



Post Authorisation Assessments

Eurican DHPPi Lyophilisate for Suspension for Injection Vm 08327/5053

11 May 2026	The variation is related to the working seed that could undergo one additional passage from the master seed virus (MSV).
16 February 2026	To remove a supplier of a starting material and to delete the certificate of suitability.
15 December 2025	To make editorial changes to the wording in the dossier to clarify the frequency of finished product testing. To make editorial changes to include reference to a starting material already authorised to adjust the pH of culture media in the dossier and to include reference to previously omitted active substance in the list of starting materials.
15 December 2025	To update the value of pH adjustment in the culture step of the manufacture of an active substance (parainfluenza virus) to align with the same pH as other active substances (from 7.0 ±0.1 to between 6.5 and 7.5).
03 July 2025	To add the compatibility claim of Eurican DHPPi with Eurican L4. To update the product literature to v.3 of the VMD's template, classified as G.I.18.
20 October 2024	This variation was aimed to change the name and address change of this subcontractor.
24 October 2023	Update to the description of starting materials of biological origin.
18 August 2023	Extension of a storage period of the active substance supported by real time data.
11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
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.
31 January 2023	Reduction of the minimum volume criterion of the CPV active ingredient for the formulation of lyophilisate.
26 January 2022	Changes in the manufacturing process of the active substance. Change of a test procedure for the active substance.
08 July 2021	Change in the batch size (including batch size range*) of the active substance used in the manufacturing process of the active substance. Change in storage conditions of the active substance. Change in the manufacturing process of the active substance.

09 April 2021	Changes to the labelling and package leaflet.
15 February 2021	Deletion of manufacturing site for the finished product.
22 July 2020	Change in the name of a manufacturer of the active substance.
18 June 2020	Change in the name of the manufacturer of the finished product.
27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
16 December 2019	Change of a test procedure for the active substance.
01 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
12 April 2018	Change of a test procedure for the finished product.
31 October 2017	Replacement of a test procedure for the active substance.
22 February 2017	Tightening of specification limits of the finished product.
02 December 2016	Change in the SPC, labelling or package leaflet due to new data.
17 June 2015	Submission of two TSE Ph. Eur. Certificates of suitability.
14 May 2014	Change in specification parameters and limits for the finished product.
30 October 2013	Change to manufacturing process of the active substance and finished product Change to test procedures performed on the finished product
23 May 2013	Update of specifications of the finished product
18 April 2013	Update of control tests performed on the finished product
30 May 2012	Removal of a manufacturing site of an active substance
09 May 2012	Update to sections 4.8, 4.9 and 6.2 of the SPC Removal of the diluent container from the pack
16 March 2011	Change of tests performed on an active substance Change of manufacturing process of the finished product Change of manufacturing process of an active substance
13 September 2010	Change in specification of the finished product
11 November 2009	Change in test procedure performed on the finished product
23 June 2009	Harmonisation of the SPC
24 October 2007	Change of manufacturer of active substance
15 August 2007	Update of EDQM certificates
26 July 2007	Deletion of a manufacturing site of an active substance
18 January 2007	Renewal
29 November 2006	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
10 February 2006	Submission of a new ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
21 January 2005	Removal of a test performed on the finished product

05 September 2003	Renewal
28 March 2003	Addition of 4 manufacturers of starting materials used during the manufacture of the active substance
20 August 2002	Addition of a manufacturing site for manufacture of the dosage form, primary and secondary packaging
07 August 2002	Addition of a manufacturing site for filling and freeze drying
27 March 2002	Change of manufacturer of the active substance
26 February 2001	Addition of a manufacturer of the active substance
31 August 2000	Addition of a new manufacturing site for QC procedures
17 January 2000	Change of manufacturing process of the active substance
15 July 1998	Change of manufacturing process of the active substance Changes to specification of the active substance