Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetoryl 10 mg Hard Capsules for Dogs

Vm 10434/5006

•	08 February 2023	Deletion of a non-significant in-process test during the manufacture of the finished product.
•	23 January 2023	Editorial changes to part 2 of the dossier.
•	07 September 2022	Deletion of a non-significant in-process test during the manufacture of the finished product.
•	28 July 2022	Editorial changes to Part II B of the dossier for the 10 mg hard capsules. Editorial changes to Part II C of the dossier for the 5 mg and 60 mg hard capsules. Editorial changes to Part II F of the dossier for the 30 mg, 60 mg and 120 mg hard capsules.
•	29 March 2022	Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	16 November 2021	Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	23 September 2021	Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
•	09 February 2021	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
•	17 October 2019	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of a new Ph. Eur. TSE certificate of suitability from a new / already approved manufacturer. Deletion of Ph. Eur. TSE certificates of suitability. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
•	24 September 2019	Changes to a test procedure for the finished product.
•	07 August 2019	Update to the ASMF.
•	18 June 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	02 April 2019	Minor change to an approved test procedure for the active substance.
•	February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.

•	08 February 2019	Introduction of a new site of manufacture.
•	01 August 2018	Change in RMS from UK to IE.
•	19 December 2017	Repeat Use application to add 2 new member states
•	02 February 2017	Changes to the labelling and package leaflet.
•	17 May 2016	Deletion of a TSE certificate. Submission of a new TSE certificate. Submission of an updated TSE certificate. Submission of a new TSE certificate. Submission of a new TSE certificate.
•	21 May 2015	Submission of updated Ph. Eur. Certificates of Suitability from an already approved manufacturer
•	01 May 2015	Change in name of a manufacturer of the active substance.
•	27 February 2015	Minor changes to an approved test procedure.
•	20 November 2014	Updates to the labelling and package leaflet.
•	10 October 2014	Change of MA holder address.
•	06 March 2014	Significant change to the SPC with regard to clinical data.
•	14 November 2013	To update the drug master file. Amendment to specifications of raw materials. Updates to manufacturing methods.
•	03 January 2013	Renewal procedure – UK as RMS.
•	03 June 2012	Submission of new or updated Ph. Eur Certificates of Suitability.
•	02 March 2012	Change in the manufacturer of the active substance.
•	09 December 2011	To change the ink used to mark the capsules.
•	01 April 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	15 December 2010	Change of Distributor.
•	06 October 2010	To change the Marketing Authorisation Holder.
•	17 September 2010	Change in immediate packaging of the finished product.
•	17 September 2010	Submission of new or updated Ph. Eur Certificates of Suitability.
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•	17 September 2010	Submission of new or updated Ph. Eur Certificates of Suitability.
•	17 September 2010	Submission of new or updated Ph. Eur Certificates of Suitability.
•	23 October 2008	Change shelf life of finished product from 2 years to 3 years.
•	03 October 2008	Change active substance batch size