DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	8/26/2024-8/30/2024
	FEI NUMBER 3005543486

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sen Lin, Vice President of Operation

FIRM NAME	STREET ADDRESS
Huangshi Hygienic Material Medicine Co., Ltd.	386 Shenxia Road
CITY, STATE, ZIP CODE, COUNTRY Huangshi, Hubei, 435003 China	TYPE ESTABLISHMENT INSPECTED 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

An adequate number of batches of each drug product are not tested nor are records of such data maintained to determine an appropriate expiration date.

Specifically,
Your firm has not tested OTC drug products manufactured for the US market for stability to determine the expiration date. The products: (b) (4) (b) (4) are assigned (b) (4) expiration date from the date of manufacture. The product (b) (4) (b) (4) is assigned (b) (4) expiration date from the date of manufacture. Over (b) (4) batches of products shipped to the US in (b) (4) are still within expiry date.

OBSERVATION 2

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,
Equipment and utensils used for the manufacture of US drug products are not cleaned and maintained to prevent contamination including the following
A) (b) (4) S02009 used for the formulation of drug product (b) (4)

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	Rafeeq A Habeeb, Investigator	Rafeeq A Habeeb Investigator Signed By: 2002600695 Date Signed: 08-30-2024 05:37:53	8/30/2024

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B) (b) (4) S02008 used for the formulation of drug product (b) (4) (b) (4)

C) (b) (4) used for transferring formulated US drug product intermediates to the (b) (4) machine room.

D) (b) (4) S01007 used for (b) (4) raw ingredients.

E) (b) (4) S01031 used for processing raw ingredients.

In additional you firm did not conduct risk assessment for sharing of equipment and/or (b) (4) between US and Domestic drug products/intermediates without performing major cleaning. Some of the ingredients used exclusively for Domestic products include (b) (4) (b) (4)

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,

You did not perform testing of your finished product for identity and strength of each active ingredient prior to release including for a total of (b) (4) batches of the following products manufactured for the US market.

(b) (4)

OBSERVATION 4

Laboratory records are deficient in that they do not include a statement of the results of tests and how they compare to the established specifications.

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Specifically,
Your firm did not perform growth promotion studies on each batch of media used for microbial testing of your finished drug products (b) (4)

OBSERVATION 5

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

Specifically,
A) Your quality unit does not review electronic raw data including but not limited to identify testing of a finished product and APIs by HPLC and GC.
B) Your quality unit does not review audit trails on test results including for HPLC (Waters Chromatography Data System Empower 3 and Lab Solutions) and GC (Chromleon and OpenLab) to ensure data integrity. HPLC and GC are used to perform identity testing of APIs and a finished product.
C) Your firm has not designed and performed cleaning validation studies on equipment used in the manufacture of US drug products including for (b) (4)
D) You do not follow your procedure for "(b) (4) operating Regulations" CZ-21-4114 for testing of (b) (4) The procedure requires (b) (4) testing of (b) (4) including for microorganisms. Your last (b) (4) testing was performed on (b) (4) The (b) (4) is used in the production of US drug products and for cleaning of production equipment.
E) You do not follow your procedure "Laboratory management regulations" GL-ZL-2026 for data backup. Your SOP requires (b) (4) data backup including for HPLC and GC data. However, your records indicate that you perform data back up (b) (4)
F) Your procedures for cleaning and cleaning verification of (b) (4) is inadequate as it does not involves cleaning the interior of the (b) (4) between batches of products considered similar.

OBSERVATION 6

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Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,
Your firm did not perform microbial testing of the finished drug product (b) (4) (b) (4) manufactured for the US market.

OBSERVATION 7

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically,
The building used in the processing and storing of the raw materials was not maintained in a good state of repair including
A) The ceiling of raw material storage room had water damage stains and peeling paint above the bags storing raw ingredients.
B) A door of the ingredient (API, (b) (4) room was damaged and had large holes with potential for rodent and pest entry.
C) Paint on the light frames above the raw material processing area and on the (b) (4) room doors was found to be peeling at multiple locations.
D) In adequate lighting in the raw material (b) (4) processing areas.
E) Raw material (b) (4) room had a dripping pipe with apparent mold on the wall.

OBSERVATION 8

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness and compliance with established standards.

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Specifically,
The reviewer of microbiological test results does not verify the original raw data for accuracy and completeness.

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