DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 1-301-348-3006 Industry Information: www.fda.gov/oc/industry	4/13/2026-4/17/2026
	FEI NUMBER 3017682080

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Naveen Sharma, President

FIRM NAME	STREET ADDRESS
Cliantha Research Limited	Tp 86, Fp 28/1, Off S.P. Ring Road, Sarkhej, Cliantha Corporate
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Ahmedabad, Gujarat, 382210, India	Biopharmaceutics Analytical and Clinical Facility

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) (WE) OBSERVED:

The following objectionable findings were observed during inspection of the analytical data:

1. The firm did not investigate significant variations in internal standard (IS) response across different studies consistently using criteria defined in SOP 100AB009 and SOP 100AB016. Specifically, the firm did not investigate a distinct inverse correlation between the analyte and IS responses in studies (b) (4) and (b) (4) (b) (4)) because the IS responses met established criteria (IS response within +/- 40% of the mean IS response of CCs and QCs). However, the firm investigated multiple subjects in studies (b) (4) and (b) (4) (b) (4)) where the IS response was lower than QC IS responses by (b) (4)% and the IS response criteria were met in all subjects investigated per SOP 100AB009 and SOP 100AB016.

2. The firm did not maintain all source documentation for bioanalytical studies. Specifically:
a. Details of samples transferred from freezer FDI-53 to freezer FDI-27 on 12 Apr 26 were recorded on a scrap piece of paper found in the trashcan of the first-floor freezer room, including the time of transfer (14:21 to 14:24) for the following studies:

- (b) (4) Set II subject samples and QCs
- Set I subject samples
- Set I and Set III samples
- Set II subject samples and QCs
- Set II subject samples and QCs

Sample movement details were subsequently transposed from the scrap paper to logbooks for freezers FDI-53 and FDI-27, and thus the logbooks are not the contemporaneous source documents.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	AMB KAA KAS MAM	Anna M. Brannen, Investigator Dr. Koffi A. Amegadje, Investigator Kara A. Scheibner, Ph.D., Pharmacologist Miguel A. Martinez, Chemist	04/17/2026

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b. Partial details of samples transferred from freezer FDI-10 to freezer FDI-44 were recorded on a scrap piece of paper found in the trashcan of the first-floor freezer room for the following studies:

- (b) (4) Set I
- Set I
- Set I

No date or time was recorded on the scrap paper, so the date and time recorded in the logbooks for freezers FDI-10 and FDI-44 cannot be verified. The logbooks are not the contemporaneous source documents.

3. The firm was unable to account for missing sample volume in samples from studies (b) (4), (b) (4), and (b) (4). Specifically:

a. In study (b) (4), aliquot 2 of subject (b) (6), period 4, sample 0.75hr was used for incurred sample reanalysis (ISR) because sufficient sample was not available in aliquot 1. However, only 100 uL from aliquot 1 of this sample was used during initial analysis of subject (b) (6) samples and the firm could not provide any accountability for use of the remaining of 300 uL out of 400 ul total sample volume in aliquot 1.

b. In study (b) (4) the aliquot 1 samples for subject (b) (6), period 2, 16hr and subject (b) (6), period 1, 2hr (100 uL used for each of 2 analyses out of 400 uL total sample volume) did not have enough volume remaining to be used for ISR analysis and aliquot 2 was used for ISR. The firm could not provide any accountability for use of the remaining sample volume in aliquot 1.

c. In study (b) (4), aliquot 2 of subject (b) (6), period 1, sample (b) (4) was used for ISR analysis because sufficient sample was not available in aliquot 1. However, 200 uL out of 700 uL total volume of aliquot 1 of this sample was used only once during initial analysis of subject (b) (6) samples and the firm could not provide any accountability for use of the remaining sample in aliquot 1.

4. The firm reported inaccurate data in the bioanalytical report for study (b) (4) ((b) (4)). Specifically, Section 5.1.2 of the report stated that aliquot 2 samples were not used in sample analysis. However, the logbook for freezer FWI-06 (A-AL-25-503) documented retrieval of aliquot 2 samples from subjects (b) (6) and (b) (6) on 07 Oct 2025 for use in ISR analysis and subsequent return of the samples on the same date.

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5. Your Quality unit failed to perform thorough and/or adequate laboratory investigations (identified by firm as event or incident) as required by the control procedure 100AB014, Version 4, Laboratory Event Management, Effective date: 23Jun2025; to ensure the appropriate root cause, propose adequate corrective / preventive actions, scientific justification to invalidate original result and management of events for any bioanalytical phase of method validation/study sample analysis, which may impact the quality and integrity of the results. However, the investigation is generated and concluded by analyst, reported as part of the remark section of the analytical worksheet, with no quality unit management review, consent or approval. This discrepancy and/or practice is permitted by your Bioanalytical Laboratory, QC Laboratory and QA unit. Examples of deficiencies are evidenced as follows:

a. During chromatographic run # 9 (for subject (b)(6), and (b)(6)) of study # (b) (4) (b) (4) injected on 08May2025 on instrument # AS-20. Disclosed that sample ID # (b)(4) and # (b)(4) chromatographic run contained no response for either of the (b) (4), or internal standard. An investigational run (re-injection identified as Investigation (b) (4)) was performed on 08May2025 that obtained both peak responses. The informal investigation was reported as part of the remark section of the analytical worksheet, with does not contain any quality unit management oversite, review, consent or approval.

b. During the chromatographic run #11 (for subject (b)(6), and (b)(6)) and run # 12 (for subject (b)(6), and (b)(6) of study # (b) (4) (b) (4) injected on 09May2025 on instrument AS-20- and AS-26, respectively. Disclosed chromatograms carry over co-eluting with main compound found to be due to short run time (7 minutes). An investigational run (re-injection identified as Investigation (b) (4)) was performed on 10May2025 performed with sample trials. Corrective action was addressed by changing run time to 10 minutes. The informal investigation was reported as part of the remark section of the analytical worksheet, with no quality unit management review, consent or approval.

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c. During the chromatographic run #27 (for subject (b) (6), and (b) (6) of study # (b) (4) (b) (4) injected on 21May 2025 on instrument AS-20. Disclosed low peak area response for sample ST-6. An investigational run (re-injection identified as Investigation (b) (4)) was performed on 21May2025. The informal investigation was generated and concluded by analyst\ that event was due to instrument error and excluded from the results table. This was reported as part of the remark section of the analytical worksheet, with no quality unit management review, consent or approval.

The following objectionable finding was observed during the clinical inspection of inspected study (b) (4):

6. Legally effective informed consent was not obtained from a subject or the subject's legally authorized representative.

Specifically, your general screening informed consent does not include a description of the specific procedures to be followed. You conducted mammograms, transvaginal ultrasounds, pap smears, and estradiol plasma concentrations on 48 enrolled subjects (plus extra subjects) prior to their study specific consent.

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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 judgement, 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."