VPA10996/133/001

Nobilis Gumboro D78 lyophilisate for use in drinking water for chickens

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	17/02/26
Vet - F.I.d.2 b)	VRA-R - Vet - F.I.d.2 b) - b) Change in storage conditions of the active substance/reference standard - F.I.d.2 b) Quality Changes - Active Substance - Stability - Change in the storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Change in storage conditions of the active substance/reference standard	28/05/25
Vet - F.I.a.2 z)	VRA-R - Vet - F.I.a.2 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.2 z) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	28/05/25
Vet - F.I.a.2 z)	VRA-R - Vet - F.I.a.2 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.2 z) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	28/05/25
Vet - F.II.f.1 z)	VRA-R - Vet - F.II.f.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.f.1 z) Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	28/05/25
Vet - F.I.a.4 z)	VRA-R - Vet - F.I.a.4 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.4 z) Quality Changes - Active Substance - Manufacture -Change to in-process tests or limits applied during the manufacture of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	28/05/25
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)	28/05/25
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	18/12/24

	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	
B.II.d.2.d	IB - B.II.d.2.d - d) Other changes to a test procedure (including replacement or addition) - B.II.d.2.d - 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)	08/12/22
B.II.d.2.d	IB - B.II.d.2.d - d) Other changes to a test procedure (including replacement or addition) - B.II.d.2.d - 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)	08/12/22
B.II.d.2.d	IB - B.II.d.2.d - d) Other changes to a test procedure (including replacement or addition) - B.II.d.2.d - 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)	08/12/22
B.II.d.2.d	IB - B.II.d.2.d - d) Other changes to a test procedure (including replacement or addition) - B.II.d.2.d - 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)	08/12/22
B.II.e.1.b.2	II - B.II.e.1.b.2 - 2. Sterile medicinal products and biological/ immunological medicinal products - B.II.e.1.b.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/ immunological medicinal products	08/12/22
B.II.b.5.b	IB - B.II.b.5.b - b) Addition of a new test(s) and limits - B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	08/12/22
B.II.b.5.b	IA - B.II.b.5.b - b) Addition of a new test(s) and limits - B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	08/12/22
B.II.b.3.c	II - B.II.b.3.c - c) The product is a biological/immunological medicinal product and the change requires an assessment of	08/12/22

	comparability - B.II.b.3.c - 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 - The product is a biological/immunological medicinal product and the change requires an assessment of comparability	