Veterinary Medicines Directorate

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Post Authorisation Assessments

Alpha Ject Micro 1 PD Emulsion for Injection for Atlantic Salmon

Vm 21714/4005

•	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.