Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Aqupharm 11 (Hartmann's) Solution for Infusion

Vm 32742/4020

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| • | 07 August 2023 | Change in test procedure for the finished product.<br>Change in test procedure for the finished product.<br>Change in test procedure for the finished product.<br>Change in test procedure for the finished product.<br>Change in test procedure for the finished product.<br>Change in test procedure for the finished product.<br>Change in test procedure for the finished product.<br>Change in test procedure for the finished product.<br>Change in test procedure for the finished product.<br>Change in the batch size of the finished product.<br>Minor change in the manufacturing process.<br>Minor change in the manufacturing process.<br>Change in the holding time of an intermediate or bulk product.<br>Minor change in the manufacturing process of a sterile finished product after the primary packaging step.<br>Minor change in the manufacturing process of a sterile finished product after the primary packaging step.<br>Replacement or addition of a site where batch release takes place.<br>Replacement or addition of a site where batch control/testing takes place.<br>Change to in-process tests or limits applied during the manufacture of the finished product.<br>Change to in-process tests or limits applied during the manufacture of the finished product.<br>Change to in-process tests or limits applied during the manufacture of the finished product.<br>Change to in-process tests or limits applied during the manufacture of the finished product.<br>Change to in-process tests or limits applied during the manufacture of the finished product.<br>Changes in the composition of the finished product.<br>Changes in the composition of the finished product.<br>Replacement or addition of a manufacturing site.<br>Replacement or addition of a manufacturing site.<br>Submission of a new or updated Ph. Eur. certificate of suitability.<br>Submission of a new or updated Ph. Eur. certificate of suitability.<br>Submission of a new or updated Ph. Eur. certificate of suitability. |

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| | | Change in immediate packaging of the finished product.<br>Substantial change to a biological/immunological/immunochemical test method.<br>Change in the specification parameters and/or limits of the finished product. |
| • | 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.<br>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 manufacture. |
| • | 23 October 2018 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>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 |