|  |
| --- |
| 1030150 75634 |
|  **FACILITY:** **West Pharmaceutical Services of Florida, Inc.** |  **PERMIT ID: 215** |
|  **West Pharmaceutical Services, Clearwater** |  **DISTRICT:** Southwest |
|  **ADDRESS:** 11600 53rd Street North | **CONTACT PHONE:**  |
|  Clearwater, FL | 727-572-6183 |
|  **ARMS NO:****1030150 002** | **PERMIT NO:** | **Expiration Date:** 8/26/13**Renewal Date:** 6/27/13 |
|  | **1030150-014-AO & 1030150-013-AC** |  |
|  |  | **Test Due Date:**  |
| **EMISSION UNIT DESCRIPTION :** **9 Rubber & aluminum lining machines, 18 Punch presses (14 use Lubex, 3 use West Blend or Lubex, and 1 uses IPA), 1 Ink station, 4 Automated pad printers, 1-5 gallon cleaning tank, and 1-75 gallon Safety Clean parts washer; 3 flip-off Assembly Machines** |
| **CMS INSPECTION DATE:** | **ARMS INSPECTION TYPE:** | **COMPLIANCE STATUS:** |
|  |
|  | **June 22, 2011** |  |  | INS**1** | **✓** | **INS2** |  | INS**3** |  | FUI | **✓** | **IN** |  | MNC |  | SNC |
|  |
|  |
| **INSPECTION TYPE:** | **✓** | **Initial** |  | Re-inspection |  | Complaint |  | Drive-by |  | Quarterly |
|  |
| **✓** | **A. General Review:** |
| **1.** | Permit File Review | *[x]*  | Yes | *[ ]*  | No |
|  | ***C****omments:*  |  |  |  |  |
| **2.** | Introduction and Entry | *[x]*  | Yes | *[ ]*  | No |
|  | ***C****omments: I was greeted by Glen York and Sharon Deck. Mr. York and Ms. Deck answered all of my questions, provided the material usage and emission logs and escorted me in the tour of the production areas.* |  |  |  |  |
| **3.** | **Is the Responsible Official/Authorized Representative still: Fred McCleery?** | *[x]*  | Yes | *[ ]*  | No |
|  | ***C****omments:* **The Responsible Official/Authorized Representative’s e-mail is:**  |
| **4.** | **Is the facility contact still:** Glenn York**?** | *[x]*  | Yes | *[ ]*  | No |
|  | ***C****omments:* **The facility contact’s e-mail is: glenn.york@westpharma.com**  |

| **IN** | **MNC** | **SNC** | **B. Specific Conditions:**  |
| --- | --- | --- | --- |
| **✓****✓****✓****✓****✓****✓****✓****✓****✓****✓****✓****✓****✓****✓** |  |  | *Inspection note: there were two permits issued simultaneously (1030150-013-AC & 1030150-014-AO). The construction permit expires on 12/31/09. The construction permit was for:* *1. Expand the facility by approximately 45,000 square feet, which will include office space, warehousing, additional shipping space, a clean area, a tool room, a grinding room, and an area for a new exempt 150 horsepower steam boiler having a maximum design heat input rate of 6.124 MMBTU/hr.*  *2. Add a piece of equipment identified as an Industrial Washing Equipment – ICOS LT-240 that uses water.* *3. Add two (2) new pieces of equipment identified as Flip-Off Assembly Machine (HTS-256) and Rubber Lining Assembly Machine – RLR-505 to be located in the new clean room.* *4. Re-locate to the new clean room the two (2) existing Flip-Off Assembly Machines (HTS-210, HTS-237), Roll Grove Machine RGR-401, Specialized Automated Packing – PKG-850, and Rubber Assembly Machines – RLR-502, RLR-503, RLR-504, RLR-520, RLR-525, and RLR-530.* *5. Install a new exhaust system for alcohol fumes in the new clean room. The system will include two (2) exhaust fans located on the roof and each fan is rated at 7,000 cubic feet minute. The fans will exhaust to the atmosphere through a common stack.* *6. Install a new Trion Air boss T1001 Electronic Air Cleaner (or equivalent) rated at a maximum usage of 500 cubic feet of natural gas per month, which will be ducted in-line with the existing West Production Blower’s ductwork.* *7. Establish the facility’s exempt grinding activities include 5 dry grinders and 3 wet grinders that are controlled by 2 baghouses that vent inside the chiller room. The chiller room’s air is then exhausted by a roof mounted fan rated at 3,000 acfm.* *8. Establish the facility is not taking any emission reduction credit from any piece of equipment that may reduce potential emissions.****Comments****:* *The plans for the 45,000 square foot expansion for additional warehouse and office space have been scrapped, per Mr. York. The addition of a tool room, a grinding room and a new 150 horsepower steam boiler have also been scrapped. However, the new clean room will be constructed in the existing production area.* *2. The Industrial Washing Equipment – ICOS LT-240 will not be purchased.* *3. The two (2) new pieces of equipment identified as Flip-Off Assembly Machine (HTS-256) and Rubber Lining Assembly Machine – RLR-505 to be located in the new clean room are pending approval of the respective Capital Requests.* *4. Re-location to the new clean room of the two (2) existing Flip-Off Assembly Machines (HTS-255, and HTS-237) is in progress. Roll Grove Machine RGR-401 has been removed from the premises. Specialized Automated Packing – PKG-850 is there. Rubber Assembly Machines – RLR-502, RLR-503, RLR-504, RLR-520, RLR-525, and RLR-530 have also been removed from the premises.* *5. Install a new exhaust system for alcohol fumes in the new clean room. The system will include two (2) exhaust fans located on the roof and each fan is rated at 7,000 cubic feet minute. The fans will exhaust to the atmosphere through a common stack. This new exhaust system for the new Clean Room is still planned.* *6. The new Trion Air boss T1001 Electronic Air Cleaner rated at a maximum usage of 500 cubic feet of natural gas per month, ducted in-line with the existing West Production Blower’s ductwork has been installed.* *7. Establish the facility’s exempt grinding activities include 5 dry grinders and 3 wet grinders that are controlled by 2 baghouses that vent inside the chiller room. The chiller room’s air is then exhausted by a roof mounted fan rated at 3,000 acfm.* *8. Establish the facility is not taking any emission reduction credit from any piece of equipment that may reduce potential emissions.* This permit or a copy thereof shall be kept at the work site of the permitted activity. [62-4.160 F.A.C. - General Condition 12.]***Comments****: The facility [x]  did have a copy of the permit on-site.*4. The total maximum allowable VOC emissions from this facility shall not exceed 78.0 tons per any consecutive 12-month period. [Construction Permit 1030150-009-AC]***Comments****: The running cumulative 12 month total VOC emissions at the end of the month of April 2011 was 50.93 tons.*5. 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, F.A.C., Definitions – Potential to Emit; Construction Permit 1030150-009-AC]***Comments****: The combined running cumulative total usage of BH Hardner and VD Thinner was 0.0105 tons at the end of the month of May 2011.*6. The 5-gal. 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]***Comments****: The parts washer now uses an aqueous solution with no VOCs or HAPS. The parts cleaner and the parts washer can be operated with one hand. The parts are drained on an internal rack while the lid is closed. The solvent throughput is in a closed loop and not exposed while being handled.* 7. 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.]***Comments****: There were no devices that appeared to reduce the momentum of the exhaust gases.*8. 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 revise the diagram dated May 23, 2008 (revised June 30, 2008), attached to the permittee’s letter June 30, 2008. B. Revised drawings shall clearly identify the equipment that is relocated and the date(s) of relocation. C. Revised 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) and 62-4.160(14)(b), F.A.C.]***Comments****: The most recent layout of the plant equipment, as of 10/19/2010, is attached.* 9. 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.]10. 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]***Comments****: There were no leaks, spills or fugitive emissions. There were no odors inside or outside the plant that could be associated with the plant operations.*11. 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. [Rule 62-210.700(4), F.A.C.]***Comments****: There were no excess emissions per Mr. York.*12. 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.]***Comments****: The entire VOC content in the materials is reported as VOC emissions. No credits or reductions are taken when recording emissions.*13. The permittee shall comply with the daily recordkeeping requirements of Rule 62-296.500(2)(b), F.A.C. for the 5-gal. 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.]14. 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. 4 and 5. 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]***Comments****: The facility was in compliance with A. through E. above for condition No. 13 and with A. through F for condition No. 14. (see example copy of records, attached).* 15. The records required by Specific Condition Nos. 13 and 14 shall be maintained for a minimum of the most recent three (3) year period and made available to the Department and PCDEM upon request. [Rules 62-4.070(3) and 62-4.160(14)(b), F.A.C.]***Comments****: I saw electronic files that contain spreadsheets (VOC Records) going back to the year 2000.*16. Submit to the Air Compliance Section of the Department’s Southwest District Office and the PCDEM each calendar year on or before April 1, a completed DEP Form 62-210.900(5), "Annual Operating Report for Air Pollutant Emitting Facility," for the preceding calendar year. **Note, the annual operating report for calendar year 2008, shall be submitted by May 1, 2009.** 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 submitted. [Rule 62-210.370(3)(a)2., F.A.C.]***Comments****: The facility Annual Operating Report (AOR) was received on 3/24/2011.*17. The permittee shall submit a complete application to renew Operation Permit 1030150-014-AO to the Air Permitting Sections of the Department's Southwest District Office and the PCDEM at least 60 days prior to the expiration date of this operation permit…. [Rules 62-4.070(3), 62‑4.090, 62-210.300(2), and 62-210.900, F.A.C.]***Comments****: I informed Mr. York and Ms. Deck that this permit condition requires TWC to submit a permit renewal application on or before 6/27/2013.* |
| **✓** |  |  | Valid Permit [Rule 62-210.300] |
| **✓** |  |  | Changes to Facility/emission unit [Rule 62-210.300] *Does the emission unit description above match what the facility is operating. [ ]  Yes [x]  No* **C**omments: *See the attached plant layout and* *the comments prior to Specific permit condition number 1 for more details.* |

| **✓** | **C. Other:** |
| --- | --- |
| **Pollution Prevention Activities*** P2 Handouts Provided: [x]  P2 Brochure; [ ]  P2 Manual; [ ]  P2 Checklist
* Have any emissions reductions occurred [ ]  *Yes /* [x]  *No*

[ ]  Chemical Substitution; [ ]  Equipment Changes; [ ]  Process Changes[ ]  Chemical/Material Reuse; [ ] On-site Recycling; [ ]  Other: ***Comments:*** *NA* |
| Closing Conference: *I informed Mr. York and Ms. Deck that TWC is in compliance with applicable rules and permit conditions.* |
| **Inspector(s)**: Jose Rodriguez, *Pinellas County, Air Quality Division* |
| **Signature(s)**: Date: | **Date: June 22, 2011** |
| ACCESS? | **✓** | EASIIR? | **✓** |

|  |  |  |
| --- | --- | --- |
| AIRS ID1030150 | OWNERWest Pharmaceutical Services of Florida, Inc. | FACILITY NAMEWest Pharmaceutical Services, Clearwater |
| [ ]  TITLE V  | [x]  SYNTHETIC MINOR | DATE OF THIS FCE 7/19/2011 |
| [ ]  TITLE V MEGA-SITE\* | [ ]  OTHER | DATE OF LAST FCE 9/22/2009 |

\*Facility with a large number of complex emissions units. It is more reasonable to evaluate a Title V Mega-Site once every 3 years instead of once every 2 years.

Review of All Required Reports

|  |  |
| --- | --- |
| PERIODIC REPORTS | COMMENTS |
| [x]  DONE [ ]  N/A | Annual operating report |  |
| [ ]  DONE [x]  N/A | Statement of compliance |  |
| [ ]  DONE [x]  N/A | Annual |  |
| [ ]  DONE [x]  N/A | Semi-annual |  |
| [ ]  DONE [x]  N/A | Quarterly |  |
| [ ]  DONE [ ]  N/A | Other : |  |
| [ ]  DONE [ ]  N/A | Other : |  |

|  |  |
| --- | --- |
| CONTINUOUS EMISSION MONITOR REPORTS | COMMENTS |
| [ ]  DONE [x]  N/A | Quarterly excess emissions |  |
| [ ]  DONE [x]  N/A | Semi-annual |  |
| [ ]  DONE [x]  N/A | RATA |  |
| [ ]  DONE [x]  N/A | CGA |  |
| [ ]  DONE [ ]  N/A | Other : |  |
| [ ]  DONE [ ]  N/A | Other :  |  |

Assessment of Control Device and Process Operating Conditions

|  |  |
| --- | --- |
| [ ]  OFF-SITE ASSESSMENT | (Describe the off-site assessment in comments) |
| [x]  ON-SITE ASSESSMENT | (Document the on-site inspection below) |

|  |  |  |
| --- | --- | --- |
| DATE OF INSPECTION | DATE OF INSPECTION REPORT | My office maintains the inspection report... |
| ...in the ARMS database through EASIIR. | ...with the paper or electronic compliance files | ...in another location (specify). |
| 6/22/2011 | 7/19/2011 | [x]  | [x]  | [ ]  |
|  |  | [ ]  | [ ]  | [ ]  |
|  |  | [ ]  | [ ]  | [ ]  |
|  |  | [ ]  | [ ]  | [ ]  |
| COMMENTS |

Review of Tests and Records

|  |  |
| --- | --- |
| TESTS, OBSERVATIONS AND RECORDS | COMMENTS |
| [ ]  DONE [x]  N/A | Visible emission observation(s) |  |
| [x]  DONE [ ]  N/A | Review of facility records and logs |  |
| [x]  DONE [ ]  N/A | Assessment of process parameters (feed rates, process rates, raw material compositions, etc.)  |  |
| [ ]  DONE [x]  N/A | Assessment of control equipment performance parameters(water flow rates, pressure drops, temperatures, ESP power levels, etc.) |  |
| [ ]  DONE [x]  N/A | Stack test(s) |  |
| [ ]  DONE [ ]  N/A | Other :  |  |
| [ ]  DONE [ ]  N/A | Other :  |  |

Compliance Monitoring (CM) Information

|  |  |
| --- | --- |
| CM ELEMENT | My office maintains this information... |
| ...electronically, in the ARMS database. | ...in the permit. | ...in the inspection report. | ...in another location (specify). |
| Facility information | [x]  | [x]  | [x]  | [ ]  |
| Applicable requirements | [x]  | [x]  | [x]  | [ ]  |
| Inventory of emission units | [x]  | [x]  | [x]  | [ ]  |
| Enforcement history | [x]  | [x]  | [x]  | [ ]  |
| Compliance activities | [x]  | [x]  | [x]  | [ ]  |
| Findings and recommendations | [ ]  | [x]  | [x]  | [ ]  |
| COMMENTS |

Other Comments

|  |
| --- |
|  |

Prepared by: Jose Rodriguez Date: 7/19/2011

Reviewed by: Date:

1. Complete the form as much as possible during for inspection; 2. The remainder of checklist, for activities in the FY, are filled in no later than 9/15; 3. Between 9/15 and 9/30, complete the FCE by closing out the FCS project in ARMS. The INSP > FCS record only accepts a completion date and a comment; it does not accept information on the lower portion of the form.  If an FCS project already exists for the fiscal year in question, enter a completion date and comment in the existing record, do not create a duplicate FCS record.