VPA22583/001/001

Iso-Vet 1000 mg/g Inhalation Vapour, liquid

Variation	Summary	Date
Vet - B3 c)	VNRA - Vet - B3 c) - c) Deletion of a non-significant in-process test during the manufacture of the active substance - B3 c) Changes to the quality part of the dossier: Deletion of a non-significant in-process test during the manufacture of the active substance (e.g. deletion of an obsolete in-process test)	12/02/24
Vet - B3 n)	VNRA - Vet - B3 n) - n) Deletion of a non-significant specification parameter (finished product) - B3 n) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) in the specification parameters or limits of the finished product	12/02/24
Vet - B10 b)	VNRA - Vet - B10 b) - b) Addition of a new in-process test and limits - B10 b) Changes to the quality part of the dossier: Change to in-process tests or limits applied during the manufacture of the active substance —addition of a new in-process test and limits	12/02/24
Vet - B12 d)	VNRA - Vet - B12 d) - d) Minor changes in the manufacturing process of an active substance - B12 d) Changes to the quality part of the dossier: Minor changes — in the manufacturing process of an active substance	12/02/24
Vet - B12 d)	VNRA - Vet - B12 d) - d) Minor changes in the manufacturing process of an active substance - B12 d) Changes to the quality part of the dossier: Minor changes — in the manufacturing process of an active substance	12/02/24
Vet - B12 d)	VNRA - Vet - B12 d) - d) Minor changes in the manufacturing process of an active substance - B12 d) Changes to the quality part of the dossier: Minor changes — in the manufacturing process of an active substance	12/02/24
Vet - B10 b)	VNRA - Vet - B10 b) - b) Addition of a new in-process test and limits - B10 b) Changes to the quality part of the dossier: Change to in-process tests or limits applied during the manufacture of the active substance —addition of a new in-process test and limits	12/02/24
Vet - F.II.d.2 b)	VRA-R - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	16/10/23
Vet - F.I.b.2 b)	VRA-R - 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	16/10/23

	procedure (including replacement or addition) for the active substance	
Vet - C5	VNRA - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location - C5 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change in the pharmacovigilance system master file (PSMF) location	09/01/23
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)	09/01/23
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	29/08/22
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)	29/08/22
B.I.a.4.z	IB - B.I.a.4.z - z Other variation - B.I.a.4.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Other variation	07/03/22
B.I.a.2.a	IB - B.I.a.2.a - a) Minor change in the manufacturing process of the active substance - B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance	07/03/22
B.I.a.2.a	IA - B.I.a.2.a - a) Minor change in the manufacturing process of the active substance - B.I.a.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance	07/03/22