Veterinary Medicines Directorate

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Post Authorisation Assessments

Isoflurane-Vet 100% w/w Inhalation Vapour, Liquid

Vm 08327/4131

•	24 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	13 January 2022	Change to in-process tests or limits applied during the manufacture of the active substance. Minor change to the restricted part of an Active Substance Master File.
•	08 November 2021	Change in the name/address of a manufacturer 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.
•	15 July 2021	Deletion of a quality control testing site from the product dossier.
•	23 June 2021	Changes to a test procedure (including replacement or addition) for a starting material.
•	13 April 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.
•	16 October 2020	Change in the manufacture of a starting material used in the manufacturing process of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier. Changes to a test procedure for a starting material.
•	15 October 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.
•	28 September 2020	Increase in batch size (from 1500 kg to 4000 kg for the 100 ml pack size and from 3000 kg to 4000 kg for the 250ml pack size) of the finished product.
•	07 May 2020	Increase in batch size (from 1500 kg to 3000 kg) of the finished product.
•	28 April 2020	Update to the part II data for the active substance.
•	25 September 2019	Minor changes to an approved test procedure of the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.

•	28 August 2019	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	09 May 2019	Replacement of a site where batch control takes place.
•	29 November 2018	Addition of a manufacturer responsible for batch release of the finished product.
•	29 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	06 November 2018	Replacement of a supplier of packaging components or devices. Change in shape or dimensions of the container or closure (immediate packaging).
•	14 May 2018	Change in the address of a manufacturer of the active substance used in the manufacture of the active substance. Change in the address of the manufacturer of the finished product. Change in the address of the manufacturer of the finished product.
•	15 February 2017	Change in the name of a manufacturer of the finished product.
•	26 November 2015	Change in address of an ASMF holder. Change in address of manufacturer of the finished product.
•	23 June 2015	To decrease the batch size of the finished product.
•	24 November 2014	To increase the batch size of the finished product.
•	07 May 2013	Change of name of manufacturer of the finished product. Change of manufacturing and assembly site of the dosage form. Change of manufacturer of the active substance.
•	29 June 2011	Changes in the manufacturing process of the active substance.
•	15 June 2011	Change of batch size. Addition of a manufacturer of a starting material used in the production of the active substance
•	25 May 2011	Change to specification of the finished product. Change to specification of the active substance.
•	26 July 2010	Change of name of manufacturing site of batch control/testing. Replacement of manufacturing sites for batch control/testing and batch release.
•	12 December 2008	Change of manufacturing site responsible for batch control/testing of the finished product.
•	13 November 2008	Change of name of manufacturer of the active substance. Change of name of a manufacturer of the finished product.
•	12 November 2008	Addition of 2 manufacturers of the active substance.
•	31 July 2008	Updates to section 4.11 of the SPC.
•	11 October 2007	Replacement of manufacturing site for the active

		substance.
•	08 October 2007	Addition of a manufacturer responsible for batch release and quality control testing of the finished product.
•	25 July 2007	Change of legal category from POM to POM-V. Changes to the SPC and Product Literature to bring in line with new legislation.
•	27 June 2006	Change of name of the manufacturing site of assembly of the dosage form.
•	17 May 2006	Renewal.
•	10 March 2006	Addition of a manufacturing site for QC testing. Change of manufacturing site for batch release. Deletion of a manufacturing site for the active substance. Change of name of a manufacturer of the finished product. Change of name of the manufacturer of the active substance.
•	05 November 2004	Changes to the SPC and Product Literature to bring in line with new legislation.
•	15 March 2002	Addition of a manufacturing site for the assembly of the finished product.
•	15 February 2002	Renewal.
•	11 October 2000	Minor change of manufacture of the active substance.
•	28 September 2000	Change of name of manufacturer of the finished product.
•	29 February 2000	Change of product name from ‘Isoflurane’ to ‘Isoflurane-Vet’.
•	06 July 1998	Change of MAH.