VPA10804/003/001

ALPHA JECT micro 1 PD emulsion for injection for Atlantic salmon

Variation	Summary	Date
Vet - F.III.1 b) 1.	VRA-S - Vet - F.III.1 b) 1. - b) European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient 1. New/updated certificate from an already- approved/new manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agents is required - F.III.1 b) 1. 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 - New/updated certificate from an already- approved/new manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agents is required	03/04/24
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Vet - F.I.a.2 b)	VRA-S - Vet - F.I.a.2 b) - b) The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - F.I.a.2 b) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol	25/03/24
Vet - F.I.a.2 b)	VRA-S - Vet - F.I.a.2 b) - b) The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - F.I.a.2 b) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use	25/03/24

	of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol	
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	08/01/24
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	08/01/24
Vet - F.II.b.1 e)	VRA-S - Vet - F.II.b.1 e) - e) Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of veterinary medicinal products - F.II.b.1 e) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of veterinary medicinal products	31/01/23
Vet - F.I.a.4 c)	VRA-R - Vet - F.I.a.4 c) - c) Addition or replacement of an in-process test as a result of a safety or quality issue - F.I.a.4 c) Quality Changes - Active Substance - Manufacture - Change to in-process tests or limits applied during the manufacture of the active substance - Addition or replacement of an in-process test as a result of a safety or quality issue	22/12/22
Vet - F.I.a.2 b)	VRA-R - Vet - F.I.a.2 b) - b) The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - F.I.a.2 b) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use	22/12/22

	of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol	
B.III.1.a.2	IA - B.III.1.a.2 - 2. Updated certificate from an already approved manufacturer - B.III.1.a.2 - 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 Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	01/02/22