Veterinary Medicines Directorate

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Post Authorisation Assessments

Otoxolan Ear Drops, Suspension for Dogs

Vm 01656/5081

•	11 January 2024	Change to comply with an update of the relevant monograph of the Ph. Eur.
•	06 November 2023	Editorial corrections to part 2 of the product dossier.
•	13 January 2023	Minor changes to an approved test procedure for the finished product.
•	16 August 2022	Replacement of test procedures for the finished product.
•	19 July 2022	Minor changes to an approved test procedure for the finished product.
•	29 March 2022	Increase in batch size (from 60L - 95L to 60L - 450L) of the finished product.
•	29 March 2022	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	02 March 2022	Renewal – UK as CMS.
•	25 June 2021	Addition of a site where batch control/testing takes place. Replacement of a primary packaging site of the finished product. Replacement of a secondary packaging site of the finished product. Replacement of a manufacturing site of the finished product.
•	11 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	06 September 2018	Minor changes to an approved test procedure of the finished product. 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.
•	27 February 2018	Change in the RMS from UK to IE.
•	15 February 2018	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 2 years.
•	26 October 2017	Change in contact details for local representative.
•	18 October 2017	Minor change in the manufacturing process of the finished product. Change in the manufacturing process of the finished product.