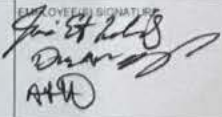


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 08/25/2025-09/05/2025	
		FED NUMBER 3013712903	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Mitesh K. Mehta, Chief -Manufacturing			
FIRM NAME Zydus Lifesciences Limited		STREET ADDRESS 434/6/B & 434/1/K Vadodara – Halol Highway, Jarod, Waghodia	
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391510, India		TYPE ESTABLISHMENT INSPECTED Sterile Drug Product Manufacturer	
<p>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.</p>			
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:			
<b>OBSERVATION 1</b>			
<p>There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.</p> <p>Specifically,</p> <p>A) Your firm failed to conduct adequate investigations into the root causes of the positive microbial contamination found during routine environmental monitoring and personnel monitoring performed during the manufacture of sterile (b) (4) drug products made in the (b) (4) filling suites (b) (4). Your firm has over 11 documented incidents spanning from 2024 through 2025 documented as microbial data deviations (MDD).</p> <p>Additionally, the majority of the excursions are only trended according to the specific location and not considering other impacted locations within the classified areas and respective equipment. Although the majority of the batches listed were rejected, your practice of only trending specific locations leads to the conclusion of each excursion being an "isolated incident." The following are not an exhaustive listing of the insufficient investigations reviewed:</p>			
SEE REVERSE OF THIS PAGE	 ATTA	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jose E Melendez, Investigator Damaris Y. Hernandez, Investigator Angelica M. Hernandez, Investigator	DATE ISSUED September 5, 2025
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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

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12420 Parklawn Drive, Room 2032 Rockville, MD 20857

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Mr. Mitesh K. Mehta, Chief -Manufacturing

FIRM NAME  
Zydus Lifesciences Limited

STREET ADDRESS  
434/6/B & 434/1/K Vadodara – Halol Highway, Jarod, Waghodia

CITY, STATE, ZIP CODE, COUNTRY  
Vadodara, Gujarat, 391510, India

TYPE ESTABLISHMENT INSPECTED  
Sterile Drug Product Manufacturer

Microbial Data Deviation (MDD)	Product Manufactured, Lot#	Type of Process and Filling Line	Grade of location, sampling type, and location	Results	Probable Root Cause from Your Quality Unit
MDD-EM/25/012	(b)(4) Injection (In-process) Semi Finished Goods# (b)(4)	Aseptic Fill Line (b)(4)	Grade A, (b)(4) RABS (b)(4) Near (b)(4)	(b)(4) CFU	- Microbiologist (b)(4) to collect Environmental Monitoring - Poor aseptic practice with the microbiologist not using fresh (b)(4) wipes while sampling
MDD-EM/25/0014; 0015	(b)(4) Injection (In-process) Semi Finished Goods# (b)(4)	Aseptic Fill Line (b)(4)	Grade A (b)(4) LAF MODA EM Toughbook	(b)(4) CFU (b)(4) CFU	During the GEMBA Walk, observed dried spillage on (b)(4) LAF, adhesive along the outer surface, and the operator using inconsistent sampling methods possibly re-using (b)(4) wipes in-between sampling
MDD-EM/24/025	(b)(4) Injection (In-process) Finished Goods Batch# (b)(4)	Aseptic Fill Line (b)(4)	(b)(4) RABS (b)(4) Near Filling Area	(b)(4) CFU	Possibly due to inconsistent sampling methods
MDD-EM/24/	(b)(4) Injection	Aseptic fill Line (b)(4)	Grade A	(b)(4) CFU, (b)(4) FU,	Possibly due to inconsistent sampling methods,

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EMPLOYEE(S) SIGNATURE  
*Jose E Melendez*  
*Damaris Y. Hernandez*  
*Angelica M. Hernandez*

EMPLOYEE(S) NAME AND TITLE (Print or Type)  
Jose E Melendez, Investigator  
Damaris Y. Hernandez, Investigator  
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Vadodara, Gujarat, 391510, India

TYPE ESTABLISHMENT INSPECTED

Sterile Drug Product Manufacturer

029, 31, 32, 33	Finished Goods Batch# (b) (4)		Personnel Monitoring (Finger Dab), (b) (4) Monitoring near (b) (4) Settle Plate, Air Sampling	(b) (4) CFU, (b) (4) ind (b) (4) CFU	Personnel movement
MDD-EM/24/030	(b) (4) Injection USP Finished Goods Batch# (b) (4)	(b) (4) Sterilization Line (b) (4)	Grade A (b) (4) RABS (b) (4) Monitoring Near Filling Area	(b) (4) CFU	Contamination probably caused by operator (b) (4) to perform (b) (4) RABS (b) (4) monitoring.
MDD-EM/24/046 & 047	(b) (4) Injection Finished Goods Batch# (b) (4)	(b) (4) Sterilization Line (b) (4)	Grade A Settle Plate near Stopper bowl Personnel Monitoring Finger Dab	(b) (4) CFU (b) (4) CFU	Possibly from operator not sanitizing their (b) (4) while performing assembly activities

B) Your investigations into unexpected out-of-specifications/out-of-trend results (OOS/OOT) are found inadequate.

i. Laboratory Investigation PR #761856, dated November 04, 2022, for (b) (4) Injection, Batch (b) (4) was initiated when the assay (by (b) (4) result was found Out-of-Specification (OOS) (b) (4) % against the specification range of (b) (4) % to (b) (4) % at the finished product stage. Your

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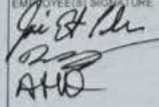
*Jose E Melendez*  
*Damaris Y Hernandez*  
*Angelica M Hernandez*

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Jose E Melendez, Investigator  
Damaris Y. Hernandez, Investigator  
Angelica M. Hernandez, Investigator

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<p>investigation inferred that the most probable cause is that the standard solution used during the analysis was injected approximately (b) (4) after preparation. Therefore, this could have caused a decrease in the standard area response. Nonetheless, the solution stability data in the analytical method report AMV-169-0-0R describes that the standard preparation is stable up to (b) (4). Your Quality Control (QC) laboratory invalidated the original OOS result, performed a reanalysis in triplicates of Batch (b) (4) and then reported the results of repeat analysis.</p> <p>ii. Laboratory Investigation PR #846189, dated May 13, 2023, for (b) (4) Injection USP (b) (4) mg/mL (b) (4) mL, stability Batch (b) (4) 3M long term stability study, was initiated when the assay (by (b) (4) results were found Out-of-Trend (OOT) (b) (4)% &amp; (b) (4)%; Mean (b) (4)% against the specification range of (b) (4)% to (b) (4)%. Your investigation disclosed that the root cause of the OOT results was "due to adsorption of analyte molecule on (b) (4) vial surface that have suppressed the signal of the analyte and resulting in lower assay results. However, as time progressed, the analyte molecule likely desorbed from the vial surface, leading to less suppression and an increase in the assay results.". Per PR #846189, the standard testing procedure (STP) did not require the use of (b) (4) glassware for the analysis. Furthermore, according to the General Manager of Analytical Development, the validation of the analytical method for (b) (4) Injection USP (b) (4) mg/mL, (b) (4) mL was performed using (b) (4) glassware. Your OC laboratory invalidated the original OOT results, performed a new triplicate analysis of stability Batch (b) (4) using (b) (4) glass (b) (4) vials, and then reported the results of the repeat analysis.</p> <p>Laboratory Investigation PR #958363, dated January 18, 2024, for (b) (4) Injection USP (b) (4) mg/mL, (b) (4) mL, Batch (b) (4) was initiated when the assay (by (b) (4) results were found OOS (b) (4)% &amp; (b) (4)%; Mean (b) (4)% against the specification range of (b) (4)% to (b) (4)% at the finished product stage. Your investigation disclosed that the root cause of the OOS results was "due to adsorption/desorption of analyte molecule on (b) (4) glass (b) (4) vial surface resulted into lower results." Adsorbed analyte release after certain period and yielded actual and consistent result." Your QC laboratory invalidated the original OOS results, performed a new triplicate analysis of Batch (b) (4) using (b) (4) glass (b) (4) vials, but holding the test solution in the vial for about (b) (4) prior to injection into (b) (4) system, and then reported the results of the repeat analysis.</p>			
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FOOD AND DRUG ADMINISTRATION

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	FEI NUMBER 3013712903

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Mr. Mitesh K. Mehta, Chief -Manufacturing

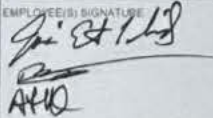
FIRM NAME Zydus Lifesciences Limited	STREET ADDRESS 434/6/B & 434/1/K Vadodara –Halol Highway, Jarod, Waghodia
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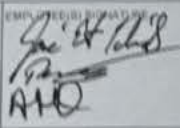
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391510, India	TYPE ESTABLISHMENT INSPECTED Sterile Drug Product Manufacturer
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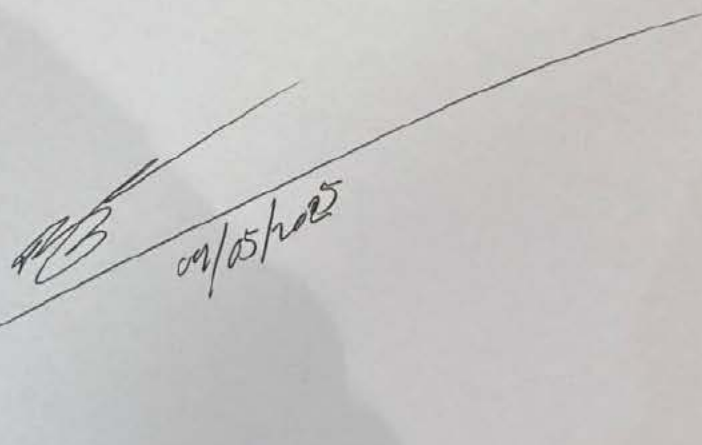

iii. Laboratory Investigation PR #1040417, dated July 03, 2024, for (b)(4) injection USP (b)(4) mg/mL, (b)(4) mL, Batch (b)(4) was initiated when the assay (by (b)(4) results were found OOS (b)(4) % & (b)(4) %; Mean (b)(4) % against the specification range of (b)(4) % to (b)(4) % at the (b)(4) stage. Your investigation revealed that the root cause for the initial OOS results identified as lower area of analyte peak in standard solution, which was further due to adsorption (adherence of the drug molecules to the glass surface) and desorption (release of the drug from the surface back into the solution) over the period. This cause was restricted to the (b)(4) vials from Batch (b)(4) used during the initial analysis. Your QC laboratory invalidated the original OOS results, performed a new triplicate analysis of Batch (b)(4) using a different (b)(4) vials (b)(4) for the repeat analysis.

iv. Laboratory Investigation PR #1069125, dated September 07, 2024, for (b)(4) injection, (b)(4) mcg/vial, validation Batch (b)(4) was initiated when the assay (by (b)(4) results were found OOS (b)(4) % & (b)(4) %; Mean (b)(4) % against the specification range of (b)(4) % to (b)(4) % at the (b)(4) stage. Your laboratory investigation did not identify a root cause for the lower assay results of (b)(4) at (b)(4) process. Thus, a manufacturing investigation was initiated, which revealed that hypothesis testing to identify a root cause for the observed OOS results were inconclusive. Nonetheless, your investigation inferred that the unexpected OOS was due to (b)(4) accumulation in the line; a small amount of (b)(4) could have resulted in a low-test result. Under the existing procedure, the (b)(4) tank must be (b)(4) (b)(4) process to remove any (b)(4) accumulated in the line after (b)(4). Then, as a corrective action, it was proposed that for the subsequent manufacture of validation batches of (b)(4) injection, (b)(4) mcg/vial, the lines should be (b)(4). However, no comprehensive evaluation of the process was conducted to determine whether the proposed (b)(4) will produce predictable results and prevent (b)(4) from recurring.

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FIRM NAME Zydus Lifesciences Limited		STREET ADDRESS 434/6/B & 434/1/K. Vadodara – Halol Highway, Jarod, Waghodia	
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391510, India		TYPE ESTABLISHMENT INSPECTED Sterile Drug Product Manufacturer	
<b>OBSERVATION 2</b>			
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.			
Specifically,			
A) Your procedures used for cleaning of the filling lines are inadequate as written. Your approved procedure fails to establish a sequence for cleaning/disinfection to ensure the proper aseptic conditions of the filling lines used in the manufacture of (b) (4) US product. Procedure SOP-MFG-00036 <i>Cleaning and Operation Vial filling machine</i> (b) (4) version 20 effective 10/05/2025 (DD/MM/YYYY) for Line (b) (4) does not specify a sequential order needed for cleaning and disinfection. Additionally, the procedure does not indicate the amount of (b) (4) to be sprayed to facilitate an accurate disinfection of the filling line.			
On September 02, 2025, we observed the cleaning and sanitization activities on Filling Line (b) (4) after the filling of commercial product, (b) (4) mg/mL. (Lot# (b) (4)) During our assessment, we noticed the following deficiencies which include, but are not limited to:			
<ul style="list-style-type: none"> <li>Your operator was using a (b) (4) mop head to clean the farthest parts of the filling line along with various other areas, including the base of the filling line to then wipe near the top again with the same mop head. Additionally, your operator did not follow any cleaning series from top to bottom.</li> <li>Your operator was spraying a portion of the filling zone with (b) (4) bottles of (b) (4) at the same time. When spraying the interior of the filling line with the (b) (4) the majority of the filling zone was saturated to the point that the solution sprayed onto the vertical surfaces were drifting and began to pool at the base of the walls within the filling area. The pooling accumulated along the back side of the filling line in an area that your operator was unable to reach.</li> <li>The (b) (4) located directly in front of the (b) (4) Tank was not cleaned.</li> <li>With the current layout of the filling line, there is no assurance that the operator can ensure the area of the back of the filling line can be adequately cleaned/disinfected and dried to avoid the pooling of solution.</li> </ul>			
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<p>Similar deficiencies were also observed in the cleaning/disinfection of Filling Line (b) (4) procedure SOP-MFG-00017 Procedure for cleaning and operation of vial filling and stoppering machine (Line (b) (4) version 20 effective 04/07/2025 (DD/MM/YYYY).</p> <p>B) Your firm (b) (4) failed to perform an adequate risk assessment for the cleaning/disinfection of the (b) (4) that are installed along each LAF (Laminar Air Flow). Your current Quantitative Risk Management Report dated 19/09/2024 (DD/MM/YYYY) concludes that the cleaning of these (b) (4) are to be performed (b) (4) without providing any empirical data to support your claim.</p>			
<b>OBSERVATION 3</b>			
The responsibilities and procedures applicable to the quality control unit are not fully followed.			
Specifically,			
Your Quality Unit failed to establish controls which prevents environmental monitoring data from being manipulated in the MODA-EM system. This system is utilized by your facility to document all environmental monitoring data including but not limited to surface sample monitoring, surface sample swabbing, active air monitoring, and passive air monitoring from the filling lines, filling suites, personnel monitoring, and finished product microbial analyses. The results from these analyses are used to determine the final disposition of a batch of sterile finished product. We observed within the MODA-EM system's roles section that the following roles have certain permissions active and enabled:			
<ul style="list-style-type: none"> <li>• Administrator role and the Approver role have access privileges to edit sample information including editing test results, attachments, attribute data, products, sampling, and testing.</li> <li>• The Section In-charge role has access privileges to edit test results.</li> </ul>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  AHO	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jose E Melendez, Investigator Damaris Y. Hernandez, Investigator Angelica M. Hernandez, Investigator	DATE ISSUED September 5, 2025
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<b>OBSERVATION 4</b>			
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.			
For Example,			
Your Protocol for evaluation of Non-Viable Particle Count (NVPC) locations in filling Line (b) (4) Document # LPL-PRT-0040-00, approved on February 22,2020 is inadequate.			
The Protocol LPL-PRT-0040-00 does not define how the filling functions such as routine/non-routine manufacturing operator interventions, including frequency, duration, and flow of open vials (empty/ filled) were evaluated to determine that the current NVPC monitoring areas of the filling Line (b) (4) represent the most critical locations. Additionally, there is no evidence regarding the orientation of the (b) (4) counting probes during the qualification study to ensure a meaningful sample. For example, there is no data describing the exact location of the (b) (4) probes (distance and height) for each monitored filling operation. Furthermore, there is no assurance that the line speed and vial size used during qualification represent the worst-case conditions of the commercial process.			
			
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