REGULATORY INSPECTION MATRIX

Name of Regulatory Authority	Scope of Inspection	Inspection Dates	Inspection Status
United States Food and Drugs Administration **(USFDA)**	Clinical Review	29-May-2024 to 04-Jun-2024	No form 483, EIR awaited
	Bioanalytical Review	06-May-2024 to 10-May-2024	No form 483, EIR awaited
	Bioequivalence: Good Clinical Practice (GCP) Inspection/ Clinical Facility	04-Jul-2022 to 08-Jul-2022	EIR Dated: 09-Jan-2023 (No observations)
	Remote Record Review	18- Apr-2022 to 21 - Apr-2022	Close out on 21-Apr-2022 (No observations)
Medicines & Healthcare products Regulatory Agency **(MHRA)**	Bioequivalence Good Clinical Practice (GCP) Inspection	9-Aug-2021 to 13-Aug-2021	Received approval on 15-Nov-2021
	Bioequivalence Good Clinical Practice (GCP) Inspection	6 -Mar-2017 to 10-Mar-2017	Received approval on 11-May-2017
World Health Organization **(WHO)**	Bioequivalence: Good Clinical Practice (GCP) Inspection	22-Jan-2024 to 26-Jan-2024	Received approval on 03-Apr-2024
	Bioequivalence: Good Clinical Practice (GCP) Inspection	24-May-2022 to 27-May-2022	Received approval on 07-Sep-2022
	Bioequivalence Good Clinical Practice (GCP) Inspection	16 -Apr-2018 to 19-Apr-2018	Received approval on 20-Jul-2018
National Pharmaceutical Regulatory Agency **(NPRA)**	Surveillance inspection	24-Jun-2024 to 28-Jun-2024	Inspection report received, Compliance response submitted
	Extension of validity of Approval	NA	Validity Extension - NPRA Compliance Certificate 21-Nov-2023
	Extension of validity of Approval	NA	Validity Extension - NPRA Compliance Certificate 24-Nov-2022
	Bioequivalence Centre Compliance	23- Sep-2019 to 27-Sep-2019	Received approval on 08 Feb -2020

REGULATORY INSPECTION MATRIX

	Programme /Surveillance Inspection		
	Bioequivalence Centre Compliance Programme	03-Oct-2016 to 7-Oct-2016	Received approval on 08-Feb-2017
Central Drugs Standard Control Organization **(CDSCO)**	Approval of Additional number of beds (100 beds to 166 beds)	10-Apr-2023 to 11-Apr-2023	Received approval on 06-Jun-2023
	Facility Renewal	18 -Aug-2020 to 19 -Aug-2020	Received approval on 09-Dec-2020
	Facility Renewal	11-Oct-2017	Received approval on 15-Nov-2017
	Facility Renewal	29-Apr-2016	Received approval on 05-Jul-2016
	Facility Approval	31-Oct-2012	Received approval on 23-Jan-2013 Name Change: Received amendment on 19-Feb-2013

U.S. FOOD & DRUG ADMINISTRATION

January 9, 2023

Raman Batheja
Chief Operating OfficerVerGo Pharma Research Laboratories Private Limited
Plot No. 24-1, D1 Mologo De Orora, Corlim
Tiswadi, Goa, 403110 India

Dear Raman Batheja,

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your premises, **VerGo Pharma Research Laboratories Private Limited, Plot No. 24-1 D1 Mologo-de-orora Corlim, Tiswadi, Goa, India**, by the United States Food and Drug Administration (FDA) from **July 4 to July 8, 2022**.

The Agency has concluded that this inspection is closed under 21 CFR 20.64(d)(3). We are therefore releasing a copy of the EIR for the inspected establishment to you. The EIR being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and Title 21, Code of Federal Regulations, part 20. However, this does not preclude you from requesting, and possibly obtaining, any additional information provided under FOIA.

The documents provided to you under FDA's FMD-145 Program have not been reviewed for public disclosure, and may contain confidential commercial information (e.g., applicant protocol information) and/or patient information (e.g., patient initials) that you already know in your capacity. FDA would normally redact this type of information before allowing the EIR's public disclosure. **If you were to disclose this information to others, you would be responsible for ensuring that sensitive information is adequately protected.**

If you would like a copy of the EIR that has been reviewed by FDA and redacted for public disclosure, you will need to submit a FOIA request specifically asking for a publicly disclosable version.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

If you have any questions about the released information, please contact me via email at CDER-OSIS-BEQ@FDA.HHS.GOV.

Sincerely,

Sean Kassim -S Digitally signed by Sean Kassim -S
Date: 2023.01.11 12:38:38 -05'00'

Sean Y. Kassim, Ph.D.
Office Director
Office of Study Integrity and Surveillance
Office of Translational Sciences
Center for Drug Evaluation and Research
Food and Drug Administration
Building 22, Room 1442
10903 New Hampshire Avenue
Silver Spring, MD 20993

Enclosure: Establishment Inspection Report (narrative portion only)

TABLE OF CONTENTS

SUMMARY

This was a Comprehensive FY22 [redacted] Surveillance BIMO Inspection [redacted] at the request of the Center for Drug Evaluation and Research (CDER), Office of Study Integrity and Surveillance, Division of New Drug Bioequivalence Evaluation and Research [redacted] It was carried out under [redacted] Compliance Program 7348.003, In Vivo Bioavailability/Bioequivalences Studies (Clinical), [redacted] for the following clinical trials:

- Study 009-20, entitled "A [redacted] bel, Balanced, Randomized, Single-Dose, Two-Treatment, Two Sequence, Two Period Cross-over, Oral Bioequivalence Study Comparing [redacted] with [redacted] 27709, United States in healthy, Adult, Human Subjects Under Fasting Conditions."
- Study 010-20, entitled "An Open Label, Balanced, Randomized, Single-Dose, Two-Treatment, Two Sequence, Two Period Cross-over, Oral Bioequivalence Study Comparing [redacted] with [redacted] 27709, United States in healthy, Adult, Human Subjects Under Fed Conditions."

The inspection covered a review of records, study procedures, and firm SOPs related to the authority, administration and conduct of the above mentioned clinical studies; Institutional Ethics Committee (IEC) submissions, approvals and oversight; subject selection, informed consents; investigational medication controls such as receipt, storage, dispensation, dosing and accountability; source data evaluation and practices; medical supervision and adverse event reporting and handling; retention/reserve samples; and concomitant therapies. Randomization schedules were compared with case report form verifying the schemes were adhered to.

The following are statistics of the reviewed studies:

- 009-20
  - Screened: 86
  - Enrolled: 72 + 2 Standby
  - Completed: 72 Dosed Period I; 71 Period II
  - Withdrawn: 2 during Period I with Standbys substituted
  - Deaths/SAEs: 0
  - Source Reviewed:
    - ICF: 50% of Enrolled Subjects
    - Source: 10 of 72 Enrolled Subjects
    - Data Listings: 10 of 72 Enrolled Subjects
    - Same protocol and ICF as supplied in background information
- 010-20
  - Screened: 61
  - Enrolled: 56 + 2 Standby
  - Completed: 56 Dosed Period I; 50 Dosed Period II
  - Withdrawn: 6 did not attend Period II due to travel/heavy monsoon rains
  - Deaths/SAEs: 0
  - Source Reviewed:
    - ICF: 50% of Enrolled Subjects
    - Source: 10 of 56 Enrolled Subjects
    - Data Listings: 10 of 56 Enrolled Subjects
    - Same protocol and ICF as supplied in background information

The studies were performed at the VerGo Clinical site address listed above in Goa, India. There is no history of previous FDA inspection at this clinical site, however a Remote Bioanalytical Record Review was performed by CDER/OSIS/Office of Translational Sciences covering method validations was performed during the February to April time periods of 2022. According to Dr. Raman Batheja, COO of VerGo; no aberrant issues were found. The current inspection disclosed no significant violations; no Form FDA 483, Inspectional Observations, was issued. There was one discussion item regarding expanding the firm's follow-up procedures for withdrawals.

Retention/Reserve samples (firm uses the term 'Archived' samples) were retained at the site. A reconciliation was confirmed along with identification of the lots being the same as used in the studies. No samples were collected. No refusals were encountered during the inspection.

ADMINISTRATIVE DATA

Inspected firm:	VerGo Pharma Research Pvt., Ltd.
Location:	Plot No. 24/1, D-1 Mologa De Orora, Corlim, Tiswadi, Goa, 403 110 India Tiswadi, Goa 403 110 India
Phone:	(+91)08326640564
Mailing address:	Plot No. 24/1, D-1 Mologa De Orora, Corlim, Tiswadi, Goa, 403 110 India
Email address:	raman.batheja@vergoclinicals.in
Website:	www.vergolabs.com
Dates of inspection:	7/4/2022-7/8/2022
Days in the facility:	5
Participants:	**Stuart W Russell, Investigator - Dedicated BIMO Cadre**

Non-FDA Participants: Not Applicable

The inspection was pre-announced through FDA's Foreign Travel Branch due to it requiring international travel during the Covid-19 pandemic. At the beginning of the inspection, I presented my FDA credentials to Dr. Raman Batheja, Chief Operating Officer. Also present at the opening meeting were:

- Mr. Pradip Kumar, Assistant General Manager Quality Assurance
- Mr. Kiran Kumar Vuppalavanchu, Assistant General Manager Clinical Research
- Mr. Keshav Khude, Head Manager of Bioanalytical Department

Dr. Batheja, COO was available throughout the inspection to answer questions as needed. All information contained in this report was supplied by Dr. Batheja, Pradip Kumar and Kiran Kumar Vuppalavanchu. An opening presentation was given by the firm providing an overview of the facility, operations and staff (**Exhibit #1**).

HISTORY

VerGo Pharma Research Private Limited, hereafter referred to as VG, is a Biopharmaceutical Clinical/Bioanalytical Facility conducting FDA regulated research in Goa, India. Previously the site operated under the name 'TEVA' and was under different ownership. The current facility was founded in 2010, gained ISO 15189 status in 2012, started operations in 2013, and is owned

by Mr. Prasad Keni, Chairman & Managing Director. The firm provides clinical pharmacology testing services, particularly for generic drugs. The firm does not handle controlled substances.

The facility is equipped for sequestered trials with 3 clinical units of 14, 38, and 48 beds. Operations can be 24 hours a day with an attending physician on-site. Normal business operations are 9:00 AM to 6:00 PM, Monday through Friday with additional operations on alternating Saturdays. I observed current personnel, the clinical investigators, and the facility management to be knowledgeable on Good Clinical Practices and their SOPs. Observed processes were performed well and in a timely manner. The clinical investigator responsible for the clinical research covered during this inspection was Dr. Mirza Mulla.

Post inspectional correspondence between VG and the agency should be directed as follows:

Dr. Raman Batheja, COO
VerGo Pharma Research, Pvt., Ltd.
Plot No. 24/1, D-1 Mologa De Orora,
Corlim, Tiswadi, Goa, 403 110
India
Email: raman.batheja@vergoclinicals.in

INTERSTATE COMMERCE / JURISDICTION

This site conducted research, producing data in support of the [redacted] The FDA regulates clinical studies authorized under §505(i) (drugs & biologics) of the Federal Food, Drug, and Cosmetic Act. The current inspection assessed the Clinical Bioequivalence site's validity of data produced and the adherence to the above stated drug study protocols conducted for the eventual use of [redacted] tablets in the United States.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Prasad Keni, Chairman & Managing Director/Owner: He oversees the Quality Management Division and authorizes large expenditures. He owns VerGo Pharma Research, Pvt., Ltd. of which VerGo Clinicals (current inspected entity) is a division.

Dr. Raman Batheja, Chief Operating Officer: In charge of day to day operations and activities at VerGo (VG). He hires/fires and signs off on firm SOPs, Protocols, assigns clinical investigators, and approves vendors. He has been at VG since 2013.

Kiran Kumar, Head Clinical Manager: Oversees medical writing team/protocol development, coordinates studies, training, hiring, SOP review. He has been at VG for 5 years.

Dr. Rajan Sharma, Principal Investigator (Mirza Mulla is his backup): These act as the Principal

Investigators or backup for each other for VG clinical studies. Other sub-investigators act under their supervision. They have authority to make medical decisions/interpretations. The PIs submit study information and communication to the Ethics Commission.

Keshav Khude, Head Bioanalytical Manager: In charge of bioanalytical operations and methods used; recommends purchases for lab and oversees staff.

Pradip Kumar Nanakbava, Head QA Manager: Oversees the site's QA operations and reports to the owner of the facility. He is in charge of vendor audits, internal audits, project audits, document change control and management, assessing and establishing CAPAs for deviations.

Pharmacists: Receives IP shipments, randomly selects study drug to be dispensed and dosed, thus randomly selecting reserve samples; their handling, storage and reconciliation.

Dr. Batheja, COO was available throughout the inspection to answer questions as needed. All information contained in this report was supplied by Dr. Batheja, Pradip Kumar and Kiran Kumar Vuppalavanchu.

Please refer to **Exhibit #2** for a copy of the firm's research facility's organization list and **Exhibit #3** for the firm's study list.

FIRM'S TRAINING PROGRAM

Upon initial hire, the employee is trained on firm SOPs pertinent to their job description. Training may be performed by QA, an individual with that specialty or the department head. A listing of the training is maintained along with written and oral competency testing. Similarly, specific protocol training is performed in the same way and training must be signed off by the trainer/department head, QA, and the COO. I reviewed selected training and found no issues of concern. Training is described in the firm's SOP QA005-05.

OPERATIONS

VG performs approximately 50-60 bioclinical studies per year. The site maintains two archive units with reserve samples stored in the pharmacy. The archivist is Shruei Mangutti.

The two audited clinical trials were conducted in Goa, India at VG. The clinical trials assessed the time and PK levels compared to the reference drug under Fasting and Fed conditions:

- Study 009-20, entitled "An Open Label, Balanced, Randomized, Single-Dose, Two-Treatment, Two Sequence, Two Period Cross-over, Oral Bioequivalence Study Comparing [redacted] of [redacted] States in healthy, Adult, Human Subjects Under Fasting Conditions."
- Study 010-20, entitled "An Open Label, Balanced, Randomized, Single-Dose, Two-Treatment, Two Sequence, Two Period Cross-over, Oral Bioequivalence Study Comparing

[redacted]

States in healthy, Adult, Human Subjects Under Fed Conditions."

ORGANIZATION

Responsible Persons

The most responsible individual for the operations at VG is Dr. Raman Batheja while the most responsible individual for day to day clinical operations is Kiran Kumar. The medical oversight for two clinical trials were Dr. Mirza Mulla and Dr. Raja Sharma. Please refer to Individual Responsibility and Persons Interviewed section of this report for further information related to their roles and responsibilities.

Personnel

VG has 123 full-time employees with 51 dedicated to the clinical team and 34 dedicated to the bioanalytical section. There are 9 on the medical team and 14 in the QAU. Refer to **Exhibit # 2** for an Organizational Chart on the reporting line which terminates with the Managing Director, Prasad Keni. Official correspondence should be directed to the Chief Operating Officer, Dr. Batheja. The following local Institutional Ethics Committee (IEC) provided oversight for these clinical trials:

Aavishkar Ethics Committee
St. Xavier Residency, Building A1,
Shop No: S6, NH4 Highway, Phase I,
Old Goa, Goa – 403402
Chairman: Dr. Padmanabh V. Rataboli

Clinical Site and Equipment

A tour of the clinical site's facility did not result in the observation of any objectionable conditions that would impact or impede the custody, processing and/or storage of drug products, biological samples, or records. This includes parts of the facility where general screening occurs, subject consulting and testing occurs, bedding area, pharmacy, dosing/sampling areas, dining rooms, recreational rooms, and lockers (**Exhibit #4** – Floorplan). Synchronized clocks are found throughout the facility and utilized in the dosing and sampling areas.

Inspection of the study test article storage areas and procedures found no observational issues that would potentially cause contamination or mix-up. The pharmacy has limited access where the study drugs are stored in a temperature/humidity controlled chamber on a dedicated shelf and where only the pharmacist and clinical investigator have access. The study storage area is monitored centrally by security and alarmed through the EuroTherm system. A review of

temperature monitoring logs found no objectionable conditions. Areas for where biological samples are collected, processed, and stored had no observable objectionable conditions. The clinical site had standard operation procedures (SOPs) and they appeared to be up to date and accessible to all individuals in each respective area. Multiple SOPs were reviewed in full with no issues of concern discovered. Calibration and maintenance of equipment is performed yearly mostly by in-house facility management personnel with some equipment calibrated by outside vendors. I reviewed agreements with outside vendors such as radiographic services, ECG interpretation, hospitals, and biohazard maintenance and found no issues.

The clinical facility is a Phase I unit with the ability to sequester subjects in a closed system. Visitors are not allowed and subjects are thoroughly checked for potential contraband.

Study Administration and Responsibility

Administrative

Please refer to Exhibit #3 for a copy of the research facility's study list and **Exhibits #5 & #6** for the signed FDA Form 1572s, Statement of Investigator, for the audited studies 009-20 and 010-20.

Study Responsibility

A review of the Protocol training records, Delegation of Authority Log, curriculum vitae, medical licenses, lab certifications and study documentation found no objectionable observations to the delegation of study tasks. All study personnel appeared to be adequately trained and possessed the requisite experience needed to complete tasks for which they were delegated.

The clinical investigators for both audited clinical trials, Dr. Mirza Mulla and Dr. Raja Sharma, or the sub-investigators were involved in the consenting and screening of subjects. All dosing of subjects was performed by the delegated study personnel with QC, QA, an assistant and the Principal Investigator in attendance. There was no change of investigator or needed backup during the conduct of this trial. No staff were involved in the study that had not undergone training for their respective duties.

Laboratory safety samples were collected and analyzed by VG labs. I reviewed the lab certification and found it to be in order. These samples are collected and immediately taken for processing, aliquot collection and storage. I reviewed the SOP for sample collection, transport and storage and found no objectionable conditions.

SUBJECT RECORDS

Subjects were procured from the firm's database of 14,500 already registered subjects. The surrounding area has a population of 1.8 million. I reviewed the generic recruiting advertisement and brochure which was found to be Ethics Committee approved. After qualifying as a healthy individual per the firm's generic screening process, they may be considered for the specific study.

The total screened number of subjects may or may not represent screen failures as the screening process ends once the protocol specified number of subjects is reached. Government issued ID or biometrics are collected to identify the participants.

Source Records

The source documentation for each audited clinical trial appeared to be attributable, legible, contemporaneous, original, and accurate. A review of source documentation found that subjects enrolled in each clinical study appeared to meet inclusion/exclusion criteria. No significant discrepancies were found regarding subject data submitted to the agency from this clinical site. I confirmed subjects were dosed according to the randomization schedule. I reviewed 50% of the Ethics Committee approved ICFs, and fully reviewed subject source documentation for 10 subjects in periods I and II for both audited studies. This review included consenting, meeting inclusion/exclusion, dosing and sampling, deviations, vitals, BMI, adverse events, laboratory and ECG results, X-Rays, alcohol and drug testing, pregnancy testing, conmeds, and follow up.

No serious adverse events were observed at the clinical site and all adverse events observed were reported. No concomitant therapies were discovered. No significant discrepancies were found according to each protocol.

All subjects were seen at the audited clinical site. The subject numbers and demographics appeared to meet the requirements of the study protocol. Subjects were healthy screened subjects and there were no reported screen failures. There were 2 subjects that withdrew for personal reasons in study 009-20 with a standby that took one's place. There were 6 subjects that withdrew due to transportation/heavy rains with no substitutes in study 010-20. Dosing with study test article only took place at the audited clinical site.

Subject 43 did not check-in for Period II for study 009-20 after completing Period I. The firm attempted to contact the subject multiple times, finally reaching them on 3 June 2021, they had the subject return for the post-study follow-up safety visit on 6 June 2021 (**Exhibit #12**). The site did not elicit the reason for the failure to check-in. I discussed this with the firm stating that determining the reason of a no-show could reveal adverse events that were unknown which could impact the study. Subject 33 had slightly high levels for ALT/AST, considered not clinically significant. I noted the investigator continued to monitor this for safety over the next two follow-up periods with values returning to normal range.

Subject 51 withdrew from the study prior to dosing in Period I, study 010-20. The firm cited the subject withdrew their consent for unspecified reasons. This subject was replaced by standby E251. Subjects 2, 7, 20, 22, 28, and 30 did not return for check-in at period II for study 010-20. The COO cited weather was the reason for the no-shows as it was monsoon season and heavy rains produced travel restrictions. Dr. Batheja showed me a newspaper clipping saved from this time period to document this incident.

Informed Consent

The site used a general informed consent for screening to accept the subjects into the healthy subject database from which the protocol selected participants were obtained from and then consented with the protocol specific informed consent which was approved by the Ethics Committee prior to use. Informed consent forms contained the required components and were obtained by the principal investigators and sub-investigators. The consent forms were given in written format and were also reviewed verbally. The general screening procedures assess the literacy of the prospective subjects. Copies of the consent form were provided to the subjects. Subject identification is well controlled with number identifiers and picture IDs.

The language for the forms were in either English, Hindu or the local dialect, Marathi. The appropriate version of the consent forms were used. No short form was used during the audited clinical trial. The IEC approval letters for each clinical trial had no additional stipulations required for the consenting of subjects. All subjects signed the required consent forms prior to enrollment in the clinical trial.

STUDY RECORDS

A review of other study records such as administrative study files, correspondence files, sign-in logs, Sponsor monitor visit logs, financial disclosure records, and written agreements found no significant objectionable conditions.

TEST ARTICLE ACCOUNTABILITY AND DISPOSITION

090-20 & 010-20

A single shipment of Test IP and a single shipment of Reference drug was sent to the site for both studies.

On April 23, 2021, the sponsor sent a single shipment of study test article, which contained nine bottles of the test drug via World Courier for Arcolab, Pvt., Ltd. to VerGo. **Exhibit #7** contains the waybill for the test drug sent to VerGo along with temperature monitoring, [redacted]CofA, VerGo receiving document, and Arcolab's invoice with package content. **Exhibit #8** contains the airwaybill from Marken for shipment of the reference drug from Espee Biopharma & Finachem LLC of Schaumburg, IL USA to VerGo, received on 21 Oct 2020, along with temperature monitoring, CofA, site inventory information, and Espee Invoice with package content. Batch/Lot #s of the Test product (#7245252) and reference product (#E76Y) matches the reserve samples randomly selected by the pharmacist that I viewed during the inspection (**Exhibit #9** – Pictures of 009-20 & 010-20). Manufacturing and expiration dates match those of the reserve samples.

Reserve Samples Selection, Identification, Storage, and Collection

I reviewed VG's SOP for reserve samples and found no issues or issues with compliance. The reserve samples appeared to be stored in conditions set forth by the supplier and protocols. These were stored onsite and not by a third party. No issues were observed regarding the quantity of reserve sample collection. Review of the study test articles reserved found that at least one

unopened bottle of each study test article was collected. The pharmacist labeled the received Test IP and Reference original bottles 1 of 'x' bottles and randomly selected these bottles to be used for dispensing/dosing while holding back those unopened bottles from the same lot to become the reserve samples (**Exhibit #9**). Reserve samples were stored in the pharmacy under specified storage conditions with limited controlled access. The reserve samples were attested to by the COO on VerGo letterhead (**Exhibit #10**).

NOTE- study 010-20, period II, bottle 3 of 9; the firm discovered this supplied bottle was 1 tablet short of the listed count. 59 of 60 were present. The sponsor, [redacted] was notified by VerGo. This should be noted in the event of a GMP inspection at [redacted] in India.

A review of the clinical site's drug accountability records found no deviations of a significant nature. Reconciliation of the study test articles found no deviations. The dosing of subjects was in accordance with the EC approved protocol. Documentation provided to me confirms the lot codes of the study test articles used at VG matches what was shipped, received and dosed. No issues were observed regarding the storage, dispensation, and dosing of subjects with the study test articles.

Collection Processing, and Storage of Study Samples Subject to Bioanalysis

I actively viewed dispensing, dosing, and sampling procedures for another study which had similar procedures to the audited studies. I found no discrepancies and staff were observed to be on time and proficient in their duties. The review of source documentation for the collection of blood samples against the requirements of the protocol found no significant systematic deviations. Deviations found matched those already reported in the background materials supplied with the assignment (example- Study 009-20; Subject 37 for periods I and II, and study 010-20 for Subjects 02 and 07, periods II). A centralized synchronized clock is present within all study activity areas in the facility and I witnessed staff adhering to its use.

A review of VerGo's SOPs related to sample collection found no issues related to potential risks to sample integrity. All study samples appeared to have been collected within protocol specified ranges. No samples appeared to be missing during the study except those identified already.

Sample shipment records are not available since all samples are processed within the VG facility however the SOP for sample transport was reviewed and found to be adhered to. Issues with sample processing, like hemolysis, were documented. A review of the calibration and maintenance records in the trial master files and 'stickered' labels on the devices revealed no significant issues.

Randomization

The audited studies were all open label clinical trials. The randomization schedules were not collected as they were identical to that supplied in the background materials/study report. No discrepancies were observed with the content of the randomization schedule, both with the use of study test articles at the clinical site and with what was reported to the agency. Given these

clinical trials were open label, the randomization schedule did not need to remain sealed.

Blinding Codes

The audited clinical trials were open label, no blinding codes were used in the conduct of them.

Review of Electronic Data

This was primarily a hardcopy CRF study. Electronic data was not reviewed because VG does not use site specific electronic data capture systems in its clinical trials.

FINANCIAL DISCLOSURE FORMS

I verified financial disclosures were on file for all individuals included on the FDA 1572 forms and no conflicts of interest were reported.

MANUFACTURING CODES

See **Exhibits #7-#10** for batch/lot codes, manufacturing dates, expiration dates used in these studies.

OBJECTIONAL CONDITIONS

No FDA Form 483 was issued at the conclusion of the inspection.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

A close out meeting was held on 8 July 2022 with Dr. Raman Batheja, COO; Mr. Pradip Kumar, QA Head Manager; and Mr. Kiran Kumar, Clinical Research Head Manager in attendance. I provided FDA contact information and described the enforcement tools and inspectional classifications available to the FDA. [redacted] I advised them that no FDA Form 483, Inspectional Observations, was being issued and recommended detailing the reason for a Subject's withdrawal as it could potentially reveal untold adverse events

ADDITIONAL INFORMATION

A listing of the Firm's SOPs Index was collected as **Exhibit #11**. SOPs reviewed consisted of GN004-05, GN010-06, GN019-05, QA005-05, QA009-05, QA012-07, QA017-07, QA018-03, CR028-07, CR037-10, CR039-05, CR044-04, CR048-06, CR082-10, CR106-07.

A USB with original collected documents was collected and scanned for threats. The USB remained in the possession of Investigator Russell and was placed and sealed in an FDA Form 525 envelope for archival purposes and listed below as an **Exhibit #13**.

A CD-ROM with original photographs is attached as a hardcopy **Exhibit #14**.

SAMPLES COLLECTED
No samples were collected.

VOLUNTARY CORRECTIONS
Not applicable.

EXHIBITS COLLECTED
1) VerGo Presentation, pgs. 13
2) Organization List, pgs. 5
3) VerGo List of Studies, pgs. 59
4) VerGo Floorplan, pgs. 5
5) Form FDA 1572, Study 009-20, pgs. 2
6) Form FDA 1572, Study 010-20, pgs. 2
7) Shipping Documentation for Test Product, pgs. 13
8) Shipping Documentation for Reference Product, pgs. 8
9) Test Product & Reference Product Photos for studies 009-20 & 010-20, pgs. 13
10) VerGo Letterhead Attestation of Reserve Test Drugs, pgs. 2
11) VerGo SOP Index, pgs. 15
12) Study 009-20, Subject 43 Follow Up Log, pg. 1
13) USB containing original collected documentation, pg. 1
14) CD-ROM containing Test Drug Photos for 009-20/010-20 Studies, pg. 1

[redacted]

Stuart W. Russell -S
Digitally signed by Stuart W. Russell -S
Date: 2022.08.05 13:49:01 -07'00'

Stuart Wm. Russell
Investigator – Dedicated BIMO Cadre

From:	Javidnia, Monica
To:	Raman Batheja
Cc:	Sanyal, Sarmistha; Lewin, Amanda; Au, Stanley; Cho, Seongeun (Julia); Benson, Kimberly; CDER OSIS BEQ
Subject:	Remote Record Review Close-out – VerGo Pharma Research Pvt., Ltd.
Date:	21/04/2022 18:15:23
Attachments:	image001.png

Dr. Batheja,

The Office of Study Integrity and Surveillance thanks you for your participation in this remote record review. We appreciate your cooperation over the past several days to meet virtually via Zoom and provide a virtual tour of your facility, engage in discussions with your staff and respond to questions to understand your operations, and provide documents via Box.com in response to requests.

As previously stated at the opening meeting, because this is not an establishment inspection, Form FDA 483 will not be issued at the close-out of the remote record review. Instead, any objectionable conditions, if identified during the remote record review, would be shared with you and your team in writing at the close-out of the remote record review.

During the current remote record review, we did not identify objectionable conditions and thus do not have any observations to discuss at the close-out meeting.

Because this is not an inspection, you will not be receiving a copy of the Establishment Inspection Report (EIR). However, a summary report will be provided to you. If the summary report is not received within 6 months, please contact us using the CDER-OSIS-BEQ@fda.hhs.gov.

In order to improve future remote record reviews, we would like to get your feedback on what went well and what could have gone better. You may submit your feedback to the following email address: CDER-OSIS-BEQ@fda.hhs.gov.

Sincerely,

Monica
Monica Javidnia, PhD
Staff Fellow, Division of Generic Drug Study Integrity
Pronouns: She/Her

Office of Study Integrity and Surveillance
Office of Translational Science
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-6642
Monica.Javidnia@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Dr. Raman Batheja
Chief Operating Officer, Site Head
VerGo Pharma Research Pvt. Ltd.
(Division – VerGo Clinicals)
Plot No 24/1, D-1, Mologa de Orora
Corlim, Tiswadi, Goa- 403110, India

Dear Dr. Batheja:

The purpose of this letter is to inform you in writing of the outcome of a U.S. Food and Drug Administration (FDA) remote record review conducted at VerGo Pharma Research Pvt., Ltd. in Goa, India during 4/18/2022 – 4/21/2022 by Dr. Monica Javidnia and Dr. Sarmistha Sanyal.

This remote record review was conducted under FDA's Bioresearch Monitoring Program which was established to assure the quality and integrity of data submitted to the agency in support of review of marketing applications, as well as to provide for protection of the rights and welfare of subjects involved in FDA regulated research..

No objectionable conditions were observed during the remote record review and discussed at the close-out meeting. No response to this letter is necessary.

We appreciate your cooperation during the remote record review. Should you have any questions or concerns regarding this letter or the remote record review, please send all correspondence to:

CDER-OSIS-BEQ@fda.hhs.gov

Seongeun Cho -S
Digitally signed by Seongeun Cho -S
Date: 2022.05.11 16:40:03 -04'00'

Seongeun Cho, Ph.D.
Director
Division of Generic Drug Study Integrity
Office of Study Integrity and Surveillance
Office of Translational Sciences
Center for Drug Evaluation and Research
United States Food and Drug Administration

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

GCP INSPECTION STATEMENT

Inspection Number	INSP GCP 44392/13345432-0002
Type and Purpose of Inspection	Bioequivalence Good Clinical Practice (GCP) Inspection
Organisation Inspected	VerGo Clinicals
Organisation Address	Plot 24/1, D-1 Mologa de Orora Corlim Tiswadi, Goa-403110 India
Organisation Type	Contract Research Organisation
Dates of Inspection	9th – 13th August 2021
Lead Inspector	Jason Wakelin-Smith, Lead Senior GCP & GLP Inspector
Accompanying Inspector	Michael McGuinness, Senior GLP & GCP Inspector
Date of Inspection Statement	15 November 2021

The organisation has provided corrective and preventative actions in response to the inspection report. These have been reviewed by the GCP Inspectorate and are considered acceptable. This inspection can be considered closed.

In summary:
There were no “critical” findings identified during this inspection.
There were no “major” findings identified during this inspection.

The factual matter contained in the GCP Inspection Report relates only to those things that the Inspection team saw and heard during the inspection process. The GCP Inspection Report and Inspection Statement are not to be taken as implying a satisfactory state of affairs in documentation, premises, equipment, personnel or procedures not examined on this occasion.

Statement Issued by
Jason Wakelin-Smith, BSc (Hons), PgDip
Lead Senior GCP & GLP Inspector, Medicines and Healthcare products Regulatory Agency

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

GCP INSPECTION SUMMARY

Inspection Number	INSP GCP 44392/13345432-0001
Type and Purpose of Inspection	Bioequivalence Good Clinical Practice (GCP) Inspection
Organisation Inspected	VerGo Clinicals
Organisation Address	Plot 24/1, D-1 Mologa de Orora Corlim Tiswadi, Goa-403110 India
Organisation Type	Contract Research Bioequivalence Facility
Dates of Inspection	6th – 10th March 2017
Lead Inspector	Jason Wakelin-Smith, Senior GCP & GLP Inspector
Accompanying Inspector(s)	Michael McGuinness, GCP & GLP Inspector
Date of Inspection Statement	11 May 2017

Dear Pradip,

Thank you for the responses dated 11 May 2017 responding to the inspection report dated 06 April 2017.

The Organisation has provided corrective and preventative actions which you have taken, or have planned, to correct the reported deficiencies and prevent future recurrence. These have been reviewed by the inspection team and are considered acceptable. This inspection can be considered closed.

The factual matter contained in the GCP Inspection Report relates only to those things that the Inspection team saw and heard during the inspection process. The GCP Inspection Report is not to be taken as implying a satisfactory state of affairs in documentation, premises, equipment, personnel or procedures not examined on this occasion.

Closing Letter Issued by

Jason Wakelin-Smith,
MHRA Senior GCP & GLP Inspector

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 33 62
Fax direct: +41 22 791 47 30
Email: prequalinspection@who.int

In reply please refer to: P5-447-3/EK/MG/1
Your reference:

Dr Raman Batheja
VerGo Pharma Research Pvt. Ltd
(Division-VerGo Clinicals)
Plot No 24/1
Address of D-1 Mologa de Orora Corlim
Tiswadi Goa 403110
Inde

3 April 2024

Dear Dr Batheja,

WHO Prequalification Unit – Inspection Services
Closing of Inspection:
VerGo Pharma Research Pvt. Ltd, (Division-VerGo Clinicals)- CRO

I refer to the inspection that was performed by the World Health Organization (WHO) Prequalification Unit (PQT) Inspection Services (INS) and specifically Dr Elham Kossary and Dr Isabella Berger the details of which are outlined below:

Name: VerGo Pharma Research Pvt Limited (Division-VerGo Clinicals)
Address: Plot No 24/1, Address of D-1 Mologa De Orora Corlim, Tiswadi, Goa 403110, India
Date: 22 to 26 January 2024

Thank you for your email correspondence dated 11 March 2024 and the corrective actions to the deficiencies listed in VerGo Pharma Research Pvt. Ltd.'s inspection report. INS has reviewed the actions taken or proposed to be taken to correct the deficiencies.

In general, they are considered to be acceptable. Therefore, taking into account these responses, as well as the findings of the inspection, INS has recommended that the studies with the following details can be considered to be performed in compliance with WHO Good Clinical Practice (GCP) and/or Good Laboratory Practice Guidelines (GLP) published by the World Health Organization (WHO).

WHO Reference number	**Name of product**	**Study number**	**Part of the study:** - **Clinical part** - **Bioanalytical part** - **Pharmacokinetics & statistical analysis part**
HA691		064-21	- Clinical part - Bioanalytical part - Pharmacokinetics & statistical analysis part
CV013		036-22	- Clinical part - Bioanalytical part

			- Pharmacokinetics & statistical analysis part
HA783		132-21	- Clinical part - Bioanalytical part - Pharmacokinetics & statistical analysis part
TB360		068-22	- Clinical part - Bioanalytical part - Pharmacokinetics & statistical analysis part
TB400		046-22	- Clinical part - Bioanalytical part - Pharmacokinetics & statistical analysis part
HA785		118-21	- Clinical part - Bioanalytical part - Pharmacokinetics & statistical analysis part
TB393		038-21	- Bioanalytical part - Pharmacokinetics & statistical analysis part
TB394		037-21	- Bioanalytical part - Pharmacokinetics & statistical analysis part

Please note that acceptance of compliance with WHO GCP and/or GLP does not necessarily mean that the product for which the study has been performed has been prequalified by WHO. You will be notified in due course of the outcome of the assessment of the said prequalification application.

Please do not hesitate to send an email to **prequalinspection@who.int** should you require any further information regarding the closing of this inspection.

Yours sincerely,

p.p.
Ms Stephanie Croft
Acting Team Lead, Inspection Services
Prequalification Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 33 62
Fax direct: +41 22 791 47 30
Email: prequalinspection@who.int
In reply please refer to: P5-447-3/EK/SC/1

Your reference:

Dr Raman Batheja
VerGo Pharma Research Pvt Limited
Division-VerGo Clinicals
Plot No 24/1, D1
Mologa-De-Orora, Corlim
Tiswadi, Goa, 403110
Inde

7 September 2022

Dear Dr Batheja,

WHO Prequalification Unit (PQT) Inspection Services
Closing of Inspection
VerGo Pharma Research Pvt Limited (Division-VerGo Clinicals)

I refer to the inspection that was performed by the WHO Prequalification Inspection Team and specifically Dr Elham Kossary and Dr Isabella Berger the details of which are outlined below:

CRO name:	VerGo Pharma Research Pvt Ltd (Division-VerGo Clinicals)
Sites address:	Plot No 24/1, D1 Mologa-De-Orora, Corlim Tiswadi Goa-403110, India
Date:	24 – 27 May 2022

Thank you for your email correspondence dated 23 July and 29 August 2022 and the corrective actions to the deficiencies listed in the inspection report of VerGo Pharma Research Pvt Limited (Division - VerGo Clinicals). The actions taken, or proposed to be taken, to correct the deficiencies have been reviewed by PQT Inspection Services.

In general, they are considered to be acceptable. Therefore, taking into account these responses, as well as the findings of the inspection, PQT Inspection Services has recommended that the studies with the following details can be considered to be performed in compliance with WHO Good Clinical Practice (GCP) and/or Good Laboratory Practice Guidelines (GLP) published by the World Health Organization (WHO).

WHO Reference number	Name of product	Study number	Part of the study: • Clinical part • Bioanalytical part • Clinical and bio-analytical parts
NT010	[redacted]	894-19	Complete study
HA731	[redacted]	009-20	Complete study
MA169	[redacted]	909-19	Complete study
TB375	[redacted]	843-18	Clinical part
NT011	[redacted]	072-20	Complete study

…/…

Please note that acceptance of compliance with WHO GCP and/or GLP does not necessarily mean that the product for which the study has been performed has been prequalified by WHO. You will be notified in due course of the outcome of the assessment of the said prequalification application.

Please do not hesitate to send an email to **prequalinspection@who.int** should you require any further information regarding the closing of this inspection.

Yours sincerely,

Dr Joey Gouws
Team Lead, Inspection Services
Prequalification Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 3362
Fax direct: +41 22 791 4730
E-mail : prequalinspection@who.int

In reply please refer to: P5-447-3/EK/AB/1

Your reference:

Dr Raman Batheja
Vice President
VerGo Pharma Research Pvt Ltd
(Division-VerGO Clinicals)
Plot No. 24/1
D-1 Mologa de Orora Corlim Tiswadi
Goa, 403110
Inde

20 July 2018

Dear Dr Batheja,

WHO Prequalification Team – Inspection Services
Closing of Inspection

I refer to the inspection that was performed by Dr Elham Kossary and Dr Alexandru Sirbu the details of which are outlined below:

CRO name:	VerGo Pharma Research Pvt Ltd (Division-VerGO Clinicals)
Clinical facility:	VerGo Pharma Research Pvt Ltd (Division-VerGO Clinicals)
Bioanalytical facility:	VerGo Pharma Research Pvt Ltd (Division-VerGO Clinicals)
Statistical facility:	VerGo Pharma Research Pvt Ltd (Division-VerGO Clinicals)
Address:	Plot No. 24/1, Address of D-1 Mologa de Orora Corlim, Tiswadi Goa, 403110, India
Date:	16 to 19 April 2018

Thank you for your email dated 23 June 2018, together with the corrective actions to the deficiencies listed in the inspection report. The actions taken, or proposed to be taken, to correct the deficiencies have been reviewed by the inspectors.

In general, they are considered to be acceptable. Therefore, taking into account these responses, as well as the findings of the inspection, the Prequalification Inspection Group has recommended that the studies with the following details are therefore can be considered to be performed in compliance with WHO Good Clinical Practice (GCP) and/or Good Laboratory Practice Guidelines (GLP) published by the World Health Organization (WHO).

../..

WHO Reference Number	Name of Product	Study Number	Part of the Study: • Clinical part • Bio-analytical part • Clinical and bio-analytical parts
TB070	[redacted] and [redacted] Tablets	650-17	Clinical part, Bio-analytical part (Analytes measured: [redacted] & [redacted] & Pharmacokinetic and statistical part
TB198	[redacted] and [redacted] Tablets	SLS-CL-0175-17	Bio-analytical part
TB199	[redacted] Tablets	SLS-CL-0126-17	Bio-analytical part (Analytes measured: [redacted] and [redacted])

Please note that acceptance of compliance with WHO GCP does not necessarily mean that the product for which the study has been performed has been prequalified by WHO. You will be notified of the outcome of the assessment of your prequalification application in due course.

Please do not hesitate to send an email to **prequalinspection@who.int** should you require any further information regarding the closing of this inspection.

Yours sincerely,

Dr Joey Gouws
Group Lead, Inspection Services
Prequalification Team
Regulation of Medicines and other Health Technologies

Kavita Gaonkar

From: Raman Batheja <raman.batheja@vergoclinicals.in>
Sent: 18/03/2021 09:40
To: 'GOUWS, Johanna'
Cc: 'LOPES, Angela Maria'
Subject: RE: [EXT] VerGo Pharma Research, Goa-India : Biostudies

Dear Dr. Joey Gouws,

Thanks for your prompt response.

Regards
Raman Batheja

From: GOUWS, Johanna <gouwsj@who.int>
Sent: 17/03/2021 20:47
To: Raman Batheja <raman.batheja@vergoclinicals.in>
Cc: LOPES, Angela Maria <LopesA@who.int>
Subject: RE: [EXT] VerGo Pharma Research, Goa-India : Biostudies

Dear Sir

Your email correspondence refer.

I wish to advise that the WHO PQT: Inspection Team has taken an informed decision that in view of the current pandemic, travel restriction imposed by various national authorities and taken in consideration regulatory flexibility, all WHOPIR published on the WHO website will be extended for 12 months following their expiry. A notice to this extend will be uploaded to the WHO PQT: Inspection web page within the next week.

I trust this clarifies and answers your question.

Kind regards

Dr Joey Gouws

Team Lead, Inspection Services

Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)
World Health Organization
Geneva, Switzerland
Office: +41 (0)22 791 26 58
Mobile: +41 (0)79 239 4143

Web: www.who.int
Follow WHO on Facebook, Twitter, YouTube, Instagram

From: Raman Batheja <raman.batheja@vergoclinicals.in>
Sent: Tuesday, March 16, 2021 7:45 AM
To: GOUWS, Johanna <gouwsj@who.int>
Subject: [EXT] VerGo Pharma Research, Goa-India : Biostudies

Dear Dr. Joey Gouws,

VerGo is a CRO, located at Goa, India and is conducting bioequivalence studies in healthy human subjects. We were inspected by WHO from 16-April-2018 to 19-April-2018 and inspection was closed on 20-July-2018. The Closing of inspection report is attached for your reference as Attachment I.

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

After WHO inspection we have been inspected by NPRA Malaysia from 23-Sep-2019 to 27-Sep-2019 and CDSCO on 18-Aug-2020 and 19th Aug-2020. The audit Certificate/Approval are attached as Attachment II and III.

As our WHOPIR will be valid till July-2021 can we continue with biostudies after the said date.

Regards
Raman Batheja
Chief Operating Officer

VerGo Pharma Research Private Limited
Plot No.24/1 D–1 Mologa de Orora, Corlim Tiswadi,
Goa–403110 India,
Phone : +91-832-6640564/+91-9765551747

KEMENTERIAN KESIHATAN MALAYSIA
(*Ministry of Health Malaysia*)
Bahagian Regulatori Farmasi Negara (NPRA)
Lot 36, Jln Profesor Diraja Ungku Aziz,
46200 Petaling Jaya
Selangor
MALAYSIA

No. Telefon : 03 - 7883 5400
No. Faksimili : 03 - 7956 2924
Portal Rasmi : http://www.npra.moh.gov.my
E-mel Rasmi : npra@npra.gov.my

Our Ref. : NPRA/007/06/R/001 (74) Jld.3
Date : 21 November 2023

VerGo Pharma Research Pvt. Ltd.,
(Division – Vergo Clinicals),
Plot 24/1, D-1, Mologa De Orora,
Corlim, Tiswadi,
Goa 403 110,
India.

Dear Sir / Madam,

EXTENSION OF VALIDITY FOR THE NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA) BIOEQUIVALENCE (BE) CENTRE COMPLIANCE PROGRAMME CERTIFICATE DUE TO MEASURES IMPLEMENTED TO CURB THE SPREAD OF COVID-19

I am writing in response to your application dated 24 January 2022, your BE centre compliance programme certificate with the reference KGCP/BE 202002, our letter with the reference number NPRA/007/06/R/001(12)Jld.3 dated 24 November 2022, and to the matter above.

2. International travel restrictions had been implemented in the letter with the reference KKM.500-6/4/2JLD 6(57) by the Chief Secretary to the Ministry of Health Malaysia dated 5 March 2020. Following the lifting of travel restrictions via the letter with the reference KKM.1000-6/1/283 Jld.2 (2) dated 20 December 2021 and letter by the Senior Director of Pharmaceutical Services with the reference KKM/NPRA.PKP/600-2/1/1 (9) Jld.4 dated 19 May 2022, inspections to foreign BE centres were restarted in stages in July 2022. Due to availability of inspectors and inspection scheduling, not all BE centres can be inspected before the end of valid listing on the NPRA BE Centre Compliance Programme.

3. As a result, the NPRA has decided to extend the validity of certification for the following facilities from 8 February 2024 to 7 February 2025.

Clinical Site	Bioanalytical Site
VerGo Pharma Research Pvt. Ltd., (Division – Vergo Clinicals), Plot 24/1, D-1, Mologa De Orora, Corlim, Tiswadi, Goa 403 110, India.	VerGo Pharma Research Pvt. Ltd., (Division – Vergo Clinicals), Plot 24/1, D-1, Mologa De Orora, Corlim, Tiswadi, Goa 403 110, India.

4. The surveillance inspection will be postponed to a later date and will take place before the end of the certificate extension granted in this letter. Please be advised that if the inspection can be closed earlier than the date of this validity extension, the date of the new certificate will be the new date of validity. For enquiries, you may contact our officers at beec@npra.gov.my.

Thank you.

"MALAYSIA MADANI"

"BERKHIDMAT UNTUK NEGARA"

Sincerely,

(DR. NORAIDA MOHAMAD ZAINOOR) RPh. 2289
Deputy Director
Centre of Compliance and Quality Control
p.p. Director
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

NLCW / *mabs*
✉ nickleow@npra.gov.my / amirrudin@npra.gov.my
☎ +603 – 7883 5480 / 5478

KEMENTERIAN KESIHATAN MALAYSIA
(*Ministry of Health Malaysia*)
Bahagian Regulatori Farmasi Negara (NPRA)
Lot 36, Jln Profesor Diraja Ungku Aziz,
46200 Petaling Jaya
Selangor
MALAYSIA

No. Telefon : 03 - 7883 5400
No. Faksimili : 03 - 7956 2924
Portal Rasmi : http://www.npra.moh.gov.my
E-mel Rasmi : npra@npra.gov.my

Our Ref. : NPRA/007/06/R/001 (12) Jld-3
Date : 24 November 2022

VerGo Pharma Research Pvt. Ltd.,
(Division – Vergo Clinicals),
Plot 24/1, D-1, Mologa De Orora,
Corlim, Tiswadi,
Goa 403 110,
India.

Dear Sir / Madam,

EXTENSION OF VALIDITY FOR THE NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA) BIOEQUIVALENCE (BE) CENTRE COMPLIANCE PROGRAMME CERTIFICATE DUE TO MEASURES IMPLEMENTED TO CURB THE SPREAD OF COVID-19

I am writing in response to your application dated 24 January 2022, your BE centre compliance programme certificate with the reference KGCP/BE 202002 and to the matter above.

2. International travel restrictions had been implemented in the letter with the reference KKM.500-6/4/2JLD 6(57) by the Chief Secretary to the Ministry of Health Malaysia dated 5 March 2020. Following the lifting of travel restrictions via the letter with the reference KKM.1000-6/1/283 Jld.2 (2) dated 20 December 2021 and letter by the Senior Director of Pharmaceutical Services with the reference KKM/NPRA.PKP/600-2/1/1 (9) Jld.4 dated 19 May 2022, inspections to foreign BE Centres will be restarting beginning July 2022 in stages. Due to availability of inspectors and inspection scheduling, not all BE Centres can be inspected before the end of valid listing on the NPRA BE Centre Compliance Program.

3. As a result, the NPRA has decided to extend the validity of certification for the following facilities from 8 February 2023 to 7 February 2024.

Clinical Site	Bioanalytical Site
VerGo Pharma Research Pvt. Ltd., (Division – Vergo Clinicals), Plot 24/1, D-1, Mologa De Orora, Corlim, Tiswadi, Goa 403 110, India.	VerGo Pharma Research Pvt. Ltd., (Division – Vergo Clinicals), Plot 24/1, D-1, Mologa De Orora, Corlim, Tiswadi, Goa 403 110, India.

4. The surveillance inspection will be postponed to a later date and will take place before the end of the certificate extension granted in this letter. For enquiries, you may contact our officers at beec@npra.gov.my.

Thank you.

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Sincerely,

(DR. NORAIDA MOHAMAD ZAINOOR) RPh. 2289
Deputy Director
Centre of Compliance and Quality Control
p.p. Director
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

NLCW / *mabs*
✉ nickleow@npra.gov.my / amirrudin@npra.gov.my
☎ +603 – 7883 5480 / 5487
🖷 +603 – 7955 1030

BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
PROGRAM KOMPLIANS PUSAT KAJIAN BIOEKUIVALENS
BIOEQUIVALENCE CENTRE COMPLIANCE PROGRAMME

NO. SIJIL *CERTIFICATE NO.*	:	**KGCP/BE 202002**
Pusat Kajian Bioekuivalens *Bioequivalence Centre*	:	VerGo Pharma Research Pvt. Ltd.
Tapak Klinikal *Clinical Site*	:	VerGo Pharma Research Pvt. Ltd. (Division - VerGo Clinicals), Plot 24/1, D-1, Mologa de Orora, Corlim, Tiswadi, Goa-403110, India
Tapak Bioanalitikal *Bioanalytical Site*	:	VerGo Pharma Research Pvt. Ltd. (Division - VerGo Clinicals), Plot 24/1, D-1, Mologa de Orora, Corlim, Tiswadi, Goa-403110, India
Tarikh Pemeriksaan *Date of Inspection*	:	23rd September 2019 – 27th September 2019
Tempoh Sah Sijil *Certificate Validity*	:	8th February 2020 – 7th February 2023

Pusat kajian bioekuivalens tersebut di atas telah disenaraikan di dalam Program Komplians Pusat Kajian Bioekuivalens, Bahagian Regulatori Farmasi Negara, Kementerian Kesihatan Malaysia.

The above mentioned bioequivalence centre is listed in the Bioequivalence Centre Compliance Programme, National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia.

Dr Hasenah binti Ali
Director
National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia

AGENSI REGULATORI FARMASI NEGARA

NATIONAL PHARMACEUTICAL REGULATORY AGENCY

KEMENTERIAN KESIHATAN MALAYSIA

MINISTRY OF HEALTH MALAYSIA

PROGRAM KOMPLIANS PUSAT KAJIAN BIOEKUIVALENS

BIOEQUIVALENCE CENTRE COMPLIANCE PROGRAMME

NO. SIJIL *CERTIFICATE NO.*	:	**KGCP/BE 201704**
Pusat Kajian Bioekuivalens *Bioequivalence Centre*	:	**VerGo Pharma Research Pvt. Ltd.**
TapakKlinikal *Clinical Site*	:	VerGo Pharma Research Pvt. Ltd. (Division – VerGo Clinicals) Plot 24/1, D-1, Mologa De Orora, Corlim, Tiswadi, Goa 403 110 India.
TapakBioanalitikal Bioanalytical Site	:	VerGo Pharma Research Pvt. Ltd. (Division – VerGo Clinicals) Plot 24/1, D-1, Mologa De Orora, Corlim, Tiswadi, Goa 403 110 India.
TarikhPemeriksaan *Date of Inspection*	:	3rd October 2016 – 7th October 2016
TempohSah Sijil *CertificateValidity*	:	8th February 2017 – 7th February 2020

Pusat kajian bioekuivalens tersebut di atas telah disenaraikan di dalam Program Komplians Pusat Kajian Bioekuivalens, Agensi Regulatori Farmasi Negara, Kementerian Kesihatan Malaysia. Sijil ini sah bagi tiga (3) tahun.

The above mentioned bioequivalence centre is listed in the Bioequivalence Centre Compliance Programme, National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia. This certificate is valid for three (3) years.

Date: 8th February 2017

Director
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

सत्यमेव जयते

GOVERNMENT OF INDIA

CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhawan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. 4-14/2012/BA-BE/21 Dated: 06 JUN 2023

To,

M/s VerGo Pharma Research Private Limited,
(Division-VerGo Clinicals),
Plot 24/1, D-1, Molga de Orora,
Corlim, Tiswadi, Goa-403110, India

Sir,

This is with reference to your application no. ref Nil dated 13.02.2023 received vide P-3013299 dated 14.02.2023 for approval of additional 66 beds in the existing registered BA-BE centre bearing Registration No. BABE/2020/0065 dated 09.12.2020.

Your application for inclusion of **66 additional beds** in the existing registered BA-BE study centre has been examined in light of documents submitted by you and it is to inform that your application has been considered. Therefore, bed capacity of aforesaid BA-BE study centre is now increased from **100 beds to 166 beds.**

All other conditions of BA-BE study centre shall remain same.

Kindly acknowledge receipt of this letter.

Yours faithfully,

Central Licensing Authority
Stamp

Dr. RAJEEV SINGH RAGHUVANSHI
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road,
New Delhi (India)

सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhawan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. 4-14/2012/BA-BE/21 Dated:

09 DEC 2020

To,

M/s VerGo Pharma Research Private Limited
(Division –VerGo Clinicals),
Plot 24/1 D-1 Mologa de Orora,
Corlim, Tiswadi, Goa-403110, India

Sir,

With reference to your application received vide letter No Nil dated 12.06.2020 please find enclosed herewith the registration certificate in Form CT-09 bearing Registration No. **BABE/2020/0065** under the provisions of New Drugs and Clinical Trial Rules, 2019 for the Bioavailability/Bioequivalence study centre having Clinical facility **with 100 beds with (02 ICU beds)** along with Bio-analytical facility at **M/s VerGo Pharma Research Private Limited, (Division –VerGo Clinicals), Plot 24/1 D-1 Mologa de Orora, Corlim, Tiswadi, Goa-403110, India.**

The registration in Form CT-09 is subject to the following conditions:

(i) The registration shall remain valid for a period of five years from the date of its issue, unless suspended or cancelled. However there will be periodic assessment of the study centre.

(ii) The centre shall maintain the facilities with adequately qualified and trained personnel as specified in the Fourth Schedule of the New Drugs and Clinical Trial Rules, 2019 for performing its functions.

(iii) The centre shall initiate any bioavailability study or bioequivalence study of any new drug or investigational new drug in human subjects after approval of the protocol and other related documents by the Ethics Committee for clinical trial and permission of such study granted by the Central Licencing Authority;

(iv) where the bioavailability or bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from another Ethics Committee for clinical trial registered under rule 8:

Provided that the approving Ethics Committee accepts the responsibility for the study at the centre and, both the approving Ethics Committee and the centre, are located within the same city or within a radius of fifty kms of the centre;

(v) the Central Licencing Authority shall be informed about the approval of the Ethics Committee for clinical trial;

(vi) Bioavailability or bioequivalence study of investigational new drug shall be registered with the Clinical Trial Registry of India before enrolling the first subject for the study.

(vii) Study shall be conducted in accordance with the approved protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and provisions of Drugs and Cosmetics Act, 1940 and New Drugs and Clinical Trial Rules, 2019.

(viii) In case of termination of any such study prematurely, the detailed reasons for such termination shall be communicated to the Central Licencing Authority immediately.

(ix) Any report of serious adverse event occurring during study to the subject of such study shall, after due analysis, be forwarded to Central Licencing Authority within fourteen days of its occurrence in the format as specified in Table 5 of the Third Schedule and in compliance with the procedures as specified in rule 42.

(x) In case of an injury to the study subject during study, the complete medical management and compensation in the case of study related injury shall be provided in accordance with the provisions of Chapter VI and details of compensation paid to the trial subject in such cases shall be intimated to the Central Licencing Authority within thirty days of receipt of the order.

(xi) In case of death, permanent disability, injury other than death and permanent disability, as the case may be, of a study subject, compensation shall be provided in accordance with the provisions of Chapter VI and details of compensation paid to the trial subject or his legal heir, as the case may be, in such cases shall be intimated to the Central Licencing Authority within thirty days of receipt of the order.

(xii) If there is any change in constitution or ownership of the bioavailability and bioequivalence study centre, the centre shall intimate about the change in writing to the Central Licencing Authority within thirty days of such change.

(xiii) The study centre shall maintain data, records, and other documents related to the conduct of the bioavailability or bioequivalence study for a period of five years after completion of such study or for at least two years after the expiration date of the batch of the new drug or investigational new drug studied, whichever is later.

(xiv) The bioavailability and bioequivalence study centre shall allow any officer authorized by the Central Licencing Authority who may be accompanied by an officer authorized by State Licencing Authority to enter the premises with or without prior notice, to inspect any record, statistical observation or results or any documents related to bioavailability study and bio-equivalence study and furnish information to the queries raised by such authorized person, in relation to the conduct of the said study.

(xv) In case an Ethics Committee of a bioavailability or bioequivalence study centre rejects the approval of the protocol, the details of the same should be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the bioavailability or bioequivalence study at the same site.

(xvi) The bioavailability or bioequivalence study shall be initiated by enrolling the first subject within a period of one year from the date of grant of permission, failing which prior permission from the Central Licencing Authority shall be required

Kindly acknowledge receipt of this letter and its enclosure.

Yours faithfully,

Central Licensing Authority
Stamp

डॉ. वी. जी. सोमानी
औषधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
एफ.डी.ए. भवन, कोटला रोड, आई.टी.ओ
नई दिल्ली-110002

Form CT-09
[See rules 47, 48, 49, 50 and 51]

GRANT OF REGISTRATION OF BIOAVAILABILITY OR BIOEQUIVALENCE STUDY CENTRE

Registration No. **BABE/2020/0065**

1.The Central Licencing Authority hereby register **M/s VerGo Pharma Research Private Limited, (Division –VerGo Clinicals), Plot 24/1 D-1 Mologa de Orora, Corlim, Tiswadi, Goa-403110, India** for conduct of bioavailability and bioequivalence studies of New Drugs and Investigational New Drugs as specified in the New Drugs and Clinical Trials Rules, 2019.

2. This registration is subject to the conditions prescribed in chapter VII of New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

Place: New Delhi

Date: .....

Central Licensing Authority
Stamp

डा. वी. जी. सोमानी
औषधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
नई दिल्ली-110002

Note: The registration shall remain valid for a period of five years from the date of its issue, unless suspended or cancelled.