



Post Authorisation Assessments

Torphasol 10 mg/ml Solution for Injection for Horses Vm 24745/4009

•	13 April 2024	Deletion of a non-significant specification parameter in the specification parameters of the finished product.
•	13 April 2024	Change in test procedure for the finished product.
•	29 November 2023	Change of Distributor address, from Animalcare Limited, Unit 7, 10 Great North Way, York Business Park, York, YO26 6RB, United Kingdom to Animalcare Limited, Moorside, Monks Cross, York, YO32 9LB, United Kingdom.
•	09 August 2023	Substantial changes in an updated version of an ASMF.
•	08 February 2022	Update of ASMF.
•	10 January 2018	Replacement of a site where batch control/testing takes place.
•	29 September 2015	Renewal – UK as CMS.
•	13 August 2014	To extend the shelf life of the finished product, from 24 months to 36 months.
•	10 June 2013	Change in distributor address.
•	25 April 2013	Up to 10 fold increase in batch size of active substance.
•	11 March 2013	Variation to make minor changes to the manufacturing process of the active substance to update the ASMF.
•	07 December 2012	To change the QPPV.
•	04 October 2012	To change the preservative used.
•	28 September 2011	Repeat Use Procedure.
•	02 March 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	02 March 2011	Changes to packaging material.
•	23 November 2010	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.
•	23 November 2010	Change in the name and/or address of a manufacturer of the active substance/starting material/reagent or intermediate used in the manufacture of the active substance.
•	23 November 2010	Change in the specification parameters and/or limits of an active substance starting material/intermediate/reagent used in the manufacturing process of the active substance
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		limits of an active substance starting material/intermediate/reagent used in the manufacturing process of the active substance.
•	23 November 2010	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.