Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00504**

08 June 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 9 May 2026. You wrote:

> *"Dear MHRA FOI Team,*
>
> *This is a request under the Freedom of Information Act.*
>
> *Please confirm whether MHRA holds recorded information relating to the following GCP Bioequivalence inspection:*
> *- Organisation: Genecht Research Private Limited, India*
> *- Inspection Number: Insp GCP 57337/31054974-0001*
> *- Type of Inspection: GCP Bioequivalence (BE) Inspection*
> *- Dates of Inspection: 11–15 December 2023*
> *- Date of Inspection Statement: 29 October 2024*
>
> *Subject to any applicable redactions, please provide the following information:*
>
> *1. Whether this inspection was systems-based, trial-specific, or both.*
>
> *2. Whether the inspection scope covered clinical activities, bioanalytical activities, or both.*
>
> *3. Whether the inspection scope included any Levothyroxine Sodium BA/BE study.*
>
> *4. Whether the inspection scope included any BA/BE study conducted after 11–15 December 2023.*
>
> *5. Whether MHRA holds any recorded information indicating that the GCP Inspection Statement was intended to support third-country regulatory submissions for BA/BE studies conducted after the inspection dates.*
>
> *6. Whether any follow-up inspection, referral to the Inspection Action Group, restriction, infringement notice, regulatory action, or other post-inspection action was issued in relation to this inspection.*

7. Whether MHRA holds any recorded information concerning limitations on the interpretation or use of this GCP Inspection Statement.

8. A redacted copy of any publicly disclosable inspection outcome summary, scope description, closure correspondence, or related documentation concerning this inspection.

For clarity, I am not requesting personal data, confidential commercial information, or the full unredacted inspection report. I am requesting recorded information sufficient to confirm the scope, status, and limitations of the MHRA GCP Inspection Statement, as it appears to be used in third-country regulatory procedures."

MHRA Response

The Agency has completed its search for the information you have requested, and we are able to confirm that we do hold the information you have requested. We will address each of your question in turn:

1. This was a systems inspection; however specific trials were selected to serve as examples.

2. The inspection scope covered both clinical and bioanalytical activities.

3. The studies selected to serves as examples for the inspection did not include Levothyroxine Sodium; however, as this was a systems inspection we are not able to confirm whether aspects of the study may have been looked at during general review.

4. The inspection looked at already completed studies and studies ongoing at the time of the inspection. The scope looked at the supporting aspects such as systems and process which were in place both at the time of the selected studies but also at the time of the inspection – there will have been used for studies conducted after the inspection, but their applicability would be subject to any changes made by the BE facility.

5. The statement of inspection was provided following the UK MHRA inspection and issued to the company to confirm the inspection was closed, highlighting areas where deficiencies had been raised.

6. Advice was sought from the Inspection Action Group (IAG2) on 21 May 2024 because of the critical findings raised during the inspection. In response, the company has provided corrective and preventative actions, to address the points that had been raised. These were reviewed by the GCP Inspectorate and were considered acceptable.

7. Any limitations regarding interpretation of the information detailed in our GCP statements are detailed on the statement itself in the final paragraph.

8. In response to your request, we are providing the following MHRA/GCP inspection report:
   - **Insp GCP 57337/31054974-0001**

Please note that some redactions have been applied to this document under the Section 40(2) and Section 43(2) of the Freedom of Information Act 2000 (FOIA):

Section 40(2)
We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018

MHRA maintains the following policy on disclosure of personal information: "All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised must be able to demonstrate that at least one of the above criteria apply.

Section 43(2)
Release of all, or part of, the information would be likely to cause harm to the third party’s commercial interests.

We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information / industrial secrets of a third party / commercial enterprise (which can include a Government Department). This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity).

This concludes our response to your request.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/