Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobilis Ma5 + Clone 30 Lyophilisate for Oculonasal Suspension/use in Drinking Water for Chickens

Vm 06376/4117

12 March 2025	Change in test procedure for starting material used in the manufacturing process of the active substance. Change test procedure for the finished product. Change in the storage conditions of the finished product. Change to in-process tests applied during the manufacture of the active substance. Minor changes in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance
18 November 2024	Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
12 March 2024	The registration dossiers of the concerned products are supplemented with (i) the information on the use of animal derived trypsin in the manufacture of the hydrolysed gelatin and with (ii) respective extraneous agents and TSE risk assessments.
20 September 2023	To decrease the minimum infectivity titre for IB Ma5 antigen from ≥ 3.5 log10 EID50/dose to ≥ 3.0 log10 EID50/dose to harmonise the EU and the UK dossier.
22 December 2022	Approval of mock-ups.
27 October 2021	Addition of new tests and limits applied during the manufacture of the finished product. Addition to a test procedure for the finished product. Addition to a test procedure for the finished product. Changes to a test procedure for the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Addition of a new container for the finished product. Changes in the manufacturing process of the finished product.
18 June 2021	Change in the address of the manufacturer of the finished product.
02 December 2020	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
15 October 2020	Change in the name of the manufacturer of the finished product.
08 April 2020	Change in immediate packaging of the finished product.
27 July 2015	Updates to SPC and product literature.

28 March 2012	Variation to change the manufacturer of the Active Substance.
22 March 2012	Variation to change the manufacturer of the finished product.
30 March 2008	Addition of an alternative site of sterility testing, as well as a variation to a sterility test method.
04 July 2007	Variation concerning further testing procedures at an existing testing site.
01 June 2007	Submission of an updated Certificate of Suitability.
25 April 2007	Addition of a pack size.
13 December 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Change of legal category from PML to POM-VPS.
21 August 2006	Renewal.
27 February 2006	Variation concerning QC Testing at an existing manufacture site.
10 June 2005	Change of address of a Distributor.
17 March 2005	Addition of a pack size.
27 May 2004	Variation to change product composition.
24 July 2003	Addition of a secondary packaging site.
28 November 2002	Renewal.
28 September 2001	Addition of a Distributor.
29 June 2000	Change in address of Marketing Authorisation Holder.
09 May 2000	Change in manufacturer of Active Substance.
27 November 1997	Change in name of a manufacturing site.
20 February 1997	New Marketing Authorisation.