

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER ORA OPQO HQ, Room #2032 12420 Parklawn Drive, Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov	DATE(S) OF INSPECTION August 26th, 2025 - September 03, 2025
	FEI NUMBER 3015283245

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Rhonda Duffy, Executive Vice President and Chief Operating Officer

FIRM NAME Biocon Biologics Limited	STREET ADDRESS Block No. M1, M2 and M6, Q1 and W3, 20th KM Hosur Road
CITY, STATE AND ZIP CODE Electronics City Bengaluru, Karnataka, 560100, India	TYPE OF ESTABLISHMENT INSPECTED Drug Substance Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 1

Written sanitation and facility maintenance procedures are not established or followed.

Specifically,

A) The ^{(b)(4)} process facility maintenance and cleanliness is inadequate for Grade C and D manufacturing areas. This includes the following deficiencies noted during the facility walkthrough on August 26th, 2025:

- Liquid ^{(b)(4)} standing puddle within the Grade C ^{(b)(4)} room and adjacent to the ^{(b)(4)} used to ^{(b)(4)} the Grade C ^{(b)(4)} Area, which houses the Grade B ^{(b)(4)} used for ^{(b)(4)} processing of ^{(b)(4)} drug substance batches.
- A soiled mop labeled as "Grade D Area Cleaning" within the Grade C ^{(b)(4)} room that adjacent to the Grade C ^{(b)(4)} Area, which houses the Grade B ^{(b)(4)} drug substance batches.
- Liquid standing puddle underneath the ^{(b)(4)} system within ^{(b)(4)} area.
- Liquid standing puddle underneath ^{(b)(4)} Tank within ^{(b)(4)} area.

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5. Large liquid standing puddle underneath (b)(4) tank within (b)(4) area.
6. A large standing puddle of (b)(4) liquid on the facility floor of (b)(4) area near In-process (b)(4) tank (b)(4). According to the Deputy Manager of Production, the (b)(4) standing puddle of liquid is likely (b)(4).
7. (b)(4) standing puddle underneath (b)(4) tank within (b)(4) area.
8. (b)(4) standing puddle underneath (b)(4) tank within (b)(4) area.
9. Liquid standing puddle underneath (b)(4) tank within (b)(4) area.
10. The Air Handling Units within the in-process (b)(4) area, including (b)(4) had visible (b)(4) stains on the pleated filter surfaces.

B) The (b)(4) process facility maintenance is inadequate. This includes the following deficiency noted during the facility walkthrough on August 26th, 2025:
The (b)(4) used for (b)(4) manufacturing operations was leaking consistently with a container bucket placed directly underneath the leak. However, there was written notification or investigation into the leak until the current inspection.

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OBSERVATION 2

Written procedures are not established or followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug substance.

Specifically,

A) On August 29th, 2025, I observed visible rust spots within the Grade B (b)(4) Laminar Air Flow (LAF) (b)(4) (b)(4) 01 and visible rust/removable (b)(4) material on the outer LAF surfaces of the Grade C environment. The LAF is used for (b)(4) activities for (b)(4) Bulk drug substance batches with a bioburden specification of NMT (b)(4) FU (b)(4) ml and Bacterial Endotoxins specification of NMT (b)(4) EU/mg of protein. This included:

1. Visible (b)(4) rust surrounding the seams and ridges of the (b)(4) valve and knob stationed within the Grade B LAF
2. Visible (b)(4) rust on the screw part within the Grade B side of the LAF view screen.
3. (b)(4) sealant observed throughout the corner and edges of the Grade B LAF.
4. Visible (b)(4) rust observed within the edges of Grade B LAF
5. Visible (b)(4) rust and brown material that was removable with a wipe on the outer surface edges on the Grade B LAF housed in the Grade C environment.

B) Dynamic Air flow visualization pattern studies for the Grade B (b)(4) Laminar Air Flow (LAF) (b)(4) (b)(4) 01 did not include the following equipment and materials routinely used during (b)(4) activities for (b)(4) Bulk drug substance batches with a bioburden specification of NMT (b)(4) FU (b)(4) ml and Bacterial Endotoxins specification of NMT (b)(4) EU/mg of protein:

1. (b)(4) that is kept inside the Grade B LAF during (b)(4) activities.
2. Other required materials loaded within the Grade B (e.g (b)(4) etc.)

In addition, Requalification of (b)(4) LAF 01 (b)(4) 01), Document No. RQ- (b)(4) 01-0007.01, Dated: July 10, 2024, listed the following demo simulations as executed, completed, and signed off with the following Test Status: PASS. Actual Result: Unidirectional Sweeping action observed.

1. (b)(4) 01 (b)(4)

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2. (b) (4)
3. (b) (4) complete process

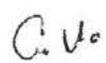
However, there was no air flow study evaluation of the (b) (4) tank used during (b) (4) activities. In addition, there is no written evaluation of the eddy currents observed to be bouncing off the LAF bench top at the following dynamic smoke video timepoints: (b) (4)

C) On August 26th, 2025, I observed very visible liquid droplets throughout the view glass within the (b) (4) same day. The level of droplets obstructed the view within the (b) (4) labeled as Cleaned and Ready for Use on the checklist drying steps marked as completed:
Equipment Drying: (b) (4)

According to the Global Compliance Head, the presence of liquid water droplets within equipment is acceptable post cleaning and drying operations. However, the acceptance level for the varying level of equipment dryness and water retention prior to equipment release is not defined or specified within the equipment release checklist.

D) (b) (4) used to store (b) (4) during (b) (4) operations within (b) (4) area was observed to be very visibly discolored. This is despite SOP Document No. (b) (4) ROD-SOP-0152 Procedure for Identification and Usage of (b) (4) effective Date: July 31, 2025. Section 6.2 d) Physical verification of (b) (4) for any discoloration, deformation, elongation etc.) (b) (4) there is no visual challenge performed for operator check for physical verification of (b) (4)

E) (b) (4) labeled as cleaned and ready for Use on August 25, 2025 had very visible metallic scratches and dents throughout the rim of the (b) (4) is used to the (b) (4) process stage.

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QUALITY SYSTEM

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and make a record of the conclusions and follow-up.

A) Out of Specification (OOS) Investigation Report No. 199753 was initiated on June 10, 2024, due to OOS observed result: (b)(4) fu/mL (Limit NMT (b)(4) fu/mL) for (b)(4) Sampling location description: (b)(4) According to the report, from the identified isolates (*Ralstonia insidiosa*, *Elizabethkingia miricola*, *Chryseobacterium indologenes*) most probable cause could be current (b)(4) sanitization procedure not able to eliminate these isolates thus that could lead to such localized microbial load build up. Additionally, Due to the rust on the surface on the (b)(4) and (b)(4) traces might have probably led to potential ingress of the microbes on the (b)(4) and which might have carried into the collected sample resulting into OOS for the sampling points. In addition, CAPA Number: 191318 was initiated as an additional control to reduce microbial ingress 192406 is logged to revise the SOP (b)(4) SOP/0158 instruction to clean the hoses used for (b)(4) collection within (b)(4) from the last usage.

However, OOS Investigation Report No. 199753, Date: June 10, 2024 did not included a detailed assessment and retrospective review of previous similar OOSs or events, including: OOS Report No. 186956 initiated on April 8, 2024 due to OOS result (b)(4) fu/mL (Limit NMT (b)(4) fu/mL) observed for Sampling point: (b)(4) Sampling location description: (b)(4) The investigation also states that form the identified isolates (*Ralstonia insidiosa*, *Kocuria palustris*) the most probable cause could be current (b)(4) sanitization procedure not able to eliminate these isolates thus that could lead to such localized microbial load build up. CAPA Number: 191318 was initiated as an additional control to reduce microbial ingress 192406 is logged to revise the SOP (b)(4) SOP/0158 instruction to clean the hoses used for (b)(4) collection within (b)(4) from the last usage.

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B) Out of Alert Limit (OOAL) Investigation No. 271752 was initiated on August 19, 2025 for (b)(4)
The following organism were identified and described:
1. (b)(4) Delftia acidovorans
2. (b)(4) Delftia acidovorans
3. (b)(4) Ralstonia pickettii

According to the report, Delftia acidovorans and Ralstonia pickettii are environmental organisms, often associated with (b)(4) systems and biofilms. Their presence may indicate a need to review (b)(4) system integrity, cleaning procedures, and biofilm control strategies, especially if they recur in future monitoring. Delftia acidovorans is a new isolate found for the (b)(4) plant and Ralstonia pickettii is a common isolate found for the (b)(4) facility when compared to past 12 months data. Ralstonia pickettii is found 3 times in past 12 months for the (b)(4) facility. However, there was no holistic assessment of the (b)(4) system integrity and validation, cleaning procedures, and biofilm control and biofilm mapping strategies concerning the issues previously identified.

C) OOS Investigation No. 223366 was initiated on October 21, 2024, for (b)(4) Sampling point:
(b)(4) Observed result: (b)(4) CFU/mL (Specification Limit: NMT (b)(4) CFU/mL). According to the investigation report, The identified isolate (Ralstonia pickettii) organism in the (b)(4) tank (b)(4) and this OOS(219531, 221217,220744) are same i.e manufacturing facility is (b)(4)

(b)(4) this might have led to increase bioburden load in this system. The same (b)(4) is transferred from this (b)(4) tank to (b)(4) here could be the possibility of carry over this might have led to increase in bioburden level in the reported OOS, hence this might be one of the probable causes for the reported OOS.

Similarly, OOS Investigation No. 220744 was initiated on October 07, 2024 for (b)(4) Sampling point:
(b)(4) Sampling location description: (b)(4) Area. Observed result: (b)(4) CFU/mL
Specification Limit: NMT (b)(4) CFU/mL, The identified isolate (Ralstonia pickettii) organism in the (b)(4) tank

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(b) (4) and this OOS(219531, 221217) are same i.e manufacturing facility is (b) (4)
(b) (4)

(b) (4) his
might have led to increase bioburden load in this system. The same (b) (4) is transferred from this (b) (4) tank to (b) (4) here could be the possibility of carry over this might have led to increase in bioburden level in the reported OOS, hence this might be one of the probable causes for the reported OOS.

However, there was no further evaluation of (b) (4) tank (b) (4) and assessment of the affected (b) (4) system integrity and validation, cleaning procedures, biofilm controls and biofilm mapping strategies concerning the issues identified (b) (4) operations.

D) Risk Assessment Report No. (b) (4) 24/002, Titled: Risk assessment for replacement of existing valves with zero dead leg valves in (b) (4) systems was initiated on April 27, 2024 due to investigation related CAPAs: 139313, 14293, 147038, 149184, and 160910 for changing current sampling valves are (b) (4) valves with (b) (4) to dead leg (b) (4) valve. This is because the (b) (4) valves with (b) (4) may lead to inefficient (b) (4) which may not ensure removal of complete hold up and allows microbial load to proliferate to proximity of (b) (4) leading to these bioburden excursions. However, a holistic assessment was not conducted for all current (b) (4) sampling (b) (4) valves currently in place for (b) (4) facilities.

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OBSERVATION 4

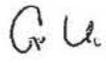
The responsibilities and procedures applicable to the quality control unit are not in writing or fully followed.

Specifically,

A) Notification No: 1000387247, (b)(4) 26 Leak Test Failed, Dated: January 24, 2024 was raised due to leak test being conducted multiple times and having multiple failed results. The (b)(4) test of the complete system found that leak was on (b)(4) side. A (b)(4) material used for engineering grade repair system for repairing and rebuilding machinery and equipment was applied on the (b)(4) with the failed leak test. However, there is no detailed impact assessment, risk analysis, cross-functional review and approval, and post-implementation verification for the effectiveness of the equipment repair operations.

B) During the inspection walkthrough on August 26, 2025, I observed a crumbled up sterilization label for (b)(4) directly on top of the (b)(4) container in Grade C (b)(4) room (b)(4) loading area) with the following hand written details:
Equipment Name: (b)(4)
Sterilized: 24/08/2025
Use Before: (b)(4)
Sign and Date: 24/08/2025

However, there is no documented reasoning as to why the label was crumbled up.

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LABORATORY CONTROL SYSTEM

OBSERVATION 5

Laboratory Control Mechanisms are not established.

A) On September 01, 2025, I observed that there is no final disposition record for one (1) out of (b)(4) media plates, Expired On: August 31, 2025 labeled as Environmental Monitoring (EM) sampling activities for (b)(4) on August 12, 2025, A.R No. (b)(4) MICRO-25-005 within the laboratory information management software.

B) There is no notification or documented follow-up to multiple errors observed within QC Analytical Balances. This consists of Analytical Balance NTP Server Error: "Because of the server down/network failure temporary."

C) The following notification reader errors were displayed on the BET Kinetic software after being released for completion of Performance Qualification (PQ) on August 27, 2024: Error #0400 code at (b)(4)
According to the software manual:

- Error #0400: Carrier x-axis failed position verify.
 - Error #:0401 Filter wheel motor failed position verify.
- Errors 0400 and 0401: indicate that an axis failed its Position Verify test. After moving a predefined number of steps from a home position, the motor should return to the home position in the proper amount of time and steps. If the axis moves back to its home position in the wrong amount of time or in too few or too many steps, the test fails. Probable causes:
- o Mechanical obstruction
 - o Carrier belt or pulley slipping
 - o Loose filter wheel hub
 - o Loose filter may be impeding filter wheel movement
 - o Defective motor drive circuit or 12-volt power problem.

However, there was no further assessment or documented follow-up with the equipment vendor, engineering team, and performance qualification status.

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