

Post Authorisation Assessments

Aftopur AISap Vm 61700/3039

25 July 2025	To declare three editorial changes in the Part II.D “in-process controls”. To implement a change in the manufacturing of the active substance “inactivated FMD virus” to remove the use of chloroform at virus harvest and to reduce the use of antibiotics in the virus culture
25 November 2024	Change in legal entity from Boehringer Ingelheim Animal Health UK Ltd., Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Vetmedica GmbH, Binger Strasse 273, 55216 Ingelheim Am Rhein, Germany.
06 July 2024	Update to the description of starting materials of biological origin.
03 May 2023	Addition of a new specification parameter to the specification with its corresponding test method for an excipient.
10 February 2023	The variation is to introduce the use of recombinant trypsin as a substitute to porcine trypsin for the manufacture of the active substance.
01 July 2022	Replacement of a site where batch testing takes place.
22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
24 September 2021	Changes to a test procedure for an excipient.
13 August 2021	Deletion of manufacturer responsible for batch release. Replacement Quality Control testing site for the finished product.
02 July 2021	Change in the specification parameters and/or limits of the immediate packaging of the finished product.
26 November 2020	Change in the name of the manufacturer of the finished product.
22 October 2020	Change in the specification parameters of the finished product. Changes in the manufacturing process of the active substance.
27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
14 October 2019	Deletion of Ph. Eur. TSE certificates of suitability for a starting material. Addition of alternative control tests for a starting material

	<p>used in the manufacture of the active substances.</p> <p>Tightening of specification limits of an excipient.</p> <p>Modification of an in-process control test applied during the manufacturing of the active ingredient.</p> <p>Introduction of a minor change in the manufacturing of the active ingredient.</p>
08 January 2019	<p>Change in the name of a manufacturer used in the manufacture of the active substance.</p> <p>Change in the name of a manufacturer of the finished product, also responsible for batch release.</p> <p>Change in the name and address of the marketing authorisation holder From Merial Animal Health Limited, PO Box 327, Sandringham House, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.</p>
20 September 2018	<p>Addition of a manufacturer responsible for batch release of the finished product.</p>
26 June 2018	<p>Addition of a new vaccine strain.</p> <p>Addition of a new vaccine strain.</p>
20 June 2018	<p>Change in RMS from UK to DE.</p>
28 February 2018	<p>Changes to a test procedure for the finished product.</p> <p>Changes in the manufacturing process of the active substance.</p> <p>Changes in the manufacturing process of the finished product.</p> <p>Changes in the manufacturing process of the active substance.</p>
31 October 2017	<p>Replacement of a test procedure for the active substance.</p>
04 June 2015	<p>Update to a starting material used in the manufacture of the finished product.</p>
05 March 2015	<p>Change in the manufacturing process of the active substance.</p>
11 September 2014	<p>Update to finished product manufacture and testing regime.</p>
03 May 2013	<p>Changes in manufacturing process of active substance.</p>
09 August 2012	<p>Submission of an updated Ph. Eur. Certificate of Suitability.</p>
24 February 2012	<p>Change to comply with Ph. Eur. or Pharmacopoeia of a member state.</p>
19 September 2011	<p>Change to comply with Ph. Eur. or Pharmacopoeia of a member state.</p>
10 June 2010	<p>Renewal (UK as RMS).</p>
25 November 2009	<p>MRP procedure (UK as RMS).</p>
25 October 2001	<p>Addition to SPC of experimental findings.</p>