Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovilis Bovipast RSP

Vm 06376/5027

02 September 2026	Addition of an alternative sterility testing method for the finished product: automated growth detection systems. Addition of an alternative sterility testing method for the active substance: automated growth detection systems.
13 March 2026	Addition of an alternative stopper of the same material. Change to the in-process control test for iron regulated proteins for Mannheimia haemolytica. Change to the in-process control test for formaldehyde for Mannheimia haemolytica. Addition of an alternative in-process control test for sterility according to Ph. Eur. 2.6.1 for Mannheimia haemolytica. Updates to the antigen production process for Mannheimia haemolytica. Addition of MSD AH Danube Biotech GmbH, Krems, Austria, as a Mannheimia haemolytica antigen production site.
08 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
20 June 2025	Deletion of an obsolete parameter in the specification parameters of an excipient.
04 February 2025	Change in legal entity of the MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
19 December 2024	One-off alignment of the product information with the GB SPC/QRD template version 3.
24 March 2023	Delete the IPC test for the M. haemolytica antigen. Introduce an HPLC test to quantify Quil A for batch release. Delete the M. haemolytica ELISA quality control test used to quantity the antigen content in the finished product. Delete the upper limit for gamma irradiation of bovine serum. Add a container used to store the M. haemolytica antigen. Replace batch release potency tests for BRSV. Replace batch release potency tests for PI3. Replace batch release potency tests for M. haemolytica. Update of the dossier according to Annex II of Regulation 2019/6 and to a VNeeS format.
14 April 2021	Changes to the labelling and package leaflet.
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.

17 July 2020	Change in the composition (excipients) of the finished product. Change in the manufacturing process of the finished product.
15 May 2019	Replacement of a site where batch control/testing takes place.
25 January 2019	Change in the specification limits of the finished product. Changes in the summary of product characteristics (SPC) and package leaflet to implement the outcome of a PSUR assessment.
17 October 2018	Change in RMS from UK to IE.
15 October 2018	Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Change in the manufacturer of the active. Replacement of a site where testing takes place. Changes in the manufacturing process of the active substance. Addition of a manufacturing site of the finished product.
12 November 2015	The addition of an alternative sterility test method for the finished product. Replacing of a preservative.
17 August 2012	Grouped variation to: change a sterility test, change a control test, remove a control test, delete an identity test, delete a microbiological test, remove an identity test, and to change the sterilisation process of excipients.
30 March 2012	Change in the name and address of the manufacturer of the active substance.
30 March 2012	Change in the name and address of the manufacturer of the finished product.
06 September 2011	Changes in the test procedure for the finished product.
08 April 2011	Changes in the test procedure for the finished product.
03 February 2010	To introduce an alternative incubation temperature for BRSV propagation.
03 February 2010	Alternative use of a serum-free medium for MDBK cells.
03 February 2010	Introduction of and end of shelf-life date for an excipient.
17 December 2009	Minor change to finished product test procedure.
17 December 2009	Minor change to finished product test procedure.
09 October 2009	Renewal procedure.
01 October 2009	Minor change to finished product test procedure.
01 September 2009	Change of Marketing Authorisation Holder name and address.
03 December 2008	To update the description of the production process.
20 February 2008	Deletion of a manufacturing site.
13 June 2007	To include compatibility between viral markers.