VPA10521/029/002

Clavaseptin 250 mg palatable tablets for dogs

Variation	Summary	Date
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	17/08/26
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	02/07/26
Vet - B12 c)	VNRA - Vet - B12 c) - - Vet - B12 c) - Minor changes: — to an approved test procedure for an in-process test — for active substance; — for the finished product	28/05/26
Vet - F.II.c.4 z)	VRA-R - Vet - F.II.c.4 z) - - Vet - F.II.c.4 z) - Change in synthesis or recovery of a non pharmacopoeial excipient (when described in the dossier) or a novel excipient - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	26/01/26
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	27/11/25
Vet - B3 m)	VNRA - Vet - B3 m) - m) Deletion of a non-significant specification parameter (excipient) - B3 m) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of an excipient	04/03/25
Vet - B28 b)	VNRA - Vet - B28 b) - b) Addition of a new specification parameter to the specification with its corresponding test method - B28 b) Changes to the quality part of the dossier: Change in the specification parameters or limits of an excipient —addition of a new specification parameter to the specification with its corresponding test method	04/03/25
Vet - B12 b)	VNRA - Vet - B12 b) - b) Minor changes to an approved test procedure (starting material, excipient) - B12 b) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient	04/03/25
Vet - B28 a)	VNRA - Vet - B28 a) - a) Tightening of specification limits - B28 a) Changes to the quality part of the dossier: Change in the specification parameters or limits of an excipient — tightening of specification limits	04/03/25
Vet - F.I.d.1 c)	VRA-R - Vet - F.I.d.1 c) - c) Extension or introduction of a re-test period/storage period supported by real time data - F.I.d.1 c) Quality Changes - Active Substance - Stability -Change in the	04/02/25

	re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Extension or introduction of a re-test period/storage period supported by real time data	
Vet - G.I.7 a)	VRA-E - Vet - G.I.7 a) - a) Addition of a new therapeutic indication or modification of an approved one - G.I.7 a) Safety, Efficacy, Pharmacovigilance changes - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	22/11/24
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	22/11/24
Vet - B45	VNRA - Vet - B45 - Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile active substance, starting material, reagent or intermediate, excipient - B45 Changes to the quality part of the dossier: Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	03/10/24
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)	20/06/23
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	20/06/23
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuirng 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	20/06/23

	administration device	
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	03/03/22
B.II.d.2.a	IA - B.II.d.2.a - a) Minor changes to an approved test procedure - B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure	02/03/22