World Health Organization

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Prequalification Unit Inspection Services
DESK ASSESSMENT
CONTRACT RESEARCH ORGANIZATION (CRO)
WHO PUBLIC REPORT
WHOPIR

Part 1	**General information**	
Company information		
Name of Company	Cliantha Research Cliantha Corporate	
Corporate address of the Company	TP 86, FP 28/1, Off S.P. Ring Road Sarkhej, Ahmedabad Gujarat 382210 India Tel# +91-2717-698500 *www.cliantha.com*	
Inspected site		
Name & address of CRO if different from that given above	Not applicable	
Clinical trial license number	Not applicable	
Desk assessment details		
Date of review	30 November – 1 December 2023 & 4 January 2024	
Product and study information covered by this desk assessment	Bioequivalence study of Sulfadoxine/ Pyrimethamine 500 mg/25 mg Dispersible tablets Bioequivalence study of Miltefosine Capsules 50 mg	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last)**	
AEMPS - Spanish Agency of Medicines and Medical Devices	Dates of inspection:	31 Jul - 04 Aug 23
	Type of inspection:	Routine GCP inspection of analytical study
	Unit:	Cliantha Research Limited Cliantha Corporate TP 86, FP 28/1 Off S.P. Ring Road, Sarkhej Ahmedabad - 382210, Gujarat India
	Type of study covered:	Bioequivalence study

US FDA	Dates of inspection:	15-19 Nov 2021
	Type of inspection:	Onsite inspection of bioequivalence study: The inspection was conducted in accordance with the BIMO Compliance Program 7348.003 (Clinical BA/BE).
	Unit:	Clinical unit Cliantha Research Limited TP 86 FP 28/1, Off S.P. Ring Road Sarkhej, Cliantha Corporate, Ahmedabad, Gujarat India
	Type of study covered:	Bioequivalence study
US FDA	Dates of inspection:	8-12 November 2021
	Type of inspection:	For remote record review of the site situated at Cliantha Research Ltd., Opposite Pushparaj Towers, Near Judges Bungalows, Bodakdev, Ahmedabad, 380054 Gujarat, India, the examination focused on the bioanalytical segment of the studies within the inspection's scope.
	Unit:	Bioanalytical
	Type of study covered:	Bioequivalence studies.
MHRA - UK	Dates of inspection:	07 – 11 & 14 – 16 June 2021
	Type of inspection:	Remote GCP Bioequivalence Inspection
	Unit:	Cliantha Research Limited, Opposite Pushparaj Towers Near Judges Bungalows Bodakdev Ahmedabad-380 054 Cliantha Research Limited Cliantha Corporate TP 86, FP 28/1 Off S.P. Ring Road, Sarkhej Ahmedabad - 382210, Gujarat India
	Type of study covered:	BE-study

Part 3	Summary of the last WHO inspection
Date and conclusion of most recent WHO inspection	The company was previously inspected during 25-29 June 2018 and was found to be compliant.
Brief description of the site's activities	Cliantha Research, a full-service Contract Research Organization (CRO), currently offers a comprehensive range of services in the Early Phase (BA-BE & Phase I), Late Phase (II-IV), Bioanalytical, Biosimilars, Nutraceutical, Dermatology, Biometrics, Cell Culture, and Consumer Research, with facilities spread across six sites in India, including three in Ahmedabad (Cliantha Corporate, Arista, and Templesafe - Archive facility), one in Vadodara, and two in Noida. Bioavailability/Bioequivalence studies are conducted at the Ahmedabad corporate office, Vadodara, and Noida locations, ensuring a diverse range of research capabilities.
Areas inspected during the last WHO inspection	The inspection focused on a bioequivalence study and covered all the sections of WHO GCP & GLP requirements, including the WHO guidance for organizations performing in-vivo bioequivalence studies.
Out of scope and restrictions (last WHO inspection)	Not applicable
WHO product(s) and clinical trial(s) covered by the last WHO inspection	Cycloserine capsule 250mg Sofosbuvir 400mg tablets
Abbreviations	**Meaning**
CCs	Calibration Curve standards
CAPA	Corrective and preventive action
CROMF	CRO master file
GCP	Good clinical practices
GLP	Good laboratory practices
NC	Non-conformity
NRA	National regulatory agency
QA	Quality assurance
QC	Quality control
SOP	Standard operating procedure
SRA	Stringent regulatory authority

Part 4	Summary of the assessment of supporting documentation

a) Clinical trial license granted by the local authority:

The grant of registration for the Bioavailability or Bioequivalence study center was officially awarded on February 26, 2021, by the National authority.

b) CRO Master File :

The CROMF document released by the organization on November 24, 2023, was electronically signed by the responsible individuals and received approval from the Company's President. The Master File included the necessary sections as per the relevant guidelines.

c) List of all regulatory inspections performed in the last 3 years and their outcome:

The list was provided.

d) Copy of any warning letter or equivalent regulatory action issued by any authority for the site:

Cliantha has not received any warning letter or regulatory actions issued by any authority for the site.

e) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the studies conducted for WHO product(s) has been performed and all matters dealt with:

A declaration certificate for the Quality Assurance audit, along with statements issued for both studies, has been provided. This declaration certifies that the studies underwent an audit conducted by the Quality Assurance team at Cliantha Research in accordance with in-house SOPs, the protocol, and relevant regulatory guidelines. These audit statements were included in the clinical study report submitted to the agency and have been duly enclosed and reviewed.

f) IRB/IEC clinical trial approval (including the approved protocol, the amended protocol and the consent form):

The study protocols and their associated documentation received approval from The Independent Ethics Committees.

g) A list of any study failures in the last three years:

A list of all studies conducted for WHO submission in the past three years has been provided.

h) Additional documents submitted:

CAPA plan(s) and proof of the plan’s implementation related to the respective stringent authority inspection report observations/deficiencies were also provided, where available.

ANVISA-Brazil inspection report certificate and the inspection report from NPRA-Malaysia for the inspection conducted from 3 October 2022 - to 7 October 2022 were also provided and reviewed.

The approval letter of CDSCO, dated 26 Feb 2021 was also submitted.

Part 5	**Conclusion – Desk assessment outcome**

Based on the previous WHO inspections and on the GCP/GLP/BE evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Cliantha Research, Cliantha Corporate*** located at **TP 86, FP 28/1, Off S.P. Ring Road, *Sarkhej, Ahmedabad, Gujarat 382210; India*** is considered to have performed the studies submitted to WHO PQT under an acceptable level of compliance with WHO guidelines.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 6	**List of guidelines referenced in this inspection report**

1. Guidance for organizations performing in vivo bioequivalence studies. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 9.
   Short name: WHO BE guidance or ***TRS996 Annex 9***
   https://apps.who.int/iris/bitstream/handle/10665/255338/9789241209960-eng.pdf?sequence=1&isAllowed=y

2. Good clinical laboratory practice (GCLP), WHO on behalf of the Special Programme for Research and Training in Tropical Diseases. Geneva, 2009
   Short name: WHO GCLP
   https://apps.who.int/iris/handle/10665/44092

3. Guidelines for good clinical practice for trials on pharmaceutical products. WHO Technical Report Series, No. 850, 1995 (pp. 97–137).
   Short name: WHO GCP
   https://www.who.int/publications/i/item/9241208503

4. Handbook – Good Laboratory Practice (GLP): quality practices for regulated non-clinical research and development – Annex I: The OECD Principles on GLP, 2nd ed., 2009. ***Short name: OECD GLP***
   http://www.who.int/tdr/publications/documents/glp-handbook.pdf

5. Standards and operational guidance for ethics review of health-related research with human participants. Guidance Document. Geneva, World Health Organization, 2011.
   Short name: WHO Ethics Committee Guidance
   https://www.who.int/publications/i/item/9789241502948

6. Guidelines for the preparation of a contract research organization master file, WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 7.
   Short name: WHO CROMF Guidelines or ***TRS No. 957, Annex 7***
   https://www.who.int/publications/i/item/WHO_TRS_957

7. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9.
   Short name: WHO storage and transport guidance or ***TRS 961 Annex 9***

https://apps.who.int/iris/bitstream/handle/10665/44079/WHO_TRS_961_eng.pdf?sequence=1&isAllowed=y

8. Glove use information leaflet, Patient Safety, Save lives clean your hands. Geneva, World Health Organization, 2009 (revised).
Short name: Glove use information leaflet
https://www.who.int/publications/m/item/glove-use-information-leaflet-(revised-august-2009)

9. Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. Republication of multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. WHO Technical Report Series No. 992, Annex 7 with a new appendix 2. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-first Report Geneva, World Health Organization, 2017 (WHO Technical Report Series, No. 1003), Annex 6.
Short name: TRS 1003 Annex 6
chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs1003-annex6-who-multisource-pharmaceutical-products-interchangeability.pdf

10. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4.
Short name: WHO TRS No. 1025, Annex 4
https://apps.who.int/iris/handle/10665/331814

11. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4.
Short name: WHO TRS 1033, Annex 4
https://apps.who.int/iris/handle/10665/340323

12. Declaration of Helsinki, World Medical Association Declaration of Helsinki, Ethical principles for medical research involving human subjects, Bulletin of the World Health Organization, 2001 (79(4)).
Short name: Declaration of Helsinki
https://apps.who.int/iris/handle/10665/268312

13. Bioanalytical Method Validation and Study Sample Analysis M10, ICH Harmonised Guideline, Final version, Adopted on 24 May 2022
Short name: ICH M10
https://database.ich.org/sites/default/files/M10_Guideline_Step4_2022_0524.pdf

14. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3.
Short name: WHO TRS No. 1019, Annex 3

https://www.who.int/publications/m/item/trs-1019---annex-3-good-manufacturing-practices-guidelines-on-validation

15. Supplementary guidelines on good manufacturing practices: validation, WHO Expert Committee on Specifications for Pharmaceutical Preparations, Frothiest report, World Health Organization, 2006 (Technical Report Series, No. 937), Annex 4.
Short name: WHO No. 937, Annex 4
https://apps.who.int/iris/handle/10665/43443ring-practices-guidelines-on-validation