Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac ILT

Vm 42058/5204

18 June 2026	To change a supplier of SPF eggs used in the manufacture of the active substance.
31 March 2026	To include Eurofins PROXY Laboratories B.V., Darwinweg 24, Leiden, 2333 CR, Netherlands as an additional finished product quality control testing site.
28 November 2025	To add an alternative PCR-based identity test for the finished product.
19 May 2025	Change of Marketing Authorisation Holder from Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland (NI-only).
22 December 2022	Deletion of extraneous agents tests on the finished product based on assessment conducted in accordance with Ph. Eur. 5.2.5. Submission of updated certificate of suitability for Bovine Serum Albumin. To keep the upper limit of the active substance in the SPC, Labelling and Package leaflet as per the current effective version.
17 September 2021	Change in the composition (excipients) of the finished product.
14 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
04 June 2019	Update of a test procedure to comply with the updated Ph. Eur. monograph. Increase in the shelf-life of the finished product as packaged for sale, from 12 months to 24 years
22 February 2019	Deletion of a test procedure for the active substance used in the manufacturing process of the active substance if an alternative test procedure is already authorised.
06 November 2018	Change of a test procedure for the finished product.
20 September 2017	Change of a test procedure for the finished product.
21 November 2016	Change in test procedure for the finished product.
25 May 2016	Addition of an alternative test method.
7 January 2016	Change in test procedure for the finished product
23 October 2015	Change in name of manufacturer of the active substance. Change in name of manufacturer of the finished product.
20 October 2015	Change in name of manufacturer.
06 June 2014	Deletion of a manufacturing site.

22 November 2013	Variation to monitor the active substance by testing the respective method recommended by the European Pharmacopoeia Monograph 5.2.2.
19 July 2013	Grouped variation to change the Marketing Authorisation Holder and distributor. Also including a change of the name of the active substance manufacturer, a change in the name of the manufacturer of the finished product (responsible for batch release), and a change in the name of the manufacturer of the finished product (for all other processes).
01 August 2012	Addition of an alternative site for finished product testing.
16 July 2012	Variation to replace test methods recommended by the European Pharmacopoeia Monograph 5.2.2.
13 June 2011	Addition of supplier for a starting material used in the manufacturing process.
08 June 2011	Variation to change the final product testing, labelling, and batch release sites.
16 December 2010	Variation to change the name of the site for batch release, the importer for final dosage form (from outside EU), and site for QC retesting if imported from outside the EU.
23 November 2010	Variation to change the name of the finished product manufacturer.
15 July 2010	Renewal.
02 June 2010	Variation to replace the currently approved antibiotics.
21 April 2010	Change in the Marketing Authorisation Holder and distributor.
13 November 2008	Variation to update a test method to the European Pharmacopoeia 5th Edition.
24 May 2007	Variation to update SPC/Labelling in line with the Veterinary Regulations, 2005. Change of legal category from PML to POM-VPS.
09 June 2006	Change to the currently approved extraneous agents testing.