hours per year).
[Rules 62-4.070(3) and 62-210.200 (definition of Potential to Emit), F.A.C.]

**A.2.** Volatile Organic Compound (VOC) Emissions - VOC emissions from this facility shall not exceed 78.0 tons per any consecutive 12-month period.
[Rule 62-4.070(3), F.A.C.; Construction Permit 1030150-013-AC]

**A.3.** Hazardous Air Pollutant (HAP) Usage - The only hazardous air pollutants (HAPs) that are used at this facility are xylenes and toluene diisocyanate, which are only contained in the VD Thinner and BH Hardner used in the ink station and printing processes. The VD Thinner contains approximately 4% of xylenes. The BH Hardner contains approximately 16% of xylenes and 0.5% of toluene diisocyanate. No other HAP-containing material shall be used. The combined maximum usage of VD Thinner, BH hardener and other insignificant sources (ink, Tekusolv, and Dibasic Ester) shall not exceed five (5) tons per any consecutive 12-month period.
[Rule 62-210.200 (definition of Potential to Emit), F.A.C.; Construction Permit 1030150-013-AC]

### EMISSIONS STANDARDS

**A.4.** Solvent Metal Cleaning - The 5-gallon equipment parts cleaning tank shall comply with the applicable VOC RACT requirements of Rule 62-296.511, F.A.C. - Solvent Metal Cleaning:

a. Equip the cleaner with a cover. The cover shall be so designed that it can be easily operated with one hand if:

1. The solvent volatility is greater than 0.3 pounds per square inch (15 millimeters of mercury or 2 kilopascals) measured at 100 degrees Fahrenheit (38 degrees Celsius);

2. The solvent is agitated;
3. The solvent is heated.

b. Equip the cleaner with a facility for draining cleaned parts. The drainage facility shall be constructed internally so that parts are enclosed under the cover while draining if the solvent volatility is greater than 0.6 pounds per square inch (31 millimeters of mercury or 4.1 kilopascals) measured at 100 degrees Fahrenheit (38 degrees Celsius), except that the drainage facility may be external for the applications where an internal type cannot fit into the cleaning system.

c. Install one of the following control devices if the solvent volatility is greater than 0.6 pounds per square inch (31 millimeters of mercury or 4.1 kilopascals) measured at 100 degrees Fahrenheit (38 degrees Celsius), or if the solvent is heated above 120 degrees Fahrenheit (50 degrees Celsius):

1. Freeboard that gives a freeboard ratio greater than or equal to 0.7; or,
2. Water cover (solvent must be insoluble in and heavier than water); or,
3. Other systems of equivalent control such as refrigerated chiller or carbon absorption.

d. Provide a permanent, conspicuous label summarizing the operating requirements.

e. Store waste solvent only in covered containers and not dispose of waste solvent or transfer it to another party, such that greater than 20 percent of the waste solvent (by weight) can evaporate into the atmosphere.

f. Close the cover whenever parts are not being handled in the cleaner.

g. Drain the cleaned parts for at least 15 seconds or until dripping ceases.

h. If used, supply a solvent spray that is a solid fluid stream (not a fine, atomized, or shower-type spray) at a pressure which does not cause excessive splashing.

[Rule 62-296.511(2), F.A.C]

**A.5.** Exhaust Gas - Regarding the three (3) blowers and the clean room's exhaust system, there shall be no device which reduces the momentum of the exhaust gas or reduces the dispersion of the exhaust gas.
[Rule 62-4.070(3), F.A.C.; Construction Permit No. 1030150-013-AC]

**A.6.** Equipment Relocation - The equipment described in the facility description of these permits may be relocated in accordance with the following:

a. Within 15 days of relocating the equipment, the permittee shall provide detailed drawings of the facility.

b. The drawings shall clearly identify the equipment that is relocated and the date(s) of relocation.

c. These drawings shall be maintained on file at the facility for at least 3 years. The drawing showing the most current equipment location shall always be on file at the facility.

[Rules 62-4.070(3), F.A.C.; Construction Permit No. 1030150-013-AC]

**A.7.** VOC or Organic Solvents (OS) Emissions - All equipment, pipes, hoses, lids, fittings, etc., shall be operated/maintained in such a manner as to minimize leaks, fugitive emissions and spills of solvent materials.
[Rule 62-296.320(1), F.A.C.]

**A.8.** Emissions Calculations - When calculating emissions, the permittee shall not take any emission reduction credit from any piece of equipment that may reduce potential emissions.
[Rule 62-4.070(3), F.A.C.; Construction Permit No. 1030150-013-AC]

**RECORDKEEPING REQUIREMENTS**

**A.9.** Daily Log for VOC Emissions - The permittee shall comply with the daily recordkeeping requirements of Rule 62-296.500(2)(b), F.A.C. for the 5-gallon equipment parts cleaning tank. The records shall be maintained on file at the facility and include at least the following:

a. Facility name, facility ID, and emission unit number (i.e., 1030150, EU 002 - Medical Vial Closure Manufacturing Line).

b. Date.

c. The rule number applicable to the operation for which the records are being maintained (i.e., Rule 62-296.511, F.A.C.).

d. The application method (e.g., cold cleaning, conveyorized, etc.) and substrate type (e.g., metal).

e. The amount and type of solvent used including surface preparation, clean-up, wash-up of solvent and including exempt compounds.

f. The VOC content of each solvent used.

The daily logs shall be completed within three (3) business days. The facility shall also maintain documentation, such as all MSD sheets, purchase orders, etc., for all solvents used, which includes sufficient information to determine VOC emissions. All of the above records shall be made available to the Department and the Pinellas County Department of Environmental Management (PCDEM) upon request.

[Rule 62-296.500(2)(b), F.A.C.; ; Construction Permit No. 1030150-013-AC]

**A.10.** Monthly Log for VOC Emissions - A monthly VOC emission and material usage log shall be kept on file at the facility to document compliance with the limitations of Specific Condition Nos. A.2. and A.3. At a minimum, the log shall indicate the following:

a. Facility name, facility ID, and emission unit number (i.e., 1030150, EU 002 - Medical Vial Closure Manufacturing Line).

b. Month and Year.

c. The amount of each VOC- and/or HAP-containing material (by identification number and name) used in gallons/month.

d. VOC emissions from each material identified in c. in tons.

e. The monthly total of VOC emissions in tons.

f. The current consecutive 12-month total of VOCs, in tons.

g. The current consecutive 12-month usage total of VD Thinner, BH hardener, ink, Tekusolv and Dibasic Ester, in tons.

h. Documentation of each solvent reclaimed, if any reduction in usage is to be claimed, which is determined by a mass balance method (amount used minus amount collected for disposal or recycle).

The monthly logs shall be completed by the 15th of the following month. Supporting documentation (MSDS sheets, purchase order, etc.) shall be kept for each material which includes sufficient information to determine VOC emissions. The log and associated records shall be made available to the Department and PCDEM upon request.
[Rule 62-4.070(3), F.A.C. and Pinellas County Code, Section 58-90; Construction Permit No. 1030150-013-AC]

**A.11.** Records Retention - All records required by this permit shall be maintained at the facility for a minimum of the most recent three (3) year period and be made available to the Department and PCDEM upon request.
[Rules 62-4.070(3) and 62-4.160(14)(b), F.A.C.]