Veterinary Medicines Directorate

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Post Authorisation Assessments

Furosemide Tablets BP (Vet) 20 mg

Vm 04409/4001

•	21 December 2022	Addition of microbiological testing site.
•	06 December 2022	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	31 August 2022	Change in the specification limits for dissolution of the finished product. Change in assay specification limits testing method. Changes in the related substances specification. Replacement of a batch release testing site for a finished product. Addition of a batch release site.
•	18 May 2022	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	22 April 2021	Change in storage conditions of the finished product.
•	18 March 2021	Addition of a new specification parameter to the specification with its corresponding test method 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. Change in the specification parameters and/or limits of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 November 2020	Change in 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.
•	28 January 2020	An update to amend the source of a supplier of an excipient.
•	14 January 2020	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	02 January 2020	Tightening of in-process limits applied during the manufacture of the finished product. Tightening of specification limits of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a site where batch control/testing takes place. Deletion of manufacturing site for an active substance.

		Deletion of manufacturing site for finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	02 January 2020	Tightening of specification limits of the finished product. Tightening of in-process limits applied during the manufacture of the finished product.
•	06 July 2018	Change in the name of a manufacturer of active substance used in the manufacture of the active substance. Replacement of a site where batch control/testing takes place.
•	29 October 2010	Addition of a manufacturing site for testing of dosage form
•	24 March 2009	Addition of a manufacturing site for all of the manufacturing process of the finished product
•	19 December 2008	Introduction of a new label type
•	19 November 2008	Change or addition of imprints, bossing or other markings (except scoring/break lines) on tablets or printing on capsules, including replacement, or addition of inks used for product marking.
•	16 November 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	31 March 2006	Renewal
•	14 October 2004	Change of name of product from ‘Frusemide Tablets BP 20mg’ to ‘Furosemide Tablets BP (Vet) 20mg’
•	16 April 2004	Addition of a manufacturing site for the finished product
•	31 January 2003	Addition of a manufacturer of the active substance
•	08 November 2002	Change of specification of the finished product
•	30 November 1999	Addition of a manufacturer of the active substance