Veterinary Medicines Directorate

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Post Authorisation Assessments

Alpha Ject 2-2 Emulsion for Injection

•	27 July 2020	Update in the description of control tests on the finished product.
•	24 September 2019	Submission of an updated Ph. Eur. certificate of suitability for a starting material from an already approved manufacturer.
•	31 January 2018	Change in specification of the finished product.
•	22 December 2017	Change in the manufacturing process of the active substance.
•	14 October 2016	Addition of an alternative testing site
•	11 December 2015	Change in control of the finished product
•	06 January 2015	Submission of a new Ph. Eur. Certificate of Suitability from an already approved manufacturer. Submission of an updated Ph. Eur. Certificate of Suitability from an already approved manufacturer.
•	27 February 2014	Change in the immediate packaging of the finished product.
•	31 October 2013	Renewal.
•	30 May 2013	Change in control of the finished product.
•	14 May 2013	Change to in-process tests applied to manufacture of the finished product.
•	14 September 2012	Addition of an alternative secondary packaging/labelling site.
•	04 July 2012	To change the in-process limits applied during the manufacture of one of the active substances.
•	14 September 2011	To change the manufacturing process of the active substance.
•	18 April 2011	To make a change to the test procedure for the finished product.
•	26 May 2010	To change the legal category from POM-V to POM-VPS.
•	12 May 2010	To make changes to the batch potency test for the IPNV component.
•	21 May 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure