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	9/18/2025-9/26/2025*
	FEI NUMBER 3002806419

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Remi Helmig, Site Director

FIRM NAME	STREET ADDRESS
Baxter Onocology GmbH	Kant Str. 2
CITY, STATE, ZIP CODE, COUNTRY Halle (Westf.), North Rhine-Westphalia, 33790 Germany	TYPE ESTABLISHMENT INSPECTED 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

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

1. The (b) (4) have a total of (b) (4) – none of which can be (b) (4) (b) (4) during (b) (4) sterilization cycle, leaving (b) (4) during the cycle.

The (b) (4) has a total of (b) (4) none of which can be (b) (4) (b) (4) during the (b) (4) sterilization cycle, leaving (b) (4) during this cycle.

2. Your investigation PR#3191411, which investigated failed (b) (4) sterilization revalidations was inadequate.

a. The first (b) (4) revalidation, which failed on April 4, 2025, had (b) (4) positive growth biological indicators. Your investigation concluded that the failure of the first (b) (4) revalidation was due to a "rouge phenomenon" of biological indicators, lot (b)(4), used in the (b) (4) cycle without providing scientific justification or evidence to support this conclusion. You conducted a "test run" on April 17, 2025, on the same (b) (4) and used the same lot of BIs, which, after incubation, showed no growth.

Your repeat of the revalidation performed on April 30, 2025, also failed, with (b) (4) positive BIs, which was again attributed to "rouge phenomenon". The same lot of BIs used on both the original revalidation and the "test run" were used for the April 30, 2025, revalidation.

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Your repeat of the re-validation on May 10, 2025, of the (b) (4) cycle also had (b) (4) biological indicator show growth, which was within your acceptance criteria ((b) (4) % are allowed to show growth). No further investigation was conducted.

Additionally, you did not notify your customer the results of your failed (b) (4) revalidation performed on April 4, 2025, until April 28, 2025. No notification was given to your customer informing them of the second failed revalidation of the (b) (4) cycle on April 30, 2025. Per your Quality Agreement with your customer, you are required to provide notification within (b) (4)

b. The deviation investigation did not evaluate the potential impact on product sterility assurance or assess whether other (b) (4) cycles performed during previous timeframes were affected. Your investigation did not consider previous validation failures for this (b) (4) for example the (b) (4) validation failure which occurred on December 13, 2023, with (b) (4) positive BIs. After this failed revalidation in 2023, you made no contact to your customer informing them of the failure.

3. Smoke studies of aseptic processing areas are deficient:

a. Smoke studies were approved by the Quality Department that showed first air was disrupted above sterile surfaces and sterile components during interventions, such as:

(b) (4) Filling Line: Stopper bowl jam intervention, installation of (b) (4) and (b) (4) intervention.

(b) (4) Filling Line: Assembly of the (b) (4)

b. Filling Line (b) (4) exchange of (b) (4) is demonstrated in the smoke study using forceps to reach over the exposed (b) (4) for the removal of (b) (4) however, on September 25, 2025, we observed the replacement of (b)(4) on Line (b) (4) using (b)(4), even though forceps were available for use inside the aseptic filling area.

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c. Your firm lacks a smoke study for the (b)(4) intervention we observed on September 23, 2025, where the (b)(4) (b)(4) and an intervention to clean directly beneath the (b)(4) was performed. This intervention has also been documented in batch (b)(4) record, recorded on August 25, 2025.

d. Your firm lacks dynamic smoke studies in the Grade A (b)(4) area.

e. The smoke studies were conducted using smoke generated from (b)(4) There has been no demonstration this system can produce neutrally buoyant smoke.

4. The media fill on (b)(4) filling line does not represent campaign filling length for this line. Media fills for the past two years fill a maximum of (b)(4) vials over the course of approximately (b)(4). However, we overserved an active campaign for this line of over (b)(4) vials spanning the course of (b)(4) Media fills include a line down time of (b)(4), however, in a campaign the line down time between batches is (b)(4) (b)(4).

5. The media fill conducted on the sterile (b)(4) line in the (b)(4) utilizes (b)(4) media, while actual production operations on this line involve processing and filling sterile (b)(4) products. You have no assurance that (b)(4) will contact inner surfaces of all equipment in a representative way and can flow through the equipment train in the same manner as your (b)(4) drug substance. In addition, media fills for this line constitute only half the number of manipulations and half the length of a normal batch, for example, we observed Batch # (b)(4) with an anticipated fill size of (b)(4) bags, in production on September 24, 2025, while all media fills for this (b)(4) over the past two years only fill (b)(4) into (b)(4) bags.

6. On September 24, 2025, (b)(4) was used to wrap a (b)(4) unit that needed to be replaced inside the (b)(4) during filling of (b)(4) batch # (b)(4). The (b)(4) is (b)(4) sterilized by (b)(4) The sterilization validation does not clearly describe the presence of the biological indicator in the bag or ensure that (b)(4) can penetrate and sterilize (b)(4) (b)(4)

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OBSERVATION 2
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

1. Aseptic behavior procedure SOP-01007, which describes avoiding reaching the (b) (4) over sterile surfaces and open containers, was not followed. For example:

a. On September 23, 2025, at approximately 10:13 am, while filling batch # (b) (4) we observed an operator on (b) (4) Line, using non-sterile (b) (4) to operate the (b) (4) reach over exposed vials which were later filled and not rejected.

b. On September 26, 2025, at approximately (b) (4) during the filling of batch # (b) (4) we observed your operator using the non-sterile (b) (4) to switch a faulty (b)(4). During the intervention the (b) (4) (b) (4) reached over the newly installed (b) (4) and (b) (4) already installed sterile (b) (4)

c. During set-up of the aseptic filling line for (b)(4) batch # (b) (4) on September 19, 2025, the operators used the (b) (4) directly above the exposed (b)(4).

d. On September 18, 2025, at approximately (b)(4), during the filling of (b)(4). Batch (b) (4) we observed your operator using the non-sterile (b) (4) to clear a blocked stopper. The (b) (4) reached over other exposed sterile stoppers that were not removed.

2. Aseptic filling occurred using (b) (4) that failed their (b) (4) integrity test. QA does not review the (b) (4) integrity test results. For example:

a. For the (b) (4) aseptic filling line (b) (4) integrity testing, (b) (4) were first tested (b) (4) and (b)(4) failed their integrity test. Only (b)(4) was retested on this day and it failed again. No further action was taken and the (b) (4) were used during aseptic filling of subsequent batches.

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On (b) (4) additional (b) (4) integrity testing was performed. (b) (4) failed four more times and (b) (4) failed once. No further action was taken, no more retesting was conducted, and the (b) (4) were used during aseptic filling of subsequent batches.

On (b) (4) failed four more times before a passing result was reported on the fifth attempt.

b. For the (b) (4) aseptic filling line (b) (4) integrity testing, (b) (4) were first tested (b) (4) (b) (4) failed, was retested, and failed again. No further action was taken and the (b) (4) was used during aseptic filling of subsequent batches.

On (b) (4) failed the integrity testing. No further action was taken before filling of subsequent batches.

On (b) (4) failed the integrity testing. No further action was taken before filling of subsequent batches.

On (b) (4) more (b) (4) integrity testing was conducted and the (b) (4) that previously had failed, now passed and this data was used for reporting the result for (b) (4)

c. (b) (4) integrity testing data could not be located for the (b) (4) line for (b) (4)

3. On September 20, 2025, during set-up for aseptic filling of (b)(4) batch # (b) (4) on line (b) (4), the (b) (4) covers used to protect the (b)(4) were observed to be generating fibers in the filling area. Visible fibers were observed on the covers. When the covers were removed, fibers were shed near the (b)(4). After the (b)(4) (b)(4) were installed, there were two visible fibers on the tubing that transfers the product to the (b) (4)

On September 23, 2025, after the set-up for aseptic filling of (b)(4) batch # (b) (4) on line (b) (4), a visible fiber was observed on the tubing above the (b) (4) A torn (b) (4) bag with tools near the area where open vials would pass to the (b) (4) had visible fibers in the area where it was torn

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When new, unused (b) (4) covers were inspected, they were observed to have loose fibers on them. The same type of covers are used to protect (b) (4) and the end of tubes used for sterile connections for all aseptic filling lines at this site that are being used to manufacture US market product.

The (b) (4) line implemented these bags on (b)(4), and all other lines implemented these bags on (b)(4) (b)(4). Your firm's change control failed to adequately evaluate the potential impact of implementing (b) (4) bags with (b) (4) (Change Controls 003543 and 005374) on particulate contamination in your sterile manufacturing environment.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

1. The cleaning process for the aseptic filling RABS includes (b) (4) to wash Grade A RABS surfaces, equipment that cannot be removed from the RABS, removable (b) (4) and (b) (4)

a. (b)(4) is not sterilized prior to use on these Grade A surfaces. To perform this cleaning, the (b) (4) (b) (4) Sampling of the (b)(4) system has identified the presence of the Gram negative biofilm forming organisms when sampling the (b) (4) points in the RABS used for this cleaning.

b. (b) (4) are installed into the RABS. The (b) (4) during cleaning (b) (4) inside the RABS. There are (b) (4) inside the (b) (4) to allow the (b) (4) to exit the area. The (b) (4) where the (b) (4) are only disinfected (b) (4)

c. The cleaning with (b)(4) results in standing (b) (4) inside the RABS. There is no assurance the equipment attached to the base of the RABS is sufficiently sealed to prevent ingress of (b) (4) that cannot be effectively dried or disinfected.

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d. There are no (b) (4) used during drying to ensure the (b) (4) can be sufficiently dried.

e. Environmental monitoring investigations have attributed the presence of Gram negative, (b) (4) organisms recovered in the Grade A areas during batch filling to residual (b)(4) after cleaning. For example:

-Investigation #2914203 resulted in the rejection of (b)(4) batch # (b) (4) aseptically filled on line (b) (4) when surface monitoring sample at the (b) (4) between the (b)(4) and stoppering had (b) (4) CFU, which were identified as *Methylobacterium radiotolerans* and *Sphingomonas melonis*. The root cause was attributed to remaining moisture and insufficient drying following cleaning with (b)(4).

-Investigation #2797826 identified *Methylobacterium rhodesianum* from a Grade A settle plate during aseptic filling of batch (b) (4) # (b) (4) Residual moisture from cleaning contributed to the identified root cause.

-Investigation #2792137 identified *Methylobacterium radiolerans* and *Cupriavidus pauculus* from a Grade A contact plate on the (b) (4) of a (b) (4) following (b) (4) batch # (b) (4) Residual moisture from cleaning contributed to the identified root cause.

2. (b)(4) is similarly used for washing surfaces of the (b) (4) Investigation #3108971 was opened when (b) (4) CFU of *Methylobacterium* was found on (b)(4) near the stoppering bowl following (b) (4) batches # (b) (4) during sampling on January 14, 2025. The root cause was attributed to (b) (4) on the machine floor that were not completely removed after cleaning of the (b)(4) and before starting (b)(4).

3. During (b) (4) of the RABs, all (b) (4) are not (b) (4) on aseptic filling lines (b) (4) (b) (4) lines.

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

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1. (b) (4) in subloops, is distributed from the subloops to use points inside the aseptic filling lines for cleaning purposes via (b) (4) piping that is up to (b)(4) long. Following use, the piping is (b) (4) There is no assurance this is sufficient to adequately (b) (4) the entire length of piping. This piping is not sanitized.

Microbial testing data from these (b) (4) distribution points at the end of the (b) (4) piping have identified 16 action and 31 alert level results since June of 2023. These have commonly identified (b) (4) source, Gram negative, biofilm forming organisms, including *Ralstonia*, *Methylobacterium*, *Sphingomonas*, and *Bradyrhizobium* species.

Investigations have identified deficiencies in this design, but effective corrective and preventative actions have not been implemented and the investigations were not extended to all use points with this design. For example:

a. Investigation #2778557 dated October 24, 2023, for excursion at point (b) (4) in the filling (b) (4) for the sterile (b) (4) identified *Bradyrhizobium dentrificans*. Contamination of the piping between the subloop and use point was identified as a potential root cause. The investigation stated a (b) (4) sanitization frequency would be implemented. This sanitization was not expanded to other use points with the same design.

The sanitization was performed (b) (4) and not again until (b) (4) after the records had been requested. Alert level findings were identified (b) (4) (*Bradyrhizobium dentrificans*), and (b) (4) (b) (4)

b. Investigation #2950023 and #2868221, for repeated excursions at point (b)(4) in the (b)(4) used a (b) (4) to inspect the internal piping and found residual (b) (4) after the (b) (4) process. The use of the (b) (4) (b) (4) to inspect all piping with a similar design was not conducted as part of the investigation.

2. (b) (4) is also distributed via (b) (4) piping from subloops to be used for cleaning applications. The (b) (4) piping sections are not sanitized (b) (4) and there is no assurance the (b) (4) is effective. Microbial monitoring data shows alert and action results identifying (b) (4) Gram negative, biofilm forming organisms.

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OBSERVATION 5

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 into foreign material observed in (b) (4) products did not thoroughly evaluate the particles or their sources in the manufacturing environment.

a. The repeated presence of extrinsic foreign particles in (b) (4) products was not thoroughly investigated to identify sources and implement effective preventive actions. The investigations repeatedly attributed extrinsic particles to inadequate gowning inside the Grade C area and introduction of extrinsic particles where filling machine parts are packaged before (b) (4) and transfer into the filling lines. These included:

-Confirmed complaint received March 12, 2025, investigation #3152302 for (b)(4) batch # (b)(4), manufactured February 1, 2024. There were two vials with fibers, including one consistent with hair and one with (b) (4) identified to be of biological origin.

-Deviation investigation DEV-000007 for (b)(4) batch # (b)(4), manufactured April 3, 2025, identifying a red fiber. It was identified as extrinsic as there is no red fibers in the manufacturing environment, but there was no specific characterization of the fiber performed. The investigation states it was likely associated with personal clothing under the pharmaceutical gowning in the Grade C area.

-Deviation investigation DEV-000175 for (b) (4) batch # (b)(4), manufactured May 11, 2025, identifying a fiber that was (b) (4) in nature and associated with an extrinsic biologic source.

-Deviation investigation DEV-000004 for media fill # (b)(4), filled June 16, 2025, identified (b) (4) fibers of an extrinsic source.

b. Deviation investigation #2722111 was opened for exceeding the visual inspection limit for foreign particles in (b)(4), batch # (b)(4). Visual inspection identified fibers and flakes that were not characterized to identify

their composition.

The investigation identified fiber particles could be generated from transfer tubes, (b) (4) material, or wiping cloths, but took no actions to investigate or address any of these potential sources.

c. Deviation investigation #3200471 was opened for failing AQL during (b) (4) batch # (b)(4) with visible particulate in (b) (4) vials. The investigation identified the foreign particles to be (b) (4) There was no thorough evaluation to identify other (b) (4) fiber sources in the environment. The investigation attributed a potential root cause as the wipes used in the aseptic filling area. No further evaluation of the wipes was performed to confirm if they are made of a material consistent with the fibers observed in the vial or whether these wipes are appropriate for use if they are generating fibers.

d. Confirmed complaint investigation #3128556 was opened for (b)(4) batch # (b)(4) when the customer identified (b) (4) vials with fibers, 3 vials with black particles, and 2 vials with red particles in a distributed lot. The investigation identified the use of face masks in Grade C during equipment packaging as a potential source of the fibers, but there was no characterization of the masks to confirm they were consistent with the fibers in the vials.

e. Confirmed complaint investigation #3172369 was opened for (b)(4) batch # (b)(4) when the customer identified two vials, each with a fiber. These were identified as (b) (4) with a potential source identified as introduction during packaging of filling machine parts. There was no further evaluation of this process to identify the source and implement preventive actions.

f. Deviation DEV-0000004 identified (b) (4) vials with fibers in them during media fill # (b)(4). The fibers were not characterized to identify a source.

2. You had four different OOS assay results for (b)(4) and each was attributed to laboratory error. However, you were not able to identify the specific laboratory errors. The OOS results were invalidated. For example:

a. Root cause investigation PR 2764214, during release testing of the (b) (4) Sterile, Batch # (b)(4),

obtained out-of-specification results for assay.

b. Root cause investigation PR 2527928, during release testing of DS (b) (4) Sterile, Batch # (b)(4) and (b)(4), obtained out of specification results for assay.

c. Root cause Investigation PR 2743540, during release testing of the (b) (4) Batch # (b)(4), obtained out-of-specification results for assay.

3. PR 3061153, "(b) (4) CFUs detected upon (b) (4) surface monitoring" opened November 18, 2024, was assigned a root cause of a hole in a (b) (4) where surface sampling found (b) (4) CFUs from the sample taken at the end of a (b) (4) batch campaign in the (b) (4) This sample was taken on November 6, 2024. You replaced the damaged (b) (4) on November 15, 2024, after the plate reading. You released the (b) (4) batches made on that campaign, per your investigation "environmental monitoring for all (b) (4) batches was reviewed. This did not result in the detection of any other CFU for all class A monitoring." Your deviation investigation did not evaluate the potential impact on product sterility assurance of the (b) (4) batches produced during the campaign, or assess whether other batches, such as (b) (4) batches, (b) (4) which were produced using the damaged (b) (4) from November 6, 2024, and November 15, 2024, were impacted.

4. On (b) (4) the customer (b)(4) held a call with a QC product specialist to explain a request for retain samples for (b) (4) The customer reported they were investigating stability results for assay. There was no investigation opened in the quality system.

Additional follow-up communication on (b) (4) confirmed the customer was investigating a failed stability assay. This ultimately led to a recall by the customer. No investigation was opened to investigate whether the manufacturing process at this site was related to this stability failure or whether other batches may be impacted, including batches potentially distributed to the US market.

OBSERVATION 6

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

1. The (b) (4) has no viable air monitoring near the filling zone, where the intervention to add product to the (b) (4) is performed, or in the stoppering area. An interoffice memo cited antimicrobial properties of the product to justify not performing viable monitoring of these areas.

No studies have been performed to identify inactivating agents to be used in the air and surface monitoring media that is used in the (b)(4).

The memo also describes not performing non-viable particle monitoring near the stoppering station or prior to the start of operations in the (b) (4) filling area due to risk of damage to the equipment, without explaining how this would cause damage or justifying the lack of data for critical areas.

2. On (b) (4) aseptic filling line the non-viable particle counter is located approximately (b)(4) from the (b)(4) (b)(4). There is no non-viable particle counter in the area with the stopper bowl.

There is no settle plate in close proximity to where filling or stoppering occur. The closest settle plate is on the (b) (4) above the level of the conveyor and not near where interventions occur for either the (b) (4) or stopper bowl. It is located approximately (b) (4) from the conveyor.

3. On filling line (b)(4) the non-viable particle counter is located approximately (b)(4) from the (b) (4) There is no non-viable particle counter in the area with the stopper bowl.

There is no settle plate in close proximity to where filling or stoppering occur. The closest settle plate is on the (b) (4) above the level of the conveyor and not near where interventions occur for either the (b) (4) or the stopper bowl.

The (b) (4) where (b) (4) vials accumulate before transfer to the (b) (4) does not have any settle plates. Active air is only taken (b) (4)

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Investigator
Signed By: 2002852115
Date Signed: 09-26-2025
17:21:32

DATE ISSUED
9/26/2025

(b) (4) used for interventions near open vials, including (b) (4) are not monitored during routine batches.

4. There is no viable monitoring from the end of set-up of the aseptic filling line until the start of filling. For example, during (b)(4) batch # (b) (4) on September 19, 2025, the viable monitoring plates were closed at (b) (4) after installing and exposing sterile surfaces including the (b) (4) stopper bowl, stoppering track, and (b) (4) stoppers. Viable sampling did not resume until (b) (4) at the start of the aseptic filling process.

5. There is no viable or non-viable monitoring when the RABS (b) (4) to load and perform initial placing of the filling equipment.

6. On September 23, 2025, during (b) (4) batch # (b) (4) an operator sprayed (b) (4) disinfectant above a settle plate on the (b) (4) before (b) (4)

OBSERVATION 7

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that in-process materials conform to appropriate standards of identity, strength, quality and purity.

Your firm failed to collect samples for bioburden analysis from the (b) (4) bulk solution during routine commercial production. The following are some examples of the products manufactured without bioburden analysis prior to any (b)(4) process:

(b) (4) mg, (b) (4) mL vials- The bulk compounded solution is (b) (4) collection of a bioburden sample.

(b) (4) mg/mL, (b) (4) mL vials- The bulk compounded solution is (b) (4) (b) (4) collection of a bioburden sample.

(b) (4) mg/mL, (b) (4) mL vials- the bulk drug product is (b) (4) (b) (4) the collection of a bioburden sample.

OBSERVATION 8

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. On September 19, 2025, the following was observed in the (b) (4) during the filling of (b) (4) batch # (b) (4)

a. There were scratches and gouges on the (b) (4) used to move vials under the (b) (4) units.

b. There were peeling stickers on parts of the (b) (4) near open vials as they are moved to the (b) (4) unit.

c. A sealant had been applied to the filling machine that created rough surfaces.

d. There was (b) (4) residue on the (b) (4) used for (b) (4) of the (b) (4)

e. There was (b) (4) drips on the walls of the (b) (4)

f. As the machine moved, there was (b) (4) contact with a (b) (4) used during (b) (4)

2. On September 23, 2025, the following was observed on the (b) (4) aseptic filling line after it had been set-up for (b)(4) batch # (b) (4)

a. There was taped on labels on (b) (4) and the stopper bowl.

b. The (b) (4) below the HEPA filters had (b) (4) residues along the edges.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	9/18/2025-9/26/2025*
	FEI NUMBER 3002806419

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Remi Helmig, Site Director

FIRM NAME	STREET ADDRESS
Baxter Onocology GmbH	Kant Str. 2
CITY, STATE, ZIP CODE, COUNTRY Halle (Westf.), North Rhine-Westphalia, 33790 Germany	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

OBSERVATION 9

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.

(b) (4) is (b) (4) stoppered (b) (4) Process validation studies have not included any (b) (4) to determine whether vials throughout the (b) (4) are (b) (4) (b) (4)

(b) (4) has not been conducted during process validation studies for any of the other US market (b) (4) products.

OBSERVATION 10

Procedures for the preparation of master production and control records are not followed.

Your Quality Unit (QU) failed to ensure adequate document control over GMP paper records. Inspection of destruction boxes located throughout Production and Laboratory areas identified the following:

1. SOP-03433/64 Anlage 5.2 Cleaning and Disinfection of the Sterile Area (b)(4). This original document, on pink sterile paper, included a sign off with initials of a Production operator documenting cleaning activities after maintenance activities on August 1, 2025. No record of this document was able to be found, other than the original which was observed in the destruction box.

2. Original copy of Audit Trail review, dated: July 26, 2025, for the (b) (4) integrity testing device in pharma production suite (b) (4) during the production of (b)(4), batch no: (b)(4), was observed discarded into the destruction box. A copy was reprinted, dated: August 04, 2025, by the quality unit representative and no reconciliation of the original document was performed.

3. Original copies of cleaning qualification protocol of (b) (4) in (b) (4) room (b) (4) enclosure

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Karen A Briggs, Investigator Justin A Boyd, Investigator Vivin George, Investigator X Vivin George Investigator Signed By: 2002852115 Date Signed: 09-26-2025 17:21:32	9/26/2025

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02 and enclosure 03, with data completed and was observed discarded in the destruction box with no quality review or reconciliation.

4. Partially completed microbiological analysis form, performed on September 04, 2025, for recovering of objectionable organisms and personnel monitoring with results were observed ripped and discarded in the document destruction box- (b)(4) stored in room (b)(4). The document was reprinted, and the data was transferred with no reconciliation of the original document.

5. Original copy of Analytical worksheet – Form- Raw Data Sheet- Imaged Capillary Electrophoresis (b) (4) DP (b) (4) vial (b) (4) Drug Substance, effective date: July 02,2024, was observed in the document destruction box- (b)(4) stored in room (b)(4).

6. Multiple copies of yield calculation page that differed from the original resulted data, dated: July 11, 2025, for the sterile drug product, (b) (4) DP (b) (4) vial (b) (4) mg/vial, batch no: (b)(4), product number: (b)(4), manufacturing date: November 11, 2024, was observed discarded in the destruction box.

7. Unused copy of Doc no: (b)(4), Cleaning instructions, were observed with post-it notes attached. The document was discarded without any quality review and reconciliation.

8. Unused copies of Controlled Form ID#CF- DOC-46531, Sterilization Protocol Document, were observed in the document destruction box- (b)(4), located in the office outside the Pharma Production (b) (4) manufacturing suites.

9. Training confirmation sheets, for the training performed for multiple employees on various subjects, including use of the OPMS system, OEE tracker etc., were observed in the destruction box with no reconciliation.

10. An intermediate discard bin, stored in room (b)(4) Supervisor's Office located in the Production Area, was observed on September 18, 2025, with what appeared to be torn GMP documents. The bin was locked, and no key could be provided on this date. This bin was emptied before the contents could be inspected.

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OBSERVATION 11
The quality control unit lacks authority to review production records to assure that no errors have occurred.

The original batch record (b) (4) was revised on several occasions without Quality Unit knowledge or approval, by the Production department to fix errors, such as missing times and missing signatures. This batch record was observed to have serval areas flagged for corrections or addition of missing information, located in the Production Supervisors Office. These corrections are recorded on uncontrolled forms, and similar flags, and uncontrolled forms were observed in the discard bins.

OBSERVATION 12
Buildings used in the manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds insects, and other vermin.

On September 18, 2025, a crawling insect, which your pest control contractor identified as a forest cockroach, was observed in room (b) (4) the Grade D area surrounding the (b) (4) used in the sterile (b) (4) area.

***DATES OF INSPECTION**
9/18/2025(Thu), 9/19/2025(Fri), 9/22/2025(Mon), 9/23/2025(Tue), 9/24/2025(Wed), 9/25/2025(Thu), 9/26/2025(Fri)

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X Karen A Briggs
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EMPLOYEE(S) SIGNATURE
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