Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

2 November 2023

Dear [redacted]

FOI 23/758: Queries on production methods of Utrogestan capsules sold in the UK

Thank you for your request for information dated 5 October 2023 where you asked for information on the production methods, quality assurance checks and chemical tests that are conducted on Utrogestan capsules sold in the United Kingdom.

In the course of writing this response, we noted that there are both oral capsules and vaginal capsules with active marketing authorisations (MAs) in the United Kingdom. Therefore, it is necessary for us to seek clarification from you in relation to the specific product or products you are interested in. Presently, we are interpreting your request to relate to the below granted licences rather than historic cancelled MAs:

PL 28397/0003 Utrogestan 100 mg Capsules
PL 28397/0004 Utrogestan 200 mg Capsules
PL 28397/0005 Utrogestan Vaginal 200 mg Capsules
PL 28397/0012 Utrogestan Vaginal 300 mg Capsules

In terms of further advice and assistance, we are able to provide some general answers to your questions on the next page, which may assist you while you consider how best to clarify your request. Please note, that any clarified request will be allocated a new FOI reference number and the 20-working day period to respond will restart.

1. **how the Progesterone in the capsules is synthesized (i.e. is it chemically synthesized or is it synthesized using the fungus *Aspergillus?*).**

   The information is likely to be contained in the quality overall summary (m2 QOS). However, as this information concerns the manufacturing process of the product it may be commercially sensitive. If you were to make a request for this document for a specific product, we would then consider whether we could release the specific information concerned.

2. **What is the purity grade required for the ingredients in the capsules?**

   Please could you confirm if you intend to request the purity/grade of excipients that make up the capsule shell, or if you are referring to the ingredients inside the capsule. Please note, this information is likely to be commercially sensitive, but as mentioned above we could examine this further with regards to a specific request.

   Excipients are most frequently controlled to a national monograph, or an in-house specification.

3. **What kinds of chemical testing is conducted on the progesterone, soy lecithin, sunflower oil and gelatin in the capsules?**

   The controls and testing of the active substance and excipients will be tailored to the specific manufacture of the product concerned, and the character of the pharmaceutical ingredient concerned. For example, considerations related to polymorphic form, dissolution, stability, impurities etc.

   If requested for a specific product we could provide a high-level summary e.g. names of the general tests performed - provided that these are not novel modes of testing which may be commercially sensitive.

4. **Do regulatory agencies do any independent testing of the ingredients or final products?**

   NIBSC, a centre of the MHRA, is the UK's National Control Laboratory that is able to conduct batch testing for biological medicines and vaccines. More information is available online here: https://www.nibsc.org/control_testing/batch-release.aspx

   In terms of testing of non-biological medicines, the MHRA can also apply independent testing of drug substance or drug products if concerns related to their quality arise.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review.

The Information Commissioner can be contacted online via an electronic form:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or

by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Service Centre
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