



Post Authorisation Assessments

Alpha Ject Micro 6 Emulsion for Injection for Atlantic Salmon

•	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.