

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 12/15/2025-12/18/2025 FEI NUMBER 3014372507					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Umesh Bisale Ananthapadmanabha, Co-CEO & Founder							
FIRM NAME Invitro Research Solutions Private Ltd		STREET ADDRESS 22-23 Kodigehalli Main Road, Sahakar Nagar Post, Hebbal					
CITY, STATE, ZIP CODE, COUNTRY Bengaluru, Karnataka, 560092 India		TYPE ESTABLISHMENT INSPECTED Control Testing Laboratory					
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 Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards. Specifically, Your firm's method validation reports for (b) (4) Impurity testing of active pharmaceutical ingredients (API) and finished product for (b) (4) do not include documentation of analyses that failed to meet predetermined acceptance criteria, nor do they include the associated investigations and corrective and preventive actions. For example: A) Your firm's method validation report titled, Method Validation for the Quantitative determination of (b) (4) impurity in (b) (4) API, MV Report ID: iVRS-(b) (4)-MV-24-001, Version: 02, Dated: 11 Nov 2024, does not include documentation of two analysis that failed to meet your predetermined acceptance criteria or the associated investigations and corrective and preventative actions. The method validation analysis that failed to meet acceptance criteria were conducted on 9/12/2024 for Linearity, Range, and Accuracy, and 9/13/2024 for Limit of Quantitation (LOQ) Accuracy. B) Your firm's method validation report titled, Method Validation for the Quantitative determination of (b) (4) impurities in							
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;"> EMPLOYEE(S) SIGNATURE Zachary L Stamm, Investigator </td> <td style="width: 40%; border: none; text-align: center;"> DATE ISSUED 12/18/2025 </td> </tr> <tr> <td style="border: none; vertical-align: bottom;"> Zachary L Stamm Investigator Signed By: ZACHARY L. STAMM S Date Signed: 12-18-2025 16:43:24 </td> <td style="border: none; vertical-align: bottom;"> X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Zachary L Stamm, Investigator	DATE ISSUED 12/18/2025	Zachary L Stamm Investigator Signed By: ZACHARY L. STAMM S Date Signed: 12-18-2025 16:43:24	X
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(b) (4) (b) (4) ”, MV Protocol ID: iVRS-(b) (4) -MV-029, Version: 01, Date: 04 May 2024, does not include documentation of seven analyses that failed to meet your predetermined acceptance criteria or the associated investigations and corrective and preventative actions. The method validation analysis that failed to meet acceptance criteria were conducted on 4/22/2024 for LOQ Accuracy and Precision, 4/24/2024 for Solution and Sample Stability, 4/24/2024 for Intermediate Method Precision, 4/24/2024 for Intermediate Precision, 4/26/2024 for Robustness, 4/26/2024 for Intermediation Method Precision, and 4/28/2024 for LOQ Accuracy and Precision.			
OBSERVATION 2 Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up. Specifically, Your firm’s investigation, iVRS-(b) (4) -MV-029-INV-01, into seven analyses that failed to meet acceptance criteria as part of the method validation for your firm's in-house (b) (4) Impurity method, iVRS-STP-144, per Validation Protocol, iVRS-(b) (4) -MV-029, was not thoroughly documented and failed to determine a specific root cause and associated corrective and preventive actions. Additionally, all seven failed analyses were re-analyzed between 4/22/2024 and 5/2/2024, which is prior to the documented initiation date of the investigation on 5/3/2024.			
OBSERVATION 3 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.			
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Specifically, The following procedures do not include Sufficient detail for consistent execution A)Your firm's procedure titled, Procurement, Numbering, Labelling, Storage and Handling of Analytical Standards, iVRS-AD-024, Ver. 07, Eff. 5/2/2025, does not include specific criteria for the acceptance and use of non-compendial reference standards in analytical testing at your firm. For example, there are no defined acceptance criteria for review of supplier's certificate of analysis; verification of storage requirements during shipment; or in-house testing to qualify the non-compendial standard for use. B)Your firm's procedure titled, Procedure for Change Control, iVRS-QA-003, Ver. 06, Eff. 7/24/23, does not require that changes to specifications or validated test methods be approved by the application sponsor prior to implementing changes as required by your firm's Technical Agreement with the Application Sponsor for (b) (4), dated 7/25/2024. C)Your firm's procedure titled, Qualification of Spreadsheet Application, iVRS-AD-016, Ver. 04, Eff. 11/19/2024, does not require that all excel spreadsheets used for accurate calculation of analytical results are qualified prior to use. For example, the spreadsheets used for calculating results for Method Precision, Sample Solution Stability, and Accuracy during method validation of (b) (4) Impurity methods, iVRS-(b) (4)-MV-24 / iVRS-(b) (4)-MV-029, were not qualified prior to use. D)Your firm's procedure titled, Procedure for Performing Analytical Method Validation, iVRS-AD-048, Ver. 04, Eff. 5/2/2025, does not include scientific justification for the established method validation acceptance criteria identified in your method validation protocols, iVRS-(b) (4)-MV-24 / iVRS-(b) (4)-MV-029, for (b) (4) Impurity testing of active pharmaceutical			
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ingredients (API) and finished drug products for (b) (4)			
OBSERVATION 4 The written stability program for drug products does not include reliable, meaningful and specific test methods. Specifically, Your firm has not demonstrated that your in-house method, iVRS-STP-144, is specific and appropriate for analyzing stability samples of finished drug product for (b) (4) Impurities. Your method validation report, Method Validation for the Quantitative determination of (b) (4) (b) (4) impurities in (b) (4) (b) (4), MV Protocol ID: iVRS-(b) (4) -MV-029, Version: 01, Date: 04 May 2024, does not include supporting evidence or justification that your method is capable of accurately identifying and quantifying (b) (4) impurities in the presence of other impurities, degradation products, and/or degradation excipients. Your firm has conducted (b) (4) Impurity analysis on (b) (4) stability samples of (b) (4) finished product. On 12/18/2025, your firm's customer confirmed these finished product samples are stability samples that are part of validation batches for (b) (4)			
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