Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetoryl 60 mg Hard Capsules

Vm 10434/5010

•	25 August 2023	Deletion of a non-significant specification parameter in the finished product specification. Deletion of a non-significant specification parameter in the finished product specification. Deletion of a non-significant specification parameter in the finished product specification.
•	25 August 2023	Minor changes:– to an approved test procedure for active substance, for the finished product, for the immediate packaging of the active substance or the finished product, or of a measuring or administration device.
•	18 August 2023	Change to an approved stability protocol of the finished product.
•	29 March 2023	Editorial changes to part 2 of the dossier. Editorial changes to part 2 of the dossier.
•	08 February 2023	Deletion of a non-significant in-process test during the manufacture of the finished product.
•	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.
•	21 April 2020	Deletion of manufacturing site where batch control takes place.
•	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.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	09 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.
•	25 November 2015	Additional site for batch testing of the finished product.
•	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
•	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	Grouped variation to change the test procedures, manufacturing process, and manufacturer of the active substance.
•	03 May 2012	Submission of a new Ph. Eur. Certificate 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.
•	07 June 2010	Renewal.
•	03 October 2008	Change active/intermediate batch size.
•	21 November 2007	Variation to endorse manufacturing process.
•	05 July 2007	Change test procedure for active/active component.
•	01 June 2007	Change shelf life of finished product as packaged for sale.
•	01 June 2007	Change finished product test procedure.
•	01 June 2007	Change finished product test procedure.
•	16 May 2007	Change/addition of imprints/bossing/markings on tabs or capsules.
•	16 May 2007	Change in batch size of finished product.
•	16 May 2007	Change to batch release arrangements.
•	08 March 2006	Change of distributor.

•	15 February 2006	Replace/add manufacturing site.