DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	2/24/2022-3/10/2022*
	FEI NUMBER 3013712903

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Laxmikant Tiwari, Site Head, Chief - Manufacturing

FIRM NAME	STREET ADDRESS
Cadila Healthcare Limited	434 B 1 K Survey Nos 434, And
CITY, STATE, ZIP CODE, COUNTRY Jarod, Gujarat, 391510 India	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

QUALITY SYSTEM

OBSERVATION 1

The written stability testing program is not followed.

Specifically, the stability program is not followed to complete the testing within predefined time frame. The Quality Unit failed to test about 250 stability samples within (b) (4) - (b) (4) days as required under, "SOP for Stability Management (Document # 0317-SOP-QC-00132, Effective Date: 7/23/2021)." Examples of stability samples that were delayed testing include:

Product / Material	Batch No.	Storage Conditions	Stability Timepoint	Total # of Days Delayed
(b) (4) INJECTION USP (b) (4) MG/VIAL	(b) (4)	25°C/60% RH	275 Day(s)	122
(b) (4) INJECTION USP (b) (4) mg/Vial	(b) (4)	25°C/60% RH	275 Day(s)	122

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EMPLOYEE(S) SIGNATURE
Saleem A Akhtar, Investigator

X Saleem A Akhtar
Investigator
Signed By: 2001638440
Date Signed: 03-10-2022
11:29:42

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(b) (4) INJECTION USP (b) (4) mg/Vial	(b) (4)	40°C/75% RH	183 Day(s)	120
(b) (4) INJECTION USP (b) (4) mg/vial	(b) (4)	30°C/65% RH	92 Day(s)	109
(b) (4) INJECTION USP (b) (4) mg/vial	(b) (4)	30°C/65% RH	92 Day(s)	110
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(b) (4) INJECTION USP (b) (4) mg/Vial	(b) (4)	40°C/75% RH	183 Day(s)	126
(b) (4) INJECTION USP (b) (4) mg/Vial	(b) (4)	25°C/60% RH	183 Day(s)	126
(b) (4) INJECTION USP (b) (4) mg/Vial	(b) (4)	25°C/60% RH	366 Day(s)	125
(b) (4) INJECTION USP (b) (4) mg/Vial	(b) (4)	25°C/60% RH	366 Day(s)	125
(b) (4) INJECTION (b) (4) mcg/mL, (b) mL	(b) (4)	5°C ± 3°C	275 Day(s)	68

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(b) (4) INJECTION (b) (4) mcg/mL, (b) mL	(b) (4)	5°C ± 3°C	275 Day(s)	68
(b) (4) E INJECTION (b) (4) mcg/mL, (b) mL	(b) (4)	5°C ± 3°C	275 Day(s)	59
(b) (4) INJECTION (b) (4) mcg/mL, (b) mL	(b) (4)	5°C ± 3°C	275 Day(s)	59
(b) (4) INJECTION (b) (4) mcg/mL, (b) mL	(b) (4)	5°C ± 3°C	275 Day(s)	59
(b) (4) INJECTION (b) (4) mcg/mL, (b) mL	(b) (4)	5°C ± 3°C	275 Day(s)	59
(b) (4) INJECTION (b) (4) mcg/mL, (b) mL	(b) (4)	5°C ± 3°C	275 Day(s)	54
(b) (4) INJECTION (b) (4) mcg/mL, (b) mL	(b) (4)	5°C ± 3°C	275 Day(s)	54
(b) (4) INJECTION (b) (4) mcg/mL, (b) mL	(b) (4)	5°C ± 3°C	275 Day(s)	34
(b) (4) INJECTION (b) (4) mcg/mL, (b) mL	(b) (4)	5°C ± 3°C	275 Day(s)	34
(b) (4) Injection (b) (4) mg/mL, (b) mL	(b) (4)	25°C/60% RH	183 Day(s)	91

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The site primarily manufactures injectable drug products for the US market. Significant number of (b) (4) batches (representative of the commercial products in the market) were delayed stability testing as well.

OBSERVATION 2

Written procedures are not followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected.

Specifically, written procedure pertaining to the Annual Product Quality Review of the commercial drug products manufactured at the site is not followed.

The firm performs Annual Product Quality Reviews (APQR) as per SOP, "Annual Product Quality Review", Document # 0317-SOP-QA-00076, Effective Date: 7/23/2021). Section 6.1.4 of this SOP states, "APQR shall be approved within (b) (4) days of scheduled time period." The scheduled time period to complete the review is the (b) (4) approval date. The Quality Unit failed complete the APQRs for the following products within due period:

Sr. No.	Product Name	Intended completion date	Actual completion date	Total number of days delayed
1	(b) (4) Inj. USP (b) mg/ml, (b) ml	12/19/2020	2/24/2021	67

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2	(b) (4) Inj. USP (b) (4) mg/ml, (b) (4) ml			
3	(b) (4) Inj. USP, (b) (4) mg/mL, (b) (4) mL	6/8/2021	7/24/2021	46
4	(b) (4) Inj. (b) (4) mg/mL, (b) mL	12/6/2020	12/26/2020	20
5	(b) (4) Inj. (b) (4) mg/mL, (b) mL			
6	(b) (4) Inj. (b) (4) mg/mL, (b) mL			
7	(b) (4) Inj. (b) (4) mg/mL, (b) mL			

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 3

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

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Specifically, the Compounding Room used in the manufacturing of sterile injectable drugs is not maintained in a good state of repair to prevent contamination. On 3/2/2022, significant deficiencies were observed during the inspection of Compounding Room (ID: (b) (4)) associated with filling line (b). For example:

A. A scratch (about one inch) with missing paint was observed on the ceiling located on top of the compounding vessel (ID: M055). The missing paint was observed on top of the HEPA filter (ID: ME044) installed above the Compounding Vessel. This is an open processing area where the API and excipients are (b) (4) into the compounding vessel (b) (4) .

B. This Compounding Room (ID: (b) (4)) has two pipes (for incoming and outgoing supply of (b) (4) (b) (4)) connected to the Compounding Vessel (ID: M055). The sealant applied around the pipes (when they go through the ceiling) was not smooth; hence making it hard to clean surface.

Filling line (b) is a high volume line used to manufacture products with bigger batch size. Currently, this line is used to manufacture (b) (4) commercial drug products for the US market.

***DATES OF INSPECTION**

2/24/2022(Thu), 2/25/2022(Fri), 2/28/2022(Mon), 3/01/2022(Tue), 3/02/2022(Wed), 3/03/2022(Thu), 3/04/2022(Fri), 3/08/2022(Tue), 3/09/2022(Wed), 3/10/2022(Thu)

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