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 CDER-OC-OMQ-International483Response@fda.hhs.gov	12/01/2025-12/05/2025 FEI NUMBER 3006057101
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Sanjay Kapadia, President Corporate Quality	
FIRM NAME Ipca Laboratories Limited	STREET ADDRESS 2 Plot No E - 41, And E - 128; E - 129 Midc Tarapur Boisar
CITY, STATE, ZIP CODE, COUNTRY Palghar, Maharashtra, 401506, India	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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Buildings and facilities used to manufacture APIs are not maintained appropriately to facilitate cleaning and to minimize potential contamination.

Specifically, the clean rooms in manufacturing block (b) (4) that are used to manufacture (b) (4) USP and (b) (4) USP for the US market, are not maintained appropriately to facilitate cleaning and to minimize potential contamination. For example:

A. On 12/1/2025, during the inspection of product (b) (4) Area in manufacturing Block (b) (4) a big chunk (approximately 5 inches long and 2.5 inches wide) of missing and peeling off paint was observed on the ceiling where (b) (4) (equipment ID: 10/(b) (4) 01) is housed. This is an open processing area where the APIs are exposed to the room environment. You failed to adequately maintain this area to ensure chipping and peeling off paint is not inadvertently impacting the quality of the APIs manufactured in this room.

B. On 12/1/2025, during the inspection of Weighing & Packing Area in manufacturing Block (b) (4) approximately more than 20 small cracks were observed on the walls and ceiling of the room. This area houses two major production equipment; (b) (4) (equipment ID: 10/(b) (4) /02) and (b) (4)

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SEE REVERSE OF THIS PAGE		Saleem A Akhtar Dedicated Drug Cadre Investigator	12/05/2025

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Palghar, Maharashtra, 401506, India	API Manufacturer

(equipment ID: 10/(b) (4)02). This is an open processing area where finished APIs are exposed to the room environment. The APIs are (b) (4) and packed for dispatch in this room. The firm failed to ensure that the area is adequately maintained to facilitate cleaning and to minimize potential contamination.

These areas are routinely inspected, maintained, and cleaned by the firm as per control procedures TARA/PRD/004/R03, Housekeeping of Manufacturing Area and TARA/ENG/010/R02, Preventive Maintenance of Premises. During routine facility inspection, maintenance, and cleaning, you failed to identify and repair the impacted surfaces. Manufacturing Block (b) (4) is used to manufacture (b) (4) APIs including (b) (4) USP for the US market. The firm is actively shipping both products to the US.

OBSERVATION 2
The suitability of analytical test methods is deficient for its intended use.

Specifically, analytical method verification studies performed to test assay and organic impurities in (b) (4) USP, are deficient.

On 12/2/2025, you tested (b) (4) US batches (b) (4) of (b) (4) USP using two HPLCs. The equipment QC-INST-07 was used for Assay by HPLC test, and equipment QC-INST-06 was used for Organic Impurities by HPLC test. For these analyses, the acceptable HPLC column temperature was set at (b) (4)°C to (b) (4)°C. Your QC Head confirmed on 12/2/2025 that slight change in column temperature can cause change in the elusion time of the peak of interest and can potentially impact the analysis. The site failed to provide any scientific data generated through a controlled study to demonstrate that the HPLC column temperate range of (b) (4)°C to (b) (4)°C can generate reproduceable and accurate results.

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On 7/31/2025, you initiated out of specification investigation PR # 384630 when out of specification results of (b) (4) % (specification: (b) (4) % to (b) (4) %) were observed when (b) (4) USP batch (b) (4) was tested for assay at 12-month long-term stability interval. During the investigation, you observed that the retention time of the main peak shifted during the analysis that might have impacted the analysis.

OBSERVATION 3

There is a lack of adequate controls in place to minimize the carryover of the residual materials into successive batches of the same intermediate or API.

Specifically, you failed to establish the maximum number of days for which the APIs can be manufactured in a campaign. For example:

Your control procedure TARA/PRD/088/R01, Procedure, Criteria, and Validity for Cleaning of Manufacturing Process Equipment requires Type-B cleaning (more rigorous cleaning) of the process equipment be performed between the different products or after (b) (4) batch of the same product. This procedure does not define the campaign length in terms of maximum number of days. For example, two manufacturing campaigns for (b) (4) USP (b) (4) and (b) (4) USP (b) (4) lasted for (b) (4) respectively. You failed to provide scientific data derived through a controlled study to demonstrate that the residual material from the previous batch is not carried over into the next batch in that many number of days.

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