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	3/9/2026-3/13/2026
	FEI NUMBER 3014217121

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tommy Huang, Quality Assurance Manager

FIRM NAME	STREET ADDRESS
TCI Co., Ltd. - BioCosme PABP BRANCH	No. 21 Nongke Rd., Changzhi Township
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pingtung County, 90846 Taiwan	Drug 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 I OBSERVED:

OBSERVATION 1

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.

Specifically,

A. Your firm has not performed process validation to support the manufacture of (b) (4) (b) (4)

B. Your firm has not performed process validation to support the manufacture of (b) (4) (b) (4)

C. Your firm failed to adequately qualify your (b) (4) system used in the manufacture of drug products. The (b) (4) system qualification does not evaluate (b) (4) or microbial limits. (b) (4) from this system was used in the manufacture of (b) (4) (b) (4) batches (b) (4) (b) (4), and is also used for cleaning drug manufacturing equipment.

OBSERVATION 2

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There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, the stability studies supporting (b) (4) (b) (4) (b) (4) do not include assay testing. In addition, the long-term stability studies do not monitor relative humidity conditions.

Your procedure governing stability studies (TCIC-W-RD-001) does not specify humidity conditions for long-term stability studies and does not require assay testing as part of stability evaluation.

OBSERVATION 3

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, your firm did not perform assay testing as part of finished product release testing for (b) (4) batches (b) (4) (b) (4). These batches were released and distributed to the U.S. without assay testing.

OBSERVATION 4

Drug product component testing is deficient in that at least one specific test to verify the identity of each component is not performed.

Specifically, your firm did not perform identity testing for the following components prior to use in drug product manufacture.

A. Components used to manufacture (b) (4) (b) (4) (b) (4) were not tested for identity, including (b) (4)

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(b) (4) batch (b) (4)

B. Components used to manufacture (b) (4) batch (b) (4) were not tested for identity, including (b) (4) batch (b) (4)

OBSERVATION 5

Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

A. Your firm manufactured drug products using components that do not appear to be USP-grade. For example,

1. (b) (4) batches (b) (4) were manufactured using (b) (4) batch (b) (4) that do not appear to be USP-grade.

2. (b) (4) batch (b) (4) was manufactured using (b) (4) batch (b) (4) that do not appear to be USP-grade.

B. There is no data to support that water used in the manufacture of (b) (4) batches (b) (4) conformed to (b) (4) USP specifications at the time of manufacture.

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Your procedure governing (b) (4) system testing (TCIC-P-QA-001) does not specify the frequency for (b) (4) testing. Firm personnel stated that (b) (4) testing is performed (b) (4) and provided testing reports. The (b) (4) testing report for (b) (4) was dated (b) (4) (b) (4) (b) (4) (b) (4) was manufactured in (b) (4)

OBSERVATION 6

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically, your firm has not qualified the following suppliers of drug components used to manufacture U.S. (b) (4) drug products:

(b) (4)

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(b) (4)

OBSERVATION 7

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, on 9-MAR-2026, during a walkthrough of the (b) (4) Filling Room, dried residue was observed on tube filler (b) (4), which was identified as "cleaned." The residue was located on equipment parts above the (b) (4). In addition, rusted equipment parts that appeared to be shedding were observed on the filler. The rust particles were also observed on equipment parts located above the (b) (4). Tube filler (b) (4) was used to manufacture (b) (4) (b) (4) batch (b) (4)

OBSERVATION 8

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition and free of infestation by rodents, birds insects, and other vermin.

Specifically,

A. On 9-MAR-2026, during a walkthrough of Building (b) (4) which houses manufacturing operations for U.S. (b) (4) drug products, dead insects were observed in the manufacturing suite and in the OTC raw material storage area. What appeared to be dead centipedes were observed in the (b) (4) Room, which houses (b) (4) equipment used to manufacture U.S. (b) (4) drug products; in the corridor immediately outside the (b) (4) Room; and in the corridor immediately outside the (b) (4) Filling Room, which houses filling equipment used to manufacture U.S. (b) (4) drug products. In the (b) (4)

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OTC raw material storage area, what appeared to be a dead roach and dead centipedes were observed in and around pallets on which drug components were stored. (b) (4) batches (b) (4), were manufactured in Building (b) (4).

B. On 9-MAR-2026, during a walkthrough of the (b) (4) raw material and finished product storage warehouse, discolored ceiling tiles that appeared to be water damaged were observed. Several ceiling tiles appeared to have black mold present. The warehouse is used to store drug components and packaging components used in the manufacture of U.S. (b) (4) drug products, in addition to finished drug products.

C. On 9-MAR-2026, during a walkthrough of the Raw Material (b) (4) Room and Raw Material Preparation Room, what appeared to be black mold was observed on air supply vents. The Raw Material (b) (4) Room is used to store raw materials awaiting entry into the manufacturing suite, and the Raw Material Preparation Room is used to weigh and stage raw materials prior to batch manufacture.

OBSERVATION 9

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

Specifically,

A. Changes to manufacturing process parameters were implemented in batch manufacturing instructions without an associated change control, as required by your change control procedure (TCI-P-QA-004), which requires initiation of change controls for changes to processing parameters. For example,

1. When reviewing the (b) (4) batch record for (b) (4), work order (b) (4), used to manufacture the bulk for batch (b) (4) were changed without an associated change control.

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2. When reviewing the (b) (4) batch record for (b) (4), work order (b) (4), used to manufacture the bulk for batches (b) (4) was changed without an associated change control.

B. Your firm did not initiate a deviation when (b) (4) for (b) (4) batch (b) (4) was performed outside the established range identified in your production instructions. Your deviation procedure (TCIC-P-QA-005) requires initiation of a deviation when production process or parameter settings deviate.

OBSERVATION 10

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing.

Specifically, the (b) (4) batch record for (b) (4), work order (b) (4) used to manufacture the bulk for batches (b) (4), (b) (4), did not document all process parameters observed during manufacturing. The batch record did not include documentation of (b) (4) for the (b) (4) step.

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