VPA10790/010/001

GLEPTOVEX 200 mg/ml solution for injection for pigs

Variation	Summary	Date
Vet - B27 b)	VNRA - Vet - B27 b) - - Vet - B27 b) -Change to in-process tests or limits applied during the manufacture of the finished product: addition of a new in-process test and limits	21/09/26
Vet - B47 b)	VNRA - Vet - B47 b) - - Vet - B47 b) - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	21/09/26
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - - Vet - F.II.d.1 a) - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	21/09/26
Vet - F.II.d.1 z)	VRA-R - Vet - F.II.d.1 z) - - Vet - F.II.d.1 z) - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	21/09/26
Vet - F.II.b.1 e)	VRA-R - Vet - F.II.b.1 e) - - Vet - F.II.b.1 e) - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Change in supplier of sterilised primary container components, which are to be used in the asepticmanufacture of veterinary medicinal products	21/09/26
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	16/01/26
Vet - F.II.b.3 b)	VRA-S - Vet - F.II.b.3 b) - - Vet - F.II.b.3 b) - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	22/10/25
Vet - F.II.b.5 a)	VRA-S - Vet - F.II.b.5 a) - - Vet - F.II.b.5 a) - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of an in-process test which may have a significant effect on the overall quality of the finished product	22/10/25
Vet - F.I.b.1 a)	VRA-S - Vet - F.I.b.1 a) - - Vet - F.I.b.1 a) - Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in	22/10/25

	the manufacturing process of the active substance - Deletion of a specification parameter which may have a significant effect on the overall quality of the active substance and/or the finished product	
Vet - F.I.a.1 z)	VRA-R - Vet - F.I.a.1 z) - - Vet - F.I.a.1 z) - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	22/10/25
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 Annex to Regulation (EU) 2021/17	20/03/25
Vet - B24(Do not use)	VNRA - Vet - B24 - Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a non- sterile finished product - B24 Changes to the quality part of the dossier: Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a non-sterile finished product	30/08/23
Vet - F.II.b.3 z)	VRA-R - Vet - F.II.b.3 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.3 z) 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 - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	22/08/23
Vet - F.I.a.1 z)	VRA-R - Vet - F.I.a.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.a.1 z) - Quality Changes - Active Substance - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	10/06/22
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 -	10/06/22

	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	