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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Mhyosphere PCV ID Emulsion for Injection for Pigs

Vm 17533/5007

11 June 2026	To adjust the upper limit of the HPLC- MS/MS in-process quantification method of PCV2. To optimise the test procedure of the HPLC-MS/MS used to quantify the Mycoplasma hyopneumoniae. To optimise the test procedure of the ELISA of the BPT of Mycoplasma hyopneumoniae. To optimise the test procedure of the ELISA of the BPT of PCV2. To widen the higher limit of the HPLC- MS/MS in-process quantification method of Mycoplasma hyopneumoniae. To remove the higher limit of the BPT of Mycoplasma hyopneumoniae. To update the product information due to new safety data.
08 November 2024	Minor adjustments have been introduced in the manufacturing process of the antigenic fraction of MHYOSPHERE PCV ID vaccine, which do not modify the process itself. To widen the maximum pre-inactivation titre for M. hyopneumoniaec pPCV2 antigenic fraction.
24 July 2023	To remove the higher specification limit for the PCV2 CP potency on the finished product specifications for batch release. Update to section 4.6 SPC and to package leaflet section 7.
16 February 2023	To introduce a new quantification method by means of Mass Spectrometry combined with High Performance Liquid Chromatography to control the amount of PCV2 CP during the manufacturing process of the antigenic fraction of MYOSPHERE PCV ID.
30 November 2022	Change(s) in the SPC, labelling or package leaflet to sections 4.6 and 6 adverse reactions.
25 November 2022	Addition of an administration device which is not an integrated part of the primary packaging.
09 March 2022	Change in the specification limits of the finished product. Changes to a test procedure. Minor change in the manufacturing process of an immediate release solid oral dosage form. Minor change in the manufacturing process of an immediate release solid oral dosage form. Minor change in the manufacturing process of the active substance.