Veterinary Medicines Directorate

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Post Authorisation Assessments

B. Braun Vet Care Hartmann's Lactated Ringers Solution for Infusion for Cattle, Horses, Sheep, Goats, Pigs, Dogs and Cats

Vm 03551/3001

•	08 December 2023	Minor changes to an approved test procedure for the finished product. Minor changes to an approved test procedure for the finished product. Minor changes to an approved test procedure for the finished product.
•	01 August 2023	Minor changes to an approved test procedure for the finished product.
•	08 November 2022	Updated Ph.Eur. certificate of suitability for an active substance. Updated Ph.Eur. certificate of suitability for an active substance. Updated Ph.Eur. certificate of suitability for an active substance.
•	04 May 2022	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product.
•	17 March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	14 January 2020	Change in the invented name in Italy of the veterinary medicinal product from B. Braun Vet Care Ringer Lattato Hartmann soluzione per

		infusion per bovini, cavalli, pecore, capre, suini, cani e gatti to Ringer Lattato Hartmann B. Braun Vet Care soluzione per infusione per bovini,cavalli, pecore, capre, porci, cani e gatti.
•	24 December 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	07 February 2019	Change in 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.
•	09 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	15 February 2017	Submission of an updated certificate of suitability. Submission of an updated certificate of suitability.
•	27 September 2016	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system (e.g. change of the major storage/archiving location, administrative changes).
•	24 July 2015	Grouped variation to submit several updated certificates of suitability, to add a new certificate of suitability from an already approved manufacturer, and to delete a manufacturing site for an active substance.
•	02 July 2015	Update to the DDPS.
•	07 May 2015	Renewal – UK as CMS.
•	20 August 2014	Submission of updated Ph. Eur. Certificates of Suitability for two already approved manufactures of the active substance.
•	23 August 2013	Change to the immediate packaging for the finished product, change in the batch size of the finished product, change in the manufacturing process and test procedures for the finished product. Also change of the manufacturing site for the manufacturing process of the finished product and changes to the batch release arrangements and quality control testing for the finished product.
•	03 April 2013	Introduction of a new Pharmacovigilance system description.
•	01 March 2013	Submission of five new Ph. Eur. Certificates of Suitability for five already approved manufacturers of the active substance.
•	28 August 2012	Change of MA holder from B. Braun Vet Care GmbH to B. Braun Melsungen AG.
•	14 June 2011	To change the name of the veterinary medicinal

		product in Spain only.
•	14 June 2011	To extend the shelf life of the finished product from 2 to 3 years.