

RCRA Compliance Branch INSPECTION REPORT

Inspection Date(s):	June 1, 2022	Inspection Announced: No
Facility or Site Name:	ScieGen Pharmaceuticals, Inc.	
Facility/Site Physical Location:	89 Arkay Dr.	
Happauge.	Happauge, New York 11788	
Mailing address (if different from above):		
(city, state, zip code)		
Facility/Site Contact:	Siva Reddy PV	Chief Operating Officer
RCRA ID Number:	NYD981495070	
Facility/Site Personnel Participating in Inspection:		
Siva Reddy PV	Chief Operating Officer	sivareddyp@sciegenpharm.com Ph: 631-434-2723, ext. 107 Cell: 631-921-5926
{name}	{title}	{email/phone no.}
Inspector(s):		
John D, Wilk (USEPA-R2-ECAD-RCB-HWCS) (lead inspector); William Chernes (USEPA-R2-ECAD-RCB-HWCS)	 JOHN WILK 2022.07.20 11:18:05 -04'00'	{date}

Derval Thomas {Supervisor name}	DERVAL THOMAS	Digitally signed by Derval THOMAS Date: 2022.07.20 11:05:29 -04'00'	{date}
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SECTION I – INTRODUCTION

Purpose of the Inspection Objective

The purpose of the inspection was to perform a RCRA compliance evaluation inspection (CEI) at this facility. This inspection was performed pursuant to the ongoing RCRA Air Emissions National Compliance Initiative and was selected from an EPA headquarters developed target list.

Opening Conference

EPA Region 2 RCRA inspectors John Wilk and William Chernes arrived at the above referenced ScieGen Pharmaceuticals facility on June 1, 2022.

The EPA inspectors met with the above referenced company representative. The facility representative was informed the purpose of the EPA inspection was to determine the facility's compliance with RCRA. The facility was apprised that the scope of the inspection was a RCRA compliance evaluation inspection (CEI) which is a general comprehensive inspection to determine overall compliance with the requirements of RCRA.

All EPA inspectors presented their credentials to the company representative noted above prior to conducting the inspection.

Facility/Site Description

The facility manufactures generic drugs (including gabopentin and metformin). Many of the generic drugs are powder formulations which are tabletized and encapsulated on-site.

Hazardous wastes include: (1) isopropyl alcohol from equipment clean-outs; and (2) hazardous waste organic solvents from laboratory activities such as extractions and HPLC operations which include toluene (especially from extractions) and methanol/acetonitrile especially from HPLC elutions.

SECTION II – OBSERVATIONS

The facility's main hazardous waste is spent organic solvents from laboratory activities. At the time of the June 1, 2022 inspection all hazardous waste storage was accomplished using container storage.

Based on the facility's process and manifest records it is a large quantity generator of hazardous waste.

At the time of the June 1, 2022 inspection, the most recent off-site manifested shipment of hazardous waste occurred on May 19, 2022 under which approximately 150 gallons of hazardous waste (D001/F005) was shipped to Republic Services (RCRA TSD), Hatfield, Pennsylvania.

During the inspection the facility stated it had recently received a RCRA enforcement action and inspection report from the New York State Department of Conservation (NYSDEC). However, the facility was unable to provide us the enforcement action at the time of the inspection.

SECTION III – AREAS OF CONCERN

Regulatory Concerns-

Potential RCRA compliance issues are as follow:

The following two (2) RCRA violations were noted by the USEPA during its June 1, 2022 inspection:

1. Failure to close hazardous waste accumulation containers in accordance with 40 CFR 265.173(a) which states:

“A container holding hazardous waste must always be closed during storage, except when it is necessary to add or remove waste.”

NOTE: During the inspection the EPA inspectors noted several open drums in violation of 40 CFR 265.173(a), as referenced by 262.34(a)(1)(i). Those drums included steel drums storing hazardous waste outside and containers inside the facility’s HPLC laboratory area.

2. Failure to electrically ground at least six (6) steel drums storing ignitable hazardous waste in an outside staging area in violation of 40 CFR 265.31, as referenced by 40 CFR 262.34(a)(4), which states:

“ Facilities must be maintained and operated to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.”

NOTE: During the inspection the EPA inspectors noted several drums in violation of 40 CFR 265.31. Those drums included ungrounded steel drums storing hazardous waste in an outside staging area which in the event of an outside energy source, i.e., static electricity, etc., could explode because they are not adequately grounded to neutral.



Above: Three ungrounded steel hazardous waste drums storing ignitable hazardous waste D001/F005. One drum with open funnel.



Above: Open top funnel.

General Concerns- None

SECTION IV – Closing Conference and Proposed Follow-up

Closing Conference:

The EPA inspectors conducted a closing conference at the close of the June 1, 2022 inspection. At the closing conference, the EPA inspectors informed the facility representative of the two (2) potential compliance issues noted above. The facility representative agreed to correct these violations in a timely manner and send the lead EPA inspector (John Wilk) proof (photographs, invoices, etc.) demonstrating the violations were corrected. The facility representative also agreed to immediately send the EPA lead inspector copies of all recent enforcement actions including inspection reports by the NYSDEC. As of the time of writing this inspection report (July 19, 2022) the EPA lead inspector has received no correspondence from the facility representative indicating the aforementioned violations have been corrected nor has the EPA lead inspector received from the facility copies of recent enforcement actions/inspection reports by the NYSDEC.

Follow-up:

This matter was referred to the NYSDEC on July 14, 2022. On July 18, 2022 the NYSDEC informed the USEPA that it would be including the two violations noted in this report in its existing case against this facility.