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	4/27/2026-5/5/2026*
	FEI NUMBER 3012977526

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Vikram Shukla, President-Corporate Parenteral

FIRM NAME	STREET ADDRESS
Zydus Lifesciences Limited	Plot Survey 23,25/P,37,40/P,42 To 47, Opp. Ramdev Masala, Village - Changodar, Sarkhej-Bavla N.H. 8a, Tal Sanand
CITY, STATE, ZIP CODE, COUNTRY Ahmedabad, Gujarat, 382213 India	TYPE ESTABLISHMENT INSPECTED Sterile 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 WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, the distance proximal to the work surface for HEPA filters in the critical area that aseptic filling transpires on the (b) (4) Filing Line (Equipment ID # (b) (4) was not defined during equipment qualification studies. Additionally, there were large changes in the working height air velocities from the initial study "Performance Qualification Report for (b) (4) Line LAFs" PQR(b) (4) /01, dated: 04/26/2018 and the requalification study "Air Flow Visualization Study (Smoke Test) Report for (b) (4) Filling Line-March 2025 & April-2025" REP-25-044-01, dated: 11/07/2025, which were not investigated, nor did your firm perform a risk assessment on the potential impact to drug product quality. Finally, the firm does not address air velocity working height specifications and/or requirements in the contamination control strategy "Contamination Control Strategy (CCS)" REP-25-054-00.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically, your firm failed to implement and maintain controls to ensure the sterility of drug products

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produced on the (b) (4) Filing Line (Equipment ID # (b) (4) On 04/28/2026, multiple locations within the ISO 5 (b) (4) Restricted Access Barrier System (b) (4) RABS) of the (b) (4) Filing Line (Equipment ID # (b) (4) appeared to have (b) (4) residues on the (b) (4) surfaces. According to you, the residues are (b) (4) used to cover gaps seen in the ISO 5 area. In addition, we observed multiple cracks on the (b) (4) above (b) (4) (b) (4) near the HEPA filter of the (b) (4) RABS. (b) (6) (General Manager Head Quality Assurance) and (b) (6) (Senior Manager- Production Manufacturer) were not aware of the residues and cracks or how long they have been present in and around the filling machine. This equipment is used to aseptically fill (b) (4) which is intended for the U.S. market.

OBSERVATION 3

Aseptic processing areas are deficient in that floors and walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically, the facility cleanroom # (b) (4) that is a Grade B background to the (b) (4) RABs which contains the (b) (4) Filing Line (Equipment ID # (b) (4) is not in a good state of repair, in that, the (b) (4) within the Grade B controlled classified cleanroom were grossly stained and (b) (4) Additionally, the (b) (4) floors within the Grade B cleanroom were visibly worn, peeling, and flaking in numerous locations which could hinder effective cleaning of the surfaces. The (b) (4) Filing Line (Equipment ID # (b) (4) is utilized to produce (b) (4) Injection, (b) (4) mg/mL).

OBSERVATION 4

In-process materials are not tested for quality and approved or rejected by the quality control unit during the production process.

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Specifically,

A) The swab sampling instructions for environmental monitoring of the (b) (4) that is associated with the Grade B facility cleanroom # (b) (4) is not sufficiently detailed in order to ensure consistent sampling of the area. According to the "Microbiological Monitoring of Surface of Grade-B by (b) (4) Plates," 0310-SOP-QC-00006-40 the (b) (4) are to be surface sampled within the (b) (4) The (b) (4) is utilized to transport material from the lower grade classifications into the Grade B cleanroom of the (b) (4) Filing Line (Equipment ID # (b) (4) . According to the "Microbiological Monitoring of Surface of Grade-B by (b) (4) Plates," the (b) (4) are to be surface sampled (b) (4) The swab sample location lacks a detailed description to ensure consistent sampling of the area to provide meaningful data.

B) The firm's procedures do not ensure that all ancillary equipment located in controlled classified Grade B cleanroom are routinely surface sampled. These ancillary equipment that are categorized as "non-routine" and located in Grade B controlled classified areas include but are not limited to, (b) (4) (b) (4) tables.(b) (4) working surfaces, and (b) (4) surfaces of (b) (4) According to the SOP #0310-SOP-QC-00006, "Environmental Monitoring Program", the equipment is surface sampled (b) (4) and the ancillary equipment selected for sampling is (b) (4) and not tracked, so the firm does not know which ancillary equipment has been sampled and which has not, at any given time.

C) According to the procedure titled "Operation of Non Viable Particle Counter (NVPC)" 0310-SOP-MFG-00099, any excursion that transpires during an intervention is "not to be considered" for a deviation. The procedure instructs for the filling machine to be stopped and resume activity "after counts comes within limit."

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D) The Grade B facility cleanroom # (b) (4) is not monitored during production or routine conditions with a suitable sample size to capture any increase in contamination or environmental deterioration that may affect sterile drug product quality. The procedure titled "Non-Viable Particle Monitoring of Grade-A and Grade B by APC" 0310-SOP-QC-00006-35, indicates that the total air volume sampled is (b) (4) m^3 for the approximately (b) (4) Grade B non-viable particulate sampling locations within the controlled classified area.

OBSERVATION 5

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, the air flow visualization study for the (b) (4) Filing Line (Equipment ID # (b) (4) that was performed in March-April 2025, was not conducted in accordance with a written protocol which describes all aspects of testing performed, and the pre-approved acceptance criteria specific to the aseptic filling line tested. The (b) (4) Filing Line (Equipment ID # (b) (4) is utilized to produce (b) (4) Injection, (b) (4) mg/mL).

OBSERVATION 6

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the sterilization process.

Specifically,

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Your firm failed to implement and maintain controls to ensure the sterility of drug products produced on the (b) (4) Filing Line (Equipment ID # (b) (4) The airflow visualization study titled "Air Flow Visualization Study (Smoke Test) Report for (b) (4) Filling Line-March 2025 & April-2025" REP-25-044-01, dated: 11/07/2025 was insufficient in the following:

A) The airflow visualization study did not demonstrate that airflow was unidirectional and free from turbulence. The following are some examples:

1. CLP30SH001- This clip shows the intervention "removal of fallen (b) (4) (b) (4) " and turbulent airflow was observed at the timepoints 01:17, 01:35, and 01:44.

2. CLP38SH001- This clip illustrates the intervention "adjustment of (b) (4) during filling" and turbulent airflow was observed at the timepoints 01:21, 01:24, 01:37, and 01:55.

B) The airflow visualization study clip # CLP19SH001, during the intervention "material movement (transfer at (b) (4) stopper bowl, stopper track, forceps, forceps holder, (b) (4) rejection bin)," did not display that the smoke swept over and out of the critical processing area when (b) (4) was (b) (4) during set up. The airflow was observed to exit horizontally and never reached the (b) (4) surface areas (i.e., stopper track and stopper bowl) at timepoints 1:31 and 4:24.

C) The air flow visualization study titled "General Study Protocol Cum [sic] Report for Verification of Generated Smoke Are Neutrally Buoyant" FP-GSP-25-037, dated: 09/25/2025, did not demonstrate that the smoke utilized was neutrally buoyant through a video demonstration that the smoke floats, or moves very little, when no HEPA air is supplied to the RABs. The study was performed with the smoke continuously blowing, not permitting an environment with still air, to allow the smoke to naturally rise, float, or fall. Additionally, the density of the smoke was not defined in the protocol.

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D) Your firm lacks uniformity assessment specifications for airflow velocities within the same filter and between adjacent filters in the ISO 5 (b) (4) Filing Line (Equipment ID # (b) (4)

OBSERVATION 7

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, your firm does not have procedures in place for electronic data review prior to batch release. The procedure titled "Review of Electronic Audit Trails" 0310-SOP-QA-00075, section 6.11.6, indicates that QA is permitted to perform batch release using print-outs of batch generated information from critical process equipment such the SCADA for (b) (4) Filling Line (Equipment ID # (b) (4), which governs the operation of the (b) (4) Machine (Equipment ID # (b) (4), (b) (4) (Equipment ID # (b) (4), and the (b) (4) Filling and Stoppering Machine (Equipment ID # (b) (4). For example, the "Checklist to Ensure Completion of Data Audit Trail Review" 0310-SOP-QA-00075-10, for (b) (4) Injection (b) (4) mg (b) (4) mL, lot # (b) (4) the SCADA for (b) (4) Filling Line raw data review was performed by "print out" by QA on 05/10/2024. Additionally, total air particulate environmental monitoring electronic data for Grade A-Grade D controlled classified areas, is not reviewed by Quality Assurance prior to batch release, only hard copies of the data are assessed.

***DATES OF INSPECTION**

4/27/2026(Mon), 4/28/2026(Tue), 4/29/2026(Wed), 4/30/2026(Thu), 5/01/2026(Fri), 5/04/2026(Mon), 5/05/2026(Tue)

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