Veterinary Medicines Directorate

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Post Authorisation Assessments

Ovipast Plus
Vm 01708/4401

•	17 April 2023	Addition of an in vitro potency ELISA for C. perfringens type C beta toxoid. Optimisation of the statistical analysis method for the Fab ELISA to confirm M. haemolytica identity and P. trehalosi identity/potency. Addition of Intervet International B.V., Boxmeer, NL, as finished product Quality Control test site for the C. perfringens type C beta toxoid potency test, M. haemolytica identity test and P. trehalosi identity/potency test.
•	19 October 2022	Endotoxin test: replacement turbidimetric kinetic method with chromogenic kinetic method at QC testing site in Boxmeer (NL).
•	12 August 2022	Replacement of test method for the finished product.
•	16 February 2022	Changes to a test procedure (including replacement or addition) 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.
•	15 July 2021	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Update of the test procedure to comply with the updated general Ph. Eur monograph. Addition to a test procedure for the finished product. Addition of a site where batch control/testing takes place.
•	15 June 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.

•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	24 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.
•	01 May 2018	Change in RMS from UK to ES.
•	30 March 2012	Change in the name of the manufacturer of the finished product.
•	08 March 2012	Updates to the Part II dossier including; change in the control of the active substance, change in the control of the finished product, change in the manufacturer of the active substance, change in the manufacturer of the finished product.
•	28 October 2009	Addition of a site of filling of the finished product.
•	01 June 2006	Renewal
•	20 June 2005	Change of distributor.
•	30 August 2002	Addition of sites for finished product labelling and packaging and change in site of batch release.
•	04 January 2002	Change of a supplier of an ingredient.
•	22 October 2001	Change of distributor.