

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov		DATE(S) OF INSPECTION 05/25/2026-05/29/2026* FEI NUMBER 3018694237	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Deepak Kumar Donthi Muniramaiah, Site Head			
FIRM NAME Shilpa Medicare Limited		STREET ADDRESS Unit-VI, Plot No 29 - A5, Avverhalli SompuraIndustrial Area, Dabaspeta	
CITY, STATE, ZIP CODE, COUNTRY Bengaluru, Karnataka 562111, India		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. <i>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.</i>			
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 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, Your Process Validation (PV) for (b) (4) (b) (4) is deficient. You failed to use the (b) (4) system during in-process checks in (b) (4) stage for all strength due to lack of qualification of the system for (b) (4) product as required per Process Validation Protocol (b) (4) (# (b) (4) 044-00). According to the During (b) (4) step, the (b) (4) system is to be used to challenge for rejection (b) (4) (b) (4) OBSERVATION 2 Written records are not always made of investigations into unexplained discrepancies. Specifically, A. On 03/01/2025 at 15:00 hour, you observed the minimum and maximum temperatures at 25.80⁰ C and 30.40⁰ C (Acceptance criteria: 28⁰ C to 32⁰ C) and the minimum and maximum relative humidity was observed at 57.30% and 79.60 % RH (Acceptance criteria 70 to 80 % RH) for stability chamber (#QC-E088, 30C/75%) where both humidity systems failed and lead to the chamber shutdown. Although			
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TYPE ESTABLISHMENT INSPECTED

Drug Manufacturer

QC notified Engineering Department and assigned Breakdown #BD/QC/25-002 to address the issues on 03/01/20225 at (b) (4) the breakdown form did not state if the chamber was loaded with stability samples, you did not perform an investigation and impact assessment for the stability samples inside the chamber, and you did not review the audit trail software (Stability Control System) for Thermolab stability chamber ID #QC-E088 to see what time the chamber actually shutdown in order to evaluate excursion time.

Acceptance criteria	Minimum & maximum value
Temperature: 30°C (28°C to 32°C)	Minimum temperature: 25.80 °C
Relative Humidity (RH): 75 % (70 to 80 %)	Minimum RH: 57.30 %
	Maximum temperature: 30.40 °C
	Maximum RH: 79.60 %

The chamber was loaded with several stability samples including (b) (4) mg (US Marketed Product).

SL. NO	Product Name	Batch number	Interval
(b) (4)			

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Drug Manufacturer

(b) (4)

On 05/27/2026, I observed stability chamber (#QC-E088, 30C/75% condition). The walls, ceiling, supply and return air covers, trays, and several stability samples were covered with mold/mildew. This chamber was loaded with several stability samples including the following listed below:

Sl. No.	Product Name	Batch number	Interval
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(b) (4)

- B. On 10/22/2025, you recorded a calibration failure in test parameter wavelength accuracy during the calibration of Agilent HPLC ID #QC-E080 where (b) (4) peak was not eluted in the standard solution. You notified your service provider on 10/28/2025 and visited your firm on 12/26/2025 for repair. You attributed the root cause to deterioration of DAD lamp and source of lens after replacing the DAD lamp and recalibrated the equipment. You then stated under impact assessment there is no impact on released product quality the calibration failure had no impact on the equipment and testing results generated on the equipment. However, you failed to conduct a thorough investigation and

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impact assessment on all the samples tested on the equipment since the last successful calibration to date. You have tested several samples including the following US marketed samples and (b) (4) on the equipment for 04/21/2025-10/16/2025 period. <table><thead><tr><th>Date</th><th>Name of the Material/Product (b) (4)</th><th>Batch No.</th><th>Test Parameter</th></tr></thead><tbody><tr><td colspan="4">(b) (4)</td></tr></tbody></table>				Date	Name of the Material/Product (b) (4)	Batch No.	Test Parameter	(b) (4)			
Date	Name of the Material/Product (b) (4)	Batch No.	Test Parameter								
(b) (4)											
OBSERVATION 3 You established (b) (4) for Clean Hold Time (CHT) and (b) (4) Dirty Hold Time Study (DHT) for the following shared equipment (non-dedicated) that is used to manufacture (b) (4) (b) (4) : (b) (4) (b) (4) which was not based on the worst-case molecules. Yet, you have not performed a Clean Hold Time (CHT) and Dirty Hold Time Study (DHT) after (b) (4) (as worst-case molecule in 2022) and (b) (4) (as worst-case molecule in 2023-2024) as required per SOP # UNIT (b) (4) PR/SOP/0017-02 “Cleaned and Dirty Equipment Hold Time, effective date 03/08/2026” as introduction of new product at the site. According to your Production Manager (b) (6) and Sr. Manager QA (b) (6) , (b) (4) is considered the worst-case molecule at the site.											
OBSERVATION 4 Production records do not contain complete information relating to the production and control of each batch.											
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You failed to document in your batch packing record (BPR # (b) (4) for (b) (4) the total number of (b) (4) rejects collected from the (b) (4) system and checkweigher rejected (b) (4), and the number of rejects actually displayed from the (b) (4) system and the checkweigher display for reconciliation. In addition, when collected rejects from the checkweigher, you do not perform a physical count of each rejected (b) (4) of (b) (4) for under count and over count.

There are no controls in place to prevent unauthorized access to rejected (b) (4) for (b) (4) system and checkweigher. Although these rejected (b) (4) are locked, rejected (b) (4) can be physically removed without unlocking the (b) (4).

OBSERVATION 5

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Specifically,

Per your Production Manager (b) (6) your firm does not review data, audit trails and alarm reports generated by the HMIs (GT-2708) and SCADA of your non-dedicated equipment (b) (4) ID #PR-E016) and (b) (4) (ID #MB-E030) utilized in the Micro Lab. Alarms generated for the (b) (4) (Production) and (b) (4) (Micro) including sterilization load cycles are not backed up and automatically overwritten by the system.

*DATES OF INSPECTION

05/25/2026 (Mon), 05/26/2026 (Tue), 05/27/2026 (Wed), 05/28/2026 (Thu), and 05/29/2026.

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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."