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	1/12/2026-1/22/2026*
	FEI NUMBER 3007058211

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Cedric Vandermeiren, General Manager

FIRM NAME	STREET ADDRESS
Excel Vision	Zone Industrielle, 27 Rue De La Lombardiere
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Annonay, Ardeche, 07100 France	Sterile 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. Failing sterility tests occurred when returned complaint samples of (b) (4) from the US market were tested. The sterility tests evaluated the remaining liquid inside samples returned for reports of visual contamination including mold, black specks, and discoloration on the (b) (4) The (b) (4) container closure system is designed with a (b) (4) to protect the product remaining inside the bottle during use. Without identifying any deficiencies in the (b) (4) the sterility failures were attributed to inadequate handling by customers.

Investigations were not timely. They were closed with no action to address the product on the market or extend the investigation to other batches of this product and other products made in the same environment, during the same time period. The investigations did not consider the manufacturing environment where these aseptic products were manufactured, which was subjected to repeated water incursion events into the aseptic manufacturing areas and persistent recovery of mold organisms.

Failure to thoroughly investigate complaints and consider the environmental conditions at the time of manufacturing is a repeat observation from the May 2025 warning letter.

Examples of failed sterility tests for returned US market complaint samples include:

a. Complaint XLV-CSCOMP-2025-38, received February 6, 2025. (b) (4) batch (b)(4) (b) (4) expiry). The

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complainant reported black discoloration on the (b) (4) and in the lid. The sterility test recovered *Alternaria alternata* on May 14, 2025. *Alternaria* species have been recovered during environmental monitoring. The investigation was still open at the time of the inspection.

b. Complaint B11319, received November 14, 2024. (b) (4) batch (b)(4) (b) (4) expiry). The complainant reported black discoloration in the (b) (4) The sterility test recovered *Curvularia lunata* on January 27, 2025. *Curvularia* species have been recovered during environmental monitoring. The investigation was closed April 17, 2025.

c. Complaint XLV-CSCOMP-2025-558, received November 18, 2025. (b)(4) batch (b)(4) (b) (4) expiry). The complainant reported discoloration. The sterility test showed growth on January 16, 2026. The investigation was still open at the time of the inspection.

d. Complaint XLV-CSCOMP-2025-593, received November 18, 2025. (b) (4) batch (b)(4) (b) (4) expiry). The complainant reported discoloration on the top of the bottle. The sterility test showed growth on January 16, 2026. The investigation was still open at the time of the inspection.

e. Complaint B11155, received August 19, 2024. (b) (4) batch (b)(4) (b) (4) expiry). The complainant reported two samples appear to have grown mold. The sterility test recovered *Cladosporium* on November 5, 2024. *Cladosporium* species have been recovered during environmental monitoring. A scan of the bottle assembly identified no defects. The investigation was closed April 4, 2025.

f. Complaint XLV-CSCOMP-2025-56, received February 12, 2025. (b)(4) batch (b)(4) (b) (4) expiry). The complainant reported discoloration on the bottle from when they first used it. The sterility test recovered *Curvularia nouhanii* on September 11, 2025. *Curvularia* species have been recovered during environmental monitoring. The investigation was closed December 8, 2025.

g. Complaint B10736, received February 21, 2024 (b) (4) batch (b)(4) (b) (4) expiry). The complainant reported discoloration on top of bottle. The sterility test recovered *Fusarium equiseti* on October 5, 2024. *Fusarium* species have been recovered during environmental monitoring. The investigation was closed July 9, 2024.

h. Complaint B10439, received September 27, 2023. (b) (4) batch (b)(4) (b) (4) expiry). The complainant reported black spots on the (b) (4) The sterility test recovered *Aspergillus* species November 6, 2023. *Aspergillus* species have been recovered during environmental monitoring. The investigation was closed April 25, 2024.

i. Complaint B10460, received October 10, 2023. (b)(4) batch (b) (4) (b) (4) expiry). The complainant reported mold on the bottle. The sterility test recovered *Stenotrophomonas maltophilia* on December 4, 2023. *Stenotrophomonas* species have been recovered during environmental monitoring. The investigation was closed January 15, 2024, and inaccurately stated the return sample was compliant during sterility testing.

2. Sterility failures were obtained for returned complaint (b) (4) products filled into tubes. The investigations were not timely and attributed the cause to patient handling without supporting evidence. They did not thoroughly investigate the manufacturing conditions for the batch. Failing sterility returned (b) (4) complaint samples include:

a. Complaint XLV-CSCOMP-2025-540, received November 4, 2025. (b) (4) batch (b)(4) (b) (4) expiry). The complainant reported the (b) (4) blackened. The sterility test showed growth on January 16, 2026. The investigation was still open at the time of the inspection.

b. Complaint XLV-CSCOMP-2025-201, received May 2, 2025. (b)(4) batch (b)(4) (b) (4) expiry). The complainant reported the product was black. A sterility test of the contents of the returned tube recovered *Candida parapsilosis* on May 20, 2025. *Candida* has been recovered during environmental monitoring. The investigation was closed on September 19, 2025.

c. Complaint B11310, received November 8, 2024. (b)(4) batch (b)(4) (b) (4) expiry). The complainant reported mold in the (b) (4) A sterility test of the contents of the returned tube recovered *Cladosporium cladosporioide* on March 14, 2025. *Cladosporium* has been recovered during environmental monitoring. The investigation was closed on September 5, 2025.

d. Complaint XLV-CSCOMP-2025-332, received July 17, 2025. (b) (4) batch (b)(4) (b) (4) expiry). The complainant reported the product had mold inside the (b)(4) and tube. A sterility test of the contents of the returned tube recovered *Cladosporium cladosporioide* on August 6, 2025. *Cladosporium* has been recovered during environmental monitoring and during the sterility test of the returned complaint sample for (b)(4). The investigation was still open at the time of the inspection.

e. Complaint XLV-CSCOMP-2025-344, received July 22, 2025. (b) (4) batch (b)(4) (b) (4) expiry). The complainant reported black mold in the (b) (4) A sterility test of the contents of the returned tube recovered *Cupriavidus pavculus, Sphingomonas paucimobilis, Staphylococcus warneri,* and *Pseudomonas cryzitabitans* September 8, 2025. These types of organisms have been recovered during environmental monitoring. The investigation was closed January 13, 2026.

f. Complaint B11221, received September 16, 2024. (b) (4) batch (b)(4) (b) (4) expiry). The complainant reported black stuff on the (b) (4) A sterility test of the contents of the returned tube recovered *Pantoea* on December 30, 2024. *Pantoea* has been recovered during environmental monitoring. The investigation was closed April 11, 2025.

3. There have been approximately 174 complaints since October 2024 reporting visual contamination including mold, black specks, and discoloration. Without supporting evidence, they were attributed to the inadequate handling by customers, even in cases where the customer stated the contamination was observed at the time the product was first opened. These investigations did not thoroughly evaluate the environmental conditions from the time of aseptic manufacturing. Examples of complaints include:

a. Complaint XLV-CSCOMP-2025-600, received December 19, 2025. (b) (4) batch (b)(4) (b) (4) expiry, US market). Complainant stated "upon first opening…black discoloration was observed under the (b) (4) " This batch has ten complaints for mold contamination.

b. Complaint XLV-CSCOMP-2025-327, received on July 10, 2025. (b) (4) batch (b)(4) (b) (4) expiry, US market). Complainant stated discoloration was noticed on it before using the product once. This batch has two complaints for mold, and four complaints for "possible reaction".

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c. Complaint XLV-2025-222, received May 13, 2025. (b) (4) batch (b)(4) (b) (4) expiry, European market). Complainant reported mold on the lid and bottle that was noticed when opening the product. This batch has two complaints for mold contamination.

d. Complaint B11253, received October 8, 2024. (b) (4) batch (b)(4) (b) (4) expiry, European market). Complainant states the patient opened the bottle for the first time and the (b) (4) and lid were dirty and brown. This batch has two complaints for mold.

4. Investigation RIG(b) (4) was opened for a trend of mold in the (b) (4) filling area in the (b) (4) (b)(4). The investigation attributed the root cause to the environment including moisture under the (b) (4) floor, damaged infrastructure, and rainwater leaking into the filling rooms. The impact assessment did not thoroughly justify the conclusion that only some batches aseptically filled during this time period were impacted and subject to rejection or recall.

(b) (4) batches were recalled due to the risk of mold contamination. The following batches that were distributed to the US market were within the scope of this investigation, but not included in the recall, even though they were aseptically filled during the time period where mold contamination was persistently identified in the aseptic filling environment:

a. (b) (4) ml, lot (b)(4), filled on (b) (4) Expiration date (b) (4) This lot has subsequently had the following market complaints:

Complaints for mold like appearance and discoloration spots on the(b) (4) complaints XLV-CSCOMP-2026-17, XLV-CSCOMP-2025-578, and XLV-CSCOMP-2025-200.

An adverse event complaint for a burning sensation: complaint XLV-CSCOMP-2025-234.

b. (b) (4) ml, lot (b)(4), filled on (b) (4) Expiration date (b) (4) This lot has subsequently had the following market complaints:

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Complaints for discoloration complaints on the (b) (4) complaints XLV-CSCOMP-2025-327 and XLV-CSCOMP-2025-275.

Complaints for adverse events or burning or painful sensation: XLV-CSCOMP-2025-359, XLV-CSCOMP-2025-179, XLV-CSCOMP-2025-162, and XLV-CSCOMP-2025-153.

c. (b) (4) ml, lot (b)(4), filled on (b) (4) Expiration date (b) (4) The lot subsequently had the following market complaints:

Complaint for discoloration around the (b) (4) complaint XLV-CSCOMP-2025-412.

d. (b) (4) ml, lot (b)(4), filled on (b) (4) Expiration date (b) (4)

e. (b) (4) ml, lot (b)(4), filled on (b) (4) Expiration date (b) (4)

f. (b) (4) ml, lot (b)(4), filled on (b) (4) Expiration date (b) (4)

g. (b) (4), lot (b)(4), filled on (b) (4) Expiration date (b) (4)

5. Since January 2024, there have been approximately 28 documented instances of water incursions from rainwater or leaking utilities into the classified areas of the (b)(4) aseptic manufacturing areas. Incursions were not thoroughly investigated to determine the extent of water damage through documented assessments, including between walls and under (b) (4) floors. (b) (4) and (b) (4) used in the construction of the area and subjected to water incursions were not always replaced and there is no assurance they can be adequately cleaned and disinfected.

Appropriate corrective and preventive actions to prevent recurrence of water incursions have not been implemented.

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6. Deviation XLV-DEV-2025-499 investigated repeated recovery of particulate matter from multiple (b) (4) (b) (4) sampling locations; however, the investigation was inadequate. Particle identification included FTIR analyses with low match scores (approximately (b) (4)% to (b) (4)%), which were used to support conclusions regarding the root cause of particulates. The investigation concluded that certain particles were compatible with gasket materials used in the (b) (4) systems.

The investigation then identified gaskets present in the (b) (4) systems that were not documented on piping and instrumentation diagrams, including gaskets with unknown installation dates that were not included in the preventative maintenance program. As the installation date for these gaskets is unknown, it is unclear how long degradation may have occurred. Despite this, your firm limited the impact assessment for batches potentially affected by (b) (4) to (b) (4) to (b) (4), while batches potentially impacted by (b) (4) were assessed over a broader period of all batches within expiry.

During the impact assessment, conclusions that there was no product risk were based on assumptions that the particulates potentially introduced during equipment cleaning with (b) (4) would not remain in the system or reach the finished drug product due to subsequent processing conditions. Your firm did not examine retain samples, perform enhanced finished product visual inspection, or otherwise verify that distributed drug products were free of particulate contamination.

Corrective and preventative actions were also inadequate. Your firm stated that gaskets associated with the (b) (4) systems were replaced; however, these activities were not documented in the investigation report or the corresponding CAPA (XLV-CAPA-2025-312), and there are no maintenance records to demonstrate completion. Additionally, (b) (4) identified during the investigation as a potential source of particulates, continues to be used as a component of the (b) (4) system.

7. There was a failure to investigate all (b) (4) integrity test failures. The procedure Handling of Events and Deviations (document # XLV-SOP-0093) requires failures to be investigated. When reviewing data in the (b)(4) system, there were approximately 25 (b) (4) integrity testing failures between December 8, 2025 and January 19, 2026. Your firm reported that only two of the failures were investigated. Several failures did not include identifying information such as product name, lot number, or (b) (4) number.

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Additionally, raw electronic data generated by the (b)(4) system is not routinely reviewed. There were 19 manually aborted tests in the (b)(4) system between December 8, 2025 and January 19, 2026 that were not reported or reviewed. The procedure Data Integrity Management (document # 910SOP602) states "Data after creation, recording and processing must be reviewed (including audit trail data) to determine if the results are consistent and comply with the established specifications. The evaluation must consider all data, including atypical, suspect, or rejected data."

OBSERVATION 2

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

1. (b) (4) and (b) (4) are used in the construction of the (b)(4) (b)(4) aseptic manufacturing areas in building (b) (4) The (b) (4) Remediation before project summary document (b) (4) identifies this material has a risk of accelerated deterioration of surfaces in contact with moisture and disinfectants, an inability to ensure complete decontamination, and a growing problem of maintaining sterile conditions in preparation areas. The document identifies the (b) (4) material is not waterproof. It is located in areas that have been subject to water incursions from rainwater or utility leaks and persistent mold recoveries. No specific remediation plan to fully replace the material throughout the (b)(4) (b)(4) manufacturing area has been established as commercial manufacturing continues using these areas.

For example, this material is located in:

a. The Grade B ceilings of (b) (4) aseptic filling rooms (b) (4)

b. The Grade C (b)(4) preparation (compounding) areas.

c. The Grade C washing area for machine parts used to support (b)(4) manufacturing.

d. The Grade C material weighing and dispensing area for (b) (4)

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e. Grade C corridors used to access compounding areas for (b) (4) manufacturing areas.

f. Throughout the unclassified packaging areas where personnel and materials pass through to enter the aseptic manufacturing areas.

2. On January 14, 2026, a crack was observed on the (b) (4) of floor in the Grade B area of the (b) (4) aseptic filling room.

3. On January 16, 2025, an unsealed gap, as observed from the above utility area, was observed at the ceiling separating the utility area and corridor (b) (4) This corridor is a Grade C area near a (b) (4) that is being used to transfer (b) (4) components into the aseptic filling area.

4. On January 19, 2026, damage was observed in the (b)(4) Grade C preparation areas:

a. Room (b) (4) Evidence of wall damage, including areas not fully sealed and gaps in the seals between walls and floors.

b. Compounding Room (b) (4) Multiple areas of floor damage, including sections where flooring was cut and separating with subflooring visible, warped and discolored flooring, and a gap between the flooring and wall.

c. Compounding Room (b) (4) Areas where sealant was peeling up with subfloor visible and apparent rust stains.

d. Compounding Room (b) (4) An area where flooring was separating with subfloor visible and apparent rust stains on the floor.

e. Washing Room (b) (4) Discolored HEPA filter grates on the ceiling and an area where wall boards were separating.

f. Corridor (b) (4) Area Near (b)(4) : Areas near the ceiling not fully sealed.

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g. Grade C Corridor: (b) (4) with severe deterioration of (b) (4) material near the (b) (4) and areas of apparent rust, flooring not fully sealed, and apparent rust on the (b) (4)

h. Compounding Room (b) (4) Cracks in the ceiling and a scratch revealing (b) (4) underneath the (b) (4)

i. Room (b) (4) Multiple ceiling and wall deficiencies, including gaps in the sealed ceiling, scratches revealing (b) (4) underneath the (b) (4), and a gap in the wall where a pipe enters the room.

5. The male changeroom (b)(4) to enter the manufacturing area has exposed and damaged (b) (4) in the area where personnel put on their plant shoes.

6. Personnel and materials enter the aseptic manufacturing areas after traveling through the unclassified area. The floor in this unclassified area consists of (b) (4) The (b) (4) appeared to accumulate debris that was not being removed by cleaning. Areas of the floor appeared to be damaged and not installed tightly to the wall. The underside of the (b) (4) appeared to have a (b) (4)

OBSERVATION 3

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

Inadequate smoke studies is a repeat observation from the May 2025 Warning Letter.

1. For (b)(4) aseptic filling line (b)(4), smoke studies were approved by the Quality Department that showed first air was disrupted above sterile surfaces and sterile components during interventions, such as:

a. During installation of the (b)(4) the operator's hands disrupt the airflow to the exposed (b)(4).

b. The airflow in the area around the (b) (4) appeared to be turbulent and flowing upward during

interventions in the May 2025 video.

c. During the May 2025 video, the bottle blockage intervention showed the operator reach across exposed (b) (4) closure contact surfaces and open bottles. Additionally, the operator contacted (b) (4) closure contact surfaces with a tool that had been handled by gloved hands.

d. Bottle addition into (b) (4) in the October 2025 video show smoke coming out at a high velocity of the smoke machine, and it is not possible to evaluate the air currents while adding materials.

e. Addition of (b) (4) in the May 2025 video show the smoke being introduced in an area not impacted by the addition of materials, and an observer is unable to observe and evaluate smoke patterns due to poor smoke coverage and design.

f. The (b) (4) track is designed to go around the bowl and under the (b) (4) chute, blocking laminar air flow to the sterile (b) (4)

2. For the smoke studies for (b) (4) line (b) (4)

a. There is no HEPA airflow that could control particles over the area of the machine where (b) (4) (b) (4)

b. The videos do not evaluate the entire air (b) (4) area where (b)(4) are located and the area directly below it. The area that is evaluated showed swirling air.

c. The active air environmental monitoring tube is pointed downwards, not within the airflow. The evaluation of pulling the air through the tube has not been evaluated.

3. For (b)(4) aseptic filling line (b) (4):

a. The smoke study video for intervention (b) (4) conducted during the loading of bottles for the (b) (4) filler, does not

demonstrate continuous, unidirectional airflow from the HEPA filters to the work area. The smoke study shows turbulence, including air rising and swirling toward the HEPA filters, and areas of apparent air stagnation beneath ceiling gaps separating adjacent HEPA filters.

b. The (b)(4) filler ceiling has gaps separating adjacent HEPA filters in the Grade A and B areas. There are no videos evaluating the effects these gaps have on unidirectional airflow.

c. The (b) (4) chute is located above the conveyor line between the (b) (4) station and the (b) (4) station. It blocks the laminar air flow above the bottles that have not yet been (b) (4)

4. During media fill (b)(4) on January 14, 2026, on the (b)(4) filling line (b)(4):

a. Media filled units that appeared integral were rejected. At the exit of the filling room, some filled and sealed bottles tipped over on the conveyor. When they passed a sensor used to detect misplaced (b)(4), these fallen bottles were rejected. The rejects are not incubated.

b. The media fill was not representative of normal production. Personnel left the filling room and cleared bottles from the filling, (b) (4) areas. This time with no exposed materials in these areas and no personnel present was used to validate the duration of filling during the media fill.

Completed media fills conducted over the past two years actively filled or simulated filling for approximately (b) (4) (b) (4) which does not represent the campaign length, such as (b)(4) that the (b)(4) line filled in January 2024.

Media Fills on Line (b)(4), (b) (4) line, does not represent campaign filling length for this line. Media fills for the past two years fill for a maximum of (b) (4) when the filling time for (b)(4) was recorded as (b)(4) in January of 2024.

OBSERVATION 4

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

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1. Inadequate Aseptic Technique was observed during media fill Batch (b)(4):

a. On January 13, 2026, an operator was observed reaching over an exposed sterile (b) (4) while installing the (b)(4).

b. Following the line set-up, an operator was observed performing a line clearance check prior to the start of the filling. During this activity, the operator: unnecessarily (b) (4) several Grade A (b)(4), partially entered the Grade A area, and (b) (4) the Grade A (b)(4) without performing any wiping or disinfection of the interior surfaces of the Grade A (b)(4) that were (b) (4)

c. Aseptic behavior procedure XLV-MOP-0517 does not include instructions to avoid reaching gloved hands over (b) (4) closure contact surfaces and open containers. Operators were observed reaching over (b) (4) closure contact surfaces, for example on January 14, 2026:

Operators reached over (b) (4) component contact surfaces to perform environmental sampling plates changes, near the (b) (4)

Operators reached over the chutes that contact the bottles and (b) (4) during component addition.

d. On January 16, 2026, during the addition of the bottles into the (b) (4) the bag touches the chute inside the Grade A filling area and is not disinfected after making contact with the bag.

2. Sterile gowning material for the (b)(4) aseptic filling area is stored in cabinets in the unclassified room (b)(4). There was a black substance on the floor and on an unused table in this room. Microbiology samples of these areas recovered growth morphologically consistent with mold. There appeared to have been a previous water leak through the ceiling in this room, leaving a brown residue and warped ceiling tile. The (b) (4) floor below the apparent water leak was bulging. There were (b) (4) pallets stored in this room.

Personnel retrieve sterile gowning, goggles, and gloves from this room and carry them through an unclassified

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corridor that had additional unaddressed water stains on the ceiling. The sterile gowning materials are carried into a Grade C gowning room.

OBSERVATION 5

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

1. Equipment surfaces that directly contact sterile (b) (4) packaging are not sterilized. On (b)(4) filling line (b) (4) equipment including the (b) (4) machine contact parts are left in place between batches and disinfected.

Failure to sterilize critical equipment surfaces is a repeat observation from the May 2025 warning letter.

2. During cleaning of the aseptic filling line (b)(4) on January 13, 2026:

a. The operator used a single wipe to clean the (b) (4) underneath the bowl, and bowl instead of getting a new wipe for each area as required by SOP. The bowl was never rotated as required by the SOP to ensure all outer areas are disinfected.

b. During cleaning of the (b) (4), the operator failed to pull the component toward themselves to clean all areas of the (b) (4).

c. An operator was observed picking up a wipe off the floor, throwing it away, and placing their hands into Grade A area without disinfection of their hands.

d. The operators did not wipe surfaces in a unidirectional manner.

e. The (b) (4) machine was not adequately cleaned, and not adequately disinfected. Due to the machine's size and height, operators were unable to reach and clean all surfaces of the equipment.

3. The (b) (4) chutes on (b)(4) aseptic filling lines (b) (4) which contact sterile (b) (4) packaging components, have been designed with (b) (4) without ensuring they can be adequately cleaned.

OBSERVATION 6

Written procedures are not established that describe the in-process controls and examinations to be conducted on appropriate samples of in-process materials of each batch.

1. For the (b) (4) sterile (b) (4) products:

a. There is no 100% visual inspection process for (b) (4) bottles to detect visible particulates, container defects, or other quality issues that could affect product safety and efficacy.

b. There is no destructive testing to detect critical defects in a statistically significant number of samples filled into (b) (4) bottles.

2. For the (b) (4) sterile (b) (4) products, destructive testing is used to (b) (4) units for visual inspection:

a. The visual inspectors were unable to consistently detect particles smaller than (b) (4) micrometers (µm). No alternative approaches were used to enhance the ability to perform the inspection and the smaller particles were eliminated from the challenge kit.

b. The defect kit does not include intrinsic particles, such as (b) (4) particles, (b) (4) particles, or extrinsic particles such as fibers or threads for the qualification for visual inspectors.

c. No sub-visible testing has been performed as part of the destructive testing.

OBSERVATION 7

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/12/2026-1/22/2026*
	FEI NUMBER 3007058211

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Cedric Vandermeiren, General Manager

FIRM NAME	STREET ADDRESS
Excel Vision	Zone Industrielle, 27 Rue De La Lombardiere
CITY, STATE, ZIP CODE, COUNTRY Annonay, Ardeche, 07100 France	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

For (b)(4) aseptic filling line (b) (4) on January 14, 2026:

1. There appeared to be corrosion on the supports for the (b) (4) and on the supporting structures above and below the (b) (4)

2. A handle used to tighten the (b)(4) bowl had a flaking black surface.

OBSERVATION 8
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

There is no surface monitoring of Grade A surfaces in the (b) (4) machine.

OBSERVATION 9
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.

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 software used to operate the (b) (4) Machine does not have individual username and passwords. Operators can make changes to parameters like filling times (volume) and (b) (4) There is no audit trail to document what settings were used and any changes made.

OBSERVATION 10
Records are not kept for the maintenance and inspection of equipment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Karen A Briggs, Investigator Justin A Boyd, Investigator Khoa Nathan V Tran, Investigator X Karen A Briggs Investigator Signed By: KAREN A. BRIGGS -S Date Signed: 01-22-2026 12:00:00	1/22/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/12/2026-1/22/2026*
	FEI NUMBER 3007058211

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Cedric Vandermeiren, General Manager

FIRM NAME	STREET ADDRESS
Excel Vision	Zone Industrielle, 27 Rue De La Lombardiere
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Annonay, Ardeche, 07100 France	Sterile Drug Manufacturer

Unofficial forms were created by production personnel to document the condition of aseptic filling machine parts. Quality personnel do not review these unofficial forms. Non-conforming equipment condition was observed on forms filled out on the following dates: September 2, 2025; October 23, 2025; October 29, 2025; November 3, 2025; and November 19, 2025.

There are no deviations associated with the non-conforming equipment parts or work orders that address whether these parts were subsequently addressed by maintenance.

OBSERVATION 11

Written procedures are not followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected.

Your firm failed to conduct annual product reviews in a timely manner to ensure that appropriate corrective actions are taken when necessary.

XLV-PQR-RAP-0046, APR for (b) (4) remains in draft status at the time of the inspection, approximately seven months after the review period ended. The draft review covers (b) (4) batches that were discarded during the review period.

(b) (4) out of (b) (4) 2025 annual product reviews were late or are not yet completed for US products.

***DATES OF INSPECTION**

1/12/2026(Mon), 1/13/2026(Tue), 1/14/2026(Wed), 1/15/2026(Thu), 1/16/2026(Fri), 1/19/2026(Mon), 1/20/2026(Tue), 1/21/2026(Wed), 1/22/2026(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Karen A Briggs, Investigator Justin A Boyd, Investigator Khoa Nathan V Tran, Investigator	X Karen A Briggs Investigator Signed By: KAREN A. BRIGGS -S Date Signed: 01-22-2026 12:00:00	1/22/2026

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	1/12/2026-1/22/2026*
	FEI NUMBER 3007058211

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Cedric Vandermeiren, General Manager

FIRM NAME	STREET ADDRESS
Excel Vision	Zone Industrielle, 27 Rue De La Lombardiere
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Annonay, Ardeche, 07100 France	Sterile Drug Manufacturer

X Khoa Nathan V Tran
Investigator
Signed By: 2003026741
Date Signed: 01-22-2026 12:00:41

X Justin A Boyd
Investigator
Signed By: 2000358686
Date Signed: 01-22-2026 12:01:21

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Karen A Briggs, Investigator
Justin A Boyd, Investigator
Khoa Nathan V Tran, Investigator

X Karen A Briggs
Investigator
Signed By: KAREN A. BRIGGS -S
Date Signed: 01-22-2026
12:00:05

DATE ISSUED
1/22/2026