



Post Authorisation Assessments

Hypermune-RE Equine Plasma

Vm 18513/4001

•	21 November 2023	Total protein to be tested at Biobest Laboratories Ltd. IgG to be tested at Veterinary Immunogenics Laboratory using Radial Immunodiffusion test kits.
•	07 September 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	09 May 2023	Change in immediate packaging of the active substance.
•	28 July 2022	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	17 December 2021	Change in the manufacturer of an intermediate used in the manufacturing process of the active.
•	17 March 2021	Addition of a site where batch control/testing takes place.
•	29 September 2020	Change in the specification limits of the finished product.
•	11 June 2020	Replacement of a site where batch control/testing takes place. Replacement of a site where batch control/testing takes place.
•	09 April 2019	Change in RMS from UK to IE
•	16 November 2012	Change of test procedure used during the manufacturing process.
•	26 June 2012	Variation to increase the release titre for the potency test.
•	09 May 2012	Renewal procedure, UK as RMS.
•	04 August 2008	New MA (MRP)
•	21 June 2007	Variation to add a new QC contract test laboratory