Veterinary Medicines Directorate

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Post Authorisation Assessments

Enterisol Ileitis Lyophilisate and Solvent for Oral Suspension for Pigs

Vm 08327/4294

•	13 April 2024	Editorial changes to part 2B of the dossier.
•	27 February 2024	Change in the specification parameters of a starting material used in the manufacturing process of the active substance. (GB)
•	18 July 2023	To use recombinant non-animal origin trypsin as an alternative to porcine origin trypsin during the dissociation of McCoy cell line.
•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	15 March 2023	To make changes in the manufacturing process of the finished product by standardising the fill line set-ups with the installation of a 225-micron stainless steel mesh screen inline between the blending and filling lines
•	19 January 2023	The aim of this variation is the introduction of an optional sterile in-line screen mesh clarification system between the blending vessel and the filling lines of the manufacturing process of the modified live vaccines, Bovela, Enterisol Ileitis, Ingelvac PRRSFLEX EU, and ReproCyc PRRS.
•	24 October 2022	Optimisation of the cell planting procedure for the antigen quantification test. Optimisation of the cell planting procedure for the finished product batch release potency test.
•	24 September 2021	Change in the name of the manufacturer of the finished product.
•	04 March 2021	Change in the SPC, labelling or package leaflet due to new data.
•	14 January 2021	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
•	19 August 2020	Change in the name of the manufacturer of the finished product. Deletion of the diluent container from the pack.
•	09 October 2019	Change in the name of a manufacturer of active substance used in the manufacture of the active substance. Change in the name of the manufacturer of the finished product. Submission of an updated Ph. Eur. TSE certificate of

		suitability from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability from an already approved manufacturer.
•	24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	06 March 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	07 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	23 October 2018	Changes to the labelling and package leaflet.
•	05 December 2017	Deletion of a manufacturing site for an active substance. Replacement of a secondary packaging site of the finished product
•	13 June 2017	Minor change to an approved test procedure for the active substance.
•	24 February 2017	Repeat Use application to add one new member state
•	10 February 2017	Deletion of a test procedure used in the manufacturing process of the active substance. Deletion of a test procedure used in the manufacturing process of the active substance. Deletion of a test procedure used in the manufacturing process of the active substance. Submission of a new Ph. Eur. TSE certificate of suitability from a new manufacturer. Widening of the specification limits used in the manufacturing process of the active substance. Submission of a new Ph. Eur. TSE certificate of suitability from a new manufacturer. Submission of a new Ph. Eur. TSE certificate of suitability from a new manufacturer. Submission of a new Ph. Eur. TSE certificate of suitability from a new manufacturer.
•	15 December 2016	Change in the SPC, labelling or package leaflet due to new data.
•	04 November 2016	Change in address of the Polish local representative.
•	12 July 2016	Revision of the primary packaging documentation
•	11 January 2016	Minor changes to the identification/potency test method Minor changes to the extraneous agents test method
•	12 November 2015	Introduction of a new pharmacovigilance system
•	14 July 2015	Repeat use procedure.
•	01 July 2015	Addition of an alternative site for secondary packaging.
•	05 January 2015	Submission of updated Ph. Eur. Certificates of Suitability.
•	24 September 2012	Addition of a manufacturing site for secondary packaging
•	05 January 2012	Change of address of the MAH

•	17 December 2009	Renewal
•	09 January 2008	Change of suppliers of a starting material used in the manufacture of the active substance Submission of an updated Ph. Eur. Certificate of Suitability for a starting material used in the manufacture of the active substance
•	19 December 2007	Corrections to the SPC and change of legal category to POM-V
•	26 July 2007	Removal of target animal safety test
•	13 February 2006	Change of batch size of finished product
•	01 September 2005	Change of shelf life for 100 dose presentation from 1 year to 2 years