

Request for a specific batch control (SBC)

NB: SBC requests may only be submitted in relation to nationally authorised products. Any application received in relation to a mutually recognised product (authorised via the mutual recognition or decentralised procedure) or centrally authorised product (authorised via the centralised procedure) will not be accepted.

An incomplete application form may delay the application process.

Further guidance about this application type is available on GOV.UK

Section 1 – administrative details

Product name:

Vm / ATC No:

Name and address of authorisation holder:

Company name:

Address:

Contact Details for this Application:

Name:

Email address:

Invoice Details: Email address of where the invoice should be sent to:

e-Issuing Details: Email address of where the authorisation documentation should be sent to (if different from application contact details above):

Section 2 – batch details

Please provide a summary of the batch deviation below:

Number of batches affected (a fee is payable for each affected batch):

Details of affected batches; please provide the following information for each affected batch and append the Certificates of Analysis for each batch:

1.Batch type:

- active substance
- excipient
- final product

Batch number:

Date of manufacture:

Batch size:

2.Batch type:

- active substance
- excipient
- final product

Batch number:

Date of manufacture:

Batch size:

3.Batch type:

- active substance
- excipient
- final product

Batch number:

Date of manufacture:

Batch size:

4.Batch type:

- active substance
- excipient
- final product

Batch number:

Date of manufacture:

Batch size:

Section 3 – related applications

Please include details of any other applications for this product that are currently under assessment by the VMD. If applicable, please include the date of any pending renewal applications.

Application number:

Application type:

Date Submitted:

Any other details in relation to ongoing variation applications:

Section 4 – declaration

I apply for the application as described above. I confirm that the information given in support of this application is correct at the time of submission.

Signature:

Name in block letters:

Job title:

Date:

If any information provided in this application is later found to be false or incorrect, the Secretary of State may suspend or revoke the authorisation.

Submission

Please submit your form to: s.response@vmd.gov.uk by email using Eudralink (normal email should not be used). The subject line should identify if it is a submission of an application or a response to the VMD