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	09/08/2025-09/17/2025
	FEI NUMBER 3005890633

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kirti Maheshwari, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Intas Pharmaceuticals Limited	Camp Road, Selaqui
CITY, STATE, ZIP CODE, COUNTRY Dehradun, Uttarakhand, 248011, India	TYPE ESTABLISHMENT INSPECTED Drug Product 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

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

Specifically,

A. Shelf-life of the drug product (b) (4) Tablets USP is not adequately supported with stability data. For example, your firm assigned a (b) (4) shelf-life of (b) (4) (b)(4) (b) (4) (b) (4) you (b) (4) the (b) (4) shelf-life of this product to (b) (4) in (b) (4) (Change Control # DND/CRF (b) (4) /0674). Again, you (b) (4) the shelf-life of this product to (b) (4) on (b) (4) (Change Control # DND/CRF (b) (4) 0697). Despite having adjusted the shelf-life twice already, you further (b) (4) the shelf-life of this product to (b) (4) on (b) (4) (b) (4) shelf-life could not be adequately supported by stability studies (Change Control # DND/CRF (b) (4) /0332). After these shelf-life changes, on 5/19/2025, you obtained an OOS result for the annual stability batch (Batch # (b) (4) of (b) (4) Tablets USP (b) (4) mcg for 12M stability assay test (OOS# DND/PQC1/F/OOS/2025/0072). Your investigation has confirmed this as a valid OOS result, and you have recalled this batch. However, your impact assessment is inadequate, and you have distributed a total of approximately (b) (4) batches of various strengths of (b) (4) Tablets USP to the US market since January 2024. You have reported approximately 22 confirmed OOS results for various batches of this product during stability studies since May 2023.

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B. OOS# DND/PQC1/F/OOS/2025/0100 was initiated on 30 July 2025 due to an assay failure of (b) (4) Tablets USP (b) (4) mcg, batch# (b)(4), with results of (b) (4) % (Spec. Limit (b) (4) % to (b) (4) %). This control batch (Manuf. Date: 10/12/2023) was tested as part of an impact assessment due to a 2024 annual batch stability failure at 12M long term condition. A probable root cause for the OOS assay result was attributed as solution preparation error and the OOS result was invalidated. Passing retest result of (b) (4) % was reported. Specifically, your firm attributed the root cause on the use of (b) (4) by the analyst during the preparation of (b)(4), which is used for sample preparation. There is no evidence that the analyst did not follow the instructions shown in the method of analysis. A training on good laboratory practices was given to the analyst and no CAPA was initiated.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. Signed electronic batch records have been modified without recording any Quality Management System (QMS) events. These actions have been taken with the help of the electronic batch record software vendor through email and telephone communications. You have also failed to maintain complete electronic communications by employees requesting changes to completed and signed batch records and no policy is in place to maintain such communication records. These instructions for changing official GMP records were handled and discussed by multiple QA employees with their individual Intas email IDs and group Intas email IDs with shared passwords. For example,

   i. On (b) (4) QA employee (b) (6) sent an email to the (b)(4) (electronic batch record) software vendor with a message, "As discussed, pls do the needful for BPCR" (Batch Production Control Record) and a subject line of "BPCR Pending". He sent a reminder on (b) (4) with a message, "Pls update". The software vendor responded on the same day with a message, "Can you re-share the file which need to be

support ?". (b) (6) responded with a screenshot image of the electronic batch record page showing the batch number (b) (4) Tablets USP (b) (4) mcg) with a signature and time stamp of the packaging material dispensing employee as "(b) (6) " indicating the employee ID of (b) (6) and a date and time of (b) (4) The software vendor after two reminders responded on (b) (4) (b) (4) with a message of "Done. Also, Kindly check and revert". The official electronic batch record now shows that a replaced signature stamping of "(b) (6) " indicating a new employee code (b) (6) has been introduced by replacing the original signature without changing the time, thus making the GMP electronic record non-compliant and unreliable. The original email sent on (b) (4) containing the names of the operators and their IDs that needed to be switched by the vendor was deleted by the email sender in his sent folder, however, it a copy of it was traced in another employee's email inbox as he was copied. The electronic audit trail of the batch record (developed by the same vendor) currently does not reflect this signature and employee change made to the batch record.

ii. On (b) (4) QA employee (b) (6) sent an email to the (b)(4) software vendor with a message, "As discussed, pls find below sheet" with a screenshot of an excel table containing already existing batch parameter details (Old Value) with a proposed change detail (New Value) for (b) (4) Tablets USP consisting of various strengths. The software vendor sent an email on (b) (4) with a message, "Please provide details of page no.". On (b) (4) (b) (6) responded with a message, "Pls find attached file with page Nos.", and an excel sheet was attached with elaborate details for (b) (4) batches of (b) (4) Tablets USP, indicating what parameter needs to be changed on what page number of the batch record. These parameters include, electronic signature time, operation time, material weight, number of tablets, calculation error, AQL sample tablets count etc. The batch record-modified batch numbers are shown below:

Product	Batch#	Stage
(b) (4)		

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(b) (4)

No further email transactions between the employee (b) (6) and the software vendor could be traced. However, no deviation was initiated for these batch record changes.

B. QA employee (b) (6) made a request through email to the software vendor on (b) (4) to change the effective date of an approved and signed copy of SOP, DND (b) (4) /00039-1, in the electronic document control system, (b) (4) Document Control (b) (4) and sent a reminder on (b) (4) (b) (4) The change was made in the DC and confirmed by the software vendor team by email, but the audit trail of the electronic system did not show the change making it noncompliant for electronic record keeping purposes. This (b)(4) platform is also used for other QMS activities like Market Complaint, Adverse Drug Event, Incident Log, Change Control, Deviation, Out of Specification (OOS), CAPA etc.

C. Your Quality Assurance, Quality Control and Manufacturing departments use multiple Group email IDs with shared passwords to conduct GMP related official and unofficial businesses. Instructions to modify existing signed GMP documents including batch records were shared by these group and individual emails and later some of these emails were found to have been deleted.

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OBSERVATION 3

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

(b) (4) suspension (b) (4) mg/mL, batch record for batch # (b)(4) (b) (4) was reported as initiated manufacturing on 7 February 2022 and later cancelled after dispensing of materials. However, this batch record was not available for review and the firm claimed it is missing and could not be traced. No deviation was raised on this issue. This batch was initially intended to be the second validation batch in a series of three batches (b) (4) The actual submitted batches (b) (4) Also, it should be noted that the three submitted batches did not have the same quantities of APIs added (b) (4) (b) (4)

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