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	11/10/2025-11/21/2025* FEI NUMBER 3009961173

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John P. Nason, Group CEO

FIRM NAME	STREET ADDRESS
Pharmathen International S.A.	Industrial Park, Sapes Rodopi Prefecture, Block No 5
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rodopi, Evrou, 693 00 Greece	Drug Manufacturer

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Microbial failure investigations have identified human source microorganisms, but failed to identify specific root causes and implement effective preventive actions. For example:

Media fill failure investigation DEVN(b) (4) 2025-0281 for batch (b) (4) filled January 8-13, 2025, identified seven contaminated vials spread across different portions of the batch. Vials identified *Staphylococcus, Micrococcus, Kocuria, Acinetobacter*, and *Bacillus* species. The root cause was attributed to poor aseptic behavior, but could not identify specific instances of poor aseptic behavior.

Sterility failure investigation OOS/L/23/013 was initiated March 21, 2023, for (b) (4) Injection batch (b) (4) aseptically filled on the (b) (4) line. The investigation identified *Corynebacterium jeikeium*. The investigation identified no root cause for the sterility failure.

Environmental monitoring excursion investigations that identified human source microorganisms recovered in the Grade A aseptic manufacturing areas and attributed root causes to inadequate aseptic techniques from January 2025-September 2025: OOS-SAPES-2025-00000052, OOS- SAPES-2025-00000084, OOS-SAPES-2025-00000120, OOS-SAPES-2025-00000200, OOS-SAPES-2025-00000203, OOS-SAPES-2025-00000319, and OOS-Sapes-2025-00000699.

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	Justin A Boyd, Investigator Khoa Nathan V Tran, Investigator X Justin A Boyd Investigator Signed By: 2000358686 Date Signed: 11-21-2025 12:36:18	11/21/2025

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The preventive actions taken to address the above investigations failed to ensure aseptic behavior procedures are established and followed. From November 10-13, 2025, the following was observed in the aseptic manufacturing areas:

1. During aseptic filling of (b) (4) Injection batch (b)(4) (US market) on November 13, 2025, the following was observed:

a. (b) (4) interventions occur at the filling machine for (b) (4) (b) (4) and during active air sampling. During these interventions the operators were seen with their heads near the (b) (4) They wear goggles with direct vent holes along the top. A forceps that is used inside the barrier comes out into the Grade B area when moving the (b) (4) (b) (4) vials before being placed back on top of the (b) (4) machine. The (b)(4), which are exposed to Grade B with the (b) (4) are not disinfected before (b) (4) the (b) (4) and subsequently used to perform interventions at the (b) (4) machine.

After one of these (b) (4) intervention for (b) (4) the Grade B side of a (b) (4) above the (b) (4) barrier (b) (4) was pressed inside the Grade A area and remained stuck there as operators continued with other activities.

b. The operator reached a (b) (4) over vials at the (b) (4) during interventions to remove fallen vials. These vials were not discarded.

c. During an intervention at the stopper station, the operator used the (b) (4) to pick up forceps kept on the (b) (4) machine. This required the operator to reach over the (b) (4) The operator reached back over the (b) (4) to put the forceps back.

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d. During loading of the vials, the operator removed a lid by lifting it over the open vials. The (b) (4) (b) (4) passes over open vials.

2. During the set-up for aseptic filling of (b) (4) Injection batch (b) (4) on November 10, 2025, the following was observed:

a. During installation of the (b) (4) the operator's hand was directly above the exposed (b) (4) (b) (4)

b. During installation of the (b) (4) the operator's hand reaches over the (b) (4) on the (b) (4) (b) (4)

c. During installation of the product (b) (4) the operator used the (b) (4) directly above the open product contact (b) (4) of the (b) (4)

d. During multiple assembly steps, the operator's head was observed inside the filling barrier. The operators wear goggles with direct vent holes along the top.

e. During an intervention to remove a fallen vial the operator used a (b) (4) to reach over the sterile surfaces of the (b) (4) to pickup forceps laying on top of the filling machine.

f. Operators were observed throwing (b) (4) covers removed from sterilized pieces of equipment onto the floor during assembly. Later, an operator picked these covers up off the floor of the clean room. On November 11, 2025, a bag of previously used (b) (4) covers was observed in a cabinet storing filling machine (b) (4) Production personnel indicated these (b) (4) covers get reused. There is no procedure for reuse of covers, including how many times they can be used.

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3. During the aseptic filling of (b) (4) Injection batch (b) (4) on November 11, 2025, the following was observed:

a. The HEPA membrane distributor on the (b) (4) line above the stoppering and filling area was missing. There had been no evaluation of how this would impact the airflow in the area below the missing membrane where there were open (b) (4) and exposed (b) (4) stoppers.

b. During interventions to remove fallen stoppers near the (b) (4) filling, the operator used the (b) (4) (b) (4) above open (b) (4)

OBSERVATION 2

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. Airflow smoke studies for the aseptic manufacturing area did not demonstrate appropriate airflow in critical areas. For example:

a. During (b) (4) interventions at the (b) (4) vial filling machine the smoke flows outward near the top of the (b) (4) The study does not show the HEPA filtered air reaches the critical product contact (b) (4) For example, during installation of the (b)(4) and during (b) (4) Similar air flow that fails to reach the working surface was observed during (b) (4) interventions at the (b)(4) (b)(4) and where (b) (4) vials are removed just after stoppering.

b. During commercial (b) (4) Injection batches on November 10 and November 13, 2025, the (b) (4) LAF was placed behind the operators performing (b) (4) interventions at the vial (b) (4) filling machine during machine assembly and filling. It was positioned with the exit air grate directed towards the operators back with air potentially flowing past the operator and towards the filling

machine during the (b) (4) interventions. During smoke studies, the room was never configured with the (b) (4) LAF in this location.

c. The static vial line smoke study shows turbulence above the filling machine.

d. During installation of the product (b) (4) on the vial line, air flows over the (b)(4) and towards the (b) (4)

e. The recorded camera views and placement of the smoke generator do not allow for adequate evaluation of airflow during aseptic operations. On the vial filling line examples included: addition of vials and installation of the product (b) (4) On the (b) (4) line this included: installation of the (b) (4) removal of a fallen stopper in the (b) (4) filling area, and cleaning of the (b) (4) filling area.

f. No dynamic smoke studies have been conducted for the (b)(4) aseptic operations.

g. The following activities were not evaluated during the smoke studies for the vial filling line: aseptic connection of the (b) (4) adjustment of the (b) (4) to the (b) (4) (b) (4) environmental monitoring activities, removal of fallen vials from the (b) (4) installation of the (b) (4) on the (b) (4) connection of the (b) (4) to the (b) (4) machine, and use of the (b) (4) LAF for equipment and component transfer. For the (b) (4) line, there is no evaluation of interventions at the stopper bowl or (b) (4) environmental monitoring.

2. Your firm's media fills that support (b) (4) vial (b) (4) filling operations are not designed or executed in a manner that is representative of routine aseptic operations. Intervention frequencies performed during media fills do not reflect routine production. There is no data or scientific justification for the intervention frequencies used, as routine operations do not document all interventions performed.

Additionally, the number of vials removed during media fill interventions is not representative of routine production, as the number of vials removed during interventions during routine operations is not documented.

Media fills also reject integral units (e.g., vials with scratches or low fill volume).

3. Commercial manufacturing for (b) (4) for the US market started in November 2023. SOP-106 requires (b) (4) verification (b) (4) audits for the (b) (4) process. Only (b) (4) audit, conducted in (b) (4) has been performed.

Additionally, there is no identification data of microorganisms recovered from pre-sterilization bioburden of (b) (4) to determine if there are organisms that could create an endotoxin risk or be particularly resistant to the (b) (4) sterilization process.

OBSERVATION 3

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

1. Differential pressures in the aseptic manufacturing areas have not been appropriately established and monitored. For example:

a. The aseptic manufacturing area is designed with the aseptic filling rooms having a lower pressure than adjacent rooms. For example, the aseptic gowning room (b) (4) where employees enter with exposed skin and put on their aseptic gowns has a pressure of +(b) (4)Pa. The adjacent gowning room where they proceed to put on goggles and sterile gloves (b) (4) is lower at +(b) (4) Pa. They proceed to the general Grade B corridor in the aseptic manufacturing area which is +(b) (4)Pa. Personnel enter from this Grade B corridor

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into the aseptic manufacturing rooms for US market products, which are all held at lower pressures including the aseptic (b) (4) filling room (b) (4) +(b) (4) Pa, (b) (4) Aseptic (b) (4) +(b) (4) Pa.

Prior to January 22, 2025, the aseptic filling rooms and aseptic (b) (4) rooms were maintained at a negative pressure (-(b) (4) Pa). Investigation DEVN (b) (4) 2024-2106 investigated persistent mold contamination in the aseptic manufacturing areas and identified the potential ingress of contaminants from technical space due to the negative pressure differentials in the aseptic filling rooms and aseptic (b) (4) rooms.

b. The differential pressure, temperature, and humidity monitoring devices installed in the (b)(4) (b) (4) facility only display real time data and do not maintain historical data, including any alarms.

The differential pressure gauge at the conveyor exit between the Grade B vial filling line and the Grade D area has no alarm that would indicate a pressure differential has been lost. In other areas there is an audible alarm if the differential pressure is out of the limit, but once the differential pressure is back within limit, the alarm stops. If an operator is not present at the time, it will not be recorded.

2. (b)(4) (terminally sterilized) is filled into (b) (4) using a (b) (4) process for (b) (4) in a room classified Grade C, equivalent to ISO 8 under dynamic filling operations. Open (b) (4) remain exposed on a (b) (4) throughout filling until the (b) (4) (b) (4) The filling rooms are held at a lower pressure (+(b) (4) Pa) than the adjacent corridor (+(b) (4) Pa) and Grade C gowning rooms (+(b) (4) Pa).

The particle data is limited to (b) (4) samples taken at (b) (4) filling (limit of (b) (4) particles ≥(b) (4) µm/m^3). There has been no identification of recovered viable

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microorganisms in the past three years from the environmental monitoring program, to evaluate if the organisms represent a risk to endotoxin formation or include microorganisms particularly resistant to the (b) (4) terminal sterilization process.

Visual inspection has identified the presence of visible particulate in the filled (b) (4) resulting in (b)(4) deviations for exceeding the (b) (4)% limit since October 2024.

OBSERVATION 4

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. In approximately October 2024, changes were made to implement a more extensive visual inspection process for (b)(4). The product is a (b) (4) difficult to inspect product. These changes were communicated verbally to visual inspectors without a documented change control, updated procedures, or documented training. The verbal instructions included increasing the (b) (4) inspection time to an undefined increased amount of time; requiring the use of (b) (4) (b) (4) and to implement the use of magnification.

Since the extensive visual inspection was implemented in October 2024, there have been deviations initiated for (b) (4) batches for exceeding the reject rate limit (b) (4) % due to the presence of foreign particles during visual inspection, including (b)(4) deviations for US market batches.

Prior to the changes to the visual inspection process, there were no deviations opened for exceeding the (b) (4) % limits for particles during visual inspection. There was no thorough investigation of batches within expiry manufactured prior to the changes to the visual inspection process in October 2024.

The deviation investigations have failed to categorize types of visible particles or perform identification

of particles. Sources of the particles are not identified in the investigations and effective preventive actions are not implemented. The following are batches that have been distributed to the US market:

(b) (4)

2. The investigation "Summary Report on identification studies of visual inspection investigations for (b) (4) and (b) (4) semi-finished product" dated February 2, 2025, addresses (b) (4) deviations during visual inspection due to the presence of foreign particles, with reject rates up to (b) (4) % of all vials in a batch (b) (4) US market). The investigation failed to identify and address specific sources of the visible particles.

a. The most common particle found in both products was identified as API with (b) (4) This meant the particle was (b) (4) due to (b) (4) exposure. No root cause was identified in the investigation for how these particles are forming. The summary report states: "(b) (4) residues can originate from product (b) (4) under the conditions of the complex bulk manufacturing process." The manufacturing (b) (4) are not product dedicated. There was no further investigation explanation of the (b) (4) in equipment, how they may have resulted in these particles, and

whether this impacts cleaning or the manufacturing process.

Since the deviations in the summary report, there have been an additional (b) (4) investigations and (b) (4) investigations opened for exceeding limits during visual inspection for particles. The visual inspection and investigations do not specifically categorize the type of particles that are observed. The investigations did not thoroughly address whether the cleaning and manufacturing processes remain in a state of control. Batches continued to be released without understanding the root cause of the particles.

b. The summary investigation also identified blue cellulose fibers in (b)(4) batch (b) (4) and (b)(4) batch (b) (4) and acrylic yarn fibers in (b)(4) batch (b) (4). The investigations identify no source of these materials in the aseptic area. There has been no further evaluation of these sources that may be extrinsic contaminants.

3. Your firm failed to adequately investigate a media fill failure on (b)(4) (batch (b) (4). The investigation (DEVN (b) (4) 2025-06) attributed the failure to a (b) (4) period during which the system underwent repeated (b) (4) cycles without (b) (4) creating stagnant (b) (4) areas that allowed proliferation of the following gram-negative, (b) (4) associated microorganisms:

- *Burkholderia cepacia*
- *Ralstonia insidiosa*
- *Ralstonia pickettii*
- *Sphingomonas paucimobilis*
- *Delftia lacustris*
- *Delftia acidovorans*
- *Comamonas testosterone*

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Your firm has not addressed critical equipment and procedural deficiencies that contributed to the failure. For example,

- System design does not ensure drainage, and stagnant (b) (4) areas were not fully identified.

- There is no procedure defining the maximum number of (b) (4) cycles allowed without (b) (4)

- The required (b) (4) hold time, as defined in your technical directives, is exceeded during routine operations on (b) (4)

- Your firm does not have a procedure specifying when microorganisms in (b) (4) systems must be identified. The retrospective review of your (b) (4) systems, as part of your investigation, primarily included an assessment of trend data as no identification was performed during the review period. No identification was performed for your (b) (4) systems following the media fill failure to ensure that the microorganisms identified in the investigation did not stem from the systems. The rationale for not performing identification post-media fill failure was due to no excursions being observed.

4. Your firm failed to adequately investigate out-of-specification (OOS) assay results for two (2) batches of (b) (4) injection associated with investigation OOS-Sapes-2024-00000263.

(Specification: (b) (4) %)
Batch # (b)(4) (b)(4): Sample 1: (b) (4) %, Sample 2: (b) (4) %, Average: (b) (4) %
Batch # (b)(4): Sample 1: (b) (4) %, Sample 2: (b) (4) %, Average: (b) (4) %,

Batch (b) (4) was determined to be a confirmed OOS and was ultimately rejected. Your firm did not initiate a Phase II manufacturing investigation to assess potential manufacturing-related causes, as

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required by your procedure Out of Specification Analytical Results (SOP-13).

For batch (b) (4), the initial OOS result was invalidated following additional testing of new samples. The investigation concluded that sample preparation was the root cause, but this conclusion is not supported by scientific evidence. No Phase II manufacturing investigation was initiated in conjunction with the retests. This batch was subsequently released.

No corrective and preventative actions (CAPAs) were established for this investigation.

5. Your firm failed to investigate (b) (4) integrity test failures. Your procedure Handling of Product and (b) (4) in Production (SOP-73) requires that (b) (4) integrity testing failures be investigated; however, I observed two (2) (b) (4) integrity testing failures recorded in the (b) (4) system which were not investigated:

- (b) (4) for (b) (4) in (b) (4) during (b) (4) integrity for (b) (4) batch # (b) (4)
- (b) (4) for (b) (4) filling (b)(4) during (b) (4) integrity for (b)(4) (b) (4) batch # (b) (4)

Additionally, raw electronic data generated by the (b) (4) system is not routinely reviewed. I observed manual aborts in the (b) (4) system with no documentation supporting that the events were reported or reviewed.

Your firm does not have a procedure governing the review of raw electronic data generated by computerized systems used in GMP operations. There is no written process defining responsibilities, requirements, or controls for the review, verification, and approval of original electronic data to ensure completeness, accuracy, and integrity.

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OBSERVATION 5

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

1. Your firm failed to perform environmental monitoring in accordance with your procedure Microbial Environmental Monitoring of Production Areas of (b) (4) facility (SOP-144). SOP-144 identifies the highest-risk locations within the Grade A vial filling line; however, during aseptic filling operations observed on 10-NOV-2025 (b) (4) mg/vial) batch #(b) (4) and on 13-NOV-2025 (b) (4) mg/vial) batch #(b) (4) settle plate locations in the Grade A area were not positioned in accordance with the procedure.

In addition, settle plates are routinely positioned away from areas where critical aseptic assembly and operator interventions occur. Your risk assessment for settle-plate placement did not include an evaluation of routine operator behavior in these high-movement areas when selecting monitoring locations.

Furthermore, your environmental monitoring program does not include sampling of product-contact surfaces. For example, the stopper bowl, stopper track, (b)(4), or forceps are not sampled as part of your EM program for the vial filling line, nor are the stopper bowl, stopper track, or forceps included in the EM program for the (b) (4) filling line. Not all (b)(4) routinely used during interventions are included in the sampling plan.

2. Your firm failed to perform non-viable environmental monitoring in accordance with your procedure Physical Parameters and Non-viable Airborne Particle Monitoring in (b) (4) Facility (SOP-171). SOP-171 requires (b) (4) non-viable monitoring of the vial filling line during assembly and filling activities.

However, during assembly and filling operations observed on 10-NOV-2025 (b) (4) (b) (4) mg/vial) batch #(b) (4) and on 13-NOV-2025 (b) (4) (b) (4) mg/vial) batch #(b) (4) non-viable monitoring was not performed when sterile product-contact equipment was exposed on the filling line and assembly activities were still occurring. These (b) (4) assembly activities involved manipulations directly above the sterile assembled equipment, yet non-viable monitoring had been stopped.

Additionally, the non-viable monitoring sampling funnel was positioned facing away from the vial filling equipment, rather than toward the area where aseptic manipulations and interventions were taking place.

3. The (b) (4) plates used for environmental monitoring with settle plates and active air samples does not include any neutralizers. These are used for monitoring the Grade A and B aseptic filling areas where spray disinfectants are routinely used.

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

1. On November 10, 2025, product sample was observed on the side of the media bottles and not submerged in media during ongoing sterility tests for (b)(4) (b) (4). For example, batches

The (b) (4) sterility test method uses (b) (4) inoculation for the (b) (4) The method validation did not assess techniques to ensure the product could be effectively dispersed in the (b) (4) media.

2. Bubbles were observed between the (b) (4) and the media for (b) (4) samples. Examples included:

a. (b) (4) swab samples associated with surface monitoring in the aseptic vial filling room (b)(4) after filling of (b)(4) batch (b) (4)

b. (b) (4) of the (b) (4) samples collected November 7, 2025.

3. During collection of a (b) (4) plate from a (b) (4) on the aseptic vial filling line after (b) (4) Injection batch (b) (4) the microbiologist did not make firm contact between the (b) (4) (b) (4) and the contact plate.

OBSERVATION 7

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. (b) (4) Injection is a (b) (4) filled into a vial. (b) (4) is a (b) (4) (b) (4) There is no alternative destructive testing included as part of the visual inspection process for either of these products.

This is a repeat observation from the 2022 FDA inspection.

2. The size and specific type of particles is unknown for the visual inspection qualification challenge kits to represent (b) (4) vials, (b) (4)

3. No documentation of the results of the (b) (4) 100% visual inspection was recorded for US market

(b)(4) batches. For example, batches (b) (4)

4. AQL is not performed for (b) (4) after the (b) (4) visual inspection unless a limit for a defect category is exceeded. AQL can be performed by the same person that did the (b) (4) visual inspection.

OBSERVATION 8

Established sampling plans and test procedures are not followed and documented at the time of performance.

1. On November 10, 2025, upon arrival in the microbiology, no documentation could be provided for ongoing testing. For example:

a. Sterility testing including, but not limited to: (b) (4) Injection batch (b) (4) (US batch) and (b) (4) bulk batch (b) (4).

b. Grade A and B environmental monitoring samples associated with batches (b) (4) (b) (4) Analysts were observed filling out the sampling information onto the paperwork during plate reading. The records were not made at the time of sampling on November 3, 2025.

c. (b) (4) samples collected November 6, 2025.

d. The (b) (4) samples from November 6 and 7, 2025, had records that were only partially complete.

2. The IQVIA software is used for printing documents that are used for recording GMP production and laboratory data. It was observed that multiple copies of documents with the same unique serial number can be printed after the document is generated. There is no audit trail for this printing. There has been no

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process to reconcile what GMP documents have been printed and what documents have been returned to QA for production and laboratory documents.

Reconciliation of sterility test reports generated in this software from November 3-6, 2025, showed the following:

a. The sterility test report for serial number (b) (4) generated November 3, 2025, could not be located.

b. There were two different versions of sterility test report with serial numbers:

(b) (4)

In each case, both versions had been used to document sterility test data from different lots. The software indicated only one document had been printed.

3. On 10-NOV-2025, we reviewed the (b) (4) Non-Viables (b) (4) binders and observed numerous unsigned, unreviewed non-viable particle monitoring result sheets, which dated back to (b) (4) for sampling locations in the sterile manufacturing suite, including Grade A and B area. Non-viable particle counter printouts were attached to these result sheets as the raw data used to demonstrate the environmental state of the classified areas. Sticky notes with employee initials were attached to incomplete sheets to indicate which personnel still needed to complete and sign the documents.

These practices do not comply with your procedure Good Documentation Practice (SOPQM001GDP)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Justin A Boyd, Investigator Khoa Nathan V Tran, Investigator X Justin A Boyd Investigator Signed By: 2000358686 Date Signed: 11-21-2025 12:36:18	11/21/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/10/2025-11/21/2025*
	FEI NUMBER 3009961173

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John P. Nason, Group CEO

FIRM NAME	STREET ADDRESS
Pharmathen International S.A.	Industrial Park, Sapes Rodopi Prefecture, Block No 5
CITY, STATE, ZIP CODE, COUNTRY Rodopi, Evrou, 693 00 Greece	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

which requires records to be completed contemporaneously.

OBSERVATION 9

Buildings used in the manufacturing of a drug product are not maintained in a good state of repair.

Your facility is not maintained in a clean and sanitary condition to prevent contamination. During the inspection, we observed the following:

1. Active ceiling leaks and discolored ceiling tiles in the facility corridor used to transfer raw materials and finished products This corridor is also used for personnel movement, including access to the sterile manufacturing suites, QC laboratories, and capsule and tablet manufacturing areas.

2. An unknown black substance on ceilings, walls, and fans surfaces of cold rooms, which is used to store finished product and raw materials. The substance was sampled by your QC microbiology laboratory and microbial growth was observed on the plates. One sampling location (b) (4) (b) (4) visually appeared to be mold.

3. HEPA filters and air diffusers in a Grade D gowning room, which is used by production personnel to enter the sterile manufacturing suite, covered in an unknown substance. This substance was also sampled by your QC microbiology laboratory and microbial growth was observed on the plates.

4. Plant debris on pallets inside cold rooms. There were active pharmaceutical ingredients, bulk, and semi-finished/finished product being stored on these pallets.

5. Insects, including flies and wasps, in the facility corridor.

***DATES OF INSPECTION**

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	Justin A Boyd, Investigator Khoa Nathan V Tran, Investigator X Justin A Boyd Investigator Signed By: 2000358686 Date Signed: 11-21-2025 12:36:18	11/21/2025

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	11/10/2025-11/21/2025*
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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rodopi, Evrou, 693 00 Greece	Drug Manufacturer

11/10/2025(Mon), 11/11/2025(Tue), 11/12/2025(Wed), 11/13/2025(Thu), 11/14/2025(Fri), 11/17/2025(Mon), 11/18/2025(Tue), 11/19/2025(Wed), 11/20/2025(Thu), 11/21/2025(Fri)

X Khoa Nathan V Tran
Investigator
Signed By: 2003026741
Date Signed: 11-21-2025 12:36:52

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Justin A Boyd, Investigator
Khoa Nathan V Tran, Investigator

X Justin A Boyd
Investigator
Signed By: 2000358686
Date Signed: 11-21-2025 12:36:18

DATE ISSUED
11/21/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."