Veterinary Medicines Directorate

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Post Authorisation Assessments

Noroclav 500 mg Palatable Tablets for Dogs

Vm 02000/5013

•	May 2024	New CEP submitted for the manufacture of an active substance.
•	28 April 2024	Minor changes to the method of analysis for Potentiated Penicillin 500mg Tablets. Minor change in the test procedure for determination of the Total Aerobic Microbial Count, the Total Combined Yeast and Mould Count and an Absence of Escherichia coli in 1 gram for the finished product.
•	23 November 2023	Introduction of a summary of the PSMF. (NI)
•	25 August 2023	Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	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.
•	19 January 2022	Deletion of a non-significant specification parameter of an excipient.
•	19 November 2019	Addition of a secondary packaging site of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	16 September 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	31 December 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph. Changes to a test procedure for the finished product.
•	02 November 2018	Change in RMS from UK to IE.
•	31 March 2016	Submission of new or updated Ph. Eur. certificates of suitability Deletion of Ph. Eur. certificates of suitability
•	28 November 2014	Update to the DDPS.
•	07 March 2013	Submission of updated Ph. Eur. Certificates of Suitability for an already approved manufacturer. Deletion of an active ingredient manufacturing site.
•	11 October 2012	To add the total content for colouring agent Lake Carmosine (2.45 mg/tablet) to the SPC and Product Literature.
•	02 November 2011	To change the distributor.

•	13 May 2011	Renewal – UK as RMS.
•	23 October 2008	New/updates Ph. Eur. Certificate of Suitability for active/active component: new manufacturer (other).
•	12 October 2007	New MA.
•	22 May 2006	Change in pack size of the finished product.