Veterinary Medicines Directorate

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Post Authorisation Assessments

Ovivac P Plus

Vm 01708/4388

•	01 November 2023	Change to comply with Ph. Eur.
•	27 June 2023	To update of the sterility test procedure performed on the finished product according to Ph.Eur. 2.6.1. Minor adjustments to the method suitability test to improve recovery of the A. brasiliensis reference strain.
•	17 March 2023	To optimise the statistical analysis method for the Fab ELISA to confirm M.haemolytica identity and P. trehalosi identity/potency. To add Intervet International B.V., Boxmeer, NL, as finished product Quality Control test site.
•	23 February 2023	Addition of an in vitro toxicity test for C. chauvoei cells and toxoid. Addition of the use of bovine liver extract in Clostridia growth medium.
•	11 August 2022	Change in test procedure for the finished product.
•	31 May 2022	Change of a test procedure for the active substance. Change of a test procedure for the active substance.
•	12 January 2022	Changes to a test procedure for the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance.
•	05 October 2021	Update of the test procedure to comply with the updated general Ph. Eur monograph. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Addition of a site where batch control/testing takes place.

•	17 March 2021	Change in the manufacturing process of the finished product.
•	01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
•	02 June 2020	Change in the name of the MAH, from Intervet UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	01 April 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	18 May 2018	Change in the manufacturing process of the active substance. Change in the manufacturing process of the active substance.
•	30 March 2017	Change in name of a manufacturer of the active substance.
•	29 May 2015	Change in specification parameter of the finished product.
•	19 July 2013	Change in the manufacturing process of the active substance, change to in-process controls of the active substance.
•	22 March 2012	Change to the manufacturer of the finished product.
•	11 May 2011	Update to Part II dossier
•	08 July 2009	Addition of a manufacturer of the finished product with a consequential change to the shape of the stopper.
•	15 April 2008	Changes to the SPC and product literature to bring them in line with new legislation.
•	15 April 2008	Change in legal category from PML to POM-VPS.
•	01 June 2006	Renewal
•	05 October 2005	Change to comply with supplements to the pharmacopoeias.
•	20 June 2005	Change of distributor.
•	21 January 2005	Change to the in-process controls for the finished product.
•	22 November 2002	Change to comply with Ph.Eur. monograph.
•	04 October 2002	Change in the shape of the packaging.
•	04 October 2002	Change of sites of assembly and batch release.
•	21 February 2002	Renewal
•	09 November 2001	Change to supplier of an ingredient.
•	31 August 2001	Addition of a distributor.
•	13 June 2001	Change to the manufacturing process.
•	15 September 2000	Change to Quality Control procedures.
•	30 August 2000	Addition of a manufacture of the active substance.
•	06 June 2000	Extension of shelf life to 36 months.
•	29 March 2000	Change in specification of the active substance.
•	21 March 2000	Change in name of MAH.
•	22 December 1999	Change in batch size of the active substance.
•	08 November 1999	Addition of a preservative.

•	14 June 1999	Change in specification of an ingredient.
•	20 October 1998	Addition of a manufacturer.