Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Noroclox DC 500 mg Intramammary Suspension

•	04 August 2021	Minor changes to an approved test procedure of the finished product. Change in shape or dimensions of the container or closure (immediate packaging).
•	27 May 2021	Deletion of a non-significant specification parameter of an excipient.
•	22 February 2021	Deletion of a non-significant specification parameter of the finished product.
•	12 January 2021	Addition of new tests and limits applied during the manufacture of the finished product. Increase in batch size (including batch size range) of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	22 May 2020	Change in immediate packaging of the active substance. Change in the name of a supplier of active substance and intermediate used in the manufacture of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Change in supplier of active substance. Deletion of a non-significant parameter of an active substance. Minor change to the restricted part of an Active Substance Master File.
•	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.
•	09 May 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	03 April 2012	Change to distributor details.

•	24 August 2011	Renewal.
•	13 July 2011	Variation to extend a withdrawal period.
•	20 November 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	15 March 2007	Variation to transfer the legal category from POM to POM-V.
•	29 November 2005	Variation concerning the addition of an Active Substance Manufacturer.
•	28 January 2005	Renewal.
•	27 February 2004	Variation concerning the addition of an Active Substance Manufacturer.
•	21 November 2003	Additional presentation.
•	26 February 2003	Additional pack type.
•	23 March 2001	Harmonisation of SPCs.
•	02 September 1998	Renewal.