Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Alpha Ject Micro 6 Emulsion for Injection for Atlantic Salmon

Vm 21714/3001

•	11 May 2024	Addition of suppliers for biological starting material.
•	25 April 2024	Addition of acceptable countries of origin for trypsin. Addition of an alternative irradiation method for trypsin.
•	27 March 2024	Deletion of a manufacturing site for an active substance.
•	22 June 2023	Unlimited renewal
•	02 June 2023	Adjustment of limits for cultivation time and optical density for pre-culture steps of Vibrio salmonicida, AL 1134.
•	21 April 2023	Replacement of authorised batch potency test for A. salmonicida with serological test. Replacement of authorised batch potency test for M. viscosa with serological test.
•	20 February 2023	To add an additional supplier for the primary container closure system for Alpha Ject Micro vaccine.
•	23 December 2022	Increase in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance.
•	16 December 2022	Addition of an alternative supplier for primary packaging.
•	17 August 2022	Introduction of ready-made solution from an external supplier as an alternative to in-house prepared solution. Introduction of ready-made solution from an external supplier as an alternative to in-house prepared solution.
•	20 July 2022	Introduction of ready-made solution from an external supplier as an alternative to in-house prepared solution. Introduction of ready-made solution from an external supplier as an alternative to in-house prepared solution.
•	23 February 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	02 February 2022	Changes in the manufacturer of a starting material used in the manufacturing process of the active substance.
•	14 January 2022	Change to in-process tests or limits applied during the manufacture of the active substance
•	03 November 2021	Change to production in process specification.
•	27 October 2021	Amendment to the in-process control limits for the product.
•	22 September 2021	Changes in the manufacturing process of the active substance
•	09 February 2021	Deletion of a non-significant in-process test applied during the manufacture of the viral active substance.

•	02 November 2020	Changes in the manufacturing process of the active substance.
•	14 May 2020	Change in the manufacturing process of the active substance.
•	17 February 2020	Submission of an updated Ph. Eur. certificate of suitability. Submission of an updated Ph. Eur. certificate of suitability.
•	30 January 2020	Widening of the in-process test limits applied during the manufacture of the active substance.