

VPA10405/003/001

Avishield ND B1, lyophilisate for ocular nasal suspension/use in drinking water for chickens.

Variation	Summary	Date
Vet - F.II.b.5 z)	VRA-R - Vet - F.II.b.5 z) - - Vet - F.II.b.5 z) - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	09/10/25
Vet - F.II.b.3 z)	VRA-R - Vet - F.II.b.3 z) - - Vet - F.II.b.3 z) - 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 this guidance	09/10/25
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	08/10/25
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	24/03/23
B.III.1.b.3	IA - B.III.1.b.3 - 3. Updated certificate from an already approved manufacturer - B.III.1.b.3 - 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 TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - Updated certificate from an already approved manufacturer	26/04/22
B.I.b.2.e	IB - B.I.b.2.e - e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - B.I.b.2.e - 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 or a starting material/intermediate	26/04/22
B.I.b.1.d	IA - B.I.b.1.d - d) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of	24/03/22

	active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	
B.I.b.2.e	IB - B.I.b.2.e - e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - B.I.b.2.e - 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 or a starting material/intermediate	24/03/22
B.I.b.2.e	IB - B.I.b.2.e - e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - B.I.b.2.e - 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 or a starting material/intermediate	24/03/22
B.II.d.1.f	II - B.II.d.1.f - f) Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product - B.II.d.1.f - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product	24/03/22