Veterinary Medicines Directorate

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Post Authorisation Assessments

Equimax Oral Gel for Horses

Vm 05653/5042

•	15 November 2021	Change to update the local representative for Ireland for all presentations. Changes to the labelling and/or package leaflet.
•	14 October 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 May 2021	Deletion of a non-significant specification parameter of the finished product.
•	07 August 2020	Submission of a new Ph. Eur. certificate of suitability for an active from a new manufacturer.
•	02 September 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Introduction of a re-test period of the active substance.
•	27 June 2019	Change in the manufacturing process of the finished product.
•	31 May 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 July 2018	Change in RMS from UK to IE.
•	27 March 2018	Change in test procedure for active substance used in the manufacturing process of the active substance
•	14 February 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	04 December 2017	Minor changes in the manufacturing process of the finished product.
•	08 May 2017	Mock-ups approved.
•	12 December 2016	Increase in batch size of the finished product.
•	15 September 2016	Change in distributor details.
•	22 June 2016	Update to existing test method for finished product. Update to existing test method for finished product. Update to existing test method for finished product. Removal of a test from ivermectin active substance specification. Submission of an updated Ph. Eur. certificate of suitability. Change in the limits of a test in the finished product specification.
•	14 April 2016	Approval of revised mock-ups

•	02 April 2015	Submission of new Ph. Eur. Certificates of Suitability.
•	09 January 2013	Change of MAH.
•	19 April 2011	Approval of previously unseen mock ups.
•	15 April 2011	Addition of warnings on the SPC and Product Literature regarding resistance to anthelmintics.
•	20 January 2011	Change of address of the MAH.
•	11 December 2009	Addition of a manufacturing site for all of the manufacturing process. Addition of a manufacturing site for batch release.
•	02 September 2009	Change of batch size of the finished product.
•	10 March 2008	Renewal.
•	13 September 2006	Change of manufacturing site of the active substance.
•	17 November 2005	Repeat use procedure.
•	09 December 2004	Increase of fill volume of non-parenteral multi dose product.
•	19 November 2004	Addition of secondary packaging sizes – 2 syringes and 40 syringes.
•	25 June 2004	Addition of indication for use in pregnant/lactating mares.
•	30 March 2004	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	04 February 2004	Repeat use procedure.
•	13 November 2003	Deletion of flavouring Addition of 12 and 48 syringe presentations.
•	23 October 2003	Repeat use procedure.
•	11 March 2003	Change of batch size of the active substance.
•	30 January 2003	Updates to SPC.
•	17 January 2002	Mutual Recognition Procedure.