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	12/15/2025-12/17/2025
	FEI NUMBER 3011219786

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tai Hang Lao, Technical Director

FIRM NAME	STREET ADDRESS
Macau-Union Pharmaceutical Limited	Rua Cinco Do Bairro Da Areia Preta, Industrial Veng Fong; Room B 1/F; 3-3a
CITY, STATE, ZIP CODE, COUNTRY Macau, Macau Macao	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

a. Your firm does not perform any finished product testing (including but not limited to testing for contamination of objectionable microorganisms and assay) for drug products intended for the U.S. market other than checking for conformance to appearance and weight per unit specifications.

There is no written documented agreement that testing and other GMP activities not performed by the firm is to be done by the customer, and that shipment is done so under quarantine.

In 2025, your firm has manufactured and distributed (b) (4) the following drug products intended for the U.S. market:

(b) (4)

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b. The finished product packaging of (b) (4) aforementioned drug product batches includes the (b) (4) ml sized, (b) (4) bottle (with internal material code (b) (4) product packaging that comes into direct contact with the drug product. Your firm does not subject this drug product container to microbiological tests before use as finished product (b) (4) packaging to ensure this drug product container does not introduce microbial contamination to the finished human drug products.

OBSERVATION 2

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically,

Your firm does not perform identity testing for components used to manufacture drug products intended for the U.S. market. Components without identity testing performed include but are not limited to:

(b) (4)

These components are the active pharmaceutical ingredients for (b) (4) (b) (4) drug products intended for the U.S. market.

OBSERVATION 3

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

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Specifically,

Your firm does not test components used to manufacture drug products intended for the U.S. market for conformance to all appropriate specifications for quality.

For example, your firm does not test the active pharmaceutical ingredients for (b) (4) (b) (4) (b) (4) to demonstrate conformance to all appropriate specifications for quality.

Additionally, your firm relies on your suppliers' certificate of analysis results but has not appropriately established the reliability of these results.

The suppliers' certificate of analysis show that components are not tested according to USP specifications. These test methods have not been demonstrated to be equivalent to or exceed USP standards.

OBSERVATION 4

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

Your firm has not validated the production processes used to manufacture the over-the-counter finished human drug products intended for the U.S. market:

(b) (4)

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(b) (4)

Additionally, your firm does not conduct in-process testing during the production of these drug products intended for the U.S. market. For example, there is no in-process testing to assess factors such as microbiological contamination, inter- and intra- batch variability, and product uniformity.

Your firm has manufactured and distributed (b) (4)
(b) (4)

OBSERVATION 5

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

Specifically,

Your firm does not perform stability testing for drug products intended for the U.S. market.

There is no written documented agreement that stability testing is to be performed by the customer.

Additionally, your firm does not have any data to demonstrate drug products intended for the U.S. market meet their established specifications throughout their labeled shelf-life of no longer than (b) (4)
(b) (4)

In 2025, your firm has manufactured and distributed (b) (4) the following drug products intended for the U.S. market:

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(b) (4)

OBSERVATION 6

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

Your firm has not validated your cleaning procedures and UV-Vis test method to demonstrate that cleaning of shared equipment is effective and reproducible at removing drug product residue and other contaminants that could adversely affect the quality of drug products intended for the U.S. market.

Additionally, shared equipment used to manufacture drug products intended for the U.S. market (b) (4) (b) (4) is cleaned using (b) (4) that has not been demonstrated to meet or exceed appropriate (b) (4) standards.

OBSERVATION 7

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically,

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Your firm does not have procedures for performing an annual visual examination of reserve samples of over-the-counter human finished drug products, including drug products intended for the U.S. market, such as: (b) (4) (b) (4) Your firm also does not have records documenting the examination and results of an annual visual examination of reserve samples for evidence of deterioration throughout the storage of their intended shelf-life.

OBSERVATION 8

Batch production and control records do not include complete labeling control records, including specimens or copies of all labeling used for each batch of drug product produced.

Specifically,

Your firm did not include specimens or copies of all completed labeling, including the label adhered to the (b) (4) packaging bottle and labeling on the (b) (4) packaging carton, in your batch production records for packaging finished over-the-counter human drug products intended for the U.S. market. Your firm did not include specimens or copies of full labeling in each of the respective batch packaging records for the following finished drug products: (b) (4) (b) (4)

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APPEARS THIS WAY ON ORIGINAL

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