Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Stabox 50% w/w Powder for Oral Solution for Pigs

Vm 05653/4115

•	14 March 2024	Update of a CEP for the manufacture of an active substance to a new version. (NI)
•	04 December 2023	Certificate of Suitability (CEP) for manufacture of active substance updated to a new version (GB).
•	22 November 2022	Change in test procedure for the finished product.
•	03 February 2022	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	05 March 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	02 June 2020	Introduction of a re-test period of the active substance.
•	17 March 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	08 July 2019	Submission of a new Ph. Eur. certificate of suitability for an from a new manufacturer. Introduction of a re-test period/storage period of the active substance.
•	13 March 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	18 January 2013	Submission of mock-ups for approval.
•	27 July 2012	Grouped variation to add a new pack type, add a new pack size, and submit a new Certificate of Suitability for a new active substance manufacturer.
•	26 July 2011	Deletion of a dosing device, and the deletion of a test for the finished product.
•	14 June 2011	Submission of a new European Pharmacopoeia Certificate of Suitability for a new manufacturer of the active substance.
•	25 August 2010	Variation to change the name of the active substance manufacturer.
•	23 April 2010	Renewal, UK as CMS.
•	24 June 2005	Renewal, UK as CMS.
•	09 July 2004	Change in the specification of the finished product.
•	20 February 2003	Repeat Use Procedure (UK as CMS).