Veterinary Medicines Directorate

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Post Authorisation Assessments

Tetroxy L.A. 200 mg/ml Oxytetracycline Solution for Injection

Vm 50146/4028

•	25 January 2024	Implementation of Article 83 referral decision affecting products including NMP as an excipient.
•	29 September 2023	Minor changes to an approved test procedure for the finished product. Replacement of a secondary packaging site for the finished product.
•	29 September 2023	Change in the batch size of the finished product. Minor changes in the manufacturing process. Replacement of a manufacturer responsible for importation and/or batch release. Replacement of a site for the manufacturing process of the finished product. Submission of a new Ph. Eur. certificate of suitability for an active substance.
•	18 March 2021	Replacement of a secondary packaging site of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	23 July 2019	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	25 October 2018	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of MAH, from Bimeda Chemicals Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
•	09 December 2014	Submission of an updated Ph. Eur. Certificate of Suitability.
•	04 July 2012	Variation to make minor changes to the manufacturing process of the finished product.
•	07 June 2011	Addition of an active substance manufacturer.
•	24 February 2011	Variation to decrease a withdrawal period (pig). Variation to change the maximum injection site volume in pigs.
•	30 April 2010	Renewal.
•	16 March 2010	Increase of the withdrawal period for cattle and pig.
•	29 December 2009	Abbreviated re-submission of a previously refused Type II variation.
•	29 July 2008	Variation to revise the contraindications with regards to

		milk product animals.
•	21 May 2008	Change in the manufacture of the active substance.
•	28 April 2008	Deletion of a manufacturing site for the active substance.
•	22 September 2007	Variation to update a Certificate of Suitability for an active substance manufacturer.
•	02 March 2007	Variation to update the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	31 January 2007	Variation to change a finished product test procedure.
•	06 June 2006	Variation to submit a new Certificate of Suitability for an active substance manufacturer.
•	22 February 2006	Increase in the withdrawal period (sheep).
•	22 May 2003	Addition of an assembler.
•	11 March 2003	Variation to change the composition of the finished product.
•	12 April 2002	Variation to change the manufacturing process.
•	09 November 2001	Variation to change the manufacturing site of the dosage form.
•	16 November 1999	Variation to change the active ingredient manufacturer.
•	04 February 1998	Renewal.
•	27 January 1998	Variation to update the pharmaceutical warnings.
•	29 September 1997	Variation to update the active substance manufacturer.
•	22 April 1996	Addition of a packaging presentation.
•	27 September 1995	Change to the safety warnings.