

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

Food and Drug Administration
1115 Dolfield Blvd, Suite 117
Owings Mills, Maryland 21117
ORAPharm1_responses@fda.hhs.gov
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

03/30/2026-04/03/2026, 04/07/2026

FEI NUMBER

3003299802

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Dr. Ke Chen, Senior Director GMP Global

FIRM NAME

ChemPacific Corporation

STREET ADDRESS

6200 Seaforth Street

CITY, STATE, ZIP CODE, COUNTRY

Baltimore, MD 21224, USA

TYPE ESTABLISHMENT INSPECTED

API Manufacture

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/WE OBSERVED:

Observation 1:

The firm failed to maintain adequate quality control systems, including data integrity controls and procedural oversight,

Specifically,

- a. Your firm failed to ensure that laboratory records include complete data derived from all tests conducted on GMP materials and failed to maintain adequate documentation of laboratory testing activities.

Review of HPLC sample injection testing data from instruments (b)(4) and (b)(4) (software: (b)(4)) revealed that analysts performed 35 undocumented HPLC sample injections on GMP materials under the non-GMP testing project name "test" and the GMP testing project name (b)(4) between April 2023 and December 2024. Both instruments are used for testing GMP and non-GMP samples. This practice is also performed on the firm's other laboratory equipment: GC, IR/UV, and (b)(4).

For example, analysts conducted sample testing without recording the activities in laboratory logbooks and analyst notebooks. The undocumented analyses fall into the following categories with the reasoning behind each injection:

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EMPLOYEE(S) SIGNATURE



Michael O. Idowu,
Investigator

DATE ISSUED

04/07/2026



Yaharn Su, Investigator

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Date	Category	Injections	Material	Claimed Purpose during FDA inspection
04/23/2023	System suitability	8	System suitability	HPLC pump condition check
04/27/2023	(b)(4) testing	6	(b)(4)	(b)(4) analysis
08/16/2023	(b)(4) testing	6	(b)(4)	(b)(4) analysis
08/28/2023	System suitability	8	System suitability	System suitability check
06/13/2024	(b)(4) testing	3	(b)(4) stage 4	Column check
12/18/2024	Unidentified GMP	4	Unknown	Unable to identify

Your firm's laboratory practices demonstrate a failure to maintain complete and accurate documentation of analytical testing performed on GMP materials.

- b. Your firm failed to establish adequate written procedures and controls for chromatographic peak (b)(4) integration used in assay and impurity testing of drug products, including intermediates and final API testing of (b)(4). Specifically, the firm lacks written procedures that establish limitations and criteria for peak area selection during manual integration of chromatographic data.

For example, analysts perform manual integration for intermediates, final API assay, and impurity testing without documented procedures governing when and how manual integration should be applied. As a result, manual integration practices may vary among analysts due to the absence of standardized

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procedures and controls. The lack of standardized procedures for chromatographic peak integration creates significant risks to data integrity and product quality.

- c. Batch production and control records are not prepared at the time each action is taken, and entries are not signed in a timely fashion. On 03/30/2026, during the walkthrough of Room (b)(4) where Stage (b)(4) production of the intermediate (b)(4) lot (b)(4) (sub lot - (b)(4)) was being performed, it was observed that data was entered and signed by the operator in the batch record; however, the checker signature field was left blank. The chemist conducting the production stated that he "signs as the operator and that the checker will usually sign later because they trust each other." This demonstrates systemic documentation issues in which: 1) Batch record entries are not being signed at the time the action is performed or verified; 2) The independent verification system is not functioning as designed; and 3) Batch records do not provide contemporaneous documentation of manufacturing operations.

Observation 2:

The firm failed to have an ongoing testing program designed to monitor the stability characteristics of active pharmaceutical ingredients.

Specifically,

Your firm has not performed an ongoing stability testing program that is established to monitor the stability characteristics of API (b)(4) to establish or verify retest dates.

For example: Your firm manufactured (b)(4) batches of API (b)(4) in (b)(4) (batches (b)(4)). Although these batches have been tested and approved for release, they have not been placed on stability studies.

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Observation 3:

Materials are not handled and stored in a manner to prevent contamination and ensure proper identification. Additionally, there is inadequate separation between materials of different statuses.

Specifically,

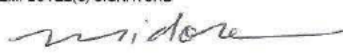
Your firm does not have material log-in records for your refrigerators and freezers used to store critical production materials. On March 30, 2026, during a facility walkthrough, it was observed that the firm stores intermediates in refrigerators (b)(4) and freezers (b)(4) but could not demonstrate adequate knowledge of the materials stored in specific units. For example, an unidentified bag of failed research and development intermediate IM-(b)(4) was found in Freezer (b)(4), which is also used to store GMP intermediates for (b)(4) production. The firm was unable to explain the reason for storing this material in the freezer or the duration of storage. The presence of this unidentified, failed research and development material in the same storage unit as approved GMP intermediates creates a risk of cross-contamination or mix-up between rejected materials and materials intended for use in drug product manufacturing.

Observation 4:

Buildings used in the manufacture, processing, packing, or holding of intermediates and API are not maintained in a good state of repair and kept in a clean condition.

Specifically,

Your firm has not maintained facility ceilings in critical GMP areas in a good state of repair. For example, during a facility walkthrough on 03/30/2026, it was observed that Room (b)(4), designated as "GMP Raw Material (Quarantine)," had damaged and discolored ceiling tiles above the sampling area. The ceiling tiles showed discolored stain marks and a crack approximately two feet long. Your QA staff observed a water leak in this room

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on 02/20/2026 but continued to use this room without repair. Room (b)(4) is used for the storage and sampling of GMP raw materials.

***DATES OF INSPECTION**

03/30/2026, 03/31/2026, 04/01/2026, 04/02/2026, 04/03/2026 and 04/07/2026

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Michael O. Idowu

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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."