VPA10988/099/002

ZOLETIL 100 (50 mg/ml + 50 mg/ml) lyophilisate and solvent for solution for injection for dogs and cats

Variation	Summary	Date
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	03/06/25
Vet - C10 a)	VNRA - Vet - C10 a) - a) Administrative information concerning the holder's representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder's representative	02/05/25
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	27/03/25
Vet - F.II.f.1 a) 3.	VRA-R - Vet - F.II.f.1 a) 3. - a) Extension of the shelf life of the finished product 3. After dilution or reconstitution (supported by real time data) - F.II.f.1 a) 3. Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)	03/02/23
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)	03/02/23
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved	03/02/23

	specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	
Vet - F.II.d.1 z)	VRA-R - Vet - F.II.d.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.d.1 z) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	03/02/23
Vet - F.II.e.7 z)	VRA-R - Vet - F.II.e.7 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.7 z) Quality Changes - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	03/02/23
Vet - F.II.e.4 b)	VRA-R - Vet - F.II.e.4 b) - b) Sterile medicinal products - F.II.e.4 b) Quality Changes - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	03/02/23
Vet - F.II.b.3 z)	VRA-R - Vet - F.II.b.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.b.3 z) Quality Changes - Finished Product -Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	03/02/23
Vet - F.II.b.4 z)	VRA-R - Vet - F.II.b.4 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.4 z) Quality Changes - Finished Product -Manufacture - Change in the batch size (including batch size ranges) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	03/02/23
Vet - F.II.a.3 b) 1.	VRA-S - Vet - F.II.a.3 b) 1. - b) Other excipients 1. Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the veterinary medicinal product - F.II.a.3 b) 1. Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the veterinary medicinal product	03/02/23
Vet - B3 g)	VNRA - Vet - B3 g) - g) Deletion of a non-significant specification parameter (packaging) - B3 g) Changes to the quality part of the dossier: Deletion of a non-significant	01/02/23

	specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of the immediate packaging of the active substance or the finished product	
Vet - B30 c)	VNRA - Vet - B30 c) - c) Addition of a new specification parameter to the specification with its corresponding test method - B30 c) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: —addition of a new specification parameter to the specification with its corresponding test method	01/02/23
Vet - B30 d)	VNRA - Vet - B30 d) - d) Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product - B30 d) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: — update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product	01/02/23
Vet - B3 g)	VNRA - Vet - B3 g) - g) Deletion of a non-significant specification parameter (packaging) - B3 g) 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 the immediate packaging of the active substance or the finished product	01/02/23
Vet - B30 c)	VNRA - Vet - B30 c) - c) Addition of a new specification parameter to the specification with its corresponding test method - B30 c) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: —addition of a new specification parameter to the specification with its corresponding test method	01/02/23
Vet - B30 c)	VNRA - Vet - B30 c) - c) Addition of a new specification parameter to the specification with its corresponding test method - B30 c) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: —addition of a new specification parameter to the specification with its corresponding test method	01/02/23