DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food & Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	07/22/2025 to 07/25/2025* FEI NUMBER 3008549263

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Peter R. Bates, Managing Director	
FIRM NAME Tripak Pharmaceuticals Pty Ltd	STREET ADDRESS 22 Neumann Rd
CITY, STATE, ZIP CODE, COUNTRY Capalaba, Queensland, Australia 4157	TYPE ESTABLISHMENT INSPECTED Finished Product (OTC) 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

The quality control unit lacks the responsibility and authority to approve, reject all drug products.

Specifically,

Your firm manufactured several products using inactive ingredients that failed testing. Following are the examples I observed during my review, but are not limited to:

a) On 09/24/2024, your firm opened an OOS investigation #122 for one of the inactive ingredients used in the manufacturing of (b) (4) mL), Lot #(b) (4) (Bulk Lot #(b) (4) Exp (b) (4) Your contract testing laboratory reported twice for failed(b) (4) content in (b) (4), Batch (b) (4) Your firm proceeded with manufacturing of finished product Lot #(b) (4) using the failed inactive ingredient. This product was later released to your customer and subsequently shipped to the US market.

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b) On 05/16/2024, your firm opened an OOS investigation #115 for the inactive ingredient used in (b) (4) Lot #(b) (4) and (b) (4) Lot #(b) (4) Your contract testing laboratory reported an OOS for impurity failure in (b) (4) (b) (4) Lot #(b) (4) Related substances were reported as more than (b) (4) % for a specification of NMT (b) (4) %. Your firm proceeded with manufacturing of finished products Lot #(b) (4) and Lot #(b) (4) using the failed inactive ingredient. These products were later released to your customer and subsequently shipped to the US market.

OBSERVATION 2

Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis.

Specifically,

a) Your firm failed to conduct identification tests for raw materials used in drug product manufacturing. Specifically, your firm failed to verify the identity of each component prior to use in manufacturing operations. For example, your firm used (b) (4) (b) (4) Lot (b) (4) in the manufacture of (b) (4) (b) (4) Lot #(b) (4) Exp: (b) (4) without performing the required identification testing to confirm these materials met established specifications. The failure to conduct proper identification testing creates a significant risk that incorrect, adulterated, or substandard raw materials may be incorporated into finished drug products, potentially compromising product safety, efficacy, and quality.

b) From 01/31/2024 to 02/07/2025, your firm released (b) (4) lots of (b) (4) (b) (4) to customer, and these lots were subsequently shipped to the US market. These lots

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were manufactured using (b) (4) as an inactive ingredient. Your firm failed to conduct specific identity analysis for each lot of (b) (4), which should include a limit test for (b) (4) and incorporate testing of samples from all containers of all lots received. Currently, your firm tests for (b) (4) (b) (4) which does not ensure the safety and quality of each individual lot used in manufacturing. For example, (b) (4), Lot #(b) (4) (Bulk Lot #(b) (4), Exp. (b) (4), was manufactured using (b) (4) Lot # (b) (4) which was accepted based solely on the supplier's Certificate of Analysis (COA) for (b) (4) (b) (4) without independent verification testing.

OBSERVATION 3

Failure to establish adequate written procedures for production and process controls.

Specifically,

Your process validation report VMP-VR0031.00 for the manufacturing of (b) (4) bulk fails to demonstrate that written procedures designed to assure that drug products have the identity, strength, quality, and purity they purport or are represented to possess are adequate. The validation lacks sufficient details regarding critical process parameters, in-process controls, and acceptance criteria for manufacturing steps. Additionally, the validation scope is limited to bulk product testing and does not address process parameter controls to ensure consistent product quality throughout the manufacturing process. Moreover, your firm failed to validate the filling/packaging process.

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OBSERVATION 4

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

Specifically,

Your firm failed to test finished drug products for all required specifications prior to release. From 05/04/2022 to 05/19/2025, your firm manufactured and released approximately (b) (4) batches to your customers without conducting comprehensive finished product testing. These lots were subsequently shipped to the US market. Your firm currently relies only on bulk drug testing results for finished product release, which is inadequate to ensure the quality and safety of the final dosage form. For example, the (b) (4) Lot # (b) (4) (Bulk Batch Lot # (b) (4) Exp: (b) (4) was released on 05/07/2024 without testing the finished dosage form, relying solely on bulk drug testing results. The absence of finished product testing creates significant risk that products not meeting quality standards may be released to the market, potentially compromising patient safety and product efficacy.

OBSERVATION 5

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

Specifically,

Your firm failed to establish a written testing program designed to assess the stability characteristics of (b) (4) Your firm currently proposes a (b) (4) expiration period without adequate supporting stability data. The proposed expiration

date is based solely on 6-month accelerated condition (ACC) data for bulk, which is insufficient to support the claimed shelf life according to established stability testing. Additionally, your firm failed to place at least one (1) batch of each commercial product on long-term stability testing under recommended storage conditions. This deficiency prevents your firm from demonstrating that the products maintain their identity, strength, quality, and purity throughout the proposed shelf-life period.

OBSERVATION 6

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically,

Your firm failed to conduct hold time studies for products manufactured at your facility. For example, on (b) (4), your firm compounded (b) (4), Bulk Lot #(b) (4), but did not complete filling operations until (b) (4) (final lot #(b) (4), representing a hold time of approximately (b) (4) between compounding and final packaging. Without proper hold time studies, your firm cannot demonstrate that the product maintains its identity, strength, quality, and purity during extended storage periods between manufacturing steps.

OBSERVATION 7

Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, drug product closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity.

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Specifically,

From 05/04/2022 to 05/19/2025 your firm released approximately (b) (4) lots of products to customers without conducting (b) (4) testing. These lots shipped to the US market. All your products contains (b) (4) an inactive ingredient in the formulations, which significantly increases the microbiological risk profile and necessitates comprehensive microbiological testing to ensure product safety. For example, the (b) (4), Lot # (b) (4), Exp: (b) (4) was released on 05/07/2024 without conducting testing for (b) (4)

OBSERVATION 8

Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that may alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements,

Specifically,

On 07/24/2025, during my walkthrough inspection at your manufacturing facility, I observed multiple (b) (4) tanks and transfer tanks without proper status labels. Specifically, I observed (b) (4) tanks in the warehouse and (b) (4) tanks in the compounding area that lacked appropriate status identification. According to the cleaning logbooks, these tanks had been cleaned; however, the status was not clearly indicated through proper labeling. According to your written procedure no. *30022.04: Status Labeling in Production*, new green cleaned labels should be attached after equipment cleaning. The absence of clear status labeling creates potential for cross-contamination and makes it difficult to verify equipment

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readiness for use. These tanks are being used in the manufacturing of several products including The (b) (4) mL).

OBSERVATION 9

Strict control shall be exercised over labeling issued for use in drug product labeling operations.

Specifically,

On 07/25/2025, during my walkthrough inspection, I observed inadequate label storage controls. Multiple different label rolls were stored together in plastic bags in an open warehouse environment accessible to all personnel, creating significant risk for label mix-ups, unauthorized access, and compromised chain of custody during labeling operations. Additionally, your firm failed to have a written procedure for the labeling issuance and control.

*** DATES OF INSPECTION**

07/22/2025 (Tue), 07/23/2025 (Wed), 07/24/2025 (Thu) and 07/25/2025 (Fri)

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