Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetoryl 30 mg Hard Capsules for Dogs

Vm 50406/3016

01 April 2026	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
14 January 2026	Tightening of specification limits of an excipient. Minor changes to an approved test procedure for an excipient.
14 October 2025	Harmonisation of the quality dossier.
29 May 2025	Submission of an updated European Pharmacopoeial TSE Certificate of suitability for an excipient. Submission of an updated European Pharmacopoeial TSE Certificate of suitability for an excipient. Submission of a new European Pharmacopoeial TSE Certificate of suitability for an excipient.
15 April 2025	Substantial changes in the updated version of the ASMF for trilostane from the currently authorised manufacturer.
03 April 2025	Addition of a new specification parameter to the specification with its corresponding test method. Addition of a new specification parameter to the specification with its corresponding test method. Addition of a new specification parameter to the specification with its corresponding test method. Deletion of a test procedure for the active substance. Deletion of a non-significant specification parameter of an active substance. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
03 April 2025	Submission of a new Ph. Eur. certificate of suitability for a starting material used in the manufacturing process of the active substance.
25 February 2025	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.
05 February 2025	Change in legal entity of MA holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
01 December 2024	Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter in the specification of the finished product.
01 December 2024	Uniformity of dosage units is introduced to replace the currently registered method.

01 December 2024	Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range. Change in the specification parameters and/or limits of the finished product: - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product. Change in the specification parameters and/or limits of the finished product: - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product. Change in the specification parameters and/or limits of the finished product: - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product. Harmonisation of the quality dossier.
20 October 2024	VeDDRA LLT weakness moved from very rare frequency to rare frequency. Alteration of wording describing mortalities following chronic administration dosage levels.
02 July 2024	Addition of a new specification parameter to the specification with its corresponding test method. Minor changes to an approved test procedure for an in-process test for active substance. Addition of a supplier of packaging components or devices (when mentioned in the dossier). Addition of a supplier of packaging components or devices (when mentioned in the dossier). Addition of a supplier of packaging components or devices (when mentioned in the dossier). Addition of a supplier of packaging components or devices (when mentioned in the dossier).
02 July 2024	Changes in the manufacturing process of the active substance.
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.