



Post Authorisation Assessments

Alpha Ject Micro 1 PD Emulsion for Injection for Atlantic Salmon Vm 21714/5000

08 April 2026	To update the Certificate of Suitability (CEP) for a starting material (foetal bovine serum) used in the manufacture of the active substance.
23 January 2026	To lower the limit of haemoglobin (4 mg/ml to 0.5 mg/ml) in a starting material (bovine serum) to comply with revision of the Ph. Eur (Ph. Eur. 11.8).
14 January 2026	To delete a supplier of the primary packaging of the product.
12 December 2025	Submission of mock ups for joint labelling with IE.
02 September 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
22 July 2025	To add new revisions of TSE certificates of suitability for foetal bovine serum from an approved supplier (Life Technologies).
08 April 2025	To add a test for total protein to the finished product control testing.
19 January 2025	Addition of pack size.
11 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
23 November 2024	Introduction of a test for antigenicity during manufacture of the active biological ingredient. Replacement of methodology used as a basis for calculation of volume input of active biological ingredient in the finished product - from a titration assay to an antigenicity assay.
20 October 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
25 April 2024	Addition of acceptable countries of origin for trypsin. Addition of an alternative irradiation method for trypsin.
24 April 2024	Addition of suppliers for biological starting material. Addition of suppliers for biological starting material. Addition of suppliers for biological starting material. Addition of suppliers for biological starting material.
19 January 2024	Deletion of a manufacturing site of the active substance. Deletion of a manufacturing site of the finished product.
20 February 2023	To add an additional supplier for the primary container closure system for Alpha Ject Micro vaccine.
16 December 2022	Addition of an alternative supplier for primary packaging.
12 December 2022	Introduction of a test for total protein in the concentrated SPDV suspension. To increase the molecular cut-off size from 50 kDa to 100 kDa for the filter used during downstream concentration/diafiltration of the inactivated SPDV suspension.

24 February 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
January 2022	Change in the manufacturer used in the manufacturing process of the active. Changes to in-process limits applied during the manufacture of the active substance.
28 July 2021	Deletion of an in-process test applied during the manufacture of the active substance.
22 July 2021	Renewal – UK as CMS.
09 March 2021	Change in the SPC, labelling or package leaflet due to new data.
11 November 2020	Change in the manufacturing process of the active substance.
27 October 2020	Extension of the storage period of the active substance.
22 April 2020	Deletion of manufacturing site where batch control takes place.
17 February 2020	Submission of an updated Ph. Eur. certificate of suitability. Submission of an updated Ph. Eur. certificate of suitability.
14 September 2018	Change in RMS from UK to NO.
23 July 2018	Changes to a test procedure for the active substance.
09 May 2017	Change in the batch size of the finished product Addition of a site where batch control/testing takes place. Addition of a manufacturing site of the finished product
23 February 2017	Addition of a site where testing takes place
29 July 2016	Deletion of an in-process test.
24 May 2016	Increase of the shelf-life of the finished product from 15 months to 2 years.