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	01/27/2026-02/03/2026
	FEI NUMBER: 3004094136

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Shil Vaz, Chief Executive Officer (CEO)/ Managing Director

FIRM NAME	STREET ADDRESS
Global Calcium Pvt. Limited	125/126 Sipcot Industrial Complex
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tamil Nadu, Hosur, 635126, India	Active Pharmaceutical Ingredient 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

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

Microbiology laboratory data is unreliable. For example, the following discrepancies were observed between the individual microbial growth counts recorded in your laboratory-controlled records and the actual counts observed in your growth media plates, which had been read by your microbiologists.

On January 27, 2026, and January 28, 2026, we observed that your microbiologist while performing Total Aerobic Microbial Count (TAMC) for (b) (4) Water (b) (4) did not count all colonies, combined separate colonies counts as one and failed to classify plate counts as Too Numerous to Count (TNTC).

For example,

Media ID:	Incubation Date: (b) (4)	Reported:	Observed Deficiency:
		(b) (4) CFU	Combined colonies, failed to count all colonies.
		(b) (4) CFU	Combined colonies, failed to count all colonies.
		(b) (4) CFU	Combined colonies, failed to count all colonies.
		(b) (4) CFU	Combined colonies, failed to count all colonies.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Alan A. Rivera, Investigator Jose E. Melendez, DDC Investigator	February 3, 2026

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CITY, STATE, ZIP CODE, COUNTRY: Tamil Nadu, Hosur, 635126, India	TYPE ESTABLISHMENT INSPECTED: Active Pharmaceutical Ingredient Manufacturer

(b) (4)	
(b) (4) CFU	Combined colonies, plate is TNTC
(b) (4) CFU	Combined colonies, failed to count all colonies.
(b) (4) CFU	Combined colonies, plate is TNTC
(b) (4) CFU	Combined colonies, plate is TNTC
(b) (4) CFU	Combined colonies, plate is TNTC

According to your QC microbiology management, your firm uses two levels of review to ensure that media plates are accurately reconciled. It was observed that the second analyst verification only consists of document review and a microbial growth recount is not performed.

Your microbiology analyst stated that, during the colony counting process, individual colonies observed to be in contact are counted as one colony and not enumerated individually. According to your microbiology analyst, he did not receive any visual training by your Microbiology Department on how to identify and classify a plate reading as TNTC. Since August 2025, your microbiology analyst has performed colony counting for approximately (b) (4) (b) (4) water samples. (b) (4) water is used as a raw material in your manufacturing process of (b) (4) API. (b) (4) is to be incorporated in (b) (4) drug products that are used (b) (4) (b) (4)

OBSERVATION 2

Established sampling plan and test procedures are not followed.

Specifically, we reviewed the biometric access control system (eSSL Security at Fingertips) for the Room (b) (4) (b) (4) located in Plant (b) (4) in where the (b) (4) water system is located, and water samples are collected. We observed the following deficiencies:

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A. Your Microbiology Officer employee ID (b) (6) documented in form QCMI022-F01-01, A.R. Number Allocation and Water Sampling Register that he collected (b) (4) Water (b) (4) samples for microbiology laboratory testing on the following dates and times:

Sample A.R. Number: (b) (4)	Collection Date:

However, the biometric access control system that limits access to the area does not show that employee ID (b) (6) entered that room during those dates. During my interview with your microbiology employee ID (b) (6) he explained that he always enters the sampling room using the biometric access panel and always performs water sampling by himself.

B. Your Quality Control employee ID (b) (6) documented in form QCMI022-F07-00, Water Sampling Register-Quality Control that he collected (b) (4) Water (b) (4) samples for the quality control laboratory in the following dates and times:

Sample A. R. Number: (b) (4)	Collection Date:

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However, the biometric access control system that limits access to the area does not show that employee ID (b) (6) entered that room during those dates. During my interview with your quality control employee ID: (b) (6) he explained that he always enters the sampling room using the biometric access panel and always performs water sampling by himself.

In addition, the biometric access system shows your Quality Control employee ID: (b) (6) entered the sampling room on January 9, 2026, at 11:06AM. Form QCMI022-F07-00, titled "Water Sampling Register- Quality Control" shows that the (b) (4) Water (b) (4) sample A.R. Number: (b) (4) was collected on January 9, 2026 at 11:06 AM but by a different employee (ID (b) (6) The biometric access system does not show that employee (ID (b) (6) entered the sampling room.

C. Your Quality Control employee ID (b) (6) documented in form QCMI022-F07-00, Water Sampling Register-Quality Control that he collected (b) (4) Water (b) (4) samples for the quality control laboratory in the following dates and times:

Sample A.R. Number: (b) (4)	Collection Date:

However, the biometric access control system that limits access to the area does not show that employee ID (b) (6) entered that room during those dates. During my interview with your quality control employee ID (b) (6) he explained that he always enters the sampling room using the biometric access panel and always performs water sampling by himself.

D. Your Microbiology Officer employee ID (b) (6) documented in form QCMI022-F01-01, "AR Number Allocation and Water Sampling Register" that on December 12, 2025, at 8:21 AM he collected (b) (4) Water (b) (4) sample A.R. Number: (b) (4) for microbiology laboratory testing. However, the biometric access control system that limits access to the area does not show that employee ID (b) (6) entered that room during those dates. During my interview with your quality control employee ID (b) (6) he explained that he

always enters the sampling room using the biometric access panel and always performs water sampling by himself.

Investigation Number: DEV/I/26/001 was initiated after these discrepancies were brought to the attention of firm's management. At the conclusion of the inspection, no system communication errors, or equipment malfunctions were identified. Investigation DEV/I/26/001 was still ongoing.

(b) (4) Water (b) (4) samples collected by your Quality Control personnel are tested by your Quality Control (QC) laboratory for microbiological analysis, Bacterial Endotoxin Test (BET), chemical analysis, and Total Organic Carbon (TOC) to ensure that (b) (4) Water meets established specifications for pharmaceutical use. (b) (4) Water is used by your firm as a raw material in the manufacturing operations of (b) (4) API.

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that in-process materials conform established specifications.

Specifically, on January 28, 2026, we observed the preparation and reading of the Bacterial Endotoxin Test (BET) following your procedure titled "Bacterial Endotoxin Test", SOP Number: QCMI011-00, Effective Date: April 17, 2025. It was observed that your firm failed to provide the conditions needed (no vibration) to prevent disturbance of the samples during incubation and allow proper gel formation. Incubator (ID: QCMIE002) was observed vibrating during the (b) (4) incubation period of routine (b) (4) Water sampling points: (b) (4) (b) (4)

Additionally, a semi solid gel formation was observed for water points (b) (4) reported as negative result. Also, gel formation was observed in water point (b) (4) but since "tears" of liquid was observed running down the test tube, the analyst classified the sample as a negative BET result.

According to your microbiologist, since he started performing the test in January 2025, he has always performed the Bacterial Endotoxin Test using the same incubator, installed in the same area in the same conditions observed

during the inspection. He also explained that at least (b) (4) he has observed semi-soli gel formation test results on (b) (4) water routine samples.

Since August 2023, your firm has approximately performed the BET on a total of approximately (b) (4) Water samples, encompassing your Active Pharmaceutical Product (b) (4) and no discrepant/atypical/invalid results have been observed. (b) (4) water is used as a raw material in your manufacturing process of (b) (4) API.

OBSERVATION 4

Cleaning procedures are not appropriate or reproducible to prevent contamination that would alter the safety, identity, strength, quality, or purity of the finished drug substances.

Your (b) (4) cleaning activities for non-dedicated (b) (4) located inside Plant (b) (4) and used in the manufacturing of (b) (4) API are not reproducible.

For example, but not limited to:

1) According to your procedure titled "Equipment Cleaning Record for (b) (4) ", Document Number: PD033-F01(V-1), Operation Number (b) states " (b) (4) (b) (4) '. On February 2, 2026, your operator replicated the cleaning procedures of this step and explained that the cleaning process starts by (b) (4) (b) (4) The total volume of (b) (4) used on each step is random and is not documented, only the combined volume of (b) (4) used in all (b) (4) steps is documented and required by the cleaning instructions. In addition, your operator demonstrated that the (b) (4) of the (b) (4) (b) (4) with a capacity of (b) (4) s performed with the use of (b) (4) (b) (4) until the tank was observed clean of residue. According to your operator, (b) (4) the (b) (4) is optional and is only performed if he believes is necessary.

2) According to your procedure titled "Equipment Cleaning Record for (b) (4) ", Document Number: PD033-F01(V-1), Operation Number (b) states " (b) (4) (b) (4) (b) (4) ". On February 2, 2026, your operator replicated the cleaning procedures of this step and explained that the form does not require him to document the time of (b) (4) of this cleaning step or volume added into the (b) (4) during cleaning.

3) According to your procedure titled "Equipment Cleaning Record for (b) (4) ", Document Number: PD033-F01(V-1), Operation Number (b) states " (b) (4) (b) (4) (b) (4) ". On February 2, 2026, your operator replicated the cleaning procedures of this step and explained that the cleaning process starts by (b) (4) (b) (4) (b) (4) The total volume of (b) (4) water used on each step is random and is not documented, only the combined volume of (b) (4) water used in all (b) (4) steps is documented as required by the cleaning instructions. In addition, your operator demonstrated that the (b) (4) of the (b) (4) (b) (4) with a capacity of (b) (4) is performed with the use of (b) (4) (b) (4)

4) There is no comprehensive, data-driven assessment demonstrating that the established (b) (4) for (b) (4) cleaning verification of non-dedicated equipment in Plant (b) (4) is adequate. Your firm did not provide empirical evidence such as residue trend data or risk-based rationale to justify that the selected cleaning verification interval of (b) (4) is representative to monitoring the equipment cleaning activities in Plant (b) (4) Similar deficiency was observed for the cleaning verification of the non-dedicated manufacturing train in Plant (b) (4)

OBSERVATION 5

Failure to establish and maintain an effective Quality System to prevent Data Integrity breaches and to ensure the employees can report GMP-related concerns without fear of identification or retaliation.

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A. Your procedure titled "Data Integrity: SOP Number: QA058-04, Effective Date: January 07, 2025, Approved On: December 19, 2024, Section 4.22 states that a (Data Integrity Check will be performed (b) (4) (b) (4) and documented on checklist form QA058-F01). When we performed a review of the form QA058-F01-03, we .erved that the checklist is limited to confirming that documented data integrity procedures of your firm remain in place. It does not include any thorough assessment or challenge of the reported raw data to determine whether the DI controls in place are being consistently followed in practice and no data integrity breach has occurred.

For example,

1. The verification to determine if data is being entered on a real time basis is performed by only reviewing notebooks. No actual observation of the employees carrying out documentation duties is made to ensure that data is documented at the time of occurrence.

2. The review of verification by a second person signatures is performed by only reviewing notebooks. No actual observation of the employees carrying out the duties is made to ensure that the verification by a second person is being performed and documented at the time of occurrence.

3. The review evaluates if original records are readily available for inspection. However, no actual inspection of the original data is performed or challenged as part of the review.

4. An instrument calibration review is performed by inspecting equipment calibration labels. However, no actual verification of calibration raw data, or observation of employees completing any calibration is performed.

5. The review of times entered on controlled documents is performed by only reviewing logbooks. No actual observation of the employees carrying out documentation duties is made to ensure that they are entering the correct time and date at the time of occurrence.

During your approved data integrity checklist, no raw data is evaluated or documents cross examined. For example, no assessment is performed to cross-reference equipment use/cleaning logbooks and manufacturing batch records

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to challenge the documented data. Furthermore, procedure QA058-04 does not require a minimum representative sample of documents to be evaluated, or how these documents are selected prior to inspection.

B. Your corrective action to implement an anonymous GMP compliant reporting mechanism is inadequate in that the compliant box was located at the main entrance of the facility, positioned underneath a security camera, and in area routinely used by employees to access the biometric lunch token system. This location compromises employee anonymity and may discourage the reporting of GMP concerns.

OBSERVATION 6

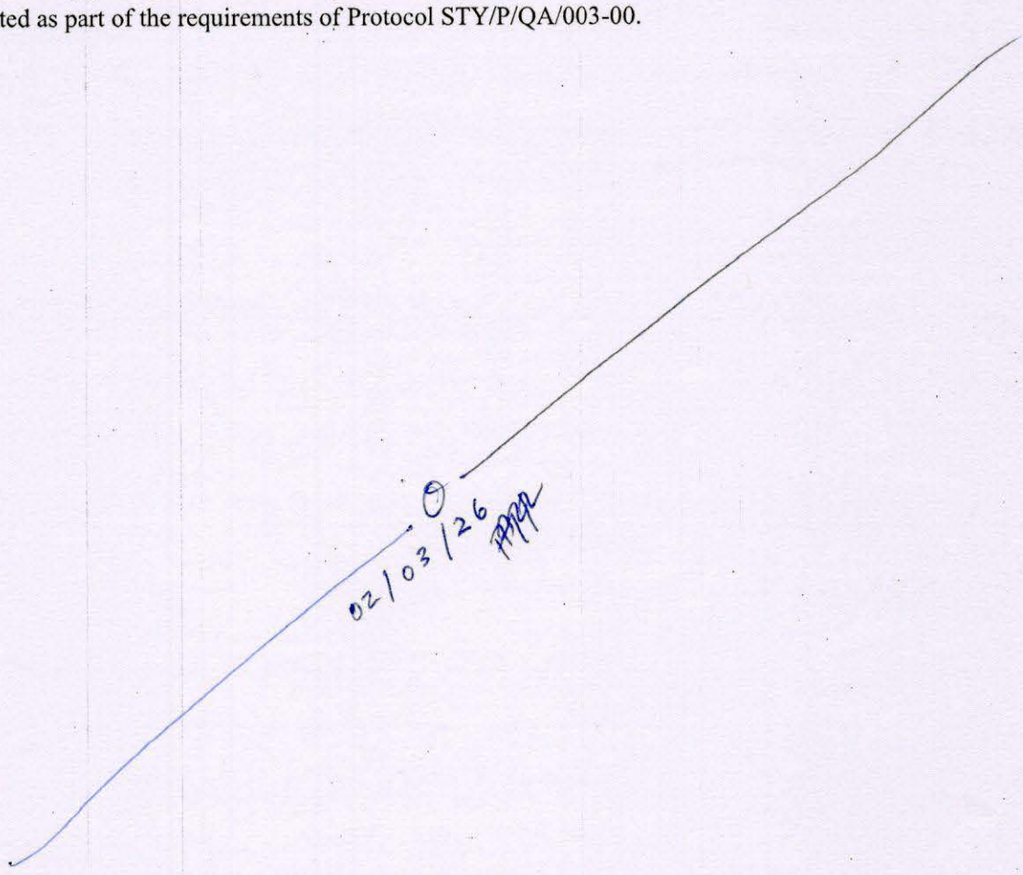
The responsibilities of your Quality Unit are not fully followed

A. Your Quality Unit failed to fulfill its commitment to conduct a comprehensive retrospective assessment by a third party of all batches manufactured during the calendar years 2022 to 2024.

For example, your firm did not conduct a comprehensive evaluation of the manufacturing records associated to all batches manufactured for the USA market to determine the extent of the breaches in data integrity cited during the previous inspection on August 2, 2024, and WL 320-25-30. Your review provides no assurance that a reconciliation of incoming raw materials and API produced and released, inventory, equipment use logbooks, test results, samples collected, and batch production records among others were evaluated to determine if additional discrepancies in the manufacturing operations had occurred as cited in WL 320-25-30. Instead, and without a justification, your Quality Unit followed the statistical approach of (b) (4) (b) (4) to evaluate the production records of the batches manufactured in 2022 and 2023. Only (b) (4) batches were evaluated from a total of (b) (4) batches manufactured during that period.

B. Your protocol Document No. STY/P/QA/003-00 titled "Protocol For Comprehensive Assessment On Data Integrity Assurance", approved on January 21, 2025, is inadequate. The objective of this protocol is to conduct a comprehensive assessment of the integrity of data generated by your firm's Quality Control, Manufacturing, and Engineering departments. A check list was designed for each functional areas to assess the data integrity compliance. However, the result of this assessment only provides information on the control procedures established in each of the referenced departments for assessing/investigating events that could be associated to

data integrity. For example, there is no information related to the computer systems, including the user privileges, the equipment logbooks (e.g. cleaning and usage), the manufacturing/packaging/calibration/qualification/preventive maintenance/analytical records that were evaluated as part of the requirements of Protocol STY/P/QA/003-00.



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."