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Post Authorisation Assessments

Paramectin Multi Injection 1% w/v Solution for Injection for Cattle, Sheep and Pigs

Vm 02000/4261

•	25 August 2023	Deletion of a non-significant specification method. Editorial changes to Part II of the dossier. Minor changes to an approved test procedure for the finished product.
•	09 March 2023	Change in any part of the primary packaging material not in contact with the finished product formulation.
•	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.
•	18 August 2022	Deletion of certificates of suitability for an active substance.
•	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.
•	14 May 2018	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. 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.
•	28 February 2018	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	07 February 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph. Tightening of specification limits of the finished product Deletion of a non-significant specification parameter of the finished product
•	13 December 2012	Submission of new Certificates of Suitability for the active substance.
•	03 February 2011	Renewal Marketing Authorisation.
•	13 January 2010	To increase the withdrawal period of cattle from 35 days to 49 days.
•	29 April 2009	Correction/ simple text layout changes to SPC or product literature

•	25 November 2006	Replace/add manufacturing site: secondary
		manufacturing site for all pharm forms