



Post Authorisation Assessments

Nobilis Salenvac T Suspension for Injection for Chickens

Vm 01708/3044

•	05 November 2024	To align the product information with version 9.0 of the QRD templates.
•	05 November 2024	Minor change to the in-process control test for formaldehyde Alternative in-process control test for sterility Alternative in-process control test for pH Increase in maximum batch size to 5000 L for the finished product. Minor changes in the manufacturing process of the finished product. Deletion of the in-process control test for specific gravity Addition of MSD AH Danube Biotech GmbH, Krems, Austria as antigen production site (including quality control testing) for the two antigen for S. Enteritidis and S. Typhimurium. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as finished product quality control testing site Minor updates to the currently licensed antigen production process for S. Enteritidis and S. Typhimurium Addition of MSD AH Danube Biotech GmbH, Krems, Austria as blending and filling site for the finished product.
•	23 November 2021	Implementation of changes foreseen in an approved change management protocol.
•	15 June 2021	Change in the manufacturing process of the finished product. Change in the storage period or storage conditions of the active substance. Replacement of a test procedure for the finished product.
•	15 December 2020	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Addition of a site where batch control/testing takes place.
•	01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	26 April 2019	Addition of a manufacturer responsible for batch release

		of the finished product.
•	10 September 2018	Change in RMS from UK to IT.
•	28 August 2018	Deletion of a non-significant specification parameter of the finished product. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	27 August 2015	Updates to the product literature.
•	20 August 2014	Change in test procedure for the finished product. Addition of an alternative in-process control test.
•	21 July 2014	Variation to change the manufacturing process of the finished product.
•	30 March 2012	Variation to change the name of the finished product manufacturer.
•	08 December 2010	Changes to therapeutic indications.
•	28 October 2009	Addition of a filling site for the finished product.
•	01 September 2009	Variation to change the address of the Marketing Authorisation Holder in Portugal.
•	11 December 2008	Renewal.
•	25 September 2008	Variation to update the detailed description of the production process.
•	19 September 2006	Variation to waive the batch safety test.
•	22 June 2006	Transfer of legal category from POM to POM-V.
•	29 November 2005	Change of Distributor.
•	19 March 2004	Renewal.
•	24 January 2003	Change of the manufacturing process of the Active Ingredient.
•	30 December 2002	Change to an in-process control test.
•	25 July 2002	Change to the packaging details.
•	20 June 2002	Change in the site of batch release.
•	14 June 2002	Addition of packaging sites for Labelling/Packaging.
•	14 June 2002	Change of product name.
•	31 January 2002	Variation concerning a change in the QC Procedures.
•	12 November 2001	Change in the manufacturing site of Dosage Form.
•	22 November 2001	Addition of a Distributor.
•	01 March 2001	New Marketing Authorisation EUDE.
•	18 August 2000	New Marketing Authorisation.