VPA22583/001/001

Iso-Vet 1000 mg/g Inhalation Vapour, liquid

Variation	Summary	Date
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	08/10/24
Vet - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 Changes to the quality part of the dossier: Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	19/07/24
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	12/02/24

	process of an active substance	
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 procedure (including replacement or addition) for the active substance	16/10/23
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 -	07/03/22

	ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance	