



Post Authorisation Assessments

Aquapharm 11 (Hartmann's) Solution for Infusion Vm 32742/4020

13 January 2026	<p>Change to in-process tests applied during the manufacture of the finished product.</p> <p>Change in immediate packaging of the finished product: - Qualitative and quantitative composition - Sterile medicinal products.</p> <p>Change in the number of units in a pack.</p> <p>Change in storage conditions of the finished product.</p> <p>Submission of an updated Ph. Eur. certificate of suitability.</p> <p>One-off alignment of the product information with version 9.0* of the QRD templates.</p>
07 August 2023	<p>Change in test procedure for the finished product.</p> <p>Change in test procedure for the finished product.</p> <p>Change in test procedure for the finished product.</p> <p>Change in test procedure for the finished product.</p> <p>Change in test procedure for the finished product.</p> <p>Change in test procedure for the finished product.</p> <p>Change in test procedure for the finished product.</p> <p>Change in test procedure for the finished product.</p> <p>Change in test procedure for the finished product.</p> <p>Change in the batch size of the finished product.</p> <p>Minor change in the manufacturing process.</p> <p>Minor change in the manufacturing process.</p> <p>Change in the holding time of an intermediate or bulk product.</p> <p>Minor change in the manufacturing process of a sterile finished product after the primary packaging step.</p> <p>Minor change in the manufacturing process of a sterile finished product after the primary packaging step.</p> <p>Replacement or addition of a site where batch release takes place.</p> <p>Replacement or addition of a site where batch control/testing takes place.</p> <p>Change to in-process tests or limits applied during the manufacture of the finished product.</p> <p>Change to in-process tests or limits applied during the manufacture of the finished product.</p> <p>Change to in-process tests or limits applied during the manufacture of the finished product.</p> <p>Change to in-process tests or limits applied during the manufacture of the finished product.</p> <p>Change to in-process tests or limits applied during the manufacture of the finished product.</p> <p>Change to in-process tests or limits applied during the</p>

	<p>manufacture of the finished product.</p> <p>Changes in the composition of the finished product.</p> <p>Changes in the composition of the finished product.</p> <p>Replacement or addition of a manufacturing site.</p> <p>Replacement or addition of a manufacturing site.</p> <p>Submission of a new or updated Ph. Eur. certificate of suitability.</p> <p>Submission of a new or updated Ph. Eur. certificate of suitability.</p> <p>Submission of a new or updated Ph. Eur. certificate of suitability.</p> <p>Change in immediate packaging of the finished product.</p> <p>Substantial change to a biological/immunological/immunochemical test method.</p> <p>Change in the specification parameters and/or limits of the finished product.</p>
14 July 2023	Replacement or addition of a secondary packaging site of the finished product.
11 August 2022	Change of MAH: from Animalcare Ltd, 10 Great North Way, York Business Park, Nether Poppleton, York, YO26 6RB, United Kingdom to Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium.
04 February 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
08 October 2021	Renewal – UK as CMS
02 December 2020	Mock-ups approved.
21 October 2020	Harmonise the product information between Belgium and France. Change in the invented name of the veterinary medicinal product in Finland.
13 December 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
23 October 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
07 February 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
09 August 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer