



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

[MHRA Website](#)

Our Ref: **FOI2026/00026**

10 March 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 13 January. You wrote:

I would like to request for Module 2.4, Module 2.5, Module 2.6 and Module 2.7 submitted for Ketoconazole 2% Shampoo, MAH: Curagenix Life Sciences Limited, (PL 59154/0004).

MHRA Response

We can confirm that the Agency holds the information you are seeking.

In response to your request, we are providing the attached:

- (i) Module 2.4 Nonclinical Overview_Ketoconazole 2% Shampoo (PL 59154_0004)
- (ii) Module 2.5 Clinical Overview_Ketoconazole 2% Shampoo (PL 59154_0004)
- (iii) Module 2.6.1 Introduction_Ketoconazole 2% Shampoo (PL 59154_0004)
- (iv) Module 2.6.2 Pharmacology Written Summary Ketoconazole 2% Shampoo (PL 59154_0004)
- (v) Module 2.6.3 Pharmacology Tabulated Summary Ketoconazole 2% Shampoo (PL 59154_0004)
- (vi) Module 2.6.4 Pharmacokinetics Written Summary Ketoconazole 2% Shampoo (PL 59154_0004)
- (vii) Module 2.6.5 Pharmacokinetics Tabulated Summary_Ketoconazole 2% Shampoo (PL 59154_0004)
- (viii) Module 2.6.6 Toxicology Written Summary_Ketoconazole 2% Shampoo (PL 59154_0004)
- (ix) Module 2.6.7 Toxicology Tabulated Summary_Ketoconazole 2% Shampoo (PL 59154_0004)
- (x) Module 2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods_Ketoconazole 2% Shampoo (PL 59154_0004)
- (xi) Module 2.7.2 Summary of Clinical Pharmacology Studies_Ketoconazole 2% Shampoo (PL 59154_0004)
- (xii) Module 2.7.3 Summary of Clinical Efficacy of Prev. & treatment of malassezia yeast infection_treatment of tinea versicolor_Ketoconazole 2% Shampoo (PL 59154_0004)
- (xiii) Module 2.7.4 Summary of Clinical Safety_Ketoconazole 2% Shampoo (PL 59154_0004)
- (xiv) Module 2.7.5 Literature References_Ketoconazole 2% Shampoo (PL 59154_0004)

(xv) Module 2.7.5 Synopses of Individual Studies_Ketoconazole 2% Shampoo
(PL 59154_0004)

We consider that some information within the documentation is exempt from disclosure and, therefore, we are not going to release this information. Hence the documents have been redacted.

Under section 17(1) of the FOIA, when we refuse any part of the requested information, we must specify the relevant exemption and explain why the exemption applies.

Section 40 – Personal Information

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.

Section 41(1) – Information Provided in Confidence

We are engaging an exemption from disclosure under Section 41(1) of the FOI Act, which protects information provided in confidence.

The information you have requested relates to third party commercial documentation we have received as part of our role as a regulator which was obtained by the Agency from another person and the Agency believes that if this information would be released it would breach the confidence of the person(s) the information pertains to, actionable by them or any other person. Therefore, we are not going to be releasing the requested information.

Section 43 – Commercial Sensitivity

Some of the information you have requested is commercially sensitive and is therefore exempt from release under Section 43(2) of the FOI Act.

Section 43(2) exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties but also the commercial interests of the Agency. It is intended to protect the ability of a public authority like MHRA to obtain goods or services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category.

As required by the FOI Act the use of this exemption requires the public interest for and against disclosure to be assessed.

To release this information would benefit in general by showing transparency in MHRA's day to-day work for the public to see assessment reports produced by MHRA in an unredacted form.

Information that details (i) medicine supply chain(s) and the contractual arrangements with third-party suppliers and (ii) methods of analysis/degradation studies, constitutes commercially sensitive information.

Disclosure of supply chain(s) and commercial arrangements with third parties can help rival companies in being able to source their active ingredient, excipients and services from these sources or can be used as market intelligence so strategies can be employed to prevent a product getting a foothold in the market.

Release of information concerning methods of analysis/degradation studies could be used by rival companies to overcome regulatory hurdles in the research and development of their own products, at the expense of the marketing authorisation holder. The exemption is to safeguard the commercially sensitive information/commercial enterprise.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

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/>