



Post Authorisation Assessments

Stabox 5% w/w Premix for Medicated Feeding Stuff for Piglets Vm 05653/4044

•	21 December 2023	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
•	12 January 2022	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Tightening of specification limits of the finished product. Replacement to a test procedure for the finished product. Replacement to a test procedure for the finished product. Change in storage conditions of the finished product. Change in the specification parameters and/or limits of the finished product. Change in the specification parameters and/or limits of the finished product.
•	24 November 2021	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	11 December 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	27 June 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance. Introduction of a re-test period of the active substance.
•	06 June 2018	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	02 September 2009	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-V.
•	05 March 2008	Addition of an active substance manufacturer.
•	05 March 2008	Addition of an active substance manufacturer.
•	19 December 2007	Variation to change a site of manufacture.
•	29 November 2005	Renewal.
•	24 October 2002	Renewal.
•	16 December 1999	Variation to change the address of a distributor.
•	02 November 1995	New Marketing Authorisation.