Veterinary Medicines Directorate

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

Post Authorisation Assessments

SynVet-50; 50 mg Solution for Injection for Horses

Vm 25297/4000

14 March 2025	Extension of the shelf life of the finished product. Addition of an in-process test as a result of a quality issue. Submission of an updated Ph. Eur. certificate of suitability for an active substance.
18 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).
11 January 2025	Change in the name and address of the Marketing Authorisation Holder from Equimed Ltd., Jeffcott, 2 Hilliards Court, Chester Business Park, Chester, Cheshire, CH4 9PX, United Kingdom to Equimed Europe Limited, 2 Hilliards Court, Chester Business Park, Chester, Cheshire, CH4 9QP, United Kingdom. (GB)
11 January 2025	Change in the name and address of the Marketing Authorisation Holder from Equimed Ltd., Jeffcott, 2 Hilliards Court, Chester Business Park, Chester, Cheshire, CH4 9PX, United Kingdom to Equimed Europe Limited, 2 Hilliards Court, Chester Business Park, Chester, Cheshire, CH4 9QP, United Kingdom. (NI)
04 May 2024	Change in shape or dimensions of the container or closure. Change in test procedure for the finished product. Change in the batch size of the finished product. Replacement of a manufacturing site responsible for batch release. Replacement of a site where batch control/testing takes place. Replacement of a manufacturing site for part or all of the manufacturing process of the finished product.
02 November 2023	Deletion of a supplier of a starting material used in the manufacturing process of the active substance.
25 February 2022	Change to part of the (primary) packaging material not in contact with the finished product formulation. Update of the test procedure to comply with the updated general Ph. Eur monograph. Minor changes to an approved test procedure of the finished product. Tightening of in-process limits applied during the manufacture of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
12 March 2020	Renewal – UK as CMS.
15 January 2019	Change in RMS from UK to IE.
23 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Change to a test procedure for the finished product.

	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
02 October 2014	Change in the manufacturing process of the finished product, from a two container method to a one container method. Change to the description of the sterilisation process. Change to the batch denomination used in the manufacturing process of the finished product. Change to in-process limits applied during the manufacture of the finished product. Addition of an in-process control applied during the manufacture of the finished product. Change to the container-closure system of the finished product.
19 September 2014	Change to the name of the veterinary medicinal product in Denmark, Finland, France, Norway and Sweden only. Changes to the product labelling to include multiple languages.
18 July 2014	MRP (UK as RMS).
15 November 2012	Change to the finished product test procedure, change to batch release arrangements and QC testing of finished product, change to in-process test limits during manufacture of finished product, submission of new/updated Ph. Eur Certificate of Suitability, change to control of excipients of the finished product, change to batch size of the finished product, changes in the manufacturing of the finished product, changes to Human and Veterinary Medicinal Products.
31 October 2012	Addition of a new test method for the finished product.
31 October 2012	Variation to change the type of rubber used in the immediate packaging (tip, cap and plunger stopper) for the finished products.
01 August 2012	Change in specification parameters of the finished product and submission of an updated certificate of suitability.
21 February 2012	Change in pack size of the finished product.
08 February 2012	To make a minor change to an approved test procedure for the finished product.
08 February 2012	Change in test procedure for the Finished Product
09 November 2011	To change the distributor.
10 November 2010	To change the distributor.
29 October 2010	Change to batch release arrangements and quality control testing of the finished product.