Veterinary Medicines Directorate

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Post Authorisation Assessments

Terramycin/LA 200 mg/ml Solution for Injection

Vm 42058/4151

•	01 March 2024	Deletion of a manufacturing process for an active substance. Deletion of site responsible for the manufacture of an active substance.
•	27 September 2023	Minor change in test procedure for an excipient.
•	27 September 2023	Change in test procedure for the finished product.
•	13 December 2022	Minor changes to an approved test procedure for active substance.
•	15 November 2022	Change in the Summary of Product Characteristics, Labelling or Package Leaflet, to sections 4.5, 4.6, 4.7, 4.8.
•	06 May 2022	Tightening of specification limits of the finished product.
•	15 February 2022	Change of a re-test period / storage period of the active substance.
•	19 May 2021	Submission of a new certificate of suitability for an active substance.
•	16 March 2021	Change of specification(s) of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Increase in batch size (from 1600 L to 4000 L to a range of 1600 L to 5000 L) of the finished product. Change in manufacturing process of the finished product.
•	11 January 2021	Introduction of a re-test period of the active substance.
•	27 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	07 July 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	21 February 2020	Change in shape or dimensions of the container or closure (immediate packaging). Change in the manufacturing process of the finished product.
•	07 February 2018	Change in the manufacturing process of the active substance.
•	07 February 2018	Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an active substance.
•	13 September 2017	Minor changes to an approved test procedure of the finished product.

		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. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	29 October 2015	Submission of new Ph. Eur. Certificates of Suitability for the active substance, from new manufacturers.
•	11 March 2015	Addition of a new manufacturing site for all manufacturing operations. Change in batch size of the finished product. Changes in the specifications of the finished product. Minor update to an approved test procedure.
•	19 December 2014	Change in the name of the manufacturer of the finished product, also responsible for batch release.
•	25 June 2014	Change to the Marketing Authorisation Holder and distributor details. Deletion of a manufacturing site for the active substance.
•	29 May 2013	Grouped variation to submit an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	16 May 2012	Variation to submit mock-ups for approval to due a change of manufacturer.
•	13 March 2012	Grouped variation to submit an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	28 July 2011	Variation to submit an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	10 August 2010	Variation to change the address of the finished product manufacturer.
•	22 November 2007	Addition of an active substance manufacturer.
•	20 July 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	01 February 2007	Renewal.
•	10 January 2007	Variation to delete a reference to a species (deer) in the Marketing Authorisation.
•	10 January 2007	Variation to change the meat withdrawal period.
•	22 June 2005	Variation to change the conditions applied within stability studies.
•	22 June 2005	Variation to increase the batch size of the finished product.
•	17 June 2005	Addition of a distributor.
•	25 February 2005	Variation to change the name of the manufacturer/assembler of the finished product.
•	30 April 2002	Variation to change the starting material.
•	21 May 2001	Renewal.
•	09 April 1999	Change in the manufacturing process of the dosage form.

•	18 June 1998	Variation concerning the therapeutic purpose.