Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetoryl 5 mg Hard Capsules for Dogs

Vm 50406/5022

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	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	Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter in the specification the finished product.
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.
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.
08 March 2023	Deletion of a non-significant specification parameter of the finished product.
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.
23 September 2021	Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
23 June 2021	Change in immediate packaging of the active substance.