



Post Authorisation Assessments

Equip FT Vm 42058/5163

•	14 November 2024	Change in legal entity of MA holder for UK(NI) from Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Co. Dublin, Ireland.
•	14 June 2024	a. The addition of acceptable countries of origin as source for the porcine pancreas used to make the porcine trypsin powder. b. The removal of the countries of origin for the lactose used in the production process of porcine trypsin. c. To make some editorial changes in the TSE risk assessment.
•	25 March 2024	Change in the source of a starting material used in the manufacturing process of the active substance.
•	28 September 2022	Change in name and address of a manufacturer of the active substance.
•	22 July 2022	Removal of the non-toxicity and in vivo residual toxicity test from in-process testing. Replacement of the absence of toxin and irreversibility of toxoid test with the absence of tetanus toxoid test performed on the purified toxoid bulk.
•	19 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	09 April 2020	Changes to a test procedure for the finished product.
•	18 February 2020	Deletion of a non-significant in-process test applied during the manufacture of the active substance. Changes in the manufacturing process of the active substance.
•	03 December 2019	Changes to a test procedure for the starting material.
•	15 November 2018	Deletion of manufacturing site for an active substance
•	26 October 2018	Changes to a test procedure for the active substance
•	27 June 2016	Deletion of a manufacturing site Change in the specification limits of the finished product
•	18 November 2015	Addition of a new presentation form
•	23 April 2013	Change of manufacturer of a starting material used in the manufacture of the active substance
•	13 December 2011	Addition of an administration device
•	14 November 2011	Renewal

•	14 September 2011	Change in manufacturing procedure of the finished product Change in test procedure performed on the finished product
•	30 December 2010	Change of name of manufacturer for the whole manufacturing process
•	01 July 2010	Addition of a manufacturing site for secondary packaging
•	29 June 2010	Addition of a manufacturing site for batch release
•	21 April 2009	Change of MAH
•	10 September 2008	Changes to test procedure performed on the finished product
•	21 August 2008	Harmonisation of SPC
•	15 August 2007	Replacement of an in-process test performed on the finished product
•	04 April 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation