

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	DATE(S) OF INSPECTION 02/23/2026-02/27/2026 FEI NUMBER 3004985767	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Rahul D. Vora, Director		
FIRM NAME Unilab Chemicals and Pharmaceuticals Private Ltd.	STREET ADDRESS Plot W 32, MIDC, Phase II, Dombivli (East)	
CITY, STATE, ZIP CODE, COUNTRY Mumbai, Maharashtra, 421204, 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 There is a failure to establish the reliability of the component supplier's report of analyses. Specifically, A) There is no supplier qualification or quality agreement established for the following non-USP solvents used for manufacturing APIs: B) Certificate of Analysis (COA) test results provided by the supplier of non-USP solvents have not been validated. This includes the lack of verification for Identity test results, (b) (4) Limit test results, (b) (4) Limit test results, Residue on Evaporation test results, pH test results, Solvent Acidity test results, Denaturant Level test results, and/or Impurity test results. In addition, the non-USP in-house test method used for Gas Chromatography (GC) purity testing has not been validated. According to the QA Manager, the test parameters for the in-house methods were solely determined based on the firm's laboratory capability.		
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C) The firm's designated contract testing laboratory for (b) (4) water TOC testing has not been qualified. In addition, there is no quality agreement that defines GMP expectations and responsibilities relating to testing of (b) (4) water samples for TOC analysis. In addition, the (b) (4) water sampling and testing plan for TOC analysis is also not clearly defined or established. According to the Quality Assurance (QA) Manager, (b) (4) water samples for TOC analysis are collected from the (b) (4) vessel and only during the manufacturing of APIs intended for the U.S market. OBSERVATION 2 There is a failure to thoroughly review any unexplained discrepancy whether or not the API batch has already been distributed. A) According to the QA Manager, there have been no deviations or non-conformances reported since the previous 2019 inspection. However, the following equipment breakdowns recorded in the Breakdown Maintenance Record Logbook, Format No.: UNI/MAIN/006 and 2024-2025 CAPA logs did not include thorough investigation of the API equipment breakdown incident (e.g., during which stage in activities), root cause analysis and product quality impact details on distributed API batches: <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 20%;">Machine/Equipment No./Plant Location</th> <th style="width: 15%;">Breakdown Date</th> <th style="width: 15%;">Restart Date</th> <th style="width: 30%;">Root Cause</th> <th style="width: 20%;">Corrective Action</th> </tr> </thead> <tbody> <tr> <td rowspan="2" style="vertical-align: top;">(b) (4)</td> <td style="text-align: center;">Jan 06, 2025</td> <td style="text-align: center;">Jan 06, 2025</td> <td>(b) (4) Leakage Problem for (b) (4)</td> <td>New (b) (4) Fitting Work Completed</td> </tr> <tr> <td style="text-align: center;">Dec 01, 2024</td> <td style="text-align: center;">Dec 01, 2024</td> <td>(b) (4) Vessel (b) (4) Valve Leakage</td> <td>New valve fitted in (b) (4)</td> </tr> </tbody> </table>				Machine/Equipment No./Plant Location	Breakdown Date	Restart Date	Root Cause	Corrective Action	(b) (4)	Jan 06, 2025	Jan 06, 2025	(b) (4) Leakage Problem for (b) (4)	New (b) (4) Fitting Work Completed	Dec 01, 2024	Dec 01, 2024	(b) (4) Vessel (b) (4) Valve Leakage	New valve fitted in (b) (4)
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CAPA No.	Details of CAPA	Date of Initiation	Initiation By	Quality Impact	CAPAs Implemented On
CAPA-043/25	Replaced the (b) (4) valve of (b) (4) Vessel (b) (4) in Formulation Manufacturing Area (b) (4) due to observed leakage). (4)	Sep. 29, 2025	Maintenance	Yes	Oct. 03, 2025
CAPA-020/25	New (b) (4) fitted to (b) (4) (b) (4) for Bulk Drug (API) Manufacturing Areas, which is connected to (b) (4) due to leakage.	March 09, 2025	Maintenance	Yes	April 01, 2025
CAPA-016/24	Replaced (b) (4) valve of (b) (4) Vessel No. (b) (4) with spare valve (Reason not specified).	March 27, 2024	Maintenance	Yes	April 01, 2024
B) During my inspection walkthrough of the Bulk Drug (API) Manufacturing Area on February 23, 2026, an uncontrolled notebook was observed to be stored away at the bottom of a box storing equipment auxiliary parts. According to the Director, the notebook contained unofficial documentation of (b) (4) (b) (4) recorded by Operators as part of (b) (4) (b) (4) study for (b) (4) USP and non-USP commercial batches. However, there is no official documentation of the study and operators' involvement during the commercial batch manufacturing process. In addition, the Director and R&D Associate stationed off-site stated that (b) (4) ml samples are (b) (4) collected from each commercial batch as part of the (b) (4) (b) (4) study. However, the collection of such samples is not documented nor included as part of the master batch manufacturing record instructions.					
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OBSERVATION 3 The responsibilities and procedures applicable to the quality control unit are not in writing or fully followed. Specifically, The following deficiencies were observed during my inspectional walkthrough of the Quality Assurance (QA) area on February 23, 2026: A. 2025 Quality Control API test results (e.g. pH and Assay test results) were observed to be documented on loose uncontrolled template paper for commercial API batches. According to the Production Manager, this document template is no longer in use as of 2026 and all the remaining uncontrolled documents previously filled with similar GMP data have already been shredded. There is no record of which GMP documents have been previously shredded in 2025 and the years prior. B. The Microbiology Department's Cleaning Record of Equipment Log No. F/MIC/008 was pre-dated with equipment cleaning (Frequency: (b) (4)) already completed on (b) (4), which is (b) (4) since the last equipment cleaning documented for completion on (b) (4). The logbook entry pre-dated for (b) (4) also included Done By, Checked By, and Reviewed By signatures that were already filled in as of (b) (4). C. According to the QA Manager, the Done By signature in Cleaning Record of Equipments Logbook is not signed by the actual person doing the work (Production Worker) due to English language barrier. The Done By signature name is instead filled in by the Microbiologist who also signs off on the adjacent Checked By column. D. (b) (4) Vessel No-1 (UNI (b) (4) /01) Preventive Maintenance Record Logbook page intended for (b) (4) was already pre-filled with observations for machine parts, including:		
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(b) (4) There is no documented reasoning as to why the observation page intended for (b) (4) were already prefilled without any signature or date. E. The Microbiology Department's Burning of (b) (4) Records Equipment Log No. F/MIC/005 was missing multiple entries of Laminar Air Flow (LAF) start and closing times. This is despite the Operated By and/or Checked By signatures already being completed. F. Multiple missing Checked By signatures in both the Equipment Logbook and Equipment Cleaning Logbook involving (b) (4) UNI (b) (4) /02 after the production operations completed on (b) (4) and then commencing again on (b) (4) (b) (4) UNI/ (b) (4) 02 is used for the manufacturing process involving (b) (4) Solution USP batches.		
OBSERVATION 4		
GMP training is not conducted with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them. Specifically, There is no documented GMP training (e.g. on Good Documentation Practices) and training on standard operating procedures applicable to the job functions of the Quality Control (QC) Lab Assistant, who is routinely involved with QC sampling activities and functions involving QC instrument cleaning and equipment upkeep. There is also a lack GMP and SOP training for the Production Worker responsible for routinely cleaning microbiology and QC laboratory equipment.		
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OBSERVATION 5 There is a failure to clean equipment and utensils to prevent contamination or carry-over of a material that would alter the quality of the API beyond the official or other established specifications. Specifically, There are no standard operating procedures or established instructions to perform and document a visual inspection of equipment subsequent to cleaning operations. For example: During my walkthrough of the Bulk Drug (API) Manufacturing Area on February 23, 2026, I observed that the (b) (4) of (b) (4) UNI (b) (4) 06 had visible (b) (4) residue product material all throughout the surfaces and (b) (4) gasket area. This is despite full equipment cleaning documented as already being completed on February 16, 2026. ***This is a Repeat Observation***			
*DATES OF INSPECTION 02/23/2026 (Mon), 02/24/2026 (Tue), 02/25/2026 (Weds), 02/26/2026 (Thurs), 02/27/2026 (Fri).			
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."