

VPA22664/007/001

**Opticlox Eye Ointment 16.7% w/w**

Variation	Summary	Date
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	26/06/24
Vet - B27 b)	VNRA - Vet - B27 b) - b) Addition of a new in-process test and limits - B27 b) Changes to the quality part of the dossier: Change to in-process tests or limits applied during the manufacture of the finished product: — addition of a new in-process test and limits	18/06/24
Vet - F.II.b.4 z)	VRA-R - Vet - F.II.b.4 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.4 z) Quality Changes - Finished Product -Manufacture - Change in the batch size (including batch size ranges) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	29/05/24
Vet - F.II.b.3 a)	VRA-R - Vet - F.II.b.3 a) - a) Minor change in the manufacturing process - F.II.b.3 a) Quality Changes - Finished Product -Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process	29/05/24
Vet - F.II.b.3 a)	VRA-R - Vet - F.II.b.3 a) - a) Minor change in the manufacturing process - F.II.b.3 a) Quality Changes - Finished Product -Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process	29/05/24
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the	20/07/23

	Annex to Regulation (EU) 2021/17	
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	12/05/23
Vet - B43	VNRA - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible - B43 Changes to the quality part of the dossier: Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	04/04/23
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	19/07/22