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	03/17/2025-03/21/2025
	FEI NUMBER: 1000589993

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr.Guo Guorong (Chairman & GM)

FIRM NAME	STREET ADDRESS
Guangxi Yulin Pharmaceutical Group Co. Ltd.	1 Chengzhan Road
CITY, STATE, ZIP CODE, COUNTRY: Yulin, Guangxi, 537001 China	TYPE ESTABLISHMENT INSPECTED: 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 **WE** OBSERVED:

OBSERVATION 1

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,

a) Your firm does not perform analytical testing to determine the concentrations of (b) (4) (b) (4) active ingredients in the (b) (4) finished OTC drug product. (b) (4) batches of this drug product were distributed to the US in July 2023.

b) Percentage concentrations of the (b) (4) active ingredients in finished dosage units of the (b) (4) OTC drug product have not been determined. The finished product test results of the (b) (4) active ingredient assay are reported in units of milligrams per milliliter (mg/mL) and no evaluation has been made to assess if this concentration meets the (b) (4) % concentration label claim for (b) (4) active ingredients. For example, (b) (4) batch (b) (4) (b) (4) mL packaging size) has finished product (b) (4) assay test results reported as (b) (4) (b) (4) mg/mL, respectively. (b) (4) batches of (b) (4) have been distributed to the US since December 2020.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Gavin T. Cua (CSO) & Crystal Monroy (CSO)	March 21, 2025

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Specifically,

a) Your firm has not validated or verified all the component, intermediate/in-process, and finished product analytical test methods performed on (b) (4) OTC drug products. Test methods including but not limited to the following, have not been validated or verified:

- Active ingredient raw material component testing:
  - (b) (4) assay [gas chromatography (GC)]
  - (b) (4) identification test (UV-visible spectroscopy and infrared spectroscopy)
  - (b) (4) related substances test (GC)
- (b) (4) intermediate/in-process testing:
  - (b) (4) assay (b) (4)
- (b) (4) finished product testing:
  - (b) (4) assay

b) Your firm follows the Chinese Pharmacopoeia (ChP) for the test procedures, specifications, and reference standards used in component, intermediate/in-process, and finished product testing of the (b) (4) OTC drug products distributed to the US. In accordance with the ChP:

- The acceptance criteria for the assay of (b) (4) active ingredients in finished product (b) (4) is, "...contains no less than (b) (4) mg per (b) mL" for each individual active ingredient (*your firm's internal standard is, "...no less than (b) (4) mg/mL"*).
- The identification tests for component testing of (b) (4) active ingredient are performed through colorimetric analysis rather than gas chromatography.
- Component testing for (b) (4) active ingredient assay has an acceptance criteria of (b) (4) %-(b) (4) %.

c) The method validation performed on the finished product in-house test method of (b) (4) assay by gas chromatography for (b) (4) OTC drug product is inadequate:

- Accuracy: It is unclear how the results of percentage of the recovery of the known added amount

of (b) (4) in the sample injections were calculated.

- Specificity: Assay test results are reported as a ratio of mg/mL with no evaluation or calculation of the percentage concentration of the (b) (4) active ingredients. As such, this test method does not provide meaningful test results providing information on the potency of the analytes in these samples.

d) System suitability testing is inadequate for the assay of (b) (4) active ingredients by gas chromatography in raw material component testing and in the assay of these active ingredients in finished product testing of (b) (4)

- There is no blank injection.
- The percent relative standard deviation is not calculated for the peak areas of the (b) (4) reference standard injections.
- System suitability testing in the method validation for (b) (4) assay by gas chromatography in (b) (4) finished product testing consists of (b) (4) reference standard injections, however, testing of finished product batches consists of (b) (4) reference standard injections.

e) Your firm lacks controls to ensure data integrity is implemented and maintained over analytical instruments and corresponding analytical software. For example:

- There is no audit trail feature for the IRSolution software used in infrared (IR) spectroscopy.
- There is no audit trail feature for the UVProbe software used in UV-Vis spectroscopy. Both analytical software systems are used for the component identification tests of the (b) (4) active ingredient.
- Raw data electronic files generated from the IR and UV-Vis software and saved locally on to the computer system can be deleted by QC personnel.
- There is no review of the audit trail of the gas chromatography OpenLab software after completion of finished product testing and prior to finished product approval and release of each batch of (b) (4) OTC drug product. This software is used for the assay of (b) (4) (b) (4) active ingredients in finished product testing.
- There is no documentation or record of the review and comparison of electronic raw data to the

printed, physical copy of the data.

OBSERVATION 3

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

Specifically,

(A) You have failed to establish how your stability testing methods are stability indicating. You do not have data to show your stability test methods meet the appropriate identity, strength, and quality attributes to support the (b) (4) shelf life of your OTC (b) (4) products, (b) (4) (b) (4)

(B) Microbial content and identification testing are not performed at appropriate intervals during your stability studies for your OTC (b) (4) products. Microbiological and identity testing is only performed at the beginning of your stability study at the end of your study at (b) (4) (b) (4) You do not have scientific rational to support this test frequency.

(C) Stability testing for (b) (4) does not testing for the active contents and you do not have scientific rational to justify not performing this test.

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.

Specifically,

a) The production processes for the (b) (4) OTC drug products have not been validated for a specific batch size. The validated batch size for (b) (4) is (b) (4)

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b) Your firm's calculation for percentage of theoretical yield has an acceptance criteria of (b) (4) %. The theoretical yield is based on a batch size of (b) (4) which can be exceeded by the actual yield due to the variation of production batch sizes.

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

You did not open a deviation investigation following issues identified with your (b) (4) equipment. In September 2022, you received a third-party suspension notification for your (b) (4) (b) (4) tank 4, equipment ID 130301011. However, upon receipt of this notification you failed to open a deviation to establish if the equipment was adequate for use and continued using tank 4 equipment ID 130301011 until it was replaced in April 2023. From September 2022 to April 2023, you manufactured approximately (b) (4) (b) (4) batches of OTC (b) (4) which were distributed to the U.S. market.

In addition, no preventive actions were assessed or proposed for deviation PC-20250201 in which an unplanned power outage led to a loss of power to your firm's stability chambers.

OBSERVATION 6

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

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Specifically,

Your firms cleaning validation studies to justify the cleaning in your (b) (4) preparation system are inadequate. For example,

(A) You do not have records to show you have validated the cleaning procedures for extended clean hold times.

(B) You failed to establish how the methods used for your cleaning validation studies are adequate to detect the number of residual contaminants in your rinse samples.

OBSERVATION 7

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically,

(A) Your firm failed to maintain records for routine supplier audits of your active pharmaceutical ingredient supplier. Records for the last (b) (4) supplier audits for your (b) (4) active pharmaceutical ingredient supplier could not be found. The last record your facility has of a routine supplier audit was dated 2016. (b) (4) is one of the active pharmaceutical ingredients for your (b) (4) (b) (4) drug products.

(B) Your quality unit failed to implement appropriate change control procedures following changes to your supplier qualification process. For example, you changed your procedures for conducting routine supplier audits. However, these changes were not included in a change control process, and you do not have justification for why these changes were not incorporated into a change control.

OBSERVATION 8

Strict control is not exercised over labeling issued for use in drug product labeling operations.

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Specifically,

a) There is no label reconciliation in the packaging record for the (b) (4) OTC drug product.

b) Reconciliation of labeling materials is inadequate as the starting quantity of packaging and labeling materials is not always confirmed to be accurate, therefore, resulting in inaccurate calculations for reconciliation.