Veterinary Medicines Directorate

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

Post Authorisation Assessments

Opticlox Eye Ointment 16.7% w/w

Vm 02000/4075

•	18 April 2023	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	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.
•	26 July 2022	Minor changes to an approved test procedure for the active substance.
•	20 July 2021	Changes to a test procedure for the finished product.
•	23 June 2021	Changes to a test procedure for the finished product.
•	27 May 2021	Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers.
•	27 May 2021	Deletion of a non-significant specification parameter of an excipient.
•	04 February 2021	Addition of new tests and limits applied during the manufacture of the finished product. Increase in batch size (140kg to 500 & 800kg) 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.
•	19 November 2008	Changes to the SPC and product literature to bring them in line with new legislation.
•	28 February 2007	Change in legal category from POM to POM-V.
•	07 February 2007	Addition of an active substance manufacturer.
•	13 November 2006	Renewal.
•	02 November 2005	Addition of a site of assembly of the finished product.
•	26 February 2004	Addition of an active substance manufacturer.
•	19 April 2004	Renewal.
•	18 December 1997	Renewal.