VPA10987/144/002

Clinacin 25 mg Tablets for Dogs

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 cerificate	10/03/26
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	23/12/24
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	23/12/24
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	23/12/24
Vet - B33 b)	VNRA - Vet - B33 b) - b) Update of the test procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number - B33 b) Changes to the quality part of the dossier: Change in test procedure for the finished product to comply with Ph. Eur.: — update of the test procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number	18/12/24
Vet - B33 b)	VNRA - Vet - B33 b) - b) Update of the test procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number - B33 b) Changes to the quality part of the dossier: Change in test procedure for the finished product to comply with Ph. Eur.: — update of the test procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number	18/12/24
Vet - B33 b)	VNRA - Vet - B33 b) - b) Update of the test procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number - B33 b) Changes to the quality part of the dossier: Change in test procedure for the finished product to comply with Ph. Eur.: — update of the test	18/12/24

	procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number	
B.III.1.a.4	IA - B.III.1.a.4 - 4. Deletion of certificates (in case multiple certificates exist per material) - B.III.1.a.4 - 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 - Deletion of certificates (in case multiple certificates exist per material)	04/03/22
B.III.1.a.3	IAin - B.III.1.a.3 - 3. New certificate from a new manufacturer (replacement or addition) - B.III.1.a.3 - 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 from a new manufacturer (replacement or addition)	04/03/22
B.III.1.a.2	IA - B.III.1.a.2 - 2. Updated certificate from an already approved manufacturer - B.III.1.a.2 - 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 - Updated certificate from an already approved manufacturer	04/03/22