Veterinary Medicines Directorate

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Post Authorisation Assessments

Pen & Strep Suspension for Injection

Vm 02000/4100

•	28 April 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	28 April 2024	Submission of a new or updated Ph. Eur. certificate of suitability for an active substance.
•	23 April 2024	Change in the shelf-life or storage conditions of the finished product: - Extension of the shelf life of the finished product - As packaged for sale. Change in the storage conditions of the finished product.
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
•	29 September 2022	Deletion of a non-significant in-process test during the manufacture of the finished product.
•	17 August 2022	Submission of an updated version of an ASMF.
•	04 April 2022	Changes in the SPC, Labelling or Package intended to implement the outcome of a PSUR.
•	02 March 2022	Deletion of manufacturing site for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	30 July 2019	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.
•	10 May 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	21 May 2018	Minor change in the manufacturing process of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer Minor change in the manufacturing process of an oral solution.

•	05 January 2018	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
•	09 February 2017	Addition of a manufacturer of the active substance.
•	30 October 2014	Addition of an active substance manufacturer.
•	25 January 2012	Change in the immediate packaging of the finished product.
•	02 November 2011	Variation to change the Distributor.
•	13 September 2011	Change in the shelf life of Veterinary Medicinal Product.
•	02 September 2011	Change in the assay limits of the shelf life specification.
•	14 July 2011	Change in the shelf life of the Veterinary Medicinal Product.
•	30 June 2010	Deletion of an Active Substance Manufacturer.
•	03 April 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	07 February 2007	Change of legal category from POM to POM-V.
•	21 December 2005	Renewal.
•	23 November 2005	Addition of a site of secondary assembly.
•	02 November 2005	Variation to submit a new milk residue study.
•	25 July 2005	Change in the Active Substance Manufacturer.
•	11 November 2004	Horse Passport.
•	05 June 2003	Change in the manufacturing process (product).
•	06 August 2002	Variation to change a withdrawal period.
•	06 August 2002	Renewal.
•	21 March 2002	Addition of an Active Substance Manufacturer.
•	15 October 1996	Renewal.