

VPA10387/039/001

Lincocin Sterile Solution

Variation	Summary	Date
Vet - B44 a)	VNRA - Vet - B44 a) - - Vet - B44 a) - Submission of a Ph. Eur. CEP for:— active substance;— starting material, reagent or intermediate used in the manufacturing process of the active substance;— excipient - Updated certificate	04/09/26
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	22/12/25
Vet - B22	VNRA - Vet - B22 - - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	12/12/25
Vet - F.II.a.3 z)	VRA-R - Vet - F.II.a.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.a.3 a) Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	21/08/24
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 Annex to Regulation (EU) 2021/17	26/07/24
Vet - F.I.b.2 b)	VRA-S - Vet - F.I.b.2 b) - b) Other changes to a test procedure (including replacement or addition) for the active substance - F.I.b.2 b) Quality Changes - Active Substance - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance	27/05/24
Vet - B44(Do not use)	VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a	05/05/23

	non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	
B.III.1.a.5	IB - B.III.1.a.5 - 5. New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free - B.III.1.a.5 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free	05/05/22