Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetoryl 30 mg Hard Capsules

Vm 10434/3003

•	28 April 2024	Deletion of a non-significant specification parameter in the specification parameters of the finished product.
•	19 March 2024	Change in the address or contact details of a manufacturer or supplier of the starting material, used in the manufacture of the active substance where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. Change to comply with Ph. Eur. for the starting material used in the manufacture of the active substance. Changes to the quality part of the dossier: Deletion of a test procedure for a reagent used in the manufacture of the active substance. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter of an active substance.
•	27 February 2024	Change in qualitative composition of the immediate packaging for a solid pharmaceutical form for a finished product.
•	28 November 2023	One-off alignment of the product information with version 9.0* of the QRD template.
•	16 November 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.
•	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.
•	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.
•	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
•	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 concerning changes to the manufacturing process, test procedures, and the 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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•	23 October 2008	Change shelf life of finished product (as packaged for sale).
•	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 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.
•	18 March 2005	Change in specifications of active substance.