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Post Authorisation Assessments

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

CircoMax Myco Emulsion for Injection for Pigs

Vm 42058/5013

11 June 2026	To change the adjuvant used to prepare antigen batches for in-process potency testing.
18 December 2025	To add an already authorised site for Physical/Chemical testing of the finished product to the manufacturing flow chart.
15 December 2025	To remove the spike control and initial 1:50 dilution for the positive control from the in-process ELISA test for porcine IgG content in the active substance.
21 February 2025	Removal of the EU Local Representative addresses.
21 January 2025	Increase in batch size of active substance without process change.
10 July 2024	Approval of mock-ups.
08 May 2024	To add the option to administer CircoMax Myco and Circomax intramuscularly using needle-free devices.
15 December 2023	Change the sterility testing method from membrane filtration to direct inoculation. Change the vials and the container closure system. To remove the thiomersal from the product composition. Replace the currently approved manufacturing site for blending of the vaccine.
27 April 2023	Removal of the warning relating to the absence of safety data during pregnancy and lactation in the SPC section 4.7 and package leaflet section 12 and replacement with 'Not applicable'. Alignment of the SPC/QRD text with the newest EU version 9.0 QRD template and GB National SPC/QRD template.
26 April 2023	Change in the specification limits of an active substance.
23 January 2023	Addition of a secondary packaging site of a finished product. Addition of a secondary packaging site of a finished product.
20 May 2021	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.