Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetoryl 120 mg Hard Capsules for Dogs

Vm 50406/5020

15 April 2025	Substantial changes in the updated version of the ASMF for trilostane from the currently authorised manufacturer.
15 April 2025	Change to quality testing arrangements for a finished product.
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.
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.
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.
14 December 2024	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.
01 December 2024	Uniformity of dosage units is introduced to replace the currently registered method.
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. 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.
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.
September 2024	Deletion of a test procedure for the active substance. Deletion of a non-significant specification parameter of a starting material used in the manufacturing process of 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. Submission of a new Ph. Eur. certificate of suitability for a manufacturer of the active substance.
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.
27 February 2024	Change in qualitative composition of the immediate packaging for a solid pharmaceutical form for a finished product.
25 January 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 a test procedure for a reagent used in the manufacturing process of the active substance:– for a reagent, which does not have a significant effect on the overall quality 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. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Minor changes: – to an approved test procedure for the active substance.
28 November 2023	One-off alignment of the product information with version 1 of the National QRD template.
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.
18 August 2023	Change to an approved stability protocol of the finished product.
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.
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.
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.
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 update the DMF, amend the raw materials specifications, update the manufacturing methods, and to optimise the active substance manufacturing method.
03 May 2012	Grouped variation to update TSE Certificates of Suitability as well as the addition of a new Certificate of Suitability for an active substance manufacturer.
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.
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.
08 March 2006	Change of distributor.