

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  ORA OPQO IIQ, Room #2032 12420 Parklawn Drive, Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov	DATE(S) OF INSPECTION 11/10/2022-11/18/2022
	FEI NUMBER 3006370489

Industry Information: [www.fda.gov/oc/industry](http://www.fda.gov/oc/industry)

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

Mr. Muralidhar Manchiganti, Associate Vice President of Operations

TO: FIRM NAME Aurobindo Pharma Limited Unit IX	STREET ADDRESS Survey No. 374 Gundlamachanoor Village
CITY, STATE, ZIP CODE, COUNTRY Hatnoora Mandal Sangareddy, Telangana, 502296, India	TYPE ESTABLISHMENT INSPECTED Active Pharmaceutical Ingredient Intermediate 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**



Out of Specification and Complaint Investigations for API Intermediate products are deficient.

Specifically, investigation's initiated and performed by your Quality Unit in response to Out of Specification results, laboratory incidents, and market complaints related to testing of intermediates manufactured by your firm are not always scientifically sound or comprehensive with respect to root cause determination. For Example:

- A. OOS U09-001589 was initiated on 26-Sep-2021 to probe the failure of (b) (4) impurity in Related Substances by HPLC in (b) (4) Crude) Stage (b) (4) Batch (b) (4) 12M Long term stability sample (b) (4) Intermediate for US market). (b) (4) Impurity (USP (b) (4) at RRT (b) (4) was found to be (b) (4) % against specification of not more than (b) (4) %. According to the investigation, failure was attributed to the revision of specification with the inclusion of (b) (4) impurity since the previous specification did not have any limits for (b) (4) Impurity. The investigation states that Batch record review and quality review of input material is not applicable, since the product is failing in Related Substances by HPLC (b) (4) impurity) during stability study. The investigation states that no OOS results are available for the past twelve months. However, review of stability data show that long term and accelerated stability results failed to meet the revised specification as detailed below:

Initial (b) (4) %, tested on August 22, 2020

1 M 40°C/75%RH - (b) (4) %, tested on Oct 23, 2020

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		Lata Mathew, Ph.D., Investigator, DDC	

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- 2 M 40°C/75%RH - (b) (4) %, tested on Nov 7, 2020
- 3 M 40°C/75%RH - (b) (4) %, tested on Dec 13, 2020
- 3 M 25°C/60%RH – Not Detected, tested on Jan 5, 2021
- 6 M 40°C/75%RH - (b) (4) % tested on 25 March 2021
- 6 M 25°C/60%RH - (b) (4) % tested on 25 March 2021
- 9 M 25°C/60%RH - (b) (4) %, tested on 14 June 2021
- 12 M 25°C/60%RH - (b) (4) %, tested on 25 September, 2021(OOS Sample)

Your Quality team stated that probable root cause for failure is due to use of re-processed input material (b) (4) and (b) (4) in (b) (4) (Crude) Stage (b) (4) Intermediate. However, it was noted that the conclusion is deficient as detailed in Observation 2. CAPA states that all batches were verified and found within specification however the statement is incorrect since 6 month, 9 month and 12 month stability sample failed to meet the specification as detailed above. Preventive Action –states that SOP IQA040 will be revised to evaluate trend of existing stock and stability batches. The batch was reprocessed to Batch (b) (4) and shipped to the US Market.

- B. Market Complaint- MC-CAD-003882 (Batch (b) (4)), MC-CAD-003883 (Batch (b) (4) and MC-CAD-003884 (Batch (b) (4) was received on 13 January 2022, from APL, Unit-I for having higher levels of (b) (4) impurity at RRT-(b) (4) in Chromatographic purity by HPLC as detailed below:

Batch No's	(b) (4)
Results	(b) (4)
Specification	NMT (b) (4) %

From review of OOS U09-001589 investigation, the complaint batches listed above utilized re-processed input material (b) (4) in the manufacturing of (b) (4) (Crude) Stage (b) (4) Intermediate. Return material was tested by the firm however no retains were evaluated on samples during OOS investigation as part of manufacturing investigation. As per market complaint

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investigation root cause states that reprocessed input material may not impact the quality of the batch contradicting the suspected root cause in OOS U09-001589, instead states that manufacturing process might require maintenance of (b) (4) atmosphere or (b) (4) to avoid (b) (4). However, review of stability data for process validation Batches (b) (4) and (b) (4) (as per report R-11P-PV-C2188232-01-00- dated March 15, 2021) does not support the root cause because batch (b) (4) failed to meet the specification for (b) (4) impurity and batch (b) (4) met the specification (NMT (b) (4) %) as detailed below in Observation 2. Both batches were not manufactured under (b) (4).

Month/Stability Condition	(b) (4)	(b) (4)
Initial Release	(b) (4) %	(b) (4) %
1 M Accelerated	(b) (4) %	Not detected
2 M Accelerated	(b) (4) %	Not detected
3 M Accelerated	(b) (4) %	(b) (4) %
3 M Long Term	(b) (4) %	(b) (4) %
6 M Accelerated	(b) (4) % (OOS U09-001587)	(b) (4) %
6 M Long Term	(b) (4) % (OOS U09-001588)	(b) (4) %
9 M Long Term	Discontinued Stability	(b) (4) %
12 M Long Term		(b) (4) %

Approximately (b) (4) batches (b) (4) (Crude) Stage (b) (4) Intermediate batches were manufactured using reprocessed input material and shipped to Unit 1 for (b) (4) purification step of (b) (4) API.

- C. OOS-U09-001568 was initiated on 12 July 2021 to probe the failure of Individual unknown impurity at RRT (b) (4) (Result=(b) (4) %, specification NMT (b) (4) %) in (b) (4) intermediate, Batch (b) (4) during determination of Chiral Chromatographic Purity. The firm re-injected the sample from the original vial and re-viald sample. The results failed to meet the specification and confirmed the original failure (b) (4) % and (b) (4) %. The root cause for failure was attributed to glass ware contamination and the initial results were invalidated based on fresh sample

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preparation in triplicate and the results were reported as not detected (ND). However, on review of analytical method validation report (ARD/4718/HPLC/VAL) it was observed that unknown peak at about (b) (4) RRT increased about (b) (4) % in about (b) (4) and failed to meet the solution stability acceptance criteria of % difference between the areas obtained at initial and different time interval should not be more than (b) (4) for related substances from spiked sample solution. The review of raw data and chromatographic data showed that from the time of sample preparation to injection for initial sample exceeded (b) (4) as detailed below. The new sample preparations were injected soon after preparation.

Sample	Time Sample weighed	Time sample injected	Time difference
Initial	(b) (4)	(b) (4)	About (b) (4)
Reanalysis new preparation 1	14:19	(b) (4)	About (b) (4)
Reanalysis new preparation 2	14:50	(b) (4)	About (b) (4)
Reanalysis new preparation 3	15:45	(b) (4)	About (b) (4)

Also, the review of 6-month accelerated stability sample showed impurity about (b) (4) % at (b) (4) RRT thus giving no assurance if the root cause attributed is correct.

D. OOS-U09-001697 was initiated on 13 September 2022 to probe the failure in any other Related Substances at RRT (b) (4) (Result=(b) (4) %, specification NMT (b) (4) %) in (b) (4) Base (US Market), (b) (4) Intermediate Batch (b) (4) in Block (b) (4). No laboratory error was identified and was concluded as a confirmed OOS. The failure was attributed to shorter duration of (b) (4) with (b) (4) (about (b) (4) for a (b) (4) batch in step (b) (4) of the batch record when compared to other neighboring batches (about (b) (4)). On review of batch records for PV batches per PV report #PVR-R-IIP-PV-C2187046-01-00, dated 22 January 2018 following were the time utilized for (b) (4).

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PV Batches	(b) (4)
(b) (4) Time	(b) (4)
% Impurity at RRT	(b) (4)
PV Batch size	(b) (4)

The (b) (4) time for the third validation batch was about (b) (4) and the amount of unknown impurity met the specification thus not supporting the root cause attributed for the failure. The batch is held for reprocessing.

E. I01/QI/GC119084, dated 12/05/2019, was initiated for (b) (4) Stage (b) (4) batch no. (b) (4) for recovered (b) (4) (solvent recovery test for (b) (4) with deviation description as "Sample run was interrupted at about (b) (4) with conclusion as "upon verifying the data it was observed that sample run was interrupted at about (b) (4) is due to analyst by over look system restarted.". Per the deviation, the corrective action consisted of "Re conditioning the column and reperformed the sample injection, run was progressed, continued and completed the sample set, recorded the result". The above is what was documented in the deviation report. During our review of the chromatographic data on Empower 3, we observed that the first injection for sample (b) (4) performed on or around 12/05/2019 starting at (b) (4) appeared to be interrupted around (b) (4) and appeared to have a (b) (4) contamination around RT of (b) (4) which was not mentioned in the deviation report. This injection was not adequately investigated to determine the potential contamination root cause or whether the injection was intentionally interrupted. Instead, a second injection of the sample was performed around 12/05/2019 on or around 12/05/2019 starting at 12:41 pm and officially reported.

F. LIR/I01/000014, dated 02/25/2022, was initiated during analysis of (b) (4) Stage (b) (4) related substance by HPLC test for unknown peak observed in the sample run at (b) (4) minutes RT for batch no. (b) (4). Your firm's investigation consisted of preparing a new sample by spiking the sample with (b) (4) which is a known impurity in the sample around (b) (4) RT per (b) (4) Stage (b) (4) in order to confirm that the (b) (4) minutes RT was in fact an unknown peak.

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After your firm confirmed the unknown peak, the assignable root cause was determined to be "sample preparation error" without performing any investigation and scientific justification. Your firm invalidated the first sample set, and prepared and tested a fresh sample solution which was within specification and reported as official result.

**OBSERVATION 2**

Process validation is deficient to demonstrate that your manufacturing process can reproducibly manufacture an API intermediate to ensure that predetermined quality attributes are met.


Specifically,

Process Validation (PV) was executed to validate the use of reprocessed input material (b) (4) and (b) (4) in the manufacture process of (b) (4) (Crude) Stage (b) (4) Intermediate. (b) (4) (Crude) Stage (b) (4) Intermediate batches (Batch (b) (4) and Batch (b) (4) were manufactured as per PV Report R-11P-PV-C2188232-01-00, dated March 15, 2021, and were placed on long term (25°C/60%RH) and accelerated stability (40°C/75%RH).

There is no assurance that use of reprocessed input material (b) (4) can reproducibly manufacture of (b) (4) (Crude) Stage (b) (4) Intermediate based on the review of stability data detailed below:

Stability data for PV Batch (b) (4) failed to meet (b) (4) Impurity (USP Impurity- (b) (4) (b) (4) Ph.Eur. Impurity E, RRT (b) (4) specification of not more than (b) (4) % for the following stability time points.

Month/Stability Condition	(b) (4)	(b) (4)
Initial Release	(b) (4) %	(b) (4) %
1 M Accelerated	(b) (4) %	Not detected

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2 M Accelerated	(b) (4) %	Not detected
3 M Accelerated	(b) (4) %	(b) (4) %
3 M Long Term	(b) (4) %	(b) (4) %
6 M Accelerated	(b) (4) % (OOS U09-001587)	(b) (4) %
6 M Long Term	(b) (4) % (OOS U09-001588)	(b) (4) %
9 M Long Term	Discontinued Stability	(b) (4) %
12 M Long Term		(b) (4) %


However, stability data for PV Batch (b) (4) met acceptance criteria for long term and accelerated stability up to 12 M.

Approximately (b) (4) batches of (b) (4) (Crude) Stage (b) (4) Intermediate batches were manufactured using reprocessed input material and shipped to Unit 1 for (b) (4) purification step of (b) (4) API.

**OBSERVATION 3**

Analytical Test Methods and cleaning analytical methods are not validated and/or appropriately validated. Specifically, your firm failed to ensure that all test procedures are scientifically sound and appropriate to ensure that raw materials and API intermediates conform to established standards of quality and or purity.

A. The analytical test method for validation of stability indicating HPLC method for the determination of related substances in (b) (4) drug substance (Protocol APL/1568/HPLC/VAL, dated November 6, 2007) is deficient. The method validation failed to establish accuracy of the method. Additionally test method TC2188232-01-01 for (b) (4) (Crude) Stage (b) (4) (for US market) states to filter the sample through (b) (4) μ or (b) (4) filter (no filter make is provided in the test method). However, method validation did not evaluate the suitability of the filter or the discard volume to ensure no material is retained on the (b) (4). The analytical method was validated at APL Research center. However, the method was not transferred to Unit 9 and instead a three-batch verification was

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performed by analyzing three batches to ensure that method specifications are met.

- B. The analytical GC method validation for the determination of residual solvents (Method-I) of (b) (4) (Protocol ARD/3727/GC/VAL, dated July 24, 2017) is deficient. The method validation failed to establish linearity of the method. Method recovery was established only for two concentrations (LOQ and (b) (4) %) instead of 3 concentrations.
- C. Swab and Rinse recovery was established at (b) (4) facility of the firm using only one concentration and three determinations at (b) (4) % (b) (4) ppm) instead of three concentrations and (b) (4) determinations during equipment cleaning analytical method validation of (b) (4) by (b) (4) (Protocol AMV/RV (b) (4) 401-01). The method was not transferred to the current site. However, during review of Interim Report of Product change over cleaning verification for (b) (4) Stage (b) (4) (Crude), (GENP/PCOCV/21/001, effective 1 January 2021) we noted that the acceptance limit for swab and rinse limit was set at (b) (4) ppm swab limit which is outside of the validated analytical cleaning method. The firm manufactured approximately (b) (4) batches of (b) (4) (Crude) Stage (b) (4) Intermediate in Block (b) (4) and about (b) (4) batches in Block (b) (4) respectively.
- D. The analytical test methods used for the release of some Final Intermediates and Key starting materials (KSM) are validated at (b) (4) facility of the firm located about (b) (4) away from the firm. However, these methods are not transferred to the current site. The firms SOP on Method Transfer SOP ZQA061 V-0 was implemented only in February of 2022. Accuracy was established only for two concentrations (LOQ and (b) (4) %) instead of three concentrations.
- E. The firm manufactures and release Final Intermediates and KSM's utilized in the manufacturing process of Final Intermediates. During our review of analytical method validation, the firms Associate Vice President of Quality stated that the firm has not performed analytical method validations for multiple Intermediates and KSM's as detailed below:

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Summary of Validated Methods

Dispatchable Intermediates

KSM

Total number of products

(b) (4)

(b) (4)

Total number of Methods

Analytical methods for which validation performed

Analytical methods for which validation is not performed

The gap assessment report dated August 8, 2022 deficiently concludes that all the methods are performing well and can be used for regular analysis.

- F. Swab recovery was established using only one preparation for 3 concentrations and three measurements at each concentration instead of 3 concentrations/3 replicates each of the total analytical procedure during equipment cleaning analytical method validation of (b) (4) Stage (b) (4) by (b) (4) (Cleaning method validation- Protocol AMV (b) (4) 1703) dated January 9, 2017. Rinse recovery was not established.

**OBSERVATION 4**

Written procedures for the cleaning and maintenance of equipment validation is deficient. Specifically

Procedure SOP ZQA045, revision 04, effective 08/06/2021 " Equipment Cleaning Validation" states in Section 5.2 that 'Cleaning validation studies shall be conducted to ensure that cleaning procedures are effective, adequate and shall consistently remove the residues of previous product to acceptable levels'. We noted the following deficiencies:

- A. No equipment cleaning validation is available for (b) (4) (Crude) Stage (b) (4) Intermediate to ensure that the current method used for equipment cleaning is suitable to remove residual carry over. No equipment cleaning validation is available for (b) (4) (Crude) Stage (b) (4) Intermediate to ensure that the current method used for equipment cleaning is suitable to remove residual carry over.

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CITY, STATE, ZIP CODE, COUNTRY

Hatnoora Mandal Sangareddy, Telangana,  
502296, India


TYPE ESTABLISHMENT INSPECTED

Active Pharmaceutical Ingredient Intermediate  
Manufacturer

Instead cleaning method verification per Protocol GENP/PCOCV/21/001 was executed to demonstrate the cleaning efficacy for non-dedicated equipment's which are used in the manufacturing of intermediates and also to establish the product change over cleaning results of previous products. The firm has manufactured about (b) (4) batches in Block (b) (4) and about (b) (4) batches in Block (b) (4) respectively.

- B. Clean equipment hold time (CEHT) is not established as required per Section 5.14 of SOP ZQA045 " Equipment Cleaning Validation".
- C. Dirty equipment hold time (DEHT) is established only for (b) (4) products out of the (b) (4) dispatchable Intermediates as required per Section 5.14 of SOP ZQA045 " Equipment Cleaning Validation"
- D. The firm has not established campaign length. Section 5.3.3 of SOP ZQA045 " Equipment Cleaning Validation" states to perform Type III cleaning or periodic cleaning for equipment which is used for manufacturing of API / Intermediate on campaign basis. The procedure further states that Type III cleaning validation shall be performed with product having higher campaign length with minimum (b) (4) cleaning cycles and each cycle with different campaign length shall be performed between specific number of batches/or days. Listed below are few examples for the number of campaign batches that were manufactured in different manufacturing blocks without periodic cleaning. The performed Type I minor cleaning only between these batch that only requires to document visual cleaning.

Block	Product	Product Code	Period	Number of Batches Manufactured
(b) (4)	(b) (4)	(b) (4)	May 22- November 22	(b) (4)

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	 	Arsen Karapetyan, Investigator, DDC Lata Mathew, Ph.D., Investigator, DDC	11/18/2022

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

ORA OPQO HQ, Room #2032  
12420 Parklawn Drive, Rockville, MD 20857  
ORAPHARMInternational483responses@fda.hhs.gov

DATE(S) OF INSPECTION

11/10/2022-11/18/2022

FEI NUMBER

3006370489

Industry Information: [www.fda.gov/oc/industry](http://www.fda.gov/oc/industry)

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

Mr. Muralidhar Manchiganti, Associate Vice President of Operations

TO:  
FIRM NAME

Aurobindo Pharma Limited Unit IX

STREET ADDRESS

Survey No. 374 Gundlamachanoor Village

CITY, STATE, ZIP CODE, COUNTRY

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(b) (4)

July 22 - November 22

(b) (4)

September 20- February 21

November 19-June 21

June 20-December 21

**OBSERVATION 5**

Established laboratory control mechanisms are not adequate. Specifically,

We observed that while performing Chromatographic Purity Analysis by GC for (b) (4) Stage (b) (4) Batch (b) (4) and (b) (4) system precision was not established thus giving no assurance on the accuracy of the reported results. The GC injection included 1 system suitability solution followed by 1 sample and last system suitability injection. The %RSD between the area response from the first and last system suitability injections were found between (b) (4) and (b) (4) % Batch (b) (4) and between (b) (4) and (b) (4) % for Batch (b) (4) respectively. The firm's procedure does not have a %RSD requirement to ensure system precision.

Batch (b) (4)

RT (min)	System Suitability 1 Area	System Suitability 2 Area	Mean Response	Std Dev	%RSD
(b) (4)					

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OF THIS PAGE

EMPLOYEE(S) SIGNATURE



EMPLOYEE(S) NAME AND TITLE (Print or Type)

Arsen Karapetyan, Investigator, DDC  
Lata Mathew, Ph.D., Investigator, DDC

DATE ISSUED

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**Mr. Muralidhar Manchiganti, Associate Vice President of Operations**

TO: FIRM NAME Aurobindo Pharma Limited Unit IX	STREET ADDRESS Survey No. 374 Gundlamachanoor Village
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(b) (4)

Batch: (b) (4)


RT (min)	System Suitability 1 Area	System Suitability 2 Area	Mean Response	Std Dev	%RSD
(b) (4)					

**OBSERVATION 6**

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

Specifically, supervisory oversight over the laboratory electronic systems and data is deficient. The list of observations noted in this form document that the Quality Unit has not performed the necessary assessments/reviews to ensure that the objectionable conditions do not negatively affect the Quality Control tests in support of API Intermediates. Specifically,

- A. During our review of your Empower 3 chromatography software, interrupted sequences were observed, which generated "Data Missing" chromatographic data. During our review of laboratory incidents, we observed what appeared to be analysts intentionally aborting/terminating chromatography sample sets during HPLC and GC testing using Empower FR2 software due to system suitability requirements found not meeting the acceptance criteria, which can lead to "Data Missing" chromatograms which your firm documented under your previous and current laboratory incident procedures. Your firm documented these interrupted injections as laboratory incidents, showing that no chromatogram had been generated. However, during review of such cases, the interrupted sample injections were not adequately documented and/or investigated. In addition, your firm has not demonstrated to understand all different circumstances which may lead communication interruptions

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during chromatography testing operations. This discrepancy in your firm's ability to review, document, and investigate all electronic data is a gap in your Data Integrity Program.

- B. There is no adequate process for the organization of electronic test data generated by your HPLC and GC systems in your Empower 3 chromatography software. Your firm's current Empower 3 configuration for electronic test data is organized via at least 50 independent HPLC and GC equipment project folders (named month/year/equipment id) which contain chromatography testing data in said individual equipment folder. Your current data file path organization structure does not consider the controls, functionality, and capability of your Empower 3 software, to establish a data file path which allows for an adequate and efficient review of electronic test data. Additionally, your firm's analysts do not always follow SOP ZQC007, titled "Procedure for Labeling of Data files, Sequences and Projects", effective date 11/30/2020 for sequence labeling procedure, which we observed during our review of HPLC and GC electronic data.
- C. The Quality Assurance Unit lacks adequate control over the issuance approved standard operating procedures. For example, during our walkthrough of your firm's QC laboratory on 11/10/2022 we observed a member of the QC laboratory holding unauthorized, blank (unsigned) procedures, specifically SOP ZQC002, titled "User Administration and System Policies in Computerized Systems" and SOP ZQC003, titled "Review of Audit Trails". Per your firm's Deviation-DE-U09-001106, initiated on 11/10/2022, the printouts were taken by the QC user without due authorization for reference only.
- D. Your firm's Empower 3 message center audit trails are purged approximately (b) (4) without adequate justification and backup consideration. Your Empower 3 message center is a logs messages such as errors related to user logins, warnings, and instrument issues. During the review of project integrity failures with missing data GC chromatograms for incidents (b) (4) I01/22/0166, dated 08/31/2022 (message center (b) (4) error"), and incident IOQ/QI/GC120027, dated 02/23/2020 (instrument error for (b) (4)), there is not audit trail to support assignable root causes.

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E. There is no adequate data integrity program in place to include a statistically sound comprehensive review of all electronic data by the Quality Assurance Unit for standalone and network systems, to ensure completeness, consistency, and accuracy of all chromatographic and non-chromatographic electronic data generated by the Quality Control Laboratory.

**OBSERVATION 7**


Storage of key starting materials, raw materials and intermediates are not adequate.

Specifically, during our walkthrough of your key starting materials, intermediates, and general raw materials warehouse facility on 11/10/2022, we observed that most written locations specified on nine (9) status white boards for nine (9) rows (Rows A – I) did not match with the actual physical locations for respective key starting materials, intermediates, and raw materials. We observed the following deviations initiated by your firm with respect to lack of adequate control in receiving, storage and issuance of materials:

-DE-U09-001003, dated 06/21/2021, where (b) (4) Batch No (b) (4) was transferred to the warehouse from production without documentation in the firm's ERP software.

-DE-U09-001065, dated 05/25/2022, where (b) (4) Stage (b) (4) third validation batch no. (b) (4) was manufactured using the incorrect (b) (4) stage (b) (4) vendor material.

-DE-U09-000968, dated 02/24/2021, where (b) (4) Stage (b) (4) and (b) (4) Batch No. (b) (4) at step no. (b) (4) in process test parameter for (b) (4) content did not comply, with result at (b) (4) % versus a specification of  $\leq$  (b) (4) %. Subsequent investigation determined the root cause to be human error, where the wrong material was dispensed by warehouse personnel, with the issuance of material (b) (4) instead of (b) (4). As a result of this deviation, the batch (b) (4) was discarded.

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-DE-U09-000948, dated 01/08/2021, where good documentation practices were not followed by warehouse personnel for the material inspection checklist of (b) (4) Stage (b) (4) return goods, with the checklist observed with unfilled columns and without signature and date.

Your firm's procedure SOP No. IWA009, titled "Storage of raw material, packing material and intermediates" is deficient, in that it does not detail the process of using white status boards for tracking material locations in the warehouse. As detailed in above deviation DE-U09-000968, root cause was determined to be human error, without adequate investigation and conclusion to what may have contributed to the human error, such as inadequate procedures for warehouse personnel to follow.


**OBSERVATION 8**

Materials and intermediates are not always re-evaluated, as appropriate, to determine their suitability for use after an established retest date.

Specifically, your procedure SOP No. IWA010, titled "Re-Testing of Raw Materials, Intermediates", effective date 08/24/2022 is deficient, in that there is no process for identifying re-test lots within a specific period to avoid using expired/re-test status material during manufacturing. During our walkthrough of your key starting materials, intermediates, and general raw materials warehouse facility on 11/10/2022, we observed approximately (b) (4) materials with "retest" labels, which are purported to be managed by your Quality Unit and ERP software procedure SOP No. ISOE078-00, titled "Retest Lots Exception Process", effective date 08/26/2021. We observed the following deviations initiated by your firm with respect to deficiencies related to retesting of key materials, raw materials, and intermediates:

-DE-U09-000811, dated 10/21/2019, where (b) (4) retest batch no. (b) (4) was missing the retest label.

-DE-U09-000967, dated 02/22/2021, where material (b) (4) lot no. (b) (4) was

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used in the manufacture of (b) (4) Stage (b) (4) batch no. (b) (4) in manufacturing Block (b) (4) on 02/21/2021 after crossing the retest date.

-DE-U09-000993, dated 05/31/2021, where (b) (4) lot no. (b) (4) was used in the manufacture of (b) (4) Stage (b) (4) batch no. (b) (4) in manufacturing Block (b) (4) without retest analysis being performed.

**OBSERVATION 9**



Schedules and procedures established for the preventive maintenance of equipment are not adequate.

Specifically, your firm's preventive maintenance program for production and laboratory, detailed in procedures SOP No. IEU004, titled "Execution of Preventive Maintenance", effective date 04/26/2021 and SOP No. IQC066, titled "Maintenance of Testing Equipment's in Quality Control Department", effective date 03/30/2022, is not always adequate with respect to timely preventive maintenance scheduling and operations. For example, we reviewed the following deviations where your firm missed PM's to be performed: DE-U09-000678, dated 05/12/2019 (PM for HPLC missed), DE-U09-000960, dated 02/03/2021 (PM for (b) (4) missed), and DE-U09-000973 (PM for (b) (4) missed).

**OBSERVATION 10**

Computer systems used in the testing of a drug substance are not of appropriate design to facilitate operations for its intended use.

Your firm does not have adequate written procedures for conducting Initial Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) for laboratory equipment. Specifically, qualification activities were performed by your software vendor for networked Empower 3 FR software, which is used for HPLC and GC chromatography testing operations, without adequate participation from the firm's Quality Unit and personnel. Your firm's current PQ does not demonstrate the suitability of the

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software to perform assigned tasks in a consistent manner over a specified period and operating environment. For Example, your firm has not demonstrated to understand the different circumstances which may lead to test injection interruptions during chromatography testing operations. This discrepancy in your firm's ability to review, document, and investigate all electronic data is a gap in your Data Integrity Program.

Similarly, your firm's current qualification for software Metrohm Tiamo used for auto titrator equipment QAT-002, QAT-003, KF titrator QKF-008, and KF titrator QKF-010 does not include an assessment to determine different circumstance which may lead to connectivity errors such as "start test errors". During review of your system audit trails for above listed equipment, we observed connectivity errors during start of sample, blank, standardization, and calibration titrations.

**\*DATES OF INSPECTION**  
 11/10/22 (Thu), 11/11/22 (Fri), 11/14/22 (Mon), 11/15/22 (Tue) 11/16/22 (Wed), 11/17/22 (Thu) and 11/18/22 (Fri)

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