Veterinary Medicines Directorate

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Post Authorisation Assessments

VetOne Fluriso 1000 mg/g Inhalation Vapour Liquid

Vm 37071/4002

•	05 March 2024	Change to in-process tests or limits applied during the manufacture of the active substance. Changes to the quality part of the dossier. Changes to the quality part of the dossier. Changes to the quality part of the dossier. Minor changes in the manufacturing process of an active substance. Minor changes in the manufacturing process of an active substance. Minor changes in the manufacturing process of an active substance.
•	21 September 2023	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance: - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate
•	29 August 2023	Change in test procedure for the finished product.
•	10 February 2022	Change in the name of a supplier of starting material used in the manufacture of the active substance. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Tightening of specification limits of the immediate packaging of the finished product.
•	06 January 2022	Minor change in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance.
•	13 October 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	30 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	15 February 2021	Processes updated for control of the active substance, according to appropriate Commission Regulations.
•	18 January 2021	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name of the manufacturer of the finished product.

•	December 2020	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 September 2020	Increase in batch size of the finished product.
•	12 August 2020	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change to part of the (primary) packaging material not in contact with the finished product formulation.