Medicines & Healthcare products
Regulatory Agency

GCP INSPECTORATE

GENECHT RESEARCH PRIVATE LIMITED
INSPECTION REPORT

INSPECTION No:
INSP GCP 57337/31054974-0001

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Inspection Summary

Inspection & Organisation Information	
Inspection Number	Insp GCP 57337/31054974-0001
Type and Purpose of Inspection	GCP Bioequivalence (BE) Inspection
Organisation Inspected	Genecht Research Private Limited
Organisation Address	Plot No. D-400, TTC Industrial Area, MIDC Nerul, Uran Phata Junction, Off Sion - Panvel Expressway, Nerul, Navi Mumbai-400 706, Maharashtra, India.
Organisation Type	Contract Research Organisation (CRO)
Dates of Inspection	11th – 15th December 2023
Lead Inspector	[redacted]
Accompanying Inspector(s)	[redacted]
Date of Closing Meeting	15th December 2023
Post Inspection Information Received	4th March 2024
Inspection Report Date	15th March 2024

Clinical Trials Reviewed	
Protocol Reference Number	[redacted]
Protocol Title	An open label, balanced, randomized, two treatment, two sequence, two period, two way crossover, single oral dose bioequivalence study [redacted]
Test Compound	[redacted]
Protocol Reference Number	[redacted]
Protocol Title	An open label, balanced, randomized, two treatment, two sequence, two period, two way crossover, single oral dose bioequivalence study of [redacted]
Test Compound	[redacted]
Protocol Reference Number	[redacted]

Protocol Title	A randomized, open label, balanced, single dose, two-treatment, two-period, two-sequence, two-way crossover, comparative bioavailability study of [redacted]
Test Compound	[redacted]

Background Information

Genecht Research Pvt Limited was founded in 2021. The company performed the first BE study in March 2022 and had performed 36 studies at the time of this inspection.

The clinic consisted of 80 beds with dining and recreation facilities for study participants. There was a dedicated pharmacy and an emergency care unit with easy access to remove subjects to hospital in the event of a medical emergency. The facility also had suitable screening, subject check-in, sample collection and processing areas with capability to store samples prior to transfer to the bioanalytical department.

The analytical laboratory contained 3 LC/MS instruments (1[redacted]), balances, freezers for sample storage at -70 ºC and -20ºC as required, refrigerators at 2-8 ºC for reagent and working solution storage, centrifuges, and extraction manifolds.

This was the first MHRA inspection for Genecht Research Pvt Limited.

Inspection Scope

The purpose of this inspection was to assess the level of compliance of the selected studies with the principles of GCP. In addition, supporting systems which underpinned the GCP compliance of the selected studies (for example quality assurance and quality systems) were also reviewed and assessed.

The majority of the inspection was based around review of documentation, including general company information, study specific document requests and requests for study data (in csv. file format and data files from the company analytical software) which was all provided in advance of the inspection following a number of formal document requests by the inspectors. Additional requests were also provided to the company daily during the inspection itself.

The inspection included several discussions with representatives from the company who were able to demonstrate ways of working and company processes/procedures in 'live' company computer systems and current quality system operations. This approach was used to answer inspector questions and address several document requests as they were identified during the inspection.

The inspection also included a walkthrough of the clinical, pharmacy, archive, emergency care unit and analytical laboratory areas and Period I dosing for study [redacted] was witnessed on day 4 of the inspection.

Definitions of Findings

Critical:

a) Where evidence exists that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that:

   i) the rights, safety or well-being of trial subjects either has been or has significant potential to be jeopardised, and/or
   ii) the clinical trial data are unreliable and/or
   iii) there are a number of Major non-compliances (defined in (d) and (e)) across areas of responsibility, indicating a systematic quality assurance failure, and/or

b) Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances (defined in (d) and (e))

c) Where provision of the Trial Master File (TMF) does not comply with Regulation 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the Regulations

Major:

d) A non-critical finding where evidence exists that a significant and unjustified departure from applicable legislative requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed, and/or

e) Where evidence exists that a number of departures from applicable legislative requirements and/or established GCP guidelines have occurred within a single area of responsibility, indicating a systematic quality assurance failure.

Other:

f) Where evidence exists that a departure from applicable legislative requirements and/or established GCP guidelines and/or procedural requirement and/or good clinical practice has occurred, but it is neither Critical nor Major.

Reference Texts

- UK Medicines Act 1968.
- The Human Medicines Regulations 2012, SI 1916 and the applicable statutory instruments including 2004/1031 (and subsequent amendments)
- ICH E6 “Note for Guidance on Good Clinical Practice”.
- Annex 13 to the EU Guide to Good Manufacturing Practice, ‘Manufacture of Investigational Medicinal Products’, July 2010.
- ICH E2A “Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting”
- Communication from the Commission — Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1) (2010/C 82/01)
- Communication from the Commission — Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use (‘CT-3’) (2011/C 172/01)
- CHMP/ICH/381/95: “Note for Guidance, Text on Validation of Analytical Procedures”.

GCP Deficiencies identified during the inspection of Genecht Research Private Limited 11th – 15th December 2023

Finding Number	Deficiency
1.0 Critical Deficiency There was one critical finding identified during this inspection relating to Subject Eligibility.	
1.1	**Subject Eligibility**
1.1.1	The urine analysis conducted as part of eligibility assessments for study [redacted] was performed at a contract pathology laboratory ([redacted]) using [redacted] urine analysis strips (a CE marked product). The kit instructions required samples to be analysed within 2 hours of sample collection, but several examples were identified across multiple studies where the duration between sample collection times in subject Case Report Forms (CRFs) and sample registration times at the laboratory exceeded this time restriction: • At least 17 out of 24 samples in study [redacted] • 26 out of 28 samples in study [redacted] As a result, it was not possible to confirm that the results obtained following analysis of urine samples using this method were valid and could be relied on for the determination of subject eligibility which for both studies required 'normal or clinically non-significant laboratory values as determined by haematological, biochemistry tests and urine analysis' according to the inclusion criteria in the corresponding study protocols. On 23rd January 2024, Genecht provided additional stability data from the kit manufacturer in an effort to demonstrate that the results obtained from analysis were valid. However, the data had been requested/obtained retrospectively, the data did not include any supporting information detailing how it had been compiled such as sample acquisition information, storage conditions applied to the samples, quality standards in place during analysis, training of staff involved in the analysis or equipment maintenance and calibration data. As such, this information was not available to Genecht at the time sample analysis was performed and the data alone could not be relied upon to support the results from analysis during BE studies. On 31st January 2024, Genecht provided an impact assessment of the data provided by the kit manufacturer. The conclusions stated that '*the overall assessment suggests that, except for a limited discrepancy in red blood and pus cell results within a specific timeframe, the reliability of the biochemical tests remains robust*' and that '*the dual confirmation of consistent negative results for blood parameter in studies* [redacted] *with both the dipstick as well as the Microscopy method reinforces the accuracy of results, demonstrating the safety and integrity of the study participants*'. However, this impact assessment did not acknowledge the absence of supporting information detailing how the data had been compiled, as detailed above. In addition, the impact assessment did not consider any additional studies aside from those reviewed during the MHRA inspection. On 4th March 2024, further correspondence was received from the company following a stability investigation conducted by [redacted] (contract pathology

	laboratory). This correspondence did confirm the source of the urine samples used for this additional investigation, the storage conditions that were applied, the maintenance and calibration status of the equipment and kits that were used for the stability analysis, the competency of staff performing the work, the level of review that had been performed on the data and the quality standards that had been applied during performance of the work. The additional information also included a conclusion from the laboratory conducting the investigation ([redacted] which stated '*these findings conclude that the storage conditions and evaluation methods employed maintained the integrity and stability of the urine samples and their associated parameters. Therefore, the results of this experiment provide confidence in the reliability and accuracy of the data obtained, supporting the validity of the analysis conducted in-house by our organisation*'. In summary, the MHRA have been provided with the outcome of the investigation conducted by [redacted] however, at the time this report was issued, the supporting information from the investigation conducted by the kit manufacturer was still outstanding. In addition, Genecht had not identified this issue prior to the inspection and clauses in the written agreement between Genecht and their contract pathology laboratory had not prevented sample analysis from being performed outside the requirements of kit instructions. In addition to providing corrective and preventative actions in response to this finding, Genecht are required to identify any additional studies where the 2-hour time restriction detailed in kit instructions has been breached and also to obtain the outstanding supporting information from the kit manufacturer regarding the suitability for use of their urinalysis kit beyond the 2 hour stability time limit stated in kit instructions.

2.0 Major Deficiencies

There were six major deficiencies identified during this inspection relating to Subject Safety, Protocol Compliance, Archiving, Clinical Sample Analysis, Computer System Validation and Data Integrity Controls.

2.1	**Subject Safety**
2.1.1	Section [redacted] clinical SOP [redacted] referred to Annex 1 for in house reference ranges for safety laboratory parameters and section 6.8 indicated that anything outside 20% of these ranges should be considered an adverse event. However, Annex [redacted] of this SOP indicated that a number of laboratory parameters were to be 'clinically correlated' rather than performing a numerical assessment of the results. In addition, at least one laboratory parameter (% RDW) detailed on subject laboratory reports for studies [redacted] was not listed in Annex [redacted]. As a result, it was not clear how these parameters could be assessed for adverse event reporting in line with the requirements of SOP section [redacted]. During the inspection, a number of laboratory results that had been clinical correlated across study [redacted] were compared with the reference ranges in SOP [redacted] and the ranges on the laboratory reports and several were found to be outside 20% of the upper/lower limit of the stated reference ranges, indicating that they met the criteria for adverse event reporting, but had not been reported as such:

	• Subject [redacted] in study [redacted], end of study RDW (%) result was [redacted] The laboratory reference range was [redacted] giving a result of [redacted] of the upper limit of reference range. • Subject [redacted] in study [redacted], end of study RDW (%) result was [redacted] The laboratory reference range was as above giving a result of [redacted] of the upper limit. • Subject [redacted] in study [redacted], end of study RDW (%) result was [redacted] giving a result of [redacted] of the upper limit of the laboratory reference range. • Subject [redacted] in study [redacted], end of study RDW (%) result was [redacted] ([redacted] of the upper limit of the laboratory reference range). • Subject [redacted] in study [redacted], end of study RDW (%) result was [redacted] ([redacted] of the upper limit of the laboratory reference range). Also, absolute basophils result was [redacted]. There was no reference range in the SOP, but the laboratory reference range was [redacted] giving a result of [redacted] of the lower limit of the reference range. • Subject [redacted] in study [redacted], end of study RDW (%) result was [redacted] ([redacted] upper limit of laboratory reference range). • Subject [redacted] in study [redacted], end of study RDW was [redacted] ([redacted] upper limit of laboratory reference range) • Subject [redacted] in study [redacted], end of study RDW was [redacted] ([redacted] upper limit of laboratory reference range) • Subject [redacted] in study [redacted] end of study RDW was [redacted] ([redacted] upper limit of laboratory reference range) • Subject [redacted] in study [redacted] end of study RDW was [redacted] ([redacted] upper limit of laboratory reference range) • Subject [redacted] in study [redacted], end of study RDW was [redacted] ([redacted] upper limit of laboratory reference range) • Subject [redacted] in study [redacted], end of study RDW was [redacted] ([redacted] upper limit of laboratory reference range) • Subject [redacted] in study [redacted], end of study indirect bilirubin result was [redacted] There was no reference range in the SOP, but the laboratory reference range was [redacted] giving a result of [redacted] of the lower limit of the laboratory range. Also, the end of study RDW (%) result was [redacted] ([redacted] upper limit of laboratory reference range) • Subject [redacted] in study [redacted], end of study RDW was [redacted] ([redacted] upper limit of laboratory reference range) • Subject [redacted] in study [redacted], end of study RDW was [redacted] ([redacted] upper limit of laboratory reference range) • Subject [redacted] in study [redacted], end of study RDW was [redacted] ([redacted] upper limit of laboratory reference range) The examples identified did not present a concern regarding subject eligibility and all results had been assessed by a trial physician as clinically not significant. They did however represent a significant SOP deviation and indicated that a large number of adverse events had not been recorded for the studies.
2.2	**Protocol Compliance**

2.2.1	Results for the following safety laboratory parameters were obtained following analysis of subject screening samples in studies [redacted]. These parameters had not been listed as required in the associated clinical trial protocols or sample request paperwork: • [redacted] • Laboratory reports for study [redacted] also included laboratory tests which were not listed in the associated trial protocol (15 parameters in total). The requirement to assess these parameters during subject sample analysis was also not included in participant information sheets or consent forms for these trials. As such, no subject consent existed for these additional tests and the associated data should not have been acquired.
2.3	**Archiving**
2.3.1	The following electronic data was not subject to formal archiving according to the Genecht quality system: • Bioanalytical data acquired using the [redacted] software. • Participant data in the current subject recruitment database ([redacted]) and the previous system ([redacted]). Both of these systems contained source data for volunteers including heights and weights used for body mass index (BMI) calculations. It was confirmed during the inspection data in all of these systems was backed up, but it was not archived. It was also confirmed that data from the systems was printed and stored in the relevant study folders however, the dynamic nature of the data and the associated metadata from the systems was lost when the data was printed for filing.
2.4	**Clinical Sample Analysis**
2.4.1	SOP [redacted] was found to contain deficiencies relating to analytical run acceptance, where in-house requirements were not in accordance with published regulatory guidance. Examples included: • Section [redacted] stated that intra batch accuracy (%) for quality control samples (at each level) should be within [redacted]. If this criterion was not met, the batch of unknown samples should be repeated. This approach was used to

	repeat runs [redacted] and [redacted] in study [redacted] and [redacted] respectively. In these examples only one replicate at the low QC level failed to meet acceptance criteria but the runs had been repeated. According to regulatory guidance, these runs should have been accepted. • Section [redacted] permitted analytical runs to be rejected if two consecutive calibration standards failed to meet acceptance criteria. This is not in line with published regulatory guidance. No examples of this practice were identified in the studies reviewed during the inspection. • Sections [redacted] and [redacted] included consideration for truncation of the calibration curve where the LLOQ and/or ULOQ failed to meet acceptance criteria. However, the SOP did not require additional consideration to ensure that the remaining calibrators adequately cover the QC sample concentrations in the analytical run. As a consequence of the SOP, analytical runs which would otherwise have been considered acceptable were being repeated and the original results were not included in subsequent pharmacokinetic analysis. In addition to providing a response to this finding, Genecht are required to investigate the use of these practices in BE studies conducted since 2022 to confirm the extent of the issue. In addition, impact assessments are required for any studies where these practices have been used.
2.5	**Computer Systems Validation**
2.5.1	The following computerised systems reviewed during the inspection were not considered to be fully validated: • Excel spreadsheet used in the bioanalytical department for calculation of multiple parameters including internal standard response variation. • Participant recruitment database [redacted] Inspectors were informed that the spreadsheet/program detailed above had been acquired from a different contract research organisation but there was no documentation available to demonstrate that there had been any validation and/or testing of the program prior to implementation at Genecht.
2.5.2	The company quality management system did not include a computer system validation (CSV) policy or SOP to ensure the approach to CSV was consistent and comprehensive.
2.6	**Data Integrity Controls**
2.6.1	Quality Assurance review of data from the bioanalytical department ([redacted] LCMS software) was not performed on the dynamic raw data set. Instead, primary record review was of flat files (PDF or paper prints outs) from the system which was considered inappropriate. The inspectors were informed that there were limited checks of electronic raw data performed by auditors via shadowing study staff. These checks were not sufficient for the process to be described as a 'hybrid' approach i.e. verifying that the print-out was a true complete copy of the raw data. As data from the software was acquired electronically in a dynamic state, and in accordance with MHRA 'GXP' Data Integrity Guidance and Definitions document

	(March 2018), paper copies of the data, in isolation, cannot be considered raw data as the dynamic nature was lost upon printing.

3.0 Other Deficiencies

There were ten other deficiencies identified during this inspection relating to Archiving, Clinical Sample Analysis, CRF/Source Data, Data Integrity Controls, Facilities and Equipment, Investigational Medicinal Product (IMP)/Pharmacy, Insurance, Method Validation, Quality Management System and Record Keeping/Essential Documents.

3.1	**Archiving**
3.1.1	Temperature monitoring data generated during transit of test product in study [redacted] was not available in the archived study package. It was noted that this data could be provided on request during the inspection.
3.2	**Clinical Sample Analysis**
3.2.1	The assessment of haemolysis was not positively recorded within the bioanalytical paperwork for studies [redacted] There were details of haemolysis assessments conducted in the clinic however the inspectors were informed that the bioanalytical department would also separately verify that the haemolysis level was sufficient to enable analysis to continue in line with established validation i.e. less than or equal to 2%. This additional verification could not be confirmed from the study data.
3.2.2	The company had established numerical criteria for the review of internal standard variation in analytical runs for analysis of subject samples. This applied a +/- 50% range of the mean from acceptable calibration standard and QC values. However, there was no requirement to investigate suspected abnormal calibration standard or QC outliers which may affect the overall mean. For example, in the run for subject [redacted] in study [redacted] calibration standard 6 had an acceptable recovery compared to the nominal concentration but the internal standard response for this sample was very low. This result had been included in the mean calculation which was then used to identify unknown samples to be repeated. It was noted that no unknown samples were repeated or not repeated where they should not have been/should have been as a result of this issue.
3.2.3	Batch acceptance review paperwork used to capture observations during batch review on analytical run completion ([redacted] indicated that run [redacted] in study [redacted] was performed using instrument [redacted] This reference was incorrect as instrument [redacted] had been used.
3.3	**CRF/Source Data**
3.3.1	Section [redacted] of the screening records for subjects [redacted] in study [redacted] (systemic medical evaluation) included 'ticks' in the 'findings = Y' boxes indicating that there were findings relating to the respiratory, central nervous system, gastrointestinal and musculoskeletal systems for these individuals. This information in the screening records suggested that these individuals should not have been suitable for inclusion in the study however, this was determined to be an error in completion of the paperwork.

3.3.2	Discrepancies were identified between subject dates of birth on ECG traces and in CRFs for subjects recruited into study [redacted] • The end of study ECG showed the date of birth for subject [redacted] as [redacted] This should have been [redacted] according to the demographic section of the screening CRF. This error was not determined to have an impact on subject eligibility for inclusion in the study. • The screening and end of study ECGs for subject [redacted] showed their date of birth as [redacted] but the associated demographic section of the screening CRF showed a date of [redacted]. This error was not determined to have an impact on subject eligibility for inclusion in the study.
3.3.3	The number of decimal places used to record subject height was not consistent in the screening CRFs for study [redacted] Some CRFs recorded the data to 3 significant figures (e.g. subject [redacted]) and some to 1 decimal places (e.g. subject [redacted]). This approach introduced the potential for error during subsequent body mass index calculations. It was noted that no calculation errors were identified during the inspection.
3.3.4	Errors were identified in the reported ages for two subjects in study [redacted]: • The screening CRF for subject [redacted] incorrectly stated the subject age as 23 years (date of birth [redacted] . This individual was 22 at the time of screening (9th September 2022). • The screening CRF for subject [redacted] incorrectly stated the subject age as 38 years (date of birth [redacted] but they were 37 at the time of screening (12th September 2022).
3.4	**Data Integrity Controls**
3.4.1	The established backup procedures for analytical data only extended to a single location despite users having the ability to create alternative locations where data could be saved. Analytical LCMS-MS data was only backed up from the established root directory and procedures did not require back up activities to include possible alternative locations, such as the acquisition PC or another external server locations. This was despite the [redacted] and users having the ability to create and set root directories from the machine as was noted during the inspection. A separate root directory was present on [redacted] however this was not in use and had been set up by external engineer during their visit.
3.5	**Facilities and Equipment**
3.5.1	The emergency alarm points present within clinical washrooms and shower areas were wireless call bells that were not considered to be water resistant to ensure working order would be maintained in areas where they were likely to get wet. It was acknowledged that the test facility addressed this issue during the inspection and were able to demonstrate that appropriate corrective action had been taken prior to completion of the on-site inspection. As such, no additional action is required in response to this finding.

3.5.2	There was an air conditioning water pipe within the archive area which was partially wrapped in plastic however this protection only covered the region above the entrance to the room and not the area directly above where study materials were being stored. This presented a risk to the integrity of archived materials in the event of a leak or damage to the water pipe.
3.5.3	Access to the archive was intended to be restricted to one individual according to the facility access list but the company owner was also found to have access with their key card at the time of the facility visit.
3.5.4	The doors for access to the female washrooms opened inwards and did not facilitate access to an individual inside the room in the event of a collapse against the door. It was acknowledged that the test facility addressed this issue during the inspection and were able to demonstrate that appropriate corrective action had been taken prior to completion of the on-site inspection. As such, no additional action is required in response to this finding.
3.5.5	The inventory of contents appended to the side of refrigerator [redacted] in the bioanalytical department (dated 9th December 2023) did not reflect the contents of the fridge. Samples on shelf [redacted] from study [redacted] (preparation date 4th December 2023) and shelf [redacted] from study [redacted] (preparation date 28th November 2023) were present in the fridge but were not listed on the inventory. Inspectors were informed that this list was updated monthly but these studies were initiated prior to the last update and had not been included.
3.6	**Investigational Medicinal Product (IMP)/Pharmacy**
3.6.1	Genecht had been provided with certificates of analysis from [redacted] for test products used in study [redacted] Microbiological parameters on these certificates had been marked as 'not applicable' but this lack of data had not been queried with the supplier to confirm that there was no resulting impact on the quality of the test products and that it was safe to proceed with study dosing. It was noted that information was provided during the inspection to indicate that this data was 'not relevant' for all batches of test product and that acceptable data for a representative test product batch was provided for review. However, this information was only made available at the time of the inspection.
3.7	**Insurance**
3.7.1	A gap was identified in the clinical trials insurance policy cover in place at Genecht. The 2022 insurance policy ended on 7th February 2023, but the subsequent policy start date was not until 21st February 2023. Clinical trial activities were determined to be ongoing during these dates according to list of Genecht studies provided as part of pre-inspection document request [redacted]
3.8	**Method Validation**
3.8.1	SOP [redacted] effective during conduct of the [redacted] method validation for study [redacted] did not contain a requirement to analyse stability samples immediately following initial preparation. As a result, no time zero stability had been performed during this validation and there was no assurance

	that fresh samples met acceptance criteria before storage and subsequent analysis where these results were to be used to demonstrate subject sample stability. In addition to providing corrective and preventative actions in response to this finding, a review should be undertaken to confirm the extent of the issue in other BA/BE studies conducted by Genecht.
3.9	**Quality Management System**
3.9.1	SOP [redacted] effective 28th September 2023) and the associated dispensing forms made no reference to the two variations for dispensing tablets from blister packs i.e. within blister packaging or removed from blister packs into dosing containers. Both of these approaches were used by Genecht for IMP dispensing. Removal of IMP from blister packaging could impact the test and/or reference product stability information that would need to be obtained from the supplier as part of IMP management activities to ensure subject safety.
3.9.2	The change control document for migration of volunteer information from [redacted] to [redacted] (initiated 6th May 2023) indicated that the scope of the migration related to 'all data from [redacted] in sections [redacted]. However, volunteer biometric data was excluded from the migration activity, but there was no deviation raised to capture this omission.
3.10	**Record Keeping/Essential Documents**
3.10.1	A haemolysis grading chart was found within the sample processing area in the bioanalytical laboratory. This chart was an extract from [redacted] effective 22 November 2023, however it was not marked as such and there was no additional document control to ensure that it was current and approved for use.
3.10.2	The identity of the balance and stadiometer used to record subject weight and height respectively was not recorded in the source data (CRF) for study [redacted].
3.10.3	There was no link between data logger printouts and the data loggers included in shipments of test and reference products for studies [redacted] in order to verify that the downloaded data was from the correct delivery.
3.10.4	Test requisition forms for clinical pathology sample analysis for subjects [redacted] at screening were not available in the archived TMF for study [redacted] It was confirmed during the inspection that this activity related to screening for another study at the facility and the associated paperwork had not been copied into the TMF in error.
3.10.5	The project specification page in analytical file [redacted] for study [redacted] (dated 2nd September 2022) summarised validation parameters and indicated that stock solution stability was established up to 23 hours at room temperature. According to the validation report ([redacted] stability had only been only established up to 22 hours. It was noted that this error had no impact on sample stability during the study.
3.10.6	Pipette calibration records for pipettes [redacted] had been copied into the archived analytical data for study [redacted] Two other pipettes ([redacted]) had been used during study activities, but the

	associated calibration records for this equipment was missing. It was noted that these additional calibration records could be provided on request during the inspection.
3.10.7	A sample requisition form in the bioanalytical data for subject [redacted] in study [redacted] contained a typographical error in the lot numbers for the high QC samples requested for analysis. The paperwork listed lot numbers [redacted], but this should have been [redacted]

Report Author and Reviewer

Report Prepared by:

[redacted]
Medicines and Healthcare products Regulatory Agency

Report Reviewed by:

[redacted]
Medicines and Healthcare products Regulatory Agency

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

Appendix I Summary of Activities

Inspected Organisation				
Clinical Trial	Assessed			Comment
	Yes	Partial	No	
[redacted]	✓			
[redacted]	✓			
[redacted]	✓			

Inspected Organisation				
Activity	Assessed			Comment
	Yes	Partial	No	
Analytical Laboratory	✓			
Archiving	✓			
BE/ BA activities	✓			
Clinical Pathology Laboratory	✓			
Clinical Trial Reporting	✓			
Computerised Systems	✓			
Contracts & Agreements		✓		
Data Management	✓			
eCRF / Diaries / IVRS			✓	
IMP Management	✓			
Medical Affairs		✓		
Monitoring			✓	
Pharmacovigilance		✓		
Project management		✓		
Quality Assurance		✓		
Quality Systems	✓			
R&D Unit (Non-commercial only)			✓	
Regulatory Affairs			✓	
Statistical Analysis			✓	
Technical Facility (i.e. x-ray)			✓	
Training		✓		
Trial Master File/Essential Documents	✓			
Other	✓			Facility visits