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	4/15/2024-4/23/2024*
	FEI NUMBER 3013712903

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rajesh Dessai, Chief - Manufacturing

FIRM NAME	STREET ADDRESS
Zydus Lifesciences Limited	Survey No. 434/6/B & 434/1/K, Vadodara - Halol Highway
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Village - Jarod, Taluka - Waghodia, Gujarat, 391510 India	Finished 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 WE OBSERVED:

OBSERVATION 1

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.

1. Investigations for cross contamination due to inadequate cleaning after [redacted] (b) (4) Injection batches were not thorough in evaluating all impacted batches. The following batches were rejected due to unknown impurity OOS/OOT results: [redacted] (b) (4) Injection batches [redacted] (b) (4) (OOS) [redacted] (b) (4) (OOT), and [redacted] (b) (4) Injection batch [redacted] (b) (4) (OOT).

   The investigations identified the root cause for these batch rejections to be cross contamination with the product [redacted] (b) (4) Injection, which had not been adequately cleaned from surfaces of shared equipment including manufacturing vessels, holding vessel, [redacted] (b) (4) tank, filling pumps, and [redacted] (b) (4) The impact on the following other batches was not thoroughly investigated:

   a. Analysis of [redacted] (b) (4) Injection batches detected the presence of an unknown impurity peak consistent with [redacted] (b) (4) cross contamination. These batches that were below the [redacted] (b) (4) % limit unspecified impurity limit for OOT were released to the US market without justifying the presence of [redacted] (b) (4) cross contamination. The batches included:

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- (b) (4) % peak consistent with (b) (4) cross contamination.
- (b) (4) % peak consistent with (b) (4) cross contamination.
- (b) (4) % peak consistent with (b) (4) cross contamination.
- (b) (4) % peak consistent with (b) (4) cross contamination.

Each of these batches was released to the US market with an (b) (4) expiration date (b) (4) or (b) (4) expiration date (b) (4)

b. Following manufacturing of batches (b) (4) and (b) (4) of (b) (4) on shared line (b) (4) equipment, the following batches were manufactured:

- (b) (4) - (b) (4) of (b) (4) OOT for an impurity related to cross contamination with (b) (4) Batch was rejected.
- (b) (4) - (b) (4) of (b) (4) impurity related to (b) (4) cross contamination was detected. Batch was not commercialized.
- (b) (4) - (b) (4) of (b) (4) impurity related to (b) (4) cross contamination was detected. Batch was not commercialized.

- (b) (4) - (b) (4) trials
- (b) (4) - (b) (4) of (b) (4) Injection. Batch was released to the US market with an expiration date of (b) (4) when testing did not detect (b) (4)
- (b) (4) - (b) (4) of (b) (4) Injection - OOT for an impurity related to cross contamination with (b) (4) Batch was rejected.

The investigation failed to thoroughly assess whether (b) (4) should have been released when batches manufactured before it and after it detected (b) (4) cross contamination. The investigation did not identify which equipment was causing the cross contamination.

c. Batches filled following (b) (4) in 2021 were not evaluated with analytical methods that were shown to be capable of detecting (b) (4) if it was present. Only the chromatograms for the existing methods were evaluated for the presence of atypical impurities. For example, the following batches were distributed to the US market: (b) (4) Injection batch (b) (4) and (b) (4) Injection batches (b) (4)

d. The investigation did not consider carryover between batches of (b) (4) since it was the same product. There was no evaluation if residues remaining on equipment could have led to increased impurities in initial vials of subsequent batches. (b) (4) is filled into (b) (4) vials due to (b) (4)

2. The following investigations were opened when the number of Particulate Type A-Glass Particles resulted in yield deviations or exceeded defect category limit for glass particles during

visual inspection of [redacted] Injection USP, [redacted] mcg/mL [redacted] mL.

a. Deviation Investigation PR#531860, dated June 03, 2021, for [redacted] Injection USP, [redacted] mcg/mL [redacted] mL, Batches [redacted] was opened when the percentage yield was found out of limit [redacted] %) against the specification of [redacted] % at the visual inspection stage. The lower yield was found to be a result of increased rejection rates for glass particles during visual inspection, including a [redacted] % reject rate for batch [redacted] and a [redacted] % reject rate for batch [redacted] Your firm's investigation inferred that the most probable root cause is glass vial lot to lot variation.

CAPA PR# 624883 was opened in response to this deviation investigation. The CAPA addressed increasing the visual inspection time of these vials due to the [redacted] vial and [redacted] liquid filled into the vial making it more difficult to visually inspect.

b. Deviation/Common Investigation (PR#s 691783, 699104, 708504 - dated July 29, 2022) was opened for exceeding the action limit [redacted] %) for glass particles during manual visual inspection. Each batch was 100% visually inspected [redacted] times with the following result:

Lot Number	Total Vials	[redacted]

Following AQL on the (b) (4) round of 100% visual inspection (VI), the batches were released to the US market.

As part of the investigation, samples were sent for microscopic analysis at a third-party laboratory. The result determined that the particles were glass that is the same type as the vial and the size of the particles in the provided sample ranged from 51.02 to 187.61 micrometers.

The lot of glass vials used to fill the product was found to be common between the three batches, the investigation determined that the most probable root cause was lot to lot variation between the vial with the (b) (4) of the (b) (4) also a contributing factor. Your investigation failed to assess other potential sources of glass particle generation. For example: product formulation, construction of the vial (b) (4) (b) (4) storage conditions of the vial containing the finished drug product, etc.

c. Deviation/Common Investigation (731813, 735565, 740156, 744450 - dated September 30, 2022) was opened when the rejection rate for glass particles exceeded the alert or action limit for the following batches:

Lot Number	Total Vials	(b) (4)

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(b) (4)

Following AQL on the (b) (4) round of 100% visual inspection (VI), the batches were released to the US market.

Your investigation identified a lot of vials which was common among the batches. (b) (4) vials of each batch under investigation were sent for characterization and particle size determination. Per your investigation the analysis confirmed the particles were glass with a variation in size ranging from 33.55 micrometers to 312 micrometers. It was determined that the particles were attributed to the specific lot of vials used for these batches. The root cause was determined to be "material".

After the release of these four batches, DEV/0317/2023/0034 (PR#853661) (batch (b) (4) mcg/mL USP (b) (4) mL, manufactured May 29, 2023, US market) was opened when vials purchased from an alternative vendor and used in production also resulted in a batch that exceeded the action limit for Particulate Type A-Glass Particles.

Lot Number	Total Vials
(b) (4)	(b) (4)

Per your deviation investigation "In earlier investigations, the root cause was identified as lot-to-lot variation in glass vials", "However, higher % glass particle rejections were found out of limit after changing the glass vial manufacturer." Based on that, your investigation inferred that lot to lot variation in the vials alone may not be the only

contributing factor.

Subsequent investigation included a study executed in February 2024 where (b) (4) Inj. USP (b) (4) mcg/mL was filled into (b) (4) vials instead of glass vials and identified a significant reduction in the rejection rate due to glass particles.

Lot Number	Total Vials	(b) (4)

Based on this finding, the investigation inferred the probable cause for glass particles in the previous batches is use of (b) (4) vial and an interaction between the product and the vial.

Following this study, your firm made the decision to reject batch (b) (4) based on the number of vials found to have glass particles exceeding the limit and for the determination that the source of the glass particles was most probably related to incompatibility/interaction between the vial and the drug. Your firm also made the decision to cease manufacturing of this product packaged in the (b) (4) mL vial due to the source of the glass particles being undetermined. However, previous batches released to the market with similar out of limit glass particle defect rates, filled into the same type and size of glass vial, were permitted to remain on the market.

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The following batches were manufactured, released and permitted to remain on the U.S. market without reevaluating the original root cause for exceeding glass particle limits as discussed in the aforementioned investigations:

(b) (4) (Finished/Packaged Batch (b) (4) Expiration (b) (4)
(Finished/Packaged Batch Expiration
(Finished/Packaged Batch Expiration
(Finished/Packaged Batch Expiration

OBSERVATION 2

Established sampling plans and test procedures are not followed.

1. Procedures 0317-SOP-QC-00193 "Sampling and Testing procedure of (b) (4) and 0317-SOP-QC-00118 "Quality monitoring of (b) (4) System" were not followed for collecting (b) (4) samples. Scheduled samples for specified sample points were not collected. However, analytical records were made to document the samples were collected and used for testing, even though QC microbiology personnel confirmed samples were not collected.

   From April 4, 2024-April 13, 2024, there were (b) (4) personnel that participated in (b) (4) sampling. Each individual on one or more occasion during this time period participated in collecting or documenting (b) (4) samples that were not collected from the specified sampling point. For example:

   a. On April 12, 2024, an employee collected (b) (4) extra bioburden (b) (4) samples from point (b) (4) These extra samples were represented as points (b) (4) (b) (4) which were not sampled. The documented samples for points (b) (4) (b) (4) were reported to have all been collected from use point (b) (4)

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There were (b) (4) samples for Bacterial Endotoxin Testing (BET) documented to be collected from (b) (4) different points on April 12, 2024. (b) (4) of these were collected from a single point, (b) (4) The other (b) (4) samples were poured into the BET test tubes in the microbiology laboratory with excess sample collected from (b) (4) so they could be submitted for testing.

The employee that collected the samples was a fixed term employee not qualified to collect (b) (4) samples, enter the production area, or make GMP records. The signed sampling records indicated a second employee had been the sampler, even though that employee confirmed that they had not collected any samples and had instructed the fixed term employee to collect the samples without sampling from each point. These analytical records contained sampling start and end times that did not correlate to actual activities. The sampler in the records was aware the samples they signed for were not collected from the actual locations and identified this was a practice that had been occurring on occasion for the past four months.

b. On April 6, 2024, an employee collected extra samples from (b) (4) sample point (b) (4) and represented these as other points that were scheduled for sampling, but not actually sampled, including (b) (4) Additionally, no sample was collected from (b) (4)

The employee that collected the samples was still under qualification and had been directed by a qualified analyst to sample this way to avoid more difficult to sample points. The qualified analyst filled out the analytical records as the sampler, aware that they had not collected samples and the samples were not from the documented location. The qualified analyst confirmed failing to sample from specified locations was not an isolated incident.

On the same day, the analyst under qualification was documented to have collected separate samples for the purpose of analyst qualification from (b) (4) The samples were not observed to be collected. A qualified analyst signed the qualification documentation documenting they had witnessed the sampling for the purpose of analyst qualification.

c. On April 4, 2024, samples were not observed to be collected from (b) (4) The analyst responsible for sampling stated samples were taken from (b) (4) instead, because it is an easier point to access. The analyst acknowledged creating records for (b) (4) samples that were not collected and confirmed this was not an isolated incident.

d. On April 5, 2024, samples were not observed to be collected from (b) (4) The analyst responsible for making the analytical records stated the samples were collected from a different room. The analyst acknowledged creating records for (b) (4) samples that were not collected and confirmed this was not an isolated incident.

During interviews with employees responsible for (b) (4) sampling on April 15-16, 2024, employees provided inaccurate statements or refused to answer questions.

2. Procedure 0317-SOP-QC-00240 "Operation and Calibration of High Performance of High Performance Liquid Chromatography (HPLC)" requires documented authorization to use different processing methods within a sequence. The documentation made lacks specific details of what was reviewed and what was found to be inappropriate that justified different processing methods that include addition of manually entered timed integration events into the processing method.

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OBSERVATION 3

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

The airflow visualization study conducted on Line (b) (4) Protocol Document CHL-QUA-00315-00, effective June 05, 2021, under dynamic conditions did not demonstrate unidirectional airflow during (b) (4) interventions. When the (b) (4) to the RABs was (b) (4) the airflow (smoke) was observed flowing out of the RABs and into the air intake duct located near the (b) (4) line. Air flow on the line was not visible when the (b) (4) was (b) (4) and thus was not able to be evaluated for unidirectional airflow.

Line (b) (4) was observed to have the same design with air intakes located directly (b) (4) where RABS (b) (4) (b) (4)

OBSERVATION 4

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

Procedure 0317-SOP-MFG-00039 "Clean room and aseptic behaviour" was not followed to ensure sterilized components are only contacted with sterile forceps and aseptic manipulations are performed from the side, so as not to disrupt the laminar air flow. For example:

1. During an intervention to adjust the stopper bowl alignment during aseptic filling of (b) (4) batch (b) (4) (US market batch), the operator allowed the (b) (4) RABS (b) (4) to contact sterile stoppers. These stoppers were subsequently returned to the stopper bowl.

2. During observation of aseptic filling activities for (b) (4) batch (b) (4) (US market batch),

media fill (b) (4) and media fill (b) (4) the (b) (4) RABS (b) (4) were observed to pass over the stopper bowl during assembly, over the stopper bowl and stoppers during change of environmental monitoring plates, and over open vials during removal of fallen vials in the incoming vial area.

OBSERVATION 5

Your firm failed to establish adequate 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.

1. Process validation studies for (b) (4) products that have been distributed to the US market including (b) (4) Injection, (b) (4) Injection, and (b) (4) Injection have not evaluated whether proper (b) (4) is achieved and maintained after stoppering throughout the batch. There has been no destructive or non-destructive testing for any of the products to show the presence of an appropriate (b) (4)

   There have been six US market complaint investigations (694519, 710383, 749188, 753359, 783672, 832994) for difficulty in administering (b) (4) Injection because they were not able to draw the full contents of the vial when administering the product. None of these investigations evaluated whether the vials had an appropriate (b) (4) There was no evaluation of retains or data collected from validation or commercial batches to demonstrate the vials had appropriate (b) (4) and were stoppered completely at the (b) (4) of (b) (4) to prevent ingress of environmental air.

2. Process validation studies do not establish statistical sampling plans that allow for evaluation of inter-batch and intra-batch variability. No acceptance criteria to evaluate intra-batch or inter-batch variability are established. For example:

a. During process validation studies for [redacted] Injection:

i. The samples to evaluate the product after [redacted] for assay of [redacted] assay of [redacted] impurities, and pH were [redacted] from vials collected from [redacted] different [redacted] and only a single result was generated for each process validation batch.

ii. For process validation batch [redacted] the assay for [redacted] ranged from [redacted]% at the [redacted] filled vials to [redacted]% for the [redacted] filled vials. The assay for [redacted] ranged from [redacted]% in the [redacted] samples to [redacted]% for the [redacted] samples. No intra-batch variability acceptance criteria were established that would further evaluate the cause of this variation.

iii. There were no acceptance criteria for intra-batch or inter-batch variability for the [redacted] content or for variability between the different [redacted] The results were only compared to the finished product specification of not more than [redacted]% without determining what amount of variation was acceptable.

For example, during 2020 process validation batch [redacted] from [redacted] the [redacted] ranged from the [redacted] sample at [redacted]% while the [redacted] sample was [redacted]%. This is inconsistent with an additional process validation batch [redacted] in 2021, where the [redacted] from [redacted] ranged from [redacted]%.

b. Process performance qualification studies for the US market (b) (4) Injection USP (b) (4) mg/ Vial, do not include an evaluation of intra-batch or inter-batch variability nor do they include acceptance criteria for variability. The process performance qualification was approved without evaluating potential sources of variability or addressing variability of results. For example:

Test for Uniformity of Dosage Units produced the following results for the process validation batches:

Batch	Result
(b) (4)	(b) (4)
(b) (4)	(b) (4)
(b) (4)	(b) (4)

Test for Total Impurities produced the following results:

Batch	Result
(b) (4)	(b) (4) %
(b) (4)	(b) (4) %
(b) (4)	(b) (4) %

The following process validation batches of (b) (4) Injection (b) (4) mg/Vial were released for distribution to the U.S. market:

(b) (4) Finished/Packaged Batch (b) (4) Expiration (b) (4)
Finished/Packaged Batch Expiration

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OBSERVATION 6

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Review of the non-viable particle count (NVPC) continuous monitoring from the [redacted], which is used to transport [redacted] vials from the filling line to the [redacted] show frequent communication errors. These occur when the unit fails to have an adequate WIFI signal or power to the NVPC is lost, leaving gaps in the ability to report NVPC data. These communication errors were first documented in a maintenance notification, July 23, 2020, but no effective actions have been taken to ensure NVPC data is available continuously during batch production activities. For example, during line set-up, filling, and [redacted] loading:

1. For batch [redacted] batch [redacted] on January 19-20, 2024, there were 49 communication errors totaling 1 hour and 30 minutes of time. This included communication errors from [redacted] on January 19, 2024, when [redacted] vials were being loaded into the [redacted]

2. For batch [redacted] batch [redacted] on April 7-8, 2024, there were 45 communication errors totaling 2 hours and 3 minutes of time. One communication error lasted 41 minutes and 46 seconds.

3. For batch [redacted] batch [redacted] on April 1-2, 2024, there were 54 communication errors totaling 58 minutes of time.

The procedure 0317-SOP-MFG-00037 requires a breakdown notification if the errors continue during the batch, but provides no specific instructions describing the threshold that would require a notification. No breakdown notification was generated for batches [redacted]

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Additionally, the alarms are not being acknowledged in a timely manner with comments entered to describe the activity occurring. For example, during batch (b) (4) communication errors on April 2, 2024, at (b) (4) (8 minutes 43 seconds duration), (b) (4) (8 minute 56 seconds duration), and (b) (4) (8 minute 42 seconds duration) were not acknowledged in the system until (b) (4) on April 2, 2024. The comment was written as "NA" and did not assess the impact of the loss of NVPC data prior to loading (b) (4) vials into the (b) (4)

OBSERVATION 7

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

1. (b) (4) on line (b) (4) were observed to have scratches, rough surfaces, and small pieces that were not fully attached during aseptic filling of (b) (4) batch (b) (4) on April 19, 2024.

2. (b) (4) on the inside of the (b) (4) RABS (b) (4) were observed to have a (b) (4) residue during aseptic filling of (b) (4) batch (b) (4) on April 19, 2024.

OBSERVATION 8

Employees engaged in the manufacture of a drug product lack the training required to perform their assigned functions.

Your firm's manual visual inspection process requires operators to inspect (b) (4) mL (b) (4) vials that contain (b) (4) Injection, USP for the presence of glass particles. Your qualification procedure for visual inspectors, Annexure No. 0317-SOP-P11-00001-01, utilizes a (b) (4) which includes (b) (4) mL (b) (4) vials of (b) (4) Inj. seeded with glass particles. This (b) (4) failed to challenge operators on identification of particulates (glass particles) that are below (b) (4) micrometers in size. Per

your out of limit investigations, PR#s 531860, 691783, 699104, 708504, 731813, 735565, 740156, 744450 and 853661, glass particles, with a measured size as low as 150 micrometers, have been identified in this same product, (b) (4) Inj. (b) (4) liquid packaged in a (b) (4) mL (b) (4) vial).

OBSERVATION 9

Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

Your firm's Equipment Cleaning Validation Master Plan (CVMP), Document ID CVMP/001-07 and Document LPL-CVAL-003-00, "Cleaning Validation Protocol cum Report", dated May 20, 2020, incorrectly identified the hardest to clean/most toxic API, manufactured on Line (b) (4) using non-dedicated equipment, as (b) (4) Deficiencies in the firm's product risk (b) (4) include failure to fully assess (b) (4) and cleanability (b) (4) of individual manufacturing surfaces. Your cleaning validation study also failed to assess the cleanability of the APIs on the full range of surfaces by excluding (b) (4) which is used in the construction of the (b) (4) of the (b) (4)

The following rejected batches of finished drug product, manufactured on Line (b) (4) were found to be cross contaminated with (b) (4)

(b) (4) Inj. (b) (4) mg/mL
(b) (4) Inj. USP. (b) (4) mg (b) (4) mL
(b) (4) Inj. (b) (4) mg/mL
(b) (4) Inj. (b) (4) mg/mL

OBSERVATION 10

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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.

The MODA software system is used for microbiology documentation of sampling and testing for the (b) (4) system (b) (4) and environmental monitoring. The system is intended to be integrated with a barcode scanner to populate sample locations, sample information, and time and date information. Analysts are permitted to override the use of the scanner and make manual entries. The software is not configured with an autosave function, allowing analysts to make changes to entry before manually saving without committing the changes to the audit trail.

***DATES OF INSPECTION**

4/15/2024(Mon), 4/16/2024(Tue), 4/17/2024(Wed), 4/18/2024(Thu), 4/19/2024(Fri), 4/22/2024(Mon), 4/23/2024(Tue)

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Investigator
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