DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	2/17/2026-3/12/2026* FEI NUMBER 3013023419

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kyle Brauer, Director of Centralized Pharmacy

FIRM NAME	STREET ADDRESS
BayCare Integrated Service Center LLC	7802 E Telecom Pkwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Temple Terrace, FL 33637-0928	Outsourcing Facility

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 I OBSERVED:

OBSERVATION 1

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

Specifically,

A. Your firm does not routinely conduct dynamic viable air monitoring within the critical ISO 5 classified filling zone of the (b) (4) machine cell area throughout filling operations as required by SOP P-204.7 "Quality Management Program for Environmental and Personnel Sampling". The procedures requires that for (b) (4) "if a (b) (4) is used on one day, it will be monitored under dynamic activity". This lack of viable air monitoring during active manufacturing phases fails to provide real-time assurance of aseptic conditions in a critical processing environment.

B. Your ISO 7 Buffer Room, ISO 8 Ante Room, and associated (b) (4), which serve as essential (b) (4) for materials and personnel supporting ISO 5 aseptic operations, are sampled (b) (4) instead of (b) (4) during production. Your procedure P-204.7, "Quality Management Program for Environmental and Personnel Sampling," explicitly states that "all support areas (ISO 7/8 buffer/ante/gowning room) in use will be monitored (b) (4)" This (b) (4) sampling frequency does not provide adequate assurance of environmental control in these critical support areas.

C. Your ISO 5 LAFW environmental and personnel monitoring samples are collected routinely in the (b) (4), typically within (b) (4) of production (b) (4) for batch processing operations that extend for (b) (4). For example, ISO 5 surface sampling and personnel glove sampling are not routinely performed at the conclusion of each shift. In addition, non-viable particle monitoring for

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(b) (4) and (b) (4) is not continuous throughout the entire process. Instead, as per SOP P-206.5 "Non-Viable Particle Testing" ISO 5 (locations will sample (b) (4) (about (b) (4)) (b) (4) and all other locations (ISO 7, ISO 8) will be sampled (b) (4) for (b) (4) (about (b) (4) This inadequate sampling frequency and timing fails to provide scientifically sound assurance that environmental conditions remain consistently acceptable throughout the entire production process.

D. On 02/17/26, during the walkthrough, I observed that petri dishes for active air sampling, swab samples, and (b) (4) plates for environmental monitoring are being incubated inside (b) (4) (b) (4) (b) (4). For example, EM plates collected on 2/10/26, 2/1126 and 2/12/26, observed during the walkthrough, were placed in a (b) (4) for incubation. SOP P-212.7 "Incubation and Inspection of Solid and Liquid Media for Microbial Growth" requires placing samples into (b) (4) (b) (4) and removing excess air or space from the (b) (4) before incubation. This practice creates a low-oxygen environment that inhibits optimal aerobic microbial growth and can result in false negative results. Your firm lacks documented growth promotion studies or other scientific evidence demonstrating that this incubation practice does not adversely affect bacterial and fungal growth.

OBSERVATION 2

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

Specifically,

A. Your disinfectant efficacy study is inadequate because it fails to demonstrate sporicidal activity.

Your firm relies on (b) (4) with a (b) (4) contact time as its primary sporicidal agent for (b) (4) ((b) (4) only). (b) (4) and (b) (4) cleaning activities, as specified in SOP P-305.7 "Cleaning and Disinfection of ISO Classified Controlled Environments and Rooms". However, the validation

for this agent, documented in the "Final Report for Disinfection Efficacy Test Study" (Protocol # PRO 22-002), is inadequate for this purpose.

The protocol explicitly states that the challenge organisms *Bacillus subtilis* and *Aspergillus brasiliensis* were tested only in their vegetative state. The study did not include any testing against their respective highly resistant spores. Therefore, your firm possesses no data to support the claim that your cleaning program is effective at killing bacterial or fungal spores, which is the primary reason for using a sporicidal agent. Manufacturer's data for (b) (4) states that a (b) (4) contact time is required to achieve a satisfactory sporicidal kill. Your (b) (4) contact time specified in SOP P-305.7 is scientifically unsupported and demonstrably ineffective for sporicidal action based on the data available for the sporicidal product.

Since July 2023, environmental monitoring data consistently shows the recovery of spore-forming bacteria, primarily from the *Bacillus* and *Paenibacillus* genera, within the facility. A total of 36 distinct instances of spore-former recovery have been identified from non-water samples between July 2023 and February 2026. These recoveries are split between personnel samples: 20 events (e.g., gloves, cuffs, sleeves, chest) and facility samples: 16 events (e.g., (b) (4) Vestibule, various critical surfaces). Notably, 19 of these 36 events occurred in 2025 alone, indicating a continued and significant presence of these resilient microorganisms.

B. Your firm failed to establish a disinfectant rotation program. Your cleaning procedures, including P-305.7, rely exclusively on a single class of chemical (an (b) (4) agent, (b) (4) for all scheduled sporicidal cleaning activities ((b) (4) . While (b) (4) is used for residue removal, it is not part of a rotational schedule with a (b) (4) chemically distinct agent.

OBSERVATION 3

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.

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Specifically,

A. Your firm's visual inspection program, as outlined in procedure P-614.5 "Visual Inspection of Ingredients and Compounded Sterile Preparations," fails to establish a scientifically sound and documented acceptance sampling plan. The required (b) (4) inspection by the Quality Services Unit after a 100% visual inspection is arbitrary and lacks scientific justification. It is not explicitly tied to a statistically sound Acceptable Quality Limit (AQL) plan, such as ANSI/ASQ Z1.4, which is a standard for ensuring the quality of batches. Furthermore, the procedure mentions defect severities (Critical, Major, Minor) but does not provide specific AQL values (e.g., percentage of acceptable defects) for each category. The procedure does not incorporate defined quality inspection criteria for the AQL assessment, including specifications for sample size determination relative to total lot quantity, the designated sampling plan, and acceptance thresholds for defect tolerance. This absence of adequate written procedures for AQL criteria compromises the ability to objectively determine if a batch conforms to appropriate quality standards for release.

B. Your visual inspection procedure, P-614.5, lacks adequate written controls for inspection parameters. It does not specify appropriate light intensity requirements (e.g., a (b) (4) range) for the "light box" used during inspection, nor does it mandate routine monitoring and calibration of these light sources.

C. The procedure, P-614.5, and its associated competency assessment form, F-410.k, fail to establish clear acceptance criteria for defect detection rates or for false rejects during the assessment. Moreover, these procedures do not detail how the qualification process simulates "worst-case" scenarios, such as inspecting a diverse range of product types, container types, and various defect challenges. Additionally, the procedure does not incorporate a requirement for the assessment and qualification of visual inspection personnel under fatigue-induced conditions to evaluate potential impacts on inspection accuracy and defect detection reliability.

OBSERVATION 4

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Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness and compliance with established standards.

Specifically,

Your firm does not perform contemporaneous two-person verification of environmental monitoring plates. A single laboratory technician reads environmental plate samples and records the results of the plate counts on a worksheet. There is no assurance that the operator has entered the data accurately.

OBSERVATION 5

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

Specifically,

Your firm's Quality Unit lacks segregation of duties among personnel involved in quality control activities, thereby compromising the independence and integrity of quality oversight. Specifically, your Quality Unit, comprised of a single quality manager and one technician, assumes multifarious roles that include:

- Collection of environmental and personnel monitoring samples.
- Reading and interpretation of environmental and personnel monitoring sample results.
- Initiation and conduct of investigations into deviations, including out-of-specification (OOS) environmental monitoring results.
- Review of batch records for compliance.
- Final release of finished drug products for distribution.

For example, from 11/17/25 to 11/25/25, Quality & Testing Manager collected, incubated, and

performed readings of lot related environmental monitoring samples for lot SUCC10020251114. On 11/25/25 the Q&T Manager segregated the lot and provided a partial release of the lot. On 11/26/25, the Q&T Manager initiated a Quality Related Event (QRE) investigation reporting a microbial recovery in one of the samples. On 12/29/26 the Q&T Manager signed final review of the investigation.

This consolidation of responsibilities within a limited number of personnel creates a significant potential for conflicts of interest and precludes independent oversight. The same individuals responsible for generating environmental monitoring data, and subsequently investigating any excursions, also hold the authority to release drug products influenced by that data.

OBSERVATION 6

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Your firm prematurely released a portion of drug product batch SUCC10020251114 for distribution prior to the initiation and completion of a thorough investigation into a detected microbial recovery, thereby failing to assure that the drug product meets its specifications for quality and purity before release. Specifically:

- Environmental monitoring samples collected during the processing of lot SUCC10020251114 detected a microbial recovery (single CFU on a pharmacist's (b) (4) glove cuff) on 11/24/25, as recorded during the final stage of incubation.

- On 11/25/25, your Quality & Testing Manager segregated the lot by loader and authorized a partial release of batch SUCC10020251114. The unaffected portion of the lot was deemed appropriate for release, and (b) (4) syringes from this portion were consequently released.

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- However, the Quality Related Event (QRE) investigation (QRE #: 25-018) reporting this critical microbial recovery was not initiated until 11/26/25 — after the partial release of the drug product had already occurred. The lot was distributed on 12/2/25.

- The identification of the microorganism (Corynebacterium afermentans ss lipophilum) was not returned until 12/11/25, and the final review and approval of this investigation were not signed until 12/29/25 and approved by the Director of Pharmacy on 1/26/26.

This practice demonstrates a lack of thorough review of an unexplained discrepancy prior to product distribution, as a significant portion of the batch was released before conclusive evidence regarding the nature, root cause, and potential impact of the microbial recovery was fully established and documented in a completed investigation.

OBSERVATION 7

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

Specifically,

Your firm's visual inspection procedures for products repackaged into intravenous (IV) bags are deficient. Your visual inspection procedures request to perform a 100% visual inspection of IV bags after bags have been labeled. For example, Batch Production Records F-671.ca for Oxytocin and F-671.yb for Fentanyl Ropivacaine Epidural, under the "Visual Inspection (light box)" section, state: "Observe each labelled bag in the light box for no less than (b) (4) … Check for product clarity and label for legibility." There is no assurance that the label, once applied to the IV bag, will not obstruct or impede the detection of particulates or other critical defects within the product.

OBSERVATION 8

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All records of production associated with a batch of drug product were not maintained at least one (1) year after the expiration date.

Specifically,

Surveillance video is used by your firm for investigation of production discrepancies including but not limited to environmental and personnel monitoring excursions. Video recordings of gowning and production activities are described and referenced in written investigation reports and have been used to establish root cause. However, these video recordings are not maintained by your firm. Examples include but are not limited to the following:

- QRE 25-018 – "Video review showed (b) (6), (b failed to disinfect the vestibule door handle (a high-touch area) and did not perform SS&D after wiping materials down before loading",
- QRE 25-017 – "Video review showed (b) (6), (b) failed to perform SS&D consistently and after retrieving supplies",
- QRE 25-016 – "Video review showed (b) (6), (b failed to change gloves after cleaning vestibules and did not fully SS&D cuffs", etc.

OBSERVATION 9

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

Specifically,

Your firm does not maintain written records for annual product reviews conducted for your aseptically produced drug products, including but not limited to the following information:

Trends, reports, or summaries of quality indicators, a summary of all media fills performed since last inspection, environmental monitoring trend data (microbial and particle counts), personnel monitoring trend data, evaluations of investigations and effectiveness of corrective actions, change management,

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evaluation of unexpected results or trends, Out-of-Specification (OOS) results, product rejects, etc.

***DATES OF INSPECTION**

2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/20/2026(Fri), 3/09/2026(Mon), 3/10/2026(Tue), 3/12/2026(Thu)

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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."