Veterinary Medicines Directorate

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Post Authorisation Assessments

Enroxil 100 mg/ml Oral Solution for Chickens and Turkeys

Vm 01656/4021

•	02 October 2023	Change in test procedure for the finished product: - Other changes to a test procedure.
•	12 January 2022	Deletion of manufacturing site for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance.
•	08 July 2020	Minor change in the manufacturing process of the finished product.
•	04 February 2020	Addition of a site where batch control/testing takes place. 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.
•	27 June 2018	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	15 December 2015	Deletion of a non-significant specification parameter of an excipient.
•	15 April 2015	Deletion of a non-significant specification parameter. Submission of new Ph. Eur. Certificates of Suitability.
•	19 June 2014	Amendments to the SPC and product literature in line with Commission Decision regarding an Article 34 referral procedure for Baytril 10% oral solution and its associated names.
•	03 April 2014	Change in batch size of the finished product.
•	24 November 2011	Variation to change the finished product specification parameters.
•	25 July 2011	Addition of an active substance manufacturer.
•	17 June 2011	Variation to increase the finished product shelf life.
•	02 June 2011	Variation to comply with the European Pharmacopoeia or a national pharmacopoeia of a member state.
•	19 November 2010	Renewal (UK as RMS).
•	30 June 2010	Addition of a distributor.
•	06 October 2009	Variation to change the Marketing Authorisation Holder.
•	11 December 2008	Change of distributor.
•	18 October 2007	Amendments to the SPC and Product literature.
•	01 February 2007	MRP (UK as RMS).