

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 5/25/2023-6/2/2023*
	FEI NUMBER 3025263427

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Jaan Pyng Hsu, Chief Executive Officer

FIRM NAME Fujian Genohope Biotech Ltd	STREET ADDRESS Renyang, No. 288 Bingluncun; Hushizhen Xiuyu
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CITY, STATE, ZIP CODE, COUNTRY Putian, Fujian, 351146 China	TYPE ESTABLISHMENT INSPECTED Sterile Manufacturer
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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:
MATERIALS SYSTEM**

OBSERVATION 1

Written procedures are not followed for the receipt, identification, storage, handling, sampling, testing, approval and rejection of components, drug product containers and closures.

Specifically,

You manufactured your (b) (4) Validation Batches with components that expired prior to the (b) (4) expiration assigned to the finished product batches. For example,

Batch (b) (4) was manufactured February 21, 2022, with lot (b) (4) of sterile (b) (4) (b) (4) with an expiration date of April 30, 2022, and lot (b) (4) with the date of February 28, 2023. The finished product was assigned a (b) (4) expiration.

Batch (b) (4) was manufactured February 24, 2022, with sterile (b) (4) (b) (4) with the expiration date of February 28, 2023. The finished product was assigned a (b) (4) expiration.

Batch (b) (4) was manufactured February 27, 2022, with sterile (b) (4) (b) (4) lot (b) (4) with the expiration date of February 28, 2023. The finished product was assigned a (b) (4) expiration.

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No documentation was available demonstrating an extension to the expiration date was requested from the component's manufacturer or (b) (4) or that a risk assessment of the short-dated components was performed. Additionally, there was no indication in the process validation that short-dated components were used in production of the (b) (4) batches.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 2

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design, of adequate size and suitably located to facilitate operations for its intended use.

Specifically,

Your (b) (4) program is deficient in that:

A. (b) (4) Integrity Tester ID YD-4 has not been qualified. This was confirmed by your Production Manager.

This equipment was used to verify the (b) (4) integrity of the (b) (4) used in production of (b) (4) validation batches (b) (4) which were submitted in support of drug application (b) (4) INJECTION.

B. The (b) (4) Test Report shows the (b) (4) the (b) (4) integrity test is required to start when the pressure is no less than (b) (4) pascals. Numerous (b) (4) tests did not begin at the predetermined pressure of (b) (4) pascals.

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For example,

- i. The (b) (4) integrity testing performed on (b) (4) 21-002 started at 2022-02-19 (b) (4) with (b) (4) pascals and completed at (b) (4) with (b) (4) pascals.
- ii. The (b) (4) integrity testing performed on (b) (4) 21-006 started at 2022-02-19 (b) (4) with (b) (4) pascals and completed at (b) (4) with (b) (4) pascals.
- iii. The (b) (4) integrity testing performed on (b) (4) 21-003 started at 2022-02-19 (b) (4) with (b) (4) pascals and completed at (b) (4) with (b) (4) pascals.
- iv. The (b) (4) integrity testing performed on (b) (4) 21-014 started at 2022-02-22 (b) (4) with (b) (4) pascals and completed at (b) (4) with (b) (4) pascals.
- v. The (b) (4) integrity testing performed on (b) (4) 21-022 started at 2022-02-22 (b) (4) with (b) (4) pascals and completed at (b) (4) with (b) (4) pascals.
- vi. The (b) (4) integrity testing performed on (b) (4) 21-018 started at (b) (4) with (b) (4) pascals. This (b) (4) integrity test did not meet the (b) (4) time requirement.

C. Firm personnel explained the (b) (4) are approved for (b) (4) prior to replacement. No scientific justification was provided. (b) (4) uses is appropriate.

OBSERVATION 3

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Input to and output from the computer and records or data are not checked for accuracy.

Specifically,

There was no review of the electronic data generated by the (b) (4) SCADA System during the (b) (4) (b) (4) validation batches (b) (4) which were submitted in support of drug application (b) (4) INJECTION.

For example,

A. There was no review of the alarm log (electronic or paper) covering production of the batches.

B. There was no electronic review of the report covering production of the batches, only the printout was reviewed. Production review personnel transferred this PDF file from the (b) (4) SCADA system via uncontrolled USB.

C. Form WI-R03-001/A2/03 was not completed as required by procedure WI-R03-001 when the data covering production of the Validation batches was backed up (b) (4) This was over (b) (4) after the (b) (4) batches were manufactured.

PRODUCTION SYSTEM

OBSERVATION 4

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.

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A. Your visual inspection procedures are inadequate in that:

- i. Procedure Manual Visual Inspection Operating Procedure GHB-M08-B-018 does not include:
 - a. Classification of the defects, such as, critical, major and minor.
 - b. A defined statistical value that will result in an investigation or rejection of a batch.
- ii. Batch record (b)(4) MMD-90001201-V01 allows a (b)(4) % failure rate for the visual inspection before red. There is no differentiation for different types of defects within these criteria.

B. Your Visual Inspector Qualification is inadequate in that:

- i. The 2021 Visual Inspector Qualification performed by Employee (b)(6) shows the inspector passed with a 100% score; however, the employee did not select all the defects according to the key.
- ii. The Visual Inspector Qualification worksheet does not include the start and finish time documenting the (b)(4) time frame required by procedure Manual Visual Inspection Operating Procedure GHB-M08-B-018 to complete the qualification. Additionally, there is no space on the worksheet to document the time.

C. No designated light source is provided, and no specific lux/lumen is required for reading the microbiology media plates.

D. No designated light source is provided, and no specific lux/lumen is required for conducting the (b)(4) review of the retain samples including (b)(4) validation batches (b)(4) Firm personnel explained they utilized the overhead lighting in the 2-8 degree Celsius walk-in chamber. Additionally, numerous trays of the finished product were stacked on top of one another inside a semi-clear, plastic outer covering and firm personnel stated

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they did not remove the covering to conduct the (b) (4) review for deterioration.

OBSERVATION 5

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

A. On 06/01/2023, we observed data on the desktop could be saved to a USB on the computer used to run the Liquid Particle Measurement Instrument which is used for determination of the particulate matter on the stoppers. Procedure Computerized System and Handling of Portable Storage Media and Security WI-R03-005-V01 states the setting for portable media connection should be disabled.

B. On 06/01/2023, we observed the date could be changed on the computer used to run the Liquid Particle Measurement Instrument. Computer System Management of Quality Control Laboratory WI-Q02-002 states IT regularly inspects personal authority settings and time settings unable to be modified in computer systems. Form WI-R03-010-A3/01 is used to document the system checks; however, this form does not specify details of the authority and time setting checks.

C. On May 31, 2023, during visual inspection of (b) (4) batch (b) (4) we observed one operator not following Manual Visual Inspection Operating Procedure GHB-M08-B-018 in that the required observation time of (b) (4) per background was not met.

D. On May 31, 2023, we observed one material transfer operator in the production area not following Management Procedure for General Production Area GHB-M06-C-005 in that the operator was not gowned.

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OBSERVATION 6

All major equipment used during the production of a batch of drug product is not properly identified at all times to indicate.

Specifically, during observation of (b) (4) setup of the (b) (4) for (b) (4) batch (b) (4) on May 29, 2023, we observed there was no equipment or room status indicating the equipment and room were in process, the associated product, or the lot number.

***DATES OF INSPECTION**

5/25/2023(Thu), 5/26/2023(Fri), 5/29/2023(Mon), 5/30/2023(Tue), 5/31/2023(Wed), 6/01/2023(Thu), 6/02/2023(Fri)

X Kevin T Nguyen
Investigator
Signed By: 2003267237
Date Signed: 06-02-2023 02:54:07

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