

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
	DATE(S) OF INSPECTION	
	FBI NUMBER	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
FIRM NAME	STREET ADDRESS	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
	Contract Drug Manufacturer	
<p>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.</p>		
<p><b>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</b></p> <p><b>OBSERVATION 1</b>            Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established, written and followed.</p> <p>Specifically, your firm failed to identify and characterize microbial and mold counts recovered from your current executed cleaning validation reports. For example:</p> <p>A. "Report for the Cleaning Validation of L10861, Report USTP-10108" indicated recovery of organisms from reported results in RUN (b)(4) and RUN (b)(4) (b)(4)</p> <p>B. "Cleaning Validation Report - (b)(4), Report USTP-10803" indicated recovery of organisms from reported results in RUN (b)(4), RUN (b)(4), and RUN (b)(4)</p> <p>C. "Cleaning Validation Report - (b)(4), Report USTP-10943" indicated recovery of organisms from reported results in RUN (b)(4) and RUN (b)(4).</p>		
<p><b>OBSERVATION 2</b>            Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling and drug products conform to appropriate standards of identity, strength, quality and purity.</p> <p>Specifically,</p> <p>A. Your current disinfectant efficacy study is inadequate. <i>Lonza Biotech Disinfectant Efficacy Study</i>, approved on 08/31/2018, failed to establish the following:</p> <ol style="list-style-type: none"> <li>a. In-house Environmental Isolates</li> <li>b. Organisms to be challenged</li> <li>c. Disinfectants to be challenged</li> </ol>		
<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kayla V Sprague, Investigator Nicole E Knowlton, Investigator Santos E Camara, Investigator	8/22/2025
Nicole E Knowlton Investigator 2450 W. MIDDLE ST KNOWLTON, IN 46160 (317) 336-1122 152/19		<input checked="" type="checkbox"/>
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<p>d. Contact times and temperatures of disinfectants to be challenged c. Surfaces to be challenged</p> <p>B. Your firm failed to establish and maintain a library of in-house isolated organisms, including yeast and mold. For example, a review of environmental bacterial, yeast and mold organisms exceeding action limits were not archived, and it was noted that they were not characterized or identified when isolated. Procedure "Environmental Monitoring Program, USTP-914, Version 12.0, Effective Date: 14-Aug-2025" states under section "7.9 Isolate Identification, 7.9.1 For each plate, if growth is present, perform identification on each unique isolate for SOP USTP-2985 and document on form USTP-3561".</p> <p>C. Your reference standards are inadequately labeled. For example, review of your Lonza logbook "Small Molecules QC (Reference Standard Receiving Logbook) Asset # N/A, Forms Binder QC-0183", and physical reference standards located in room "Reference Standard &amp; Sample Storage", indicated that USP reference standard [REDACTED] (b)(4) lot# [REDACTED] (b)(4) received on 17 Apr 2025, stored in refrigerated condition at [REDACTED] (b)(4) did not have the storage condition documented on the label nor the COA stated the storage conditions. Your "Procedure for Receipt, Storage, and Handling of Reference Material and Impurity Markers for the Laboratories USTP, Version: 7.0, Effective Date: 31-Jul-2025" under section 6.3.1 requires that you record the "Storage Conditions" on the label.</p> <p>D. The cleaning process for the laboratory glassware caps, stoppers, bulbs, and glass caps has not been validated.</p> <p>During the inspectional walkthrough of the dirty glassware washroom on 19 August 2025 we observed numerous laboratory glassware caps, stoppers, bulbs, and glass caps in a basket labeled as dirty glassware. Firm personnel explained the filled basket is rinsed, soaked in [REDACTED] (b)(4) rinsed, and then placed in the dishwasher. The items in the basket are visually inspected after cleaning and before use. On 21 August 2025, your Quality Control Manager confirmed this process of cleaning has not been validated and you would not know if any residues remained.</p>		
<p><b>OBSERVATION 3</b> Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.</p>		
<p><b>SEE REVERSE OF THIS PAGE</b></p>	<p>EMPLOYEE(S) SIGNATURE Kayla V Sprague, Investigator Nicole E Knowlton, Investigator Santos E Camara, Investigator</p>	<p>DATE ISSUED 8/22/2025</p> <p style="font-size: small;">Nicole E Knowlton Investigator SANTOS E CAMARA KNOWLTON E X Date signed: 8/22/2025 152/19</p>
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<p>Specifically,</p> <p>A. During the inspectional walkthrough on 18 August 2025 of Blending Room (b)(4) that was listed as cleaned (major) on 14 August 2025, we observed a white powdery residue on numerous surfaces including but not limited to: Transport cart holding (b)(4) V-Blender Drive Asset /ID # (b)(4) (Major Cleaning on 10 July 2025), the seat of a stool and the base of the blender tower.</p> <p>Additionally, we observed a hole in the base of the blender tower leaking what was identified by firm personnel as lubricant/grease.</p> <p>The line clearance releasing the room for use was performed on 18 August 2025.</p> <p>B. Your firm failed to establish a written procedure for cleaning, disinfecting, and documenting the transport activities of the stainless-steel pallet jack throughout the GMP areas of your facility. No asset number is assigned to the pallet jack, there is no established written scheduled frequency for cleaning the pallet jack, and the cleaning performed is not documented.</p> <p>During the inspectional walkthrough on 18 August 2025 of Clean Equipment Room (b)(4) firm management stated a stainless-steel pallet jack is utilized to move the clean equipment to allow for cleaning of the room to include the ceiling, walls, floor.</p> <p>Procedure USTP-914 Environmental Monitoring Program Version 12.0 which is applicable to all GMP sites shows that no environmental monitoring surface swabbing is performed in (b)(4)</p> <p>C. During the inspectional walkthrough on 18 August 2025 of Blending Room (b)(4) that was listed as cleaned on 14 August 2025, we observed sifting collection pan Asset (b)(4) was cleaned on 30 JUN 2025 and was passed its (b)(4) clean hold time. The line clearance releasing the room for use was performed on 18 August 2025.</p> <p>Upon further inspection, we observed a white powdery residue on the interior of this collection pan.</p>		
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<p><b>OBSERVATION 4</b> Equipment for adequate control over air pressure, micro-organisms, dust, humidity and temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.</p> <p>Specifically, you firm failed to update HVAC (Heating Ventilation &amp; Air Conditioning) flow schematic drawings for Air Handling Unit (AHU) after components have been changed or replaced. For example, during the review of your HEPA (High Efficiency Particulate Air) filter "HEPA Integrity Test Result Form", it was noted that the exhaust data reported did not match with the schematic drawings.</p> <p>Additionally, the "HEPA Integrity Test Result Form" were missing initial or re-test checks, 'smoke detector ports uncovered' were not performed, and HEP 104-1 and HEP 104-2 were missing exhaust results data. For example,</p> <ul style="list-style-type: none"> <li>A. HEPA Integrity Test Result Form (reviewed/approved by date: 21 June 2023)-Room / Tested: M105, HVAC Unit Serving Space: TP03-FAC-HVAC-002821 was incorrectly identified. Correct identification of TP03-FAC-HVAC-Z12 was made on 08/20/2025.</li> <li>B. HEPA Integrity Test Result Form (reviewed/approved by date: 13 May 2024)-Room / Tested: C-1A, G3, HVAC Zone Tested: TP01-FAC-HVAC-Z14 was missing initial or Re-test checks and Smoke Detector Ports Uncovered were not verified. Additionally, there were no certificates available for rooms: C-1A, G3; M-1, M-1A, M1B; and M-2, M-2A.</li> <li>C. HEPA Integrity Test Result Form (reviewed/approved by date: 20 Aug 2025): Room: M-102, HVAC Zone Tested: TP03-FAC-HVAC-Z12 (b)(4) exhaust leak rate lacked certificate and HEPA Integrity Test Result Form.</li> </ul>		
<p><b>OBSERVATION 5</b> Records are not kept for the maintenance, cleaning, sanitizing and inspection of equipment.</p> <p>Specifically, your firm failed to maintain and archive the dark green Released tags that are the primary documentation showing the cleaning date and the (b)(4) (b)(4) expiration. Your management stated not all equipment have equipment cleaning and use logbooks to document this information. The data from the Released tags is transposed into the batch record and are discarded.</p>		
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<p><b>OBSERVATION 6</b> Procedures for the cleaning and maintenance of equipment are deficient regarding assignment of responsibility for cleaning and maintaining equipment.</p> <p>Specifically, no data was available in your cleaning validations or other documentation to justify the practice of only wiping equipment with (b)(4) after the clean hold time expires.</p> <p>Procedure USTP-489 Equipment Cleaning and Sanitizing Version 12.0 states if the clean hold time expires, the equipment is required to be wiped down (on all product contact surfaces) with (b)(4) and using low lint or lint-free disposable cloth prior to manufacturing and if the equipment was transferred from offsite, stored in a non-GMP area or transported into manufacturing through a non-GMP area, the equipment must be cleaned by being sprayed with (b)(4) followed with a wipe down with a lint-free disposable cloth.</p> <p>Your Quality Assurance Validation Lead and Manufacturing Science and Technology Lead confirmed no documentation was available.</p>		
<p><b>OBSERVATION 7</b> The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.</p> <p>Specifically, your quality control unit is unable to perform investigations in a timely manner because you are not receiving product quality complaints within a reasonable timeframe from your customer (drug product owner). For example, on April 24, 2024, you received notification from your customer for 32 lack of effect product complaints they received for drug product (b)(4) capsules Lot# (b)(4) (Lonza manufacturer lot (b)(4)). You were provided the client product complaint form for the 32<sup>nd</sup> complaint, QE-PC-9907, but none of the other 31 complaint forms. Your quality control unit investigated the complaint and concluded that "a root cause for the lack of effect product complaint could not be attributed to the manufacturing process, bulk product storage, nor analytical testing performed" on May 22, 2024. Per your quality agreement you do not have any time requirement for your customer to communicate the complaints received. In addition, your USTP-889 <i>Product Complaints</i> procedure does not define any controls to follow-up with your customer when complaints are not received in a timely manner.</p>		
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	 <small>Nicole E Knowlton Investigator DATE: 08/22/2025 KNOWLTON, NICOLE E KNOWLTON, NICOLE E DATE SIGNED: 08-22-2025 152/15</small> <input checked="" type="checkbox"/>	
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<p>This is a repeated observation from the previous inspection conducted 09/25-29/2023.</p>		
<p><b>OBSERVATION 8</b> In-process materials are not tested for identity, strength, quality and purity and approved or rejected by the quality control unit during the production process and after storage for long periods.</p> <p>Specifically, the in-process checks by Quality Assurance are not always documented contemporaneously.</p> <p>During the inspectional walkthrough on 20 August 2025 of primary packaging room P-103, I observed a Quality Assurance employee performing an in-process inspection of samples for (b)(4) batch (b)(4). I entered the packaging facility at 9:24 am and observed the in-process check taking place at 10:02am. The time documented in the batch record for the inspection of (b)(4) bottles for IPC completion is listed as 0845.</p> <p>Your Quality Assurance Manager for the Packaging Cell explained the Quality Assurance employee inspected the first bottles, went on break for (b)(4), re-gowned, and resumed the inspection of the bottles.</p> <p>The batch record, USTP-2927 Version 3.0, states when periods between checks are interrupted (e.g., work break), record stoppage times, start or stop time, and reason. No entries were made in the batch record to indicate the Quality Assurance employee began inspection, went on break, and resumed inspection.</p>		
<p><b>OBSERVATION 9</b> 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.</p> <p>Specifically, your firm failed to establish controls, including but not limited to audit trails and electronic data backup, to ensure your non-validated (b)(4) Asset #002766 used to test IPC tablets/ for hardness, thickness, width, diameter, and weight is compliant with established cGMP standards for electronic data.</p>		
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<p>Santos E Camara Investigator Signed By: Santos E. Camara-G Date Signed: 08-22-2025 15:47:54</p> <p>X</p> <p>Kayla V Sprague Investigator Signed By: KAYLA V. SPRAGUE-G Date Signed: 08-22-2025 15:48:33</p> <p>X</p>		
		
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		<p>Nicole E Knowlton Investigator Signed By: NICOLE E KNOWLTON-G Date Signed: 08-22-2025 15:27:19</p> <p>X</p>
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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."

