

VPA10465/003/001

**B. Braun Vet Care Hartmann's Lactated Ringers Solution for infusion for cattle, horses, sheep, goats, pigs, dogs and cats**

Variation	Summary	Date
Vet - F.III.1 a) 1.	VRA-R - Vet - F.III.1 a) 1. - a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. 1. New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free - F.III.1 a) 1. Quality Changes - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: -For an active substance -For a starting material/reagent/intermediate used in the manufacturing process of the active substance -For an excipient European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free	10/11/22
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B.II.d.3	II - B.II.d.3 - B.II.d.3 Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product - B.II.d.3 - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product	28/04/22
B.II.b.5.b	IA - B.II.b.5.b - b) Addition of a new test(s) and limits - B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	28/04/22
B.II.b.5.b	IA - B.II.b.5.b - b) Addition of a new test(s) and limits - B.II.b.5.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	28/04/22
B.II.b.5.c	IA - B.II.b.5.c - c) Deletion of a non-significant in-process test - B.II.b.5.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	28/04/22
B.II.d.1.h	IA in - B.II.d.1.h - h) Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product* - B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*	28/04/22