

Post Authorisation Assessments

Nobilis Salenvac ETC Suspension for Injection for Chickens Vm 01708/5073

•	12 March 2024	Minor change to the in-process control test for formaldehyde.
		Alternative in-process control test for sterility to align with Ph. Eur. requirements.
		Alternative in-process control test for pH.
		Addition of MSD AH Danube Biotech GmbH, Krems,
		Austria as antigen production site for S. Enteritidis, S. Typhimurium and S. Infantis.
		Minor updates to the currently licensed antigen
		production process for S. Enteritidis, S. Typhimurium and S. Infantis.
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		S. Infantis.
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		production process for S. Enteritidis, S. Typhimurium and S. Infantis.
•	11 May 2023	To extend the shelf life to 36 months from current 24
		months.
		Extension of the storage period of the antigens to 24
		months from current 12 months.
		To align the current product information with version 9.0
		of the QRD template.
•	22 December 2021	Addition of a site where batch control/testing takes place.
		Deletion of a non-significant specification parameter of
		the finished product.
		Minor changes to an approved test procedure of the
		finished product.
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		finished product.
•	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.