# Prequalification Unit Inspection Services

**DESK ASSESSMENT**  
**CONTRACT RESEARCH ORGANIZATION (CRO)**  
**WHO PUBLIC REPORT**  
**WHOPIR**

<table>
<thead>
<tr>
<th>Part 1</th>
<th>General information</th>
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<tbody>
<tr>
<td><strong>Company information</strong></td>
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</tbody>
</table>
| 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 |
| 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 |

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<tr>
<th>Part 2</th>
<th>Summary of SRA/NRA inspection evidence considered (from most recent to last)</th>
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</table>
| 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 |
<table>
<thead>
<tr>
<th>Agency</th>
<th>Dates of inspection</th>
<th>Type of inspection</th>
<th>Unit</th>
<th>Type of study covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>US FDA</td>
<td>15-19 Nov 2021</td>
<td>Onsite inspection of bioequivalence study: The inspection was conducted in accordance with the BIMO Compliance Program 7348.003 (Clinical BA/BE).</td>
<td>Clinical unit Cliantha Research Limited TP 86 FP 28/1, Off S.P. Ring Road Sarkhej, Cliantha Corporate, Ahmedabad, Gujarat India</td>
<td>Bioequivalence study</td>
</tr>
<tr>
<td>US FDA</td>
<td>8-12 November 2021</td>
<td>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.</td>
<td>Bioanalytical</td>
<td>Bioequivalence studies</td>
</tr>
<tr>
<td>MHRA - UK</td>
<td>07 – 11 &amp; 14 – 16 June 2021</td>
<td>Remote GCP Bioequivalence Inspection</td>
<td>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</td>
<td>BE-study</td>
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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**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<tr>
<td>CCs</td>
<td>Calibration Curve standards</td>
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<tr>
<td>CAPA</td>
<td>Corrective and preventive action</td>
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<td>CROMF</td>
<td>CRO master file</td>
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<td>GCP</td>
<td>Good clinical practices</td>
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<tr>
<td>GLP</td>
<td>Good laboratory practices</td>
</tr>
<tr>
<td>NC</td>
<td>Non-conformity</td>
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<td>NRA</td>
<td>National regulatory agency</td>
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<td>QA</td>
<td>Quality assurance</td>
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<td>QC</td>
<td>Quality control</td>
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<td>SOP</td>
<td>Standard operating procedure</td>
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<tr>
<td>SRA</td>
<td>Stringent regulatory authority</td>
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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.

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<tr>
<th>Part 5</th>
<th>Conclusion – Desk assessment outcome</th>
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<tr>
<td>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.</td>
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Cliantha Research, Ahmedabad, India - CRO  
30 Nov – 4 Dec 2023 & 4 Jan 2024  
This inspection report is the property of the WHO  
Contact: prequalinspection@who.int
This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

### Part 6

<table>
<thead>
<tr>
<th>List of guidelines referenced in this inspection report</th>
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  *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](https://apps.who.int/iris/bitstream/handle/10665/255338/9789241209960-eng.pdf?sequence=1&isAllowed=y) |
  *Short name: WHO GCLP*  
  [https://apps.who.int/iris/handle/10665/44092](https://apps.who.int/iris/handle/10665/44092) |
  *Short name: WHO GCP*  
  [https://www.who.int/publications/i/item/9241208503](https://www.who.int/publications/i/item/9241208503) |
  *Short name: OECD GLP*  
  *Short name: WHO Ethics Committee Guidance*  
  [https://www.who.int/publications/i/item/9789241502948](https://www.who.int/publications/i/item/9789241502948) |
  *Short name: WHO CROMF Guidelines* or *TRS No. 957, Annex 7*  
  [https://www.who.int/publications/i/item/WHO_TRS_957](https://www.who.int/publications/i/item/WHO_TRS_957) |
  *Short name: WHO storage and transport guidance* or *TRS 961 Annex 9* |

Cliantha Research, Ahmedabad, India - CRO

30 Nov – 4 Dec 2023 & 4 Jan 2024

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Contact: prequalinspection@who.int
   **Short name: Glove use information leaflet**
   [https://www.who.int/publications/m/item/glove-use-information-leaflet-(revised-august-2009)](https://www.who.int/publications/m/item/glove-use-information-leaflet-(revised-august-2009))

   **Short name: TRS 1003 Annex 6**

    **Short name: WHO TRS No. 1025, Annex 4**
    [https://apps.who.int/iris/handle/10665/331814](https://apps.who.int/iris/handle/10665/331814)

    **Short name: WHO TRS 1033, Annex 4**
    [https://apps.who.int/iris/handle/10665/340323](https://apps.who.int/iris/handle/10665/340323)

    **Short name: Declaration of Helsinki**
    [https://apps.who.int/iris/handle/10665/268312](https://apps.who.int/iris/handle/10665/268312)

    **Short name: ICH M10**

    **Short name: WHO TRS No. 1019, Annex 3**

*Short name: WHO No. 937, Annex 4*

https://apps.who.int/iris/handle/10665/43443ring-practices-guidelines-on-validation