DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	July 29, 2024 - August 2, 2024
	FEI NUMBER 3004094136

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Satish Hebbar, Site Head

FIRM NAME	STREET ADDRESS
Global Calcium Pvt. Limited	Plot No 125/126 Sipcot Industrial Complex
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hosur, Tamil Nadu, India 635126	API Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION #1
Production records do not contain complete information relating to the production and control of each batch.

The Production Head stated that he directed employees to create batch records and supporting records including cleaning records and equipment use logs for activities that did not actually occur in Plant (b) (4) Plant (b) (4) is intended to be used for the manufacturing of the US market product (b) (4) Injection Grade API.

The Plant (b) (4) Manager stated he used Microsoft Excel to generate plans with dates, production start and stop times, sampling dates, and product weights to instruct employees how to create these records for activities that did not occur. Production employees present (b) (4) of Plant (b) (4) participated in the creation of these batch records, cleaning records, and equipment logs for activities that did not occur. Duplicate sets of cleaning records and equipment logs were created for the same time period and document different batches being manufactured on the same equipment, at the same time.

On July 29, 2024, examples of the plans, which were identified by the manager of Plant (b) (4) as being used in the fabrication of batch records for activities that did not occur, were observed in the Plant (b) (4) production office attached to blank batch records. This included plans associated with (b) (4) batches), (b) (4) Powder (b) (4) Batches), (b) (4) Liquid (b) (4) batches), and (b) (4) batch).

All Microsoft Excel files present on the Plant (b) (4) Manager's computer, where the plans for fabricating batch records were created, were deleted by the Production Head on the evening of July 29, 2024, preventing additional plans that may have been present on the computer from being reviewed during the inspection.

Review of batch records, cleaning records, and equipment use logs for (b) (4) Injection API released for the US market identified the following conflicts that demonstrate the records are not accurate, since at least January of

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2023:

1. (b) (4) Injection API batch (b) (4) was a (b) (4) batch (b) (4) that was shipped on (b) (4) for supply to the US market. The (b) (4) batch record had not yet been reviewed and approved by QA as of July 29, 2024. Review of the (b) (4) batch (b) (4) had the following conflicts in its batch record, equipment use log, and cleaning record documentation:

The (b) (4) batch record and equipment use log for (b) (4) 16/(b) (4) 01 show the batch was (b) (4) from (b) (4) to (b) (4) on (b) (4) This conflicts with the batch record for (b) (4) batch (b) (4) which documents use of the same (b) (4) from (b) (4) to (b) (4) on (b) (4) Duplicate sets of equipment use and cleaning logs documenting these different products were made.

The (b) (4) batch record and equipment use log for (b) (4) 02 (b) (4) /02 show the batch was (b) (4) from (b) (4) to (b) (4) on (b) (4) This conflicts with the batch record for (b) (4) batch (b) (4) and a different (b) (4) /02 (b) (4) /02 equipment log, which document use of the same (b) (4) from (b) (4) to (b) (4) on (b) (4) (b) (4)

The (b) (4) batch record and equipment use log for (b) (4) 02 (b) (4) /03 show the batch was in the (b) (4) from (b) (4) on (b) (4) until (b) (4) on (b) (4) This conflicts with the batch record for (b) (4) batch (b) (4) and a different (b) (4) 02 (b) (4) /03 equipment log, which document use of the same (b) (4) from (b) (4) to (b) (4) on (b) (4)

The Plant (b) (4) Work Report Sheet was described by the Plant (b) (4) Manager as a log that documents the activities occurring (b) (4) and documents what equipment is being used, as a form of communication between the (b) (4) For (b) (4) the Plant (b) (4) Work Report Sheet make references to (b) (4) batches (b) (4) and (b) (4) manufacturing in Plant (b) (4) but no references to any (b) (4) manufacturing in Plant (b) (4) on these days.

2. (b) (4) Injection API batch (b) (4) was (b) (4) batch (b) (4) and distributed on (b) (4) for the US market. QA review and release had not been completed for the (b) (4) batch or the (b) (4) batch as of July 29, 2024. (b) (4) Injection API batch (b) (4) had the following conflicts in its

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batch record, equipment use log, and cleaning record documentation:

The (b) (4) batch record and equipment use log for (b) (4) 16/(b) (4)/01 show the batch was in (b) (4) from (b) (4) to (b) (4) on (b) (4) This conflicts with the batch records for (b) (4) batch (b) (4) which documents use of the same (b) (4) from (b) (4) on (b) (4) to (b) (4) on (b) (4) and (b) (4) batch (b) (4) which documents the used of the same (b) (4) from (b) (4) to (b) (4) on (b) (4) Duplicate sets of equipment use and cleaning logs documenting these different products were made.

The (b) (4) batch record and equipment use log for (b) (4) 02/(b) (4)/02 show the batch was (b) (4) from (b) (4) on (b) (4) to (b) (4) on (b) (4) This conflicts with the batch record for (b) (4) batch (b) (4) and a different (b) (4) 02 (b) (4)/02 equipment log, which document use of the same (b) (4) from (b) (4) on (b) (4) to (b) (4) on (b) (4)

The (b) (4) batch record and equipment use log for (b) (4) 02/(b) (4)/01 show the batch was in the (b) (4) from (b) (4) on (b) (4) until (b) (4) on (b) (4) This conflicts with the batch record for (b) (4) batch (b) (4) and a different (b) (4) 02/(b) (4) 01 equipment log, which document use of the same (b) (4) from (b) (4) to (b) (4) on (b) (4)

For (b) (4) the Plant (b) (4) Work Report Sheet make references to (b) (4) batches (b) (4) and (b) (4) manufacturing in Plant (b) (4) but no references to any (b) (4) manufacturing in Plant (b) (4) on these days.

3. (b) (4) Injection API batch (b) (4) was (b) (4) batch (b) (4) which was distributed on (b) (4) for the US market. The batch record for (b) (4) shows the following conflicts:

The batch record shows use of (b) (4) 16/(b) (4)/01 from (b) (4) on (b) (4) to (b) (4) on (b) (4) (b) (4) The batch record for (b) (4) batch (b) (4) shows that the same equipment was used from (b) (4) on (b) (4) (b) (4) to (b) (4) on (b) (4)

The batch record shows the use of (b) (4) from (b) (4) to (b) (4) on

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(b) (4) The batch record for (b) (4) batch (b) (4) shows the use of the same equipment from (b) (4) to (b) (4) on (b) (4)

4. (b) (4) Injection API batch (b) (4) was (b) (4) batch (b) (4) which was distributed on (b) (4) for the US market. The batch record for (b) (4) shows the following conflict:

The batch record shows (b) (4) 02/ (b) (4) /01 was used from (b) (4) on (b) (4) to (b) (4) on (b) (4) The batch record for (b) (4) batch (b) (4) shows the use of same equipment from (b) (4) to (b) (4) on (b) (4)

OBSERVATION #2
Procedures for issuance and controls of documents are not followed.

1. QA issues duplicate equipment use logs and cleaning logs with the same issuance number. These duplicate logs are used in creation of records that document activities that did not occur. QA subsequently reviews and approves both sets of contradictory records.

2. The QC laboratory keeps uncontrolled notebooks which contain measurements associated with assay, LOD, pH, (b) (4) uncontrolled sample weights, etc. During the inspection employees were observed transcribing measurements from these uncontrolled pages into controlled test reports. Review of pages revealed testing for products manufactured in the different blocks including (b) (4) injection reported to be manufactured in Plant (b) (4)

OBSERVATION #3
An on-going testing program to monitor the stability characteristics of APIs is not established and followed.

1. 2023 yearly stability samples for (b) (4) batch (b) (4) as required by Protocol STB/23/ (b) (4) /001/00 could not be located. These samples were confirmed to be representative of commercial product distributed to the US market.

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2. [(b) (4)] samples for batches [(b) (4)] and [(b) (4)] were observed inside stability chamber QC 90, but your site did not have a protocol for these samples which described packaging, number of samples, and conditions of storage. In addition, the samples for these batches were kept in [(b) (4)] bags but the three additional stability samples kept for investigation purposes were kept inside [(b) (4)] bags. These samples were confirmed verbally to be representative of the commercial product for the US market.

3. Protocol STB/21[(b) (4)]-24/00 -[(b) (4)] for the year 2021, requires samples of batches [(b) (4)] [(b) (4)] and [(b) (4)] to be monitored for 60 months. These samples could not be located inside stability chamber QC 90.

4. Samples for [(b) (4)] batch [(b) (4)] did not have a sample for 24-month time point as required by Protocol STB/23/[(b) (4)]-USP/002/00. The 24-month time point is due for testing in March of 2025. [(b) (4)] API has been distributed to the US market.

5. Samples for [(b) (4)] lot [(b) (4)] only had two (2) additional investigational samples instead of three (3) as described by Protocol STB/24/[(b) (4)]-USP/002/00. There have been no documented investigations.

6. [(b) (4)] stability samples for lot [(b) (4)] as required by Protocol STB/23[(b) (4)]/001/00 could not be located.

7. [(b) (4)] injection USP stability sample set for lot [(b) (4)] did not have a sample for the 48-month time point. The 48-month time point sample is due for testing in May 2026. In addition, no protocol for this lot could be provided.

8. There are no records of the transfer of samples located inside stability chamber QC 89 to stability chamber QC 90, when chamber QC 89 stopped working.

9. The methods used for stability testing of [(b) (4)] injection USP have not been shown to be stability indicating.

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OBSERVATION #4
Established impurity profiles for US market APIs are inadequate.

Impurity profiles describing the identified and unidentified impurities present in a typical batch of US market APIs such as (b) (4) injection USP, (b) (4) and (b) (4) have not been established. The document provided as impurity profile does not include the identity or some qualitative analytical designation such as retention time and classification of each identified impurity (e.g., inorganic, organic, solvent, etc).

OBSERVATION #5
Facility and equipment are not maintained in a manner that prevents contamination of APIs by other materials.

On July 30, 2024, unidentified (b) (4) liquid was observed surrounding the (b) (4) pipe which transfers (b) (4) (b) (4) This area is located (b) (4) the (b) (4) area.

Similar (b) (4) liquid was also observed dripping from the ceiling pipe junctions in the (b) (4) area. The liquid was dripping on the floor and cover of the (b) (4) equipment. This area is where (b) (4) APIs are manually (b) (4)

OBSERVATION #6
Deviations from established procedures were not documented in batch records and investigated.

1. The Plant (b) (4) Work Report Sheet identifies on May 22, 2024, the (b) (4) (b) (4) indicator malfunctioned and the (b) (4) raised in (b) (4) above the (b) (4) to (b) (4) during batch (b) (4) This caused the (b) (4) It states an extra (b) (4) material was added.

None of this information is written in the batch record or further investigated for (b) (4) batch (b) (4) which used (b) (4) #1 on May 22, 2024. There is no associated maintenance records for the (b) (4) indicator.

2. The Plant (b) (4) Work Report Sheet identifies on June 3, 2024, that during (b) (4) of

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(b) (4) the (b) (4) -01 (b) (4) was broken and it was changed. This was not documented in the batch record for (b) (4) batch (b) (4) in any maintenance record, or further investigated.

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