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	6/15/2023-6/23/2023*
	FEI NUMBER 3007574780

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Arindom Sen, Site Head, Senior General Manager Operations

FIRM NAME	STREET ADDRESS
Ipca Laboratories Limited	1 Pharma Zone, SEZ Indore, Pithampur
CITY, STATE, ZIP CODE, COUNTRY Dhar, Madhya Pradesh, 454775 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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. On 12/2/2022, the lab recorded OOS result PIT/OOS/2020/050 for (b) (4) Tablet (b) (4) mg dissolution test by UV-visible Spectrophotometer. The OOS result was reported for Batch No. (b) (4) (non-US market) (Unit (b) (4) result (b) (4) %, Stability Sample 25 ± 2 °C/60 ± 5 %RH, 9 month), against the Specification NLT (b) (4) % (Q) of the labeled amount of (b) (4) dissolved in (b) (4)

In the Phase I of the investigation, no assignable root cause was identified. In Phase IIA manufacturing investigation no assignable root cause was identified. In Phase IIB investigation, you hypothesized improper (b) (4) as the probable root cause. You attempted to verify lower assay value from "improper (b) (4) " through a hypothesis test using a new sample solution that was obtained from an additional dissolution study for one single tablet. You obtained a higher value from (b) (4) sample solution (b) (4) %) but lower values from (b) (4) (b) (4) %) as well as from (b) (4) %). It is not clear why lower value (b) (4) %, Specification NLT (b) (4) % (Q)) was obtained when the analyst followed the required test procedure STP No. TP/DR/0691/00 Dissolution (By UV) for (b) (4) Tablets, Effective date 10/25/2019, in line with your analytical method validation report, AMV/R/2017/009/00, Effective date 8/21/2017. Based on this inconclusive hypothesis, you retested the samples for dissolution and based on the passing results, you invalidated

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the initial OOS results.

B. On 12/5/2022, the lab recorded OOS result PIT/OOS/2020/051 for (b) (4) Tablet(b) (4) mg assay test by HPLC. The OOS result was reported for one of the batches out of the three batches run in the same sequence: Batch No. (b) (4) Tablet(b) (4) mg, non-US market, OOS batch) (result (b) (4)%, Stability Sample 25 ± 2 °C/60 ± 5 %RH, 3 month), Batch No. (b) (4) ((b) (4) Tablet(b) (4) mg, non-US market) (result(b) (4)%, Stability Sample 25 ± 2 °C/60 ± 5 %RH, 9 month) and Batch No.(b) (4) (b) (4) Tablet(b) (4) mg, non-US market) (result (b) (4)%, Stability Sample 25 ± 2 °C/60 ± 5 %RH, 3 month) against the Specification(b) (4)%-(b) (4)%. You tested the sample using test procedure, STP No. TP/AS/0950/00 Assay (By HPLC) for (b) (4) Tablets, Effective date 10/25/2019, in line with your analytical method validation report, AMV/R/2017/010/00, Effective date 8/23/2017.

In the Phase IA of the investigation, no assignable root cause was identified. In Phase IB investigation no laboratory error was identified. However, you suspected (b) (4) at the sample preparation stage as the probable cause. You attempted to verify higher assay value from "improper (b) (4) through a hypothesis test by re-preparing and testing the sample solution which resulted in a passing assay result (b) (4)%). From these results, you concluded "error in (b) (4) " as the root cause and you further stated that the analyst might have applied higher pressure that might have (b) (4) and caused higher assay (b) (4)%).

Your investigation stated that all the three samples that were analyzed in the sequence were prepared by the same analyst (Ms.(b) (6) who was trained in the sample preparation. Also, you did not investigate why a (b) (4) will cause higher assay value (b) (4)%, that is ~(b) (4)% higher than the higher end of the Specification, (b) (4)%. In addition, you do not verify whether or not the (b) (4) was(b) (4) Based on this inconclusive hypothesis, you retested the samples for assay and based on the passing results, you invalidated the initial OOS results.

C. On 11/29/2021, the lab recorded OOS result PIT/OOS/2021/035 for (b) (4) Tablet(b) (4) mg assay test by HPLC. The OOS result was reported for one of the batches out of the three batches run in the same sequence: Batch No. (b) (4) Tablet(b) (4) mg, non-US market, OOS batch) (result (b) (4)%, Finished product), Batch No. (b) (4) Tablet(b) (4) mg, non-US market) (result(b) (4)%, Finished product), and (b) (4) Tablet(b) (4) mg, non-US market) (result(b) (4)%, Finished product) against the Specification(b) (4)%-(b) (4)%. You tested the sample using test procedure, STP No. TP/AS/0278/01 Assay Test for (b) (4) Tablets, Effective date 11/13/2014, in line with your analytical method validation report, PRO/SIM/01/01/51/MUM, Effective date 9/16/2007.

In the Phase IA of the investigation, no assignable root cause was identified. In Phase IB investigation no laboratory error was identified. However, you suspected(b) (4) at the sample preparation stage and/or(b) (4) of the vial (for HPLC) as the probable cause. You attempted to verify higher assay value from (b) (4) issue and/or(b) (4)" through a hypothesis test by (b) (4) refilling the sample and testing for the assay. Based on the passing assay values, you concluded "there might be chance of error during vial filling of(b) (4) issue" as the assignable cause.

Your investigation is deficient such that the hypothesis test did not conclusively support the root cause. You did not extend your investigation into Phase II including the Manufacturing stage. Based on this inconclusive hypothesis, you retested the samples for assay and based on the passing results, you invalidated the initial OOS results.

D. On 1/29/2022, the lab recorded OOS result PIT/OOS/2022/001 for (b) (4) Tablet(b) (4) mg (b) (4) test by HPLC. The OOS result was reported for 2 units out of(b) (4) units (Sets 1, 2 and 3, Sample Size 1x-3x) sample tested for one of the process validations batches: Batch No.

(b) (4) (non-US market) (Set 2 Location (b) (4) result (b) (4)%, Set 3 Location (b) (4) result (b) (4)%, Stage (b) (4) against the Specification (b) (4)%-(b) (4)% for individual results. You tested the sample using test procedure, STP No. TP/(b) (4)/0439/000 (b) (4) (By UPLC) for (b) (4) Tablets, Effective date 2/19/2021, in line with your analytical method validation report, AMV/R/16027-A/00, Effective date 11/10/2020.

In the Phase I of the investigation, no assignable root cause was identified. In Phase IIA manufacturing investigation no assignable root cause was identified. In Phase IIB investigation, you followed your Protocol No. PPQP/PIT/(b) (4)/2020/00, Dated 1/22/2022, page no. 39 of 96 and tested increased sample size 3x-5x. However, once again OOS result was reported for 2 units out of (b) (4) units (Sets 1, 2 and 3, Sample Size 3x-5x) sample (Set 2 Location (b) (4) result (b) (4)%, Set 3 Location (b) (4) result (b) (4)%, Stage (b) (4) After the two failing results, you created Addendum-1 to the protocol for process validation for (b) (4) Tablets (b) (4) mg (PPQP/PIT/(b) (4)/2022/00) Dated 2/28/2022 and carried out the (b) (4) for increased sample size, 5x-7x and collected the samples from the In Process Bulk Container, IBC ID # 068 and not from the original (b) (4) ID # MFG-005 where the initial samples for (b) (4) test were collected.

Your investigation is deficient such that the 5x-7x samples are completely different (collected from IBC ID # 068 and not from (b) (4) MFG-005). In addition, the 5x-7x samples were collected on (b) (4) that was beyond the (b) (4) hold time for the (b) (4) Based on passing (b) (4) (b) (4) data recorded from a deficient/inconclusive hypothesis, you invalidated the initial OOS results and proceeded for compression stage.

OBSERVATION 2

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

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Specifically,

The (b) (4) data for the (b) (4) is not assured in the process validations as well as in the hold time studies such that,

A. You carried out hold time study for (b) (4) for (b) (4) Tablets USP(b) (4) mg as per your Protocol No. HTS/(b) (4)-001/00 (Effective date 1/22/2022) and established (b) (4) hold time for the (b) (4) as per the Report No. HTR(b) (4)-001/00 (Effective date 8/31/2022). According to the hold time study protocol, you collected the samples for hold time study from the in-process bulk container, IBC-057 at the completion of the (b) (4) process on (b) (4) MFG-005. The hold time sample was analyzed for appearance, (b) (4) analysis, and assay. The only (b) (4) data you collect is for the samples collected from the (b) (4) MFG-005 at the completion of (b) (4) stage as per your process validation protocol, PPQP/PIT/(b) (4)/2022/00 (Effective date 1/22/2022). The (b) (4) stored in the IBC-057 is not analyzed for (b) (4) You use (b) (4) stored in IBC-057 for tablet compression.

B. You carried out hold time study for (b) (4) for (b) (4) Tablets USP(b) (4) mg as per your Protocol No. HTS/CAB-001/00 (Effective date 10/5/2013) and established (b) (4) hold time for the (b) (4) as per the Report No. HTR/CAB-001/00 (Effective date 7/28/2015). According to the hold time study protocol, you collected the samples for hold time study from the in-process bulk containers, IBC-013 and IBC-061 at the completion of the (b) (4) process on (b) (4) ID-MFG-017. The hold time sample was analyzed for description, (b) (4) assay, and related compound. The only (b) (4) data you collect is for the samples collected from the (b) (4) ID-MFG017 at the completion of (b) (4) stage as per your process validation protocol, PVP/CAB-001/00 (Effective date 10/5/2013). The (b) (4) stored in the IBC-013 and IBC-061 is not analyzed for (b) (4) You use (b) (4) stored in

IBC-013 and IBC-061 for tablet compression.

C. You carried out hold time study for (b) (4) for (b) (4) Tablets USP (b) (4) mg as per your Protocol No. HTS/CBD-001/00 (Effective date 2/6/2014) and established (b) (4) (b) (4) hold time for the (b) (4) as per the Report No. HTR/CDB-001/00 (Effective date 8/4/2015). According to the hold time study protocol, you collected the samples for hold time study from the in-process bulk container, IBC-062 at the completion of the (b) (4) process on (b) (4) (b) (4) ID # MFG-165. The hold time sample was analyzed for appearance, (b) (4) assay, and degradation products. The only (b) (4) data you collect is for the samples collected from the (b) (4) ID # MFG-165 at the completion of (b) (4) stage as per your process validation protocol, PVP/CDB-001/00 (Effective date 2/6/2014). The (b) (4) stored in the IBC-062 is not analyzed for (b) (4) You use (b) (4) stored in IBC-062 for tablet compression.

D. You carried out hold time study for (b) (4) for (b) (4) Tablets USP (b) (4) mg as per your Protocol No. HTS/EFH-001/00 (Effective date 11/16/2013) and established (b) (4) hold time for the (b) (4) as per the Report No. HTR/EFH-001/00 (Effective date 3/4/2015). According to the hold time study protocol, you collected the samples for hold time study from the in-process bulk containers, IBC-014 and IBC-046 at the completion of the (b) (4) process on (b) (4) ID # MFG-011. The hold time sample was analyzed for description, (b) (4) (b) (4) assay, and related substances. The only (b) (4) you collect is for the samples collected from the (b) (4) ID # MFG-011 at the completion of (b) (4) stage as per your process validation protocol, PVP/EFH-001/00 (Effective date 11/7/2013). The (b) (4) stored in the IBC-014 and IBC-046 is not analyzed for (b) (4) You use (b) (4) stored in IBC-014 and IBC-046 for tablet compression.

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Dhar, Madhya Pradesh, 454775 India	Drug Manufacturer

Your General Manager of Quality Assurance (Mr. RS) stated that the (b) (4) data recorded for the (b) (4) in the (b) (4) is extrapolated to the Hold time sample. Your hold time study data are inadequate for the (b) (4) of (b) (4) from the process validation to the (b) (4) stored in IBC bins that was/is actually used in the drug product manufacturing. Between 2020 and 2023, you have recorded at least twelve OOS results related to assay including (b) (4) assay, content uniformity, and dissolution. You have invalidated 10 of the aforementioned OOS results. Some of the drug products that are implicated with assay related OOS results, including but are not limited to; (b) (4) tablets (b) (4) mg, (b) (4) tablets (b) (4) mg, (b) (4) mg, (b) (4) tablets (b) (4) mg, (b) (4) tablets (b) (4) mg, (b) (4) (b) (4) tablets (b) (4) mg, (b) (4) tablets (b) (4) mg, (b) (4) tablets (b) (4) mg.

OBSERVATION 3

The suitability of all testing methods is not verified under actual conditions of use.

Specifically,

Your firm uses the UV method to quantitate the release of drug product in dissolution testing of (b) (4) (b) (4) drug products.

However, the sample sequence described in your UV methods (one blank, one standard, one sample) for (b) (4) of the (b) (4) drug products did not establish the system suitability whenever the method was used for dissolution testing.

Your firm has been using the UV methods without system suitability established to test the dissolution of the (b) (4) drug products for batch release and stability study since eac (b) (4) was submitted to the Agency (refer to the table below).

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Without demonstrating system suitability, all the dissolution data analyzed by the UV method for the commercial and exhibit batches of your (b) (4) drug products are invalid, and data for the corresponding batches may not be reliable. Among the (b) (4) 1 has been commercialized, 1 was approved and (b) (4) are pending.

Table: System Suitability and Data Validity in UV Method for Dissolution Testing of (b) (4) Drug Products

#	(b) (4) **Drug Products**	(b) (4)	**Approval/ Submission Date**	**Is System Suitability Established in UV Method for Dissolution Testing of Drug Product? (Yes/No)**	**Is Dissolution Data for Commercial or Exhibit Batches Valid or Invalid?**
Commercialized (b) (4)					
(b) (4)					

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(b) (4)

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(b) (4)

OBSERVATION 4

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

Specifically, major non-dedicated production equipment such as (b) (4) (equipment ID: MFG-159) and two (b) (4) (equipment ID: MFG-162 and MFG-163) used in (b) (4) Area (b) (4) are not cleaned, and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product. For example:

A. On 6/19/2023, during the inspection of the (b) (4) (equipment ID: MFG-159) that was labeled "Clean", significant scratches were observed inside the (b) (4) (potential contact surface) and (b) (4) (potential contact surface inside the (b) (4) (b) (4). Scratches/dents were more apparent on the (b) (4) The equipment was Type-A cleaned (change over cleaning) and verified by Quality on 6/14/2023. DGM Production stated, in the past, the firm had been using (b) (4) to scrape the product inside the (b) (4) and to dismantle the (b) (4) for cleaning. As a result of the scratches the site stopped using (b) (4) in 04/2022. However, the firm continued using the impacted equipment and did not perform any risk assessment if specifically, this issue has impacted any marketed batches.

B. After the (b) (4) process (b) (4) are (b) (4) using two (b) (4) equipment IDs: MFG-162 and MFG-163) in (b) (4) Area (b) (4) Deficiencies were observed with the "Clean" (b) (4) ID: MFG-162-T1 and MFG-163-T1 that are used with (b) (4) (b) (4) ID: MFG-162 and MFG-163 respectively. During the inspection, the (b) (4) (placed inside these (b) (4) to (b) (4) potential contact surface) appeared clogged at various locations with the unknown residue that appeared to be buildup. Type-A (change over) cleaning was performed and verified on both equipment on 6/14/2023.

(b) (4) area (b) (4) and the production equipment inside this area such as: MFG-159, MFG-162-T1 and 1 are shared use equipment. This equipment is used to manufactured following drugs: (b) (4) Tablets (b) (4) mg, (b) (4) mg), (b) (4) Tablets (b) (4) mg), (b) (4) Tablets (b) (4) mg), (b) (4) Tablets (b) (4) mg), (b) (4) Tablets (b) (4) mg, (b) (4) mg).

OBSERVATION 5

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

Specifically, scientifically sound, and appropriate test procedures are not deployed to establish the identity, strength, quality, and purity of the drug products manufactured at the site. For example:

On 6/19/2023, I observed the dissolution test that was performed for (b) (4) Tablets, (b) (4) mg batch (b) (4) using Dissolution apparatus (ID: QCD-333) connected with an autosampler. Both batches were stability batches stored under long-term stability conditions (25 C, 60% RH) and were tested for dissolution at 24-month stability interval as per Test Method STP # TP/DR/0178. This test method requires, dissolution test to run for (b) (4) using (b) (4) at the speed of (b) (4) rpm. Batch (b) (4) did not pass the S-1 dissolution stage and was tested for S-2 stage on 6/21/2023. Following deficiencies were observed when lab analyst performed the test:

A. The dissolution test did not start when the (b) (4) tablets are immersed into the dissolution media. Instead, the test was manually started after about (b) (4) when temperature sensor read the temperature of the dissolution media in the specified range i.e., (b) (4) (b) (4) C. The addition time of about (b) (4) when the drug product stays in contact with

the dissolution media) is not considered towards the required (b) (4) dissolution time.

B. After the completion of the (b) (4) test, the autosampler rinses the sampling tubes (used to draw sample from the dissolution vessel) in (b) (4) cycles (about (b) (4) mL/cycle) and then (b) (4) mL sample is pulled in (b) (4) cycles (about (b) (4) mL/cycle). This process takes little more than (b) (4) (about (b) (4) before the actual dissolution sample is pulled by the autosampler. During this time, the baskets containing the tablets do not stop; instead, they keep (b) (4) at the speed of (b) (4) rpm. It appeared the (b) (4) tablets were in direct contact with the dissolution media for about (b) (4) when the autosampler completed the sampling process.

C. Rinsing of the sample tubes is done as per Protocol 5, programmed in the dissolution apparatus. This protocol requires removal of about (b) (4) mL of sample from the dissolution vessel before actual dissolution sample has been drawn. At the end of the test, when rinsed solution from all (b) (4) dissolution vessels was measured it was about (b) (4) mL; about (b) (4) % of the rinsed solution was missing.

This dissolution equipment (ID: QCD-333) along with other similar dissolution equipment are used by the firm to perform dissolution profile test for about following (b) (4) products: (b) (4)

Tablets.

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OBSERVATION 6

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

Specifically, the quality unit failed to control the laboratory test methods created and then transferred in LES Development server as per SOP CSOP/2016/047, "Method Creation on Method Builder Software".

Computerized system LES (Laboratory Execution System) is used by the quality control laboratory for documentation and to perform analysis. LES has three servers: Development, Validation, and Production. Test methods are created as per SOP CSOP/2016/047, "Method Creation on Method Builder Software" and then moved in LES Development server. After verification, the test methods in Development server are transferred on Production server. CSOP/2016/047 requires all methods to be names with the product such as(b) (4) USP. However, it was observed numerous procedures (about more than 60) were not associated with any product. Instead, the procedure name was showing as "Trail, Test, 0, 123, *, Test 123, Testing, TESTING" etc. Few examples are shown as below:

CATEGORY	PROCEDURE NAME	PROCEDURE ID	VERSION	STATUS
Formulation	Testing	Trial_29	1.0	Current
Formulation	Testing	Trial_007	1.0	Draft
Formulation	TRIAL	XYZ	0.0	Current
Formulation	Testing	Final verification	0.0	Draft
Raw Material	Testing	Testing_Demo_02	1.0	Draft
Formulation	TRIAL	ABC_test	1.0	Current

API	Testing	Testing123	1.0.0	Draft
Testing	Testing_123	Testing_123	1.0	Current
API	Testing	Test_API	1.0	Draft
Formulation	TEST	0		Draft
Formulation	test	testing_123	1.0.0	Draft
Formulation	Testing	Test_123	0.0	Draft
Finished Goods	TEST	Demo_1	1.0.0	Draft
Formulation	Test	ID For Testing	1.0.0	Superseded
Formulation	Test	ID For Testing	1.0.1	Draft
Formulation	Test	ID For Testing	1.0.2	Current
Formulation	Testing	PITH_TESTING	0.0	Draft
Testing	Testing	Demo Testing	1.0.0	Draft
Finished Goods	Testing	(b) (4) Testing	00	Draft
FG	Test	Test_999	1.0	Draft

OBSERVATION 7

Clothing of personnel engaged in the manufacturing, processing, packing and holding of drug products is not appropriate for the duties they perform.

Specifically, personal gowning used in the core manufacturing areas including dispensing and compression areas is not maintained clean to prevent contamination. On 6/15/2023, during the

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	6/15/2023-6/23/2023* FEI NUMBER 3007574780

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Arindom Sen, Site Head, Senior General Manager Operations	
FIRM NAME Ipca Laboratories Limited	STREET ADDRESS 1 Pharma Zone, SEZ Indore, Pithampur
CITY, STATE, ZIP CODE, COUNTRY Dhar, Madhya Pradesh, 454775 India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

inspection of Dispensing Room (b) (4) and Compression Are (b) (4) "Clean" personal gowning intended to be used in the respective area appeared worn out and torn (with holes measuring more than 2 inches). It appeared soiled with black, white, (b) (4) colored stains.

In the core manufacturing areas, additional arm sleeves are required as per Gowning SOP # PIT/MGG/002/19. During the inspection of Dispensing Area (b) (4) (b) (4) black, and (b) (4) colored stains were observed on the "Clean; intended to be used in the dispensing room" arm sleeves. One sleeve appeared to be torn. Additionally, bottom fabric of the "Clean" booties intended to be used in the dispensing area appeared worn out at numerous places exposing the underneath padding. On 6/15/2023, an operator wearing the gowning with excessive stains and marks was observed inside the Compression Area (b) (4) where (b) (4) is compressed into tablets. Your Laundry Procedure (# PIT/HRD/028/14) requires checking the gowning for any damaged and torn aprons, booties, and trousers before washing. As per this SOP such gowning should not be considered for next washing cycle. In this regard, you failed to follow your procedure to ensure clean gowning is used in the core manufacturing areas.

OBSERVATION 8

Procedures describing the handling of all written and oral complaints regarding a drug product are not written and followed.

Specifically,

Your firm's Corporate Standard Operating Procedure for Handling of Product Complaint (CSOP Number: CSOP/2013/004/R09, Effective Date: June 02, 2022; CSOP/2013/004/R08, Effective Date: Feb 03, 2022; CSOP/2013/004/R07, Effective Date: Sept 16, 2020) requires that all CAPAs initiated in reference to product complaints shall be reviewed for effectiveness check; if the CAPA is found to be ineffective, a new CAPA shall be assigned by reinvestigating the complaint.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Saleem A Akhtar, Investigator Rajiv R Srivastava, Office of Global Policy and Strategy Employee Wenzheng Zhang, Investigator	X Saleem A Akhtar Investigator Signed By: 2001638440 Date Signed: 06-23-2023 15:50:54	6/23/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	6/15/2023-6/23/2023* FEI NUMBER 3007574780

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Your firm received four complaints regarding the issue of no label on the bottle of (b) (4) Tablets (b) (4) mg from your (b) (4) client in 2021 (refer to the table below). Your firm classified the no-label complaints as major, conducted investigations, and implemented CAPA/Change Control (CAPA# 202191) in 06/2021. Your firm also performed a CAPA effectiveness check and closed the CAPA in 07/2021. However, the same no-label issue re-occurred for the same drug product four times in 2022 and twice to date in 2023 (refer to the table below), demonstrating your CAPA is not effective. Your firm did not assign a new CAPA to investigate the new complaints.

Table: No-Label Complaints from 2021 to 2023

Complaint #	Complaint Received Date	Brief Complain Description	(b) (4) (b) (4) mg (b) (4) mg Batch#	Expiration Date
MKT/034/2021	06/04/2021	No Label	(b) (4) mg)	02/2023
MKT/059/2021	09/08/2021	No Label	(b) (4) mg)	10/2023
MKT/069/2021	11/10/2021	No Label (1 bottle)	(b) (4) mg)	10/2023
MKT/073/2021	12/23/2021	No Label	(b) (4) mg)	10/2023
MKT/009/2022	03/01/2022	No Label (2 bottles)	Not Available (b) (4) mg)	Not Available

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12420 Parklawn Drive, Room 2032 Rockville, MD 20857	6/15/2023-6/23/2023* FEI NUMBER 3007574780

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Arindom Sen, Site Head, Senior General Manager Operations

FIRM NAME	STREET ADDRESS
Ipca Laboratories Limited	1 Pharma Zone, SEZ Indore, Pithampur
CITY, STATE, ZIP CODE, COUNTRY Dhar, Madhya Pradesh, 454775 India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

MKT/012/2022	03/28/2022	No Label	(b) (4) mg)	03/2024
252465	10/07/2022	Label is missing on the bottle	Not Available (b) (4) mg)	Not Available
252504	10/07/2022	Label is missing on the bottle	Not Available (b) (4) mg)	Not Available
272501	03/31/2023	No label on the bottle	Not Available (b) (4) mg)	Not Available
276943	05/09/2023	Partial label is missing	(b) (4) mg)	01/2025

***DATES OF INSPECTION**
6/15/2023(Thu), 6/16/2023(Fri), 6/19/2023(Mon), 6/20/2023(Tue), 6/21/2023(Wed), 6/22/2023(Thu), 6/23/2023(Fri)

X Rajiv R. Srivastava -S Digitally signed by Rajiv R. Srivastava -S Date: 2023.06.23 15:52:53 +05'30'

X Wenzheng Zhang -S Digitally signed by Wenzheng Zhang -S Date: 2023.06.23 15:54:53 +05'30'

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Saleem A Akhtar, Investigator Rajiv R Srivastava, Office of Global Policy and Strategy Employee Wenzheng Zhang, Investigator	X Saleem A Akhtar Investigator Signed By: 2001638440 Date Signed: 06-23-2023 15:50:54	6/23/2023