Veterinary Medicines Directorate

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Post Authorisation Assessments

Surantel P Horse Wormer 40% w/w Oral Paste

Vm 50146/4012

•	24 July 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	23 November 2022	Minor changes to an approved test procedure for the active substance.
•	06 May 2021	Change in distributor details. From D&H Group, Maple House, Hamlin Way, Kings Lynn, PE30 4NG, United Kingdom, Tel: 0845 270 224 Fax: 0845 270 3334, Email: info@dandhgroup.co.uk to D&H Limited, Deerfields, Lynn Road, Setchey, King's Lynn, Norfolk, PE33 0BD, United Kingdom, Tel: 01553 819590, Email: sales@dandhdirect.com.
•	18 March 2021	Replacement of a secondary packaging site of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	05 August 2019	Change in the name used in the manufacture of the active substance. Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	25 October 2018	Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	11 September 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 May 2018	Deletion of manufacturing site for an active substance.
•	26 May 2017	Mock-ups approved. Change in distributor details from Janssen Animal Health to D&H Group.
•	22 November 2016	Changes in the invented name of the product from Exodus Horse Wormer 40% w/w Oral Paste to Surantel P Horse Wormer 40% w/w Oral Paste.
•	03 December 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
•	06 September 2012	Change to specification limits of an antioxidant in the finished product.

		Minor change to test procedure performed on the finished product.
•	22 September 2011	Addition of a manufacturing site for batch release. Submission of an updated Ph. Eur. Certificate of Suitability for an excipient from an already approved manufacturer.
•	08 March 2011	Change in test procedure performed on the finished product.
•	15 February 2011	Submission of a new Ph. Eur. Certificate of Suitability for an excipient from an already approved manufacturer.
•	30 June 2010	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	20 October 2009	Change of specification of the finished product.
•	07 July 2009	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	16 April 2009	Renewal
•	07 April 2009	Minor change to the manufacturing process of the finished product.
•	17 February 2009	Change of distributor
•	11 June 2008	Change of legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation.
•	11 November 2007	Change in packaging component.
•	13 June 2007	Minor change to the manufacturing process of the active substance.
•	14 January 2005	Addition of manufacturing site of assembly.