DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Dr., Room 2037, Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	02/17/2025-02/21/2025 FEI NUMBER 3003941038

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Li Hongcheng - Vice President	
FIRM NAME Shouguang Fukang Pharmaceutical Co., Ltd.	STREET ADDRESS North-East of Dongwaihuan Road, Dongcheng Industrial Area
CITY, STATE, ZIP CODE, COUNTRY Shouguang City, Shandong, China 262700	TYPE ESTABLISHMENT INSPECTED API 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Observation #1

The quality control unit lacks responsibility to approve final testing results for product release.

Specifically, a review of completed analytical testing records for the API [redacted] (b) (4) Batch # [redacted] (b) (4) regarding HPLC # [redacted] (b) (4) ZL-002 and GC # [redacted] (b) (4) ZL-016 testing results noted that QC performs the review/approval without review/approval by the QA department. For example, the chemist uses Excel Spreadsheets to manual input testing result data from both the HPLC and GC. The spreadsheets are used to calculate final testing results for Related Compounds, Impurity [redacted] (b) (4) and Residual Solvents. Once the data has been entered and values obtained, the chemist prints a hardcopy of the spreadsheet and then resets the Excel Spreadsheet back to the original status. The original data is not saved and QA is not able to review this data for final approval for the batch. In addition, a review of the final testing records for this batch noted that the HPLC and GC chromatographs are not included in the final release packet for QA review.

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Observation #2

Equipment is not cleaned or maintained at appropriate intervals to prevent contamination that would alter the quality or purity of the API product.

A) Specifically, on 2/18/2025, inspection of the Workshop # (b) (4) where the API (b) (4) is manufactured noted excess residual product remaining on the bottom, upper wall, and (b) (4) shaft for the (b) (4) Machine # (b) (4) 002 and (b) (4) Machine # (b) (4) 003. These units are used for the (b) (4) processing step. The previous API (b) (4) (b) (4) batches processed in Unit # (b) (4) 002 was Batch # (b) (4) and Unit # (b) (4) 003 was Batch # (b) (4) Per management, in-between batches of (b) (4) only external cleaning of these units are performed and internal cleaning is only performed on a (b) (4) Also, Unit # (b) (4) 003 was observed to have corroded (b) (4) bolts and other corroded (b) (4) parts located on the (b) (4) shaft of this unit. Per record review, the last internal cleaning of Unit # (b) (4) 002 and Unit # (b) (4) 003 was 2/3/2025. Also, a review of the last maintenance record for Unit # (b) (4) 003 dated (b) (4) noted no issues regarding corroded (b) (4) parts. The excess residual product carryovers and corroded (b) (4) parts create contamination issues.

B) Specifically, on 2/18/2025, inspection of the Workshop # (b) (4) where the API (b) (4) is manufactured noted extensive damage to the bottom of the (b) (4) vessel # (b) (4) 022 which was being used to process (b) (4) Batch # (b) (4) was observed to be dripping onto the floor from the bottom of this vessel. Management stated that this (b) (4) was from the (b) (4) that was being generated during this processing step in this vessel. The last preventive maintenance was performed on 9/22/2024 and no issues were noted regarding the current condition of the damaged bottom of this vessel.

C) Specifically, on 2/17/2025, inspection of the firm's (b) (4) water system located in Building # (b) (4) that supplies (b) (4) water to Workshop # (b) (4) where the API (b) (4) is

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manufactured noted that the distribution (b) (4) that supplies (b) (4) water to this workshop was observed to be leaking. (b) (4) water in Workshop # (b) (4) s used to clean processing equipment.

D) SOP-CH-E09 "Procedure for Usage Maintenance and Servicing of (b) (4)", identifies a (b) (4) check of the (b) (4) level for the (b) (4) Operators are required to record this (b) (4) check in the equipment log book. However, during my review of the equipment log books for the (b) (4) Equipment ID (b) (4) I observed the operators are not performing or recording this (b) (4) activity as required by SOP-CH-E09. This equipment is located in Workshop # (b) (4) and used in the manufacturing of the API (b) (4) for the U.S. market.

Observation #3

Separate or defined areas to prevent contamination are deficient regarding operations related to the storage of raw materials and finished API products.

A) Specifically, on 2/17/2025, inspection of the firm's raw material warehouse (b) (4) noted raw materials (b) (4) being stored in unsanitary conditions and not properly identified. For example, poor lighting conditions, raw materials were not identified, raw materials stored against walls, leaking (b) (4) tote and (b) (4) tote, black residues on concrete floor, and exterior door with large gaps for possible rodent/insect entry.

B) Specifically, on 2/17/2025, inspection of the firm's finished API non-dedicated storage warehouse # (b) (4) noted the API (b) (4) was being stored in random locations throughout this warehouse. This API is a (b) (4) and cross-contamination issues can occur with this product being randomly stored with (b) (4) API products such as (b) (4) (b) (4) for the U.S. market. Per the firm's Site Master File, preventative measures will be taken to prevent cross-contamination.

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Observation #4

The firm has failed to identify all critical control steps in the manufacturing process.

Specifically,

Your firm identified an out of trend (OOT) for the related substances analytical results for (b) (4) (b) (4) According to the investigation the related substances results were identified as (b) (4) %, OOT limit is (b) (4) %, and the release specification is (b) (4) %. The root cause for the OOT identified that the product remained in the (b) (4) for approximately (b) (4) To this date, your firm has not performed a risk assessment to identify the impact that this manufacturing step may have on the API and the controlling of impurities. Additionally, your firm has not identified the hold time in the (b) (4) (b) (4) as a critical step in the batch records, process validation, or any related SOPs.

Observation #5

Analytical methods are not suitable for their intended use and/or have not been established.

Specifically,

A. The validation report, "Validation Report of Analytical Procedure for Related Substances in (b) (4) (USP/EP), does not reference the batch numbers associated with the validation. There is no assurance that any (b) (4) batches were associated with this method validation.

B. The validation report, "Validation Report of Analytical Procedure for HPLC Method for Impurity (b) (4) in (b) (4) (USP/EP), does not reference the batch numbers associated with

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the validation. There is no assurance that any [(b) (4)] batches were associated with this method validation.

Observation #6

Samples taken of products for determination of conformance to written specifications are not properly released to the QC department of testing.

Specifically, on 2/19/2025, during the inspection of the firm's sample receiving department, concerns were noted regarding the chain of custody of samples to ensure accountability of sample materials and sample integrity issues. For example, samples for [(b) (4)] Batch # [(b) (4)] with Sample ID as [(b) (4)] and [(b) (4)] where taken by the QC department to perform required testing on 2/19/2025. The initial weights for these samples were [(b) (4)] and [(b) (4)] respectively. The date and amount returned by the QC department to the sample department for storage is not documented. During this inspection, these samples were re-weighted and the weights were [(b) (4)] and [(b) (4)] respectively.

Observation #7

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

A) Specifically, hold time studies regarding the time between each different processing step for the production of the API [(b) (4)] have not been established or validated for Workshop # [(b) (4)] located in Building # [(b) (4)]

B) Specifically, Dirty and Clean hold time studies for processing equipment located in the non-classified air quality areas in Workshop # [(b) (4)] in Building # [(b) (4)] where the API [(b) (4)] is processed have not been established or validated.

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Observation #8

Failure to perform proper aseptic techniques during microbial testing of products.

Specifically, on 2/19/2025, Technicians in the firm's QC microbial department were observe not performing proper aseptic techniques for the inoculation of media plates for (b) (4) tablet microbial testing. For example, one technician was observed on numerous occasions placing gloved hands outside into the Class C area and then inside the Class A hood without sanitizing gloved hands upon reentry to the hood. Another technician working under the same hood was observed on numerous occasion retrieving sample bottles located on a (b) (4) in the Class C area outside of the hood and then placing these sample bottles inside the Class A hood without sanitizing the exterior of the sample bottles or gloved hands prior to reentry into the hood. Also, it should be noted that no sanitizing agent was available for these technicians to use in this area and no microbial settling plates were used in the Class A hood while performing microbial testing. Microbial testing is performed on environmental monitoring and (b) (4) water used for the production/cleaning of the APIs (b) (4) and (b) (4) for the U.S. market.

Observation #9

Adequate lighting is not provided in all areas.

Specifically, on 2/17/2025, inspection of the firm's raw material warehouse # (b) (4) where raw materials for the API (b) (4) and (b) (4) are stored noted dim lighting conditions in this warehouse. These conditions hinder the proper monitoring of raw materials stored in this warehouse such as for temperature/humidity monitoring and identification of stored raw materials.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."