US Environmental Protection Agency – Region 2
Caribbean Environmental Protection Division
Response and Remediation Branch

Resource Conservation and Recovery Act (RCRA)
Choose an item.

Facility Name:	TEVA PR LLC		
EPA ID Number:	PRD091144709		
Date of Inspection:	July 19, 2023		
Generator Status in Record:	Large Quantity Generator		
Generator Status at the time of inspection:	LQG		
RCRA Permitted:	No		
Corrective Action:			
Project ID	CEPD-RCRA-23-0438		
Record Schedule:	1044(c)		
Facility Physical Location: (Municipality, PR, zip code)	Union Street Road 195 Km. 1.1 Fajardo, PR 00738-1005		
Mailing address:	P.O. Box 1005 Fajardo, PR 00738-1005		
Geographical Coordinates:	18.3317955,-65.8447019		
Facility Owner:	Warner Chilcott Company LCC		
	Not provided		
Facility email	Ruben.lugolopez@tevapharm.com		
	Arleen.sandoz@tevapharm.com		
Facility Contact:			
Personnel participating in inspection:			
Ruben Lugo	TEVA PR LLC	EHS Director	787-655-8220
Edgar Ortiz	TEVA PR LLC	Engineering Director	787-655-8226
Kirsten Lopez	TEVA PR LLC	EHS Coordinator	787-655-8268
Arleen Sandoz	TEVA PR LLC	General Manager	787-655-8202
NAICS: 325412	Pharmaceutical Preparation Manufacturing		
SIC:	Not provided		
Area:	16.6 acres		
Number Employees:	190 approximately		
Basis for Inspection: Core Program			
Status: **FINAL**			
Referral: None			
EPA Lead Inspector Signature/Date [Date of approving email]	Khrystian M. Vazquez		6 Nov 2023
	{Inspector name}		Date
Supervisor Signature/Date [Date of approving email]	DAVID CUEVAS-MIRANDA Digitally signed by DAVID CUEVAS-MIRANDA Date: 2023.11.07 06:57:16 -04'00'		7Nov 2023
	{Supervisor name}		Date

1 INTRODUCTION

A Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection was conducted on July 19, 2023 at TEVA PR LLC (the facility). The facility is located at Union Street Road 195 KM. 1.1 Fajardo, PR 00738. Refer to Appendix 1- Picture 1 for the location and to Picture 2 for an aerial photograph of the facility.

The purpose of the Inspection was to evaluate facility's compliance. As part of the Inspection, an opening meeting, walkthrough, documents review and closing meeting were conducted to evaluate facility's compliance with the requirements that govern hazardous waste generators, universal waste handlers and used oil generators, as applicable.

According to EPA records, this was the first EPA inspection under this name for this facility.

2 OPENING MEETING

I met with Ruben Lugo for the opening meeting. I identified myself as EPA RCRA enforcement officer and told the facility representative(s) that the purpose of my visit was to conduct a CEI at the facility to evaluate its hazardous waste management practices and compliance.

At this time Mr. Lugo identified himself as the Environmental Safety & Health (EHS) Director for the facility. Mr. Lugo has been an EHS Director for the facility since 2014. He also introduced me to Ms. Kirsteen Lopez, the EHS Coordinator that has been working with Mr. Lugo since September 2022. Mr. Lugo along with Ms. Lopez and Mr. Edgar Ortiz,Engineering Director, managed the environmental affairs of the facility. Ms. Lopez accompanyied me throughout the inspection for the most part.

I explained the EHS representatives that the inspection would consist of the opening meeting, the walkthrough through the facility and the review of the regulated documents according to their waste generation and a final closure meeting to discuss observations made during the inspection. The facility's representatives acknowledged the inspection routine and then we proceeded to gather more information about the facility operation.

2.1 FACILITY PHYSICAL DESCRIPTION AND OPERATION

TEVA main operation consist of the generic manufacturing and packaging of birth control (oral contraceptive) and vaginal ring. The facility started operation in 1970 under a different company name (Partab Corporation at Parke-Davis). In 1982 the facility changed its name to Warner Lambert until year 2000 when once again facility was under the name of Pfizer. On 2004 it change its name to Warner Chilcott and continued its operation with partnerships (Warner Actavis 2013, Warner Teva 2016). The facility acquired a new EPA ID when the land where Warner Chicott formerly operated entered on a corrective action cleanup activity. They decided to work the cleaning activities separately and move manufacturing activities to the adjacent land with a new EPA ID and new name. Manufacturing activities remains the same.

The facility has approximately 160 employees, including contractors. Facility hours of operation consist of 2 Shifts that runs between 0600 hours to 2200 hours and utilities that runs 24 hours.

2.2 SOLID AND HAZARDOUS WASTE GENERATION

According to Ms. Lopez the facility is a Large Quantity Generator (LQG) and waste streams generated at the facility are mostly IPA, ethyl alcohol, rags with alcohol and labspacks. All hazardous waste and non hazardous waste are dispose through Clean Harbor. Typical hazardous waste is generated in laboratories/manufacturing and packaging areas. The facility also dispose of recycling materials with IFCO, used oil with Clean Harbor and electronics. According to Ms. Lopez last disposal was June 12, 2023. In order to organize the inspection walkthrough, I asked the staff for the facility layout. The facility layout helped me to understand the areas where hazardous waste is generated and how many areas are in the facilty.

They are five areas where hazardous waste is generated:

- 90-Days Storage Warehouse
- Waste Water Treatment Plan(WWTP) (SAA)
- Quality Laboratory (SAA) (located between Building 2 and 3)
- Non-Hazardous Waste Area
- Maintenance Room (SAA)

SAA (Satellite Accumulation Area)

3 FACILITY WALKTHROUGH

Ms. Lopez accompanied me during the facility walkthrough. During the facility walkthrough the five abovementioned areas were inspected. The observations for each area are described below. Refer to Appendix 2 for pictures taken during the inspection.

3.1 90-DAYS STORAGE WAREHOUSE

The 90-Days Storage Warehouse is a pre-fabricated metal box unit container. The container is equipped with a spill containment floor. The containment capacity of the floor is about 375 gallons. The area is provided with warning signs, telephone, automatic fire chemical sprinkler system and alarm, fire extinguishers and spill response equipment and materials. The door is labeled with warning signs, and emergency contact information. The emergency phone is located on the left outside the container with the numbers to dial in case on an emergency, and it was operable. Inside the 90-days storage warehouse I observed the alarm system, fire extinguisher system, spill kit, and the storage area log book. The log book contained the storage inventory. We discussed the alternative of having a backup log book in case of an emergency innaccesibility and Ms. Lopez explained they have an electronic backup system at the office. Hazardous waste observed during the inspection goes as follow:

- Three- (30 gallon) plastic container with rags with alcohol, dated 07-14-2023- 07-10-2023(2qty)
- One- (15 gallon) container with flammable liquid 07-07-2023
- One- (5 gallon) container with vialis, dated 07-07-2023

I observed and told Ms. Lopez that only one container had hazard pictograms and instructed her that all containers should be have the hazard pictogram labels. Ms. Lopez proceeded to label them on the spot.

(See Appendix 3 Pictures 1-11)

3.2 WASTE WATER TREATMENT PLANT (SAA)

In the WWTP, Chemical Oxygen Demand (COD), pH, Dissolve O^2, Effluent under external laboratory, and temperature testing are performed before discharging. At the WWTP laboratory I observed one pile (5 gallons) of spent solvent cod vials waste.

The SAA was properly labeled and identified as hazardous waste, nevertheless, no hazard pictogram labels or indication of the hazardous waste characteristic content was observed on the container.

(See Appendix 3 Pictures 12-13)

3.3 RECYCLING STORAGE COMPARTMENT

In this area the facility stores used scrubs from laboratory employees to be sent to a laundry facility to be washed. Outside the recycling compartment, there's a designated area for storage of recycling materials such as cardboard and scrap metals.

(See Appendix 3 Pictures 14-20)
(No concern observed)

3.4 NON-HAZARDOUS AND USED OIL AREA

The Non-Hazardous and Used Oil Area is a separated building right next to the WWTP. The small building is labeled outside with signs of non-hazardous storage area. At the time of the inspection the Non-Hazardous waste Storage area was empty.

(See Appendix 3 Pictures 21-22)
(No concern observed)

3.5 QUALITY LABORATORY (SAA) BUILDING 3

The SAA at this building (SAA-PK002) is at the packaging area includes the following:

- One- (55 gallon) container with rags containing alcohol
- One- (5 gallon) container with INK
- One- (15 gallon) steel container with IPA 70%

The SAA was properly labeled and identified as hazardous waste, nevertheless, no hazard pictogram labels or indication of the hazardous waste characteristic content was observed on these containers.

(See Appendix 3 Pictures 23-26)

3.6 QUALITY LABORATORY (SAA) BUILDING 2

The SAA at this building includes Manufacturing, Packaging and Analytical Laboratory Observations at these areas are as follow:

3.5.1 FAJ-L003- Raw Material Lab

- One- (30 gallon) plastic blue container with D.I water T.O.C. Test (1,4 Benzoquinone, Nitric Acid, Hydrocloric Acid, KHP)
- One- (30 gallon) steel container with Flammable waste containing propanol, butanol, ethanol, methanol, acetone and a mix of other solvents

All containers were properly labeled with hazardous waste marking and identified with waste characteristics indicators.

(See Appendix 3 Pictures 27-31)
(No concern observed)

3.5.2 LAB-010- Hazardous Waste Cabinet FC-03-B-2

This SAA is a yellow cabinet with two double doors identified as flammable hazardous waste. Inside it has three shelves with small cap glass bottles with the following waste:

- Chloroform
- Sulfuric Acid
- Perchloric Acid/Nitric Acid
- HCL, Sodium Thiosulfate, Sodium Bicarbonate
- K.F Water

Each one of the small cap glass bottles were identified with its content

(See Appendix 3 Pictures 32-41)
(No concern observed)

3.5.3 RAW Lab 210.2

- One- (30 gallon) plastic blue container with laboratory debris (gloves)

The SAA was properly labeled and identified as hazardous waste, nevertheless, no hazard pictogram label or indication of the hazardous waste characteristic content was observed on this containers.

(See Appendix 3 Pictures 42-43)

3.5.4 SAA-FAJ-L006

- Three (15 gallon) steel containers with flammable liquid waste contaning propanol, butanol, ethanol, methanol, acetone and a mix of other solvents. Two of them were empty.

The container was properly labeled with hazardous waste marking and identified with waste characteristics indicators.

(See Appendix 3 Pictures 44-46)
(No concern observed)

3.5.5 SAA-FAJ-L010

- One- (15 gallon) steel containers with flammable liquid waste contaning propanol, butanol, ethanol, methanol, acetone and a mix of other solvents
- Two- (15 gallon) steel containers empty

The container was properly labeled with hazardous waste marking and identified with waste characteristics indicators.

(See Appendix 3 Pictures 47-49)
(No concern observed)

3.5.6 SAA-RAW LAB

- One (30 gallon) plastic yellow container identified with gloves debris
- One (15 gallon) plastic container with lamps labeled as universal waste
- One (15 gallon) plastic container with flammable liquid

The SAA was properly labeled and identified as hazardous waste and universal waste, nevertheless, no hazard pictogram labels or indication of the hazardous waste characteristic content was observed on the one (30 gallon) plastic yellow container identified with gloves debris.

(See Appendix 3 Pictures 50-53)

3.5.7 SAA-PK-001- Washroom 2031

- One- (55 gallon) plastic container with rags with alcohol
- One- (5 gallon) plastic container with INK
- One- (15 gallon) steel container with IPA

The SAA was properly labeled and identified as hazardous waste, nevertheless, only one container (15 gallon steel with IPA) displayed the hazard pictogram label or indication of the hazardous waste characteristic content.

(See Appendix 3 Pictures 54-57)

4 DOCUMENTS REVIEW

I reviewed the required documents after the facility walkthrough for a LQG. Ms. Lopez along with the EHS staff provided the following documents and stayed with me to answer any questions.

- Facility Contingency Plan
- 90-Days Storage Log Book
- Waste Minimization Plan
- Biennial
- Job Description
- Training Courses & Certifications
- Hazardous Waste Manifests and LDR
- Other Manifests (Oil, Electronics, Batteries)

4.1 FACILITY CONTINGENCY PLAN

The facility Contingency Plan was dated on March-2023 and is still under revision. The plan included Emergency Personnel names and telephone numbers that needed to be updated. The SAA's are under evaluation because on their list some areas are to be deleted or change in location. Nevertheless, the Contingency Plan contains all the emergency preparedness in accordance to RCRA regulations.

Additional information can be seen in **Appendix 3 Pictures 58-67**

4.2 90-DAYS HW STORAGE LOG BOOK

The 90-Days HW Storage log book was reviewed at the 90 days hazardous storage area. The log book was current and it was discussed to have an electronic backup log book in case on an innacesible reach on an emergency event.

4.3 BIENNIAL

Biennial report was in compliance. Submitted on February 28, 2022.

4.4 WASTE MINIMIZATION PLAN

The facility 10-01-2016 waste minimization plan does not include metrics to compare their minimization goals. It was highly recommended that the Waste Minimization plan contains the metrics on how they are monitoring hazardous waste minimization efforts.

4.5 JOB DESCRIPTION

The Job Description of the following positions were provided:

- Environmental Health & Safety Coordinator
- Environmental Health & Safety Director
- Director of Environmental Health & Safety

All job positions contained the description and duties related with hazardous waste management

4.6 TRAINING COURSES & CERTIFICATIONS

The following training documents were provided:

The EHS staff provided documents and certifications with the most recent hazardous waste training they have taken to comply with LQG training requirements.

- Risk Communication Training
- Hazardous Waste Labeling

4.7 HAZARDOUS WASTE MANIFESTS AND LDR

During the evaluation of the three year hazardous waste manifest with LDR attached I observed that most of the waste codes generated in their manifest were the following:

D001, D002, D003, D006, D007, D009, D011, D022, D035, D038, F003, F005, U003, U112, U117, U154, U162, U188, U213, U218, U222, U080,

Under 2.0 lbs
P030 (nitroferricyanide ammonium thyocyanide) 11-01-22
P022 (carbon disulfide) 07-20-22

2023

Hazardous waste from January to Jun were evaluated all manifest have attached LDR and signed. Manifest documents for that year period were in compliance.

2022

Hazardous waste from January to December were evaluated all manifest have attached LDR and signed. Manifest documents for that year period were in compliance.

2021

Hazardous waste from January to December were evaluated all manifest have attached LDR and signed. Manifest documents for that year period were in compliance.

4.8 OTHER MANIFESTS (OIL, ELECTRONICS, BATTERIES)

Other manifest provided during the inspection were:

Oil- Clean Harbor Manifest 04/2023 and 06/2023

5 CLOSING MEETING

After completion of the walkthrough and documents review, I met with Mr. Ruiz and the staff to conduct a closing meeting. I indicated that the purpose of the closing meeting is to inform the facility about the CEI observations. I communicated the facility the following:

According to my observations the facility was complying with most of the RCRA regulation as a LQG. Nevertheless, it was highly recommended to include metrics that monitors their efforts on hazardous minimization waste. Also, there was some inconsistence on the marking of the containers when it comes to pictograms or the identification of the characteristics of the hazardous waste.

6 POTENTIAL AREAS OF CONCERN

6.1 GENERATORS

The Facility notified of its hazardous waste activities as large quantity generator. During the inspection, I confirmed facility's generator status by verifying its disposal events as described in the manifests and/or the quantity of hazardous waste that was being accumulated onsite. Based on the observations and information gathered during the inspection, the following areas of concern were identified:

6.1.1 Pre Transport Requirements (40 CFR § 262 Subpart C)

According to RCRA regulation § 262.15 (5.(i) (ii) Satellite accumulation area regulations for small and large quantity generators.

5. A generator must mark or label its container with the following:

(i) The words "Hazardous Waste" and

(ii) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704).

At the time of the inspection the facility had several containers throughout the hazardous waste satellite and storage areas that had no hazard pictogram labels or indication of the hazardous waste characteristic content.

7 ATTACHMENTS

I. Figure 1- Facility Location Map
II. Figure 2- Aerial Photograph
III. Photolog (include all pictures taken in addition to photolog)