Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetivex 11 (Hartmann's) Solution for Infusion for Cattle, Horses, Dogs and Cats

Vm 10434/4080

•	25 August 2023	Correction of typo in microbiological class designation of filling room. (GB)
•	18 August 2023	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State:– change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State:– change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Change to importer, batch control arrangements and quality testing for a finished product. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Replacement or addition of a secondary packaging site of a finished product.
•	18 August 2023	Change in pack size within the range of the currently approved pack size. Change in pack size within the range of the currently approved pack size.
•	18 August 2023	Change in shape or dimensions of the container or:- Sterile medicinal products. Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance: - Change in the testing frequency of specification parameter, from routine testing to skip or periodic testing. Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance: - Change in the testing frequency of specification parameter, from routine testing to skip or periodic testing. Change to importer, batch release arrangements and quality control testing of the finished product:- Replacement or addition of a manufacturer responsible for importation and/or batch release - Other changes. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product: - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile veterinary medicinal products

		excluding biological/immunological veterinary medicinal products. 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, or For an excipient. 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, or For an excipient. 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, or For an excipient.
•	July 2023	Change to update the specification of an active substance to comply with the current Ph. Eur. Submission of a new Ph. Eur. CEP from a new manufacturer. (NI)
•	07 July 2023	Change to comply with Ph. Eur. Replacement certificate of suitability from a new manufacturer. (NI)
•	14 February 2023	Change to update the specification of an active substance to comply with the current Ph. Eur. New certificate of suitability from a new manufacturer.
•	17 January 2023	Change to update the specification of an active substance to comply with the current Ph. Eur.
•	17 January 2023	Change to update the specification of an active substance to comply with the current Ph. Eur. New certificate of suitability from a new manufacturer.
•	30 December 2022	Change to comply with the current Ph. Eur. pharmacopoeia. Replacement certificate of suitability from a new manufacturer.
•	27 November 2020	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	01 August 2018	Change in RMS from UK to IE.
•	24 July 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 July 2018	Renewal – UK as RMS.
•	14 November 2017	Deletion of manufacturing site. Deletion of manufacturer responsible for batch release.
•	16 August 2016	Change of analytical method for assay on active substance to Ph. Eur. method.
•	28 July 2016	Minor change in the manufacturing process of an immediate release of an oral solution. Opportunity also taken to harmonise the QRD text with the SPC.

•	02 December 2015	Addition of a manufacturer responsible for batch release, including batch control/testing. Addition of a secondary packaging site. Submission of new or updated Ph. Eur. certificates of suitability. Changes in test procedure for the finished product Minor changes in the manufacturing process for the finished product Change to comply with a national pharmacopoeia of a Member State Addition of a manufacturing site of the finished product
•	02 December 2015	Variation to change the address of the marketing authorisation holder from Dechra Limited, Jamage Industrial Estate to Dechra Limited, Snaygill Industrial Estate.
•	30 April 2015	Change in the (invented) name of the medicinal product
•	19 March 2015	To increase the shelf-life of the finished product, from 18 months to 2 years.
•	30 October 2014	Variation to introduce multi-pack sizes of 20 x 250 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 3000 ml, 2 x 5000 ml, and 2 x 5000 ml combi.
•	15 May 2014	Change of active substance manufacturer.